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As filed with the Securities and Exchange Commission on October 11, 2019

Registration No. 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

89bio, Inc.
(Exact name of registrant as specified in its charter)

Delaware	2834	36-4946844
(State or other jurisdiction of incorporation or organization)	**(Primary Standard Industrial Classification Code Number)**	**(I.R.S. Employer Identification Number)**

535 Mission Street, 14th Floor
San Francisco, CA 94105
(415) 500-4614
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Rohan Palekar
Chief Executive Officer
89bio, Inc.
535 Mission Street, 14th Floor
San Francisco, CA 94105
(415) 500-4614
(Name, address, including zip code, and telephone number, including area code, of agent for service)

With copies to:

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Approximate date of commencement of proposed sale to the public: As soon as practicable after this registration statement becomes effective.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☐

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. ☐

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price(1)(2)	Amount of Registration Fee
Common Stock, par value $0.001 per share	$70,000,000	$9,086

(1) Estimated solely for purposes of calculating the registration fee in accordance with Rule 457(o) under the Securities Act of 1933, as amended.
(2) Includes the additional shares that the underwriters have the option to purchase from the registrant. See "Underwriting."

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to such Section 8(a), may determine.

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The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to Completion
Preliminary Prospectus dated October 11, 2019

PROSPECTUS

Shares

Common Stock

This is 89bio, Inc.'s initial public offering. We are selling shares of our common stock.

We expect the public offering price to be between $ and $ per share. Currently, no public market exists for the shares. After pricing of the offering, we expect that the shares will trade on The Nasdaq Global Market under the symbol "ETNB."

We are an "emerging growth company" as defined under the federal securities laws and, as such, we have elected to comply with certain reduced public company reporting requirements for this prospectus and may elect to do so in future filings.

Investing in the common stock involves risks that are described in the "Risk Factors" section beginning on page 10 of this prospectus.

	Per Share	Total
Public offering price	$	$
Underwriting discounts and commissions(1)	$	$
Proceeds, before expenses, to us	$	$

(1) See the section titled "Underwriting" for additional information regarding compensation payable to the underwriters.

The underwriters may also exercise their option to purchase up to an additional shares from us, at the public offering price, less the underwriting discount, for 30 days after the date of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The shares will be ready for delivery on or about , 2019.

BofA Merrill Lynch **SVB Leerink** **RBC Capital Markets**

Oppenheimer & Co.

The date of this prospectus is , 2019.

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Neither we nor the underwriters have authorized anyone to provide you with information other than that contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters are offering to sell, and seeking offers to buy, common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus or any free writing prospectus is accurate only as of its date, regardless of its time of delivery or of any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside of the United States: We have not, and the underwriters have not, done anything that would permit this offering, or possession or distribution of this prospectus, in any jurisdiction where action for that purpose is required, other than the United States. Persons outside of the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of our common stock and the distribution of this prospectus outside of the United States.

PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this prospectus. This summary does not contain all of the information that you should consider before deciding to invest in our common stock. You should read the entire prospectus carefully, including "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and notes to those consolidated financial statements included elsewhere in this prospectus, before making an investment decision. Some of the statements in this summary constitute forward-looking statements, see "Special Note Regarding Forward-Looking Statements." In this prospectus, unless the context requires otherwise, references to "we," "us," "our," "89bio" or the "company" refer to (i) 89Bio Ltd. for the periods prior to the Reorganization (as defined below) and (ii) 89bio, Inc. for the periods after completion of the Reorganization, in each case together with its consolidated subsidiaries.

Our Company

Overview

We are a clinical-stage biopharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of liver and cardio-metabolic diseases. Our lead product candidate, BIO89-100, a specifically engineered glycoPEGylated analog of fibroblast growth factor 21 ("FGF21"), is currently being developed for the treatment of nonalcoholic steatohepatitis ("NASH"). NASH is a severe form of nonalcoholic fatty liver disease ("NAFLD"), characterized by inflammation and fibrosis in the liver that can progress to cirrhosis, liver failure, hepatocellular carcinoma ("HCC") and death. There are currently no approved products for the treatment of NASH. FGF21 is a clinically-validated mechanism that has been shown in humans to reduce liver fat (steatosis) and address cardio-metabolic dysregulation. We believe BIO89-100 may be a differentiated FGF21 therapy based on its robust and durable biological effects and a favorable tolerability profile, as well its potential for a longer dosing interval. Combining these characteristics with the ability to address the key liver pathologies in NASH, as well as the underlying metabolic dysregulation in NASH patients, BIO89-100 has the potential to become a mainstay of NASH therapy. We successfully completed a Phase 1a, first-in-human, single ascending dose ("SAD") clinical trial with 58 healthy volunteers. The magnitude and significance of BIO89-100's biological effects after a single dose on lipid parameters were robust and durable. In July 2019, we initiated our proof of concept ("POC") Phase 1b/2a clinical trial in patients with NASH or patients with NAFLD and a high risk of NASH and we expect to report topline data in the second half of 2020.

The prevalence of NAFLD, which affects approximately 25% of the global population, and NASH, which develops in approximately 20% to 25% of NAFLD patients, is growing and is driven primarily by the worldwide obesity epidemic. The critical pathophysiologic mechanisms underlying the development and progression of NASH include reduced ability to handle lipids, increased insulin resistance, injury to hepatocytes and liver fibrosis in response to hepatocyte injury. Patients with NASH frequently have other significant metabolic co-morbidities such as obesity, hyperglycemia, dyslipidemia and systemic hypertension (a constellation of which is commonly referred to as metabolic syndrome) and these further contribute to the risk of cardiovascular disease. The number of NASH cases in the United States is projected to expand from 16.5 million in 2015 to 27 million in 2030, with similar prevalence growth expected in Europe. Diet and exercise are currently the standard of care for NAFLD and NASH, but adherence to this treatment regimen is poor and there remains a high unmet need in the treatment of NASH.

We also intend to develop BIO89-100 for the treatment of severe hypertriglyceridemia ("SHTG"), a condition identified by severely elevated levels of triglycerides ("TG") (greater than or equal to 500 mg/dL), which is associated with an increased risk of NASH, cardiovascular events and acute pancreatitis. SHTG accounts for up to 10% of all acute pancreatitis episodes. It is estimated that there are 2.5 million to 4 million patients in the United States with TG ³ 500 mg/dL and up to 50% of SHTG patients treated with certain

approved drugs are refractory to current standard of care. We expect to initiate our Phase 2 trial in SHTG patients in the first half of 2020 in order to evaluate the ability of BIO89-100 to reduce fasting plasma triglyceride levels compared to baseline levels and to report topline data in the first half of 2021. At this stage, we have not sought a Special Protocol Assessment or other agreement with the FDA on the required clinical trials needed to support an application for approval of BIO89-100 in SHTG. However, based on FDA guidance for the development of SHTG treatments, as well as the regulatory path followed by other companies that have successfully developed SHTG therapies, we believe that a combination of smaller clinical trials and shorter development timelines could mean that SHTG potentially represents a quicker path to market for BIO89-100.

We believe BIO89-100 has the potential to address multiple drivers underlying metabolic dysregulation, which would make it an ideal candidate for selected liver and cardio-metabolic diseases.

Our Lead Product Candidate, BIO89-100

BIO89-100 is a specifically engineered FGF21 analog that we believe has the potential to address the critical pathophysiologic mechanisms underlying NASH. FGF21 is a metabolic hormone that regulates energy expenditure and glucose and lipid metabolism. FGF21 has been clinically shown to reduce liver fat (steatosis). It is also thought to exert effects on liver fibrosis by improving metabolic regulation, which reduces ongoing liver injury thus giving the liver time to heal. FGF21 also generates an on-target effect to increase adiponectin, a hormone released from adipose tissue that, among other functions, can suppress development and progression of hepatic fibrosis. However, FGF21 in its native form suffers from a short half-life and a tendency to aggregate in solution, both of which impact its suitability as a viable drug. To address these challenges, we have specifically engineered BIO89-100 to maintain the clinical benefits of FGF21, while extending half-life in vivo, protecting against proteolysis, reducing renal clearance, minimizing susceptibility to aggregate in solution and optimizing potency.

BIO89-100 has been evaluated in seven animal studies of NASH, diabetes and obesity, including studies in mice and non-human primates. Each study was customized to assess endpoints relevant to liver and metabolic diseases and conducted according to standard practices at experienced contract research organizations (“CROs”). In these preclinical studies, consistent beneficial effects across a range of endpoints were observed, including improvements in hepatic steatosis, injury and fibrosis in a diet-induced NASH study of 50 mice (see “Business—BIO89-100—Results of DIN Mouse Studies” Figure 11 which illustrates that statistically significant mean changes with respect to hepatic steatosis and fibrosis were each observed and Figure 12 which illustrates that statistically significant mean changes with respect to injury were observed) and improved glycemic control and lipid handling in a study of 24 spontaneously diabetic obese cynomolgus monkeys with elevated triglycerides (see “Business—BIO89-100—Results of Spontaneously Diabetic Obese Cynomolgus Monkey Studies” Figures 20 and 21, respectively which illustrate that statistically significant mean changes with respect to glycemic control and lipid handling were each observed).

In May 2019, we announced positive topline data from our Phase 1a, first-in-human, SAD clinical trial of BIO89-100 in 58 healthy volunteers. In this SAD study, BIO89-100 demonstrated a favorable tolerability profile in the 43 volunteers who received BIO89-100 with a half-life of 55 to 100 hours. At single doses of 9.1 mg and higher, BIO89-100 demonstrated significant improvements in key lipid parameters measured at Day 8 and Day 15 after dosing on Day 1. The mean changes versus baseline include reductions in triglycerides (up to 51%) and LDL-C (up to 37%) and increase in HDL-C (up to 36%) despite the baseline values being in the normal range. As compared to placebo treatment, these mean changes were all statistically significant ($p < 0.001$). BIO89-100 demonstrated rapid (beginning from Day 2), sustained and durable improvements in lipid parameters for two weeks or more after single dose administration. Based on these findings and results from our animal studies, we believe such a lengthy duration of effect may confer longer dosing intervals to BIO89-100. We are currently enrolling our POC Phase 1b/2a trial with 83 total patients randomized to receive once weekly or

once every two weeks subcutaneous dosing of either BIO89-100 or placebo, in each case, for up to 12 weeks. This trial is designed to assess the safety, tolerability and pharmacokinetic ("PK") properties of BIO89-100, as well as changes in liver steatosis and key biomarker assessments.

We also intend to develop BIO89-100 for the treatment of SHTG. In diabetic obese cynomolgus monkeys with elevated triglycerides, BIO89-100 showed significant effects on triglycerides at doses as low as 0.1 mg/kg/week, with a 78% reduction from baseline observed at the highest dose level of 1.0 mg/kg/week. In our Phase 1a SAD study, BIO89-100 showed a significant reduction in triglycerides of up to 51% after a single dose in healthy volunteers. While currently approved SHTG therapies decrease TG levels, they generally do not have broader metabolic benefits. To the extent that we are able to show in subsequent human clinical trials that BIO89-100 significantly decreases both TG and LDL-C levels and improves other metabolic parameters, we believe that BIO89-100 could be a differentiated therapy in this indication. We expect to initiate our Phase 2 trial in SHTG patients in the first half of 2020 in order to evaluate the ability of BIO89-100 to reduce fasting plasma triglyceride levels compared to baseline levels and to report topline data in the first half of 2021.

BIO89-100 Patent Rights

We retain exclusive worldwide rights to BIO89-100. BIO89-100 is protected by a family of issued patents with claims directed to composition of matter and methods of use. The first of our patents for BIO89-100 are projected to expire in the United States in 2028, with the final composition-of-matter patent projected to expire in the United States in 2038, in each case, without patent term extensions. Because BIO89-100 is a biologic drug, marketing approval is also expected to provide 12 years of market exclusivity in the United States from the approval date of a biologics license application ("BLA").

Our Team

Our management team has extensive drug development, manufacturing and commercialization experience, having brought many successful drugs to market, including biologic agents. We are also supported by a group of directors and leading investors whose collective experience will assist us in realizing our corporate strategy. Our existing investors include OrbiMed, Longitude Capital, RA Capital and Pontifax.

Strategy

Our goal is to become a leading biopharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of liver and cardio-metabolic diseases. The key components of our strategy are to:

- Rapidly advance BIO89-100 through clinical development for the treatment of NASH.
- Expand the breadth of indications for BIO89-100 with an initial focus on SHTG.
- Scale-up and optimize the manufacturing of BIO89-100.
- Establish a commercial infrastructure in key geographies.
- Construct a diversified multi-asset pipeline of novel therapies.

Risks Associated with our Business

Our business is subject to a number of risks that you should be aware of before making an investment decision. You should carefully consider all of the information set forth in this prospectus and, in particular, you

should evaluate the specific factors set forth under “Risk Factors” in deciding whether to invest in our common stock. Among these important risks are the following:

- We are a clinical-stage biopharmaceutical company with a limited operating history and no products approved for commercial sale. We have incurred net losses since our inception, we expect to incur significant and increasing operating losses and we may never be profitable. Our stock is a highly speculative investment.
- Even if this offering is successful, we will require substantial additional capital to finance our operations, which may not be available to us on acceptable terms, or at all. As a result, we may not complete the development and commercialization of BIO89-100 or develop new product candidates.
- Our financial condition raises substantial doubt as to our ability to continue as a going concern.
- Our business depends on the success of BIO89-100, our only product candidate under clinical development, which is in the early stages of clinical development and has not completed a pivotal trial. If we are unable to obtain regulatory approval for and successfully commercialize BIO89-100 or other future product candidates, or we experience significant delays in doing so, our business will be materially harmed.
- Clinical drug development involves a lengthy and expensive process with uncertain timelines and uncertain outcomes, and the results of prior preclinical or clinical trials are not necessarily predictive of our future results. Our clinical trials may fail to adequately demonstrate the safety and efficacy of BIO89-100 or any future product candidates.
- We are initially developing BIO89-100 for the treatment of NASH, an indication for which there are no approved products. This makes it difficult to predict the timing and costs of the clinical development of BIO89-100 in NASH.
- BIO89-100 and any future product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval or limit the commercial profile of an approved label.
- We face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than us.
- Lack of efficacy, adverse events or undesirable side effects may emerge in clinical trials conducted by third parties developing FGF product candidates, which could adversely affect our stock price, our ability to attract additional capital and our development program.
- We have relied on, and expect to continue to rely on, third-party manufacturers to produce BIO89-100 or any future product candidates. Any failure by a third-party manufacturer to produce acceptable product candidates for us pursuant to our specifications and regulatory standards may delay or impair our ability to initiate or complete our clinical trials, obtain and maintain regulatory approvals or commercialize approved products.
- We rely on third parties to conduct our clinical trials and some aspects of our research and preclinical testing, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research or testing.
- Our success depends upon our ability to obtain and maintain intellectual property protection for our products and technologies.

- We rely on a license from Teva Pharmaceutical Industries Ltd. ("Teva") and a sublicense from ratiopharm GmbH ("ratiopharm"), a Teva affiliate, to patents and know-how related to glycoPEGylation technology that are used in the development, manufacture and commercialization of BIO89-100. Any termination or loss of significant rights, including the right to glycoPEGylation technology, or breach, under these agreements or any future license agreement related to our product candidates, would materially and adversely affect our ability to continue the development and commercialization of the related product candidates.

Corporate Information

We were incorporated in January 2018 in Israel under the name 89Bio Ltd. 89bio, Inc., the registrant whose name appears on the cover page of this prospectus, was incorporated in June 2019 for the purpose of an internal reorganization transaction. In September 2019, all of the equity holders of 89Bio Ltd. exchanged 100% of the equity of 89Bio Ltd. for 100% of the equity of 89bio, Inc. Following this exchange (the "Reorganization"), 89Bio Ltd. became a wholly owned subsidiary of 89bio, Inc. and 89bio, Inc. owns the business described and for which historical financial information is included elsewhere in this prospectus. Shares of the common stock of 89bio, Inc. are being offered by this prospectus.

Our principal executive offices are located at 535 Mission Street, 14th Floor, San Francisco, California 94105 and our telephone number is (415) 500-4614. Our website is *www.89bio.com*. The information on, or that can be accessed through, our website is not part of this prospectus and is not incorporated by reference herein.

Implications of Being an Emerging Growth Company

We are an emerging growth company, as defined in Section 2(a) of the Securities Act of 1933, as amended (the "Securities Act"), as modified by the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"), and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including relief from the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, less extensive disclosure obligations regarding executive compensation in our registration statements, periodic reports and proxy statements, exemptions from the requirements to hold a nonbinding advisory vote on executive compensation, and exemptions from stockholder approval of any golden parachute payments not previously approved. We may also elect to take advantage of other reduced reporting requirements in future filings. As a result, our stockholders may not have access to certain information that they may deem important and the information that we provide to our stockholders may be different than, and not comparable to, information presented by other public reporting companies. We could remain an emerging growth company until the earlier of (1) the last day of the year following the fifth anniversary of the completion of this offering, (2) the last day of the year in which we have total annual gross revenue of at least $1.07 billion, (3) the last day of the year in which we are deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which would occur if the market value of our common stock held by non-affiliates exceeded $700.0 million as of the last business day of the second fiscal quarter of such year or (4) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

In addition, the JOBS Act also provides that an emerging growth company may take advantage of the extended transition period provided in the Securities Act for complying with new or revised accounting standards. An emerging growth company may therefore delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, as a result, will not be subject to the same implementation timing for new or revised accounting standards as are required of other public companies that are not emerging growth companies, which may make comparison of our consolidated financial information to those of other public companies more difficult.

The Offering

Common stock offered by us	shares.
Option to purchase additional shares of common stock	The underwriters have a 30-day option to purchase up to additional shares of our common stock.
Common stock to be outstanding immediately after this offering	shares (or shares if the underwriters exercise in full their option to purchase additional shares of our common stock).
Use of proceeds	We expect that our net proceeds from this offering will be approximately $ million (or approximately $ million if the underwriters exercise in full their option to purchase additional shares), assuming an initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, to fund the development of BIO89-100 for the treatment of NASH and SHTG, for the manufacture of BIO89-100 and scale up, to evaluate potential new indications for BIO89-100 and for working capital and general corporate purposes. See "Use of Proceeds" for additional information.
Risk factors	You should carefully read and consider the information set forth in the "Risk Factors" section of this prospectus together with all of the other information set forth in this prospectus, before deciding whether to invest in shares of our common stock.
Proposed Nasdaq Global Market trading symbol	"ETNB"

The number of shares of common stock to be outstanding following this offering (i) is based on 3,800,000 shares of our common stock and 42,826,389 shares of our convertible preferred stock outstanding as of June 30, 2019, (ii) includes 1,173,611 shares of our convertible preferred stock issued in July 2019, (iii) gives effect to the Reorganization and the automatic conversion immediately prior to the completion of this offering of all outstanding shares of our convertible preferred stock into 44,000,000 shares of our common stock, and (iv) excludes the following:

- 4,482,991 shares of our common stock issuable upon the exercise of stock options outstanding as of June 30, 2019 under our 2019 Equity Incentive Plan (the "2019 Plan") at a weighted-average exercise price of $0.31 per share;
- 3,300,101 options to purchase shares of our common stock granted subsequent to June 30, 2019 at an exercise price of $0.50 per share;
- shares of our common stock reserved for future issuance under our 2019 Plan as of June 30, 2019, as well as any automatic increase in the number of shares of common stock reserved for future issuance thereunder; and

- shares of our common stock to be reserved for future issuance under our 2019 Employee Stock Purchase Plan, which we expect to enter into and which will become effective immediately prior to the completion of this offering, as well as any automatic increase in the number of shares of common stock reserved for future issuance thereunder.

Except as otherwise noted, we have presented the information in this prospectus based on the following assumptions:

- completion of the Reorganization;
- the conversion, in accordance with our amended and restated certificate of incorporation to be filed in connection with the Reorganization, of all shares of our convertible preferred stock outstanding, which conversion will occur immediately prior to the completion of this offering;
- the one-for- reverse stock split for our common stock and a proportional adjustment to the conversion ratio of our convertible preferred stock effected on , 2019;
- no exercise by the underwriters of their option to purchase additional shares of our common stock in this offering;
- no exercise of outstanding stock options after June 30, 2019; and
- the filing and effectiveness of our second amended and restated certificate of incorporation (the "Amended Certificate") with the Secretary of State of the State of Delaware, and the adoption of our second amended and restated bylaws (the "Amended Bylaws"), each of which will occur immediately prior to the completion of this offering. See "Description of Capital Stock—Anti-Takeover Effects of Our Amended Certificate, Amended Bylaws and Delaware Law."

Summary Consolidated Financial Data

The following summary consolidated statement of operations data for the period from January 18, 2018 (inception) to December 31, 2018 are derived from our audited consolidated financial statements included elsewhere in this prospectus. The following summary consolidated statement of operations data for the period from January 18, 2018 (inception) to June 30, 2018 and the six months ended June 30, 2019 and summary consolidated balance sheet data as of June 30, 2019 are derived from our unaudited interim condensed consolidated financial statements included elsewhere in this prospectus. Our unaudited interim condensed consolidated financial statements were prepared on the same basis as our audited consolidated financial statements and, in our opinion, reflect all adjustments, consisting only of normal recurring adjustments, that are necessary for the fair statement of our unaudited interim condensed consolidated financial statements. Our historical results presented below are not necessarily indicative of the results to be expected for any future period, and our interim results are not necessarily indicative of the results to be expected for the full year or any future period. You should read this information in conjunction with the information in "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Selected Consolidated Financial Data" and our consolidated financial statements and the related notes included elsewhere in this prospectus.

	Period from January 18, 2018 (inception) to December 31, 2018	Period from January 18, 2018 (inception) to June 30, 2018	Six Months Ended June 30, 2019
	(in thousands, except share and per share amounts)		
Consolidated Statement of Operations Data:			
Operating expenses:			
Research and development	$ 13,681	$ 6,700	$ 7,474
General and administrative	1,481	268	1,357
Total operating expenses	15,162	6,968	8,831
Loss from operations	15,162	6,968	8,831
Other (income) expenses, net	986	405	10,552
Net loss before tax	16,148	7,373	19,383
Income tax expense	28	—	29
Net loss and comprehensive loss	$ 16,176	$ 7,373	$ 19,412
Net loss per share, basic and diluted(1)	$ 5.86	$ 4.34	$ 5.11
Weighted-average shares used to compute net loss per share, basic and diluted(1)	2,758,904	1,700,552	3,800,000
Pro forma net loss per share, basic and diluted (unaudited) (1)	$ 1.22		$ 0.68
Weighted-average shares used to compute pro forma net loss per share, basic and diluted (unaudited)(1)	13,224,780		28,496,861

(1) See Notes 2 and 11 to our audited consolidated financial statements and Notes 2 and 10 to our unaudited interim condensed consolidated financial statements included elsewhere in this prospectus for an explanation of the calculations of our net loss per share, basic and diluted, and the weighted-average number of shares used in the computation of per-share amounts.

	As of June 30, 2019		
	Actual	Pro Forma(1)	Pro Forma As Adjusted(2)
	(in thousands)		
Consolidated Balance Sheet Data:			
Cash and cash equivalents	$ 21,919	$ 23,093	
Total assets	22,347	23,521	
Total current liabilities	9,537	9,537	
Convertible preferred shares	48,168	—	
Accumulated deficit	(35,588)	(35,588)	
Total shareholders' (deficit) equity	(35,358)	13,984	

(1) The pro forma column reflects (i) the issuance in July 2019 of 1,173,611 shares of our convertible preferred stock and (ii) the automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of 44,000,000 shares of our common stock immediately prior to the completion of this offering.

(2) The pro forma as adjusted column reflects $ million in estimated proceeds from the issuance and sale of shares of our common stock in this offering, assuming an initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each $1.00 increase (decrease) in the assumed initial public offering price would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, total assets, total current liabilities and total shareholders' (deficit) equity by $ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each increase (decrease) of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, total assets, total current liabilities and total shareholders' (deficit) equity by $ million, assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

RISK FACTORS

An investment in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below before deciding whether to purchase shares of our common stock. You should also refer to the other information contained in this prospectus, including our audited consolidated financial statements and related notes included elsewhere in this prospectus and "Management's Discussion and Analysis of Financial Condition and Results of Operations." Our business, financial condition, results of operations and prospects could be materially and adversely affected by any of these risks or uncertainties. In any such case, the trading price of our common stock could decline, and you could lose all or part of your investment.

Risks Related to Our Business and Industry

We are a clinical-stage biopharmaceutical company with a limited operating history and no products approved for commercial sale. We have incurred net losses since our inception, we expect to incur significant and increasing operating losses and we may never be profitable. Our stock is a highly speculative investment.

We are a clinical-stage biopharmaceutical company with a limited operating history that may make it difficult to evaluate the success of our business to date and to assess our future viability. We commenced operations in 2018, and to date, our operations have been limited to organizing and staffing our company, business planning, raising capital, acquiring our initial product candidate, BIO89-100 and licensing certain related technology, conducting research and development activities, including preclinical studies and early clinical trials, and providing general and administrative support for these operations. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect and/or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved for commercial sale, we have not generated any revenue from product sales to date and we continue to incur significant research and development and other expenses related to our ongoing operations. We have limited experience as a company conducting clinical trials and no experience as a company commercializing any products.

We are not profitable and have incurred net losses since our inception. As of June 30, 2019, we had an accumulated deficit of $35.6 million. Consequently, predictions about our future success or viability may not be as accurate as they would be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products. We have spent, and expect to continue to spend, significant resources to fund research and development of, and seek regulatory approvals for, BIO89-100 and any future product candidates. We expect to incur substantial and increasing operating losses over the next several years as our research, development, preclinical testing and clinical trial activities increase. As a result, our accumulated deficit will also increase significantly. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our shareholders' (deficit) equity and working capital. The net losses we incur may fluctuate significantly from quarter-to-quarter such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. Even if we eventually generate product revenue, we may never be profitable and, if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

We currently have no source of product revenue and may never become profitable.

BIO89-100 is in the early stages of development. To date, we have not generated any revenue from the licensing or commercialization of BIO89-100. We will not be able to generate product revenue unless and until BIO89-100 or any future product candidate, alone or with future partners, successfully completes clinical trials,

receives regulatory approval and is successfully commercialized. As BIO89-100 is in the early stages of development, we do not expect to receive revenue from it for a number of years, if ever. Although we may seek to obtain revenue from collaboration or licensing agreements with third parties, we currently have no such agreements that could provide us with material, ongoing future revenue and we may never enter into any such agreements. Our ability to generate future product revenue from BIO89-100 or any future product candidates also depends on a number of additional factors, including our or our future partners' ability to:

- successfully complete research and clinical development of BIO89-100 and any future product candidates;
- establish and maintain supply and manufacturing relationships with third parties, and ensure adequate and legally compliant manufacturing of bulk drug substances and drug products to maintain that supply;
- launch and commercialize future product candidates for which we obtain marketing approval, if any, and, if launched independently, successfully establish a sales force, marketing and distribution infrastructure;
- demonstrate the necessary safety data post-approval to ensure continued regulatory approval;
- obtain coverage and adequate product reimbursement from third-party payors, including government payors;
- achieve market acceptance for our or our future partners' products, if any;
- establish, maintain, protect and enforce our intellectual property rights; and
- attract, hire and retain qualified personnel.

In addition, because of the numerous risks and uncertainties associated with pharmaceutical product development, including that our product candidates may not advance through development or achieve the endpoints of applicable clinical trials, we are unable to predict the timing or amount of increased expenses, or if or when we will achieve or maintain profitability. In addition, our expenses could increase beyond expectations if we decide, or are required by the U.S. Food and Drug Administration (the "FDA") or comparable foreign regulatory authorities, to perform studies or trials in addition to those that we currently anticipate. Even if we complete the development and regulatory processes described above, we anticipate incurring significant costs associated with launching and commercializing these products.

Even if we generate revenue from the sale of any of our product candidates that may be approved, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or do not sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce our operations.

Even if this offering is successful, we will require substantial additional capital to finance our operations, which may not be available to us on acceptable terms, or at all. As a result, we may not complete the development and commercialization of BIO89-100 or develop new product candidates.

As a clinical-stage biopharmaceutical company, our operations have consumed significant amounts of cash since our inception. We expect our research and development expenses to increase substantially in connection with our ongoing activities, particularly as we conduct our Phase 1b/2a clinical trial of BIO89-100 and seek regulatory approvals for BIO89-100.

We believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will fund our projected operating requirements through at least the next months. Our forecast of the period of time through which our financial resources will adequately support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this "Risk Factors" section. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Our future funding requirements, both short and long-term, will depend on many factors, including:

- the initiation, progress, timing, costs and results of preclinical and clinical studies for BIO89-100 and any future product candidates we may develop;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA and comparable foreign regulatory authorities, including the potential for such authorities to require that we perform more studies than those that we currently expect or change their requirements on studies that had previously been agreed to;
- the cost to establish, maintain, expand, enforce and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecuting, defending and enforcing of any patents or other intellectual property rights;
- the effect of competing technological and market developments;
- market acceptance of any approved product candidates, including product pricing and product coverage and adequate reimbursement by third-party payors;
- the cost of acquiring, licensing or investing in additional businesses, products, product candidates and technologies;
- the cost and timing of selecting, auditing and potentially validating a manufacturing site for commercial-scale manufacturing of BIO89-100; and
- the cost of establishing sales, marketing and distribution capabilities for BIO89-100 and any future product candidates for which we may receive regulatory approval and that we determine to commercialize ourselves or in collaboration with our future partners.

We will require additional capital to discover, develop, obtain regulatory approval for and commercialize BIO89-100 and any future product candidates. We do not have any committed external source of funds. We expect to finance future cash needs through public or private equity or debt offerings or product collaborations. Additional capital may not be available in sufficient amounts or on reasonable terms, if at all. If we do not raise additional capital, we may not be able to expand our operations or otherwise capitalize on our business opportunities, our business and financial condition will be negatively impacted and we may need to:

- significantly delay, scale back or discontinue research and discovery efforts and the development or commercialization of any product candidates or cease operations altogether;
- seek strategic alliances for research and development programs when we otherwise would not, or at an earlier stage than we would otherwise desire or on terms less favorable than might otherwise be available; or
- relinquish, or license on unfavorable terms, our rights to technologies or any product candidates that we otherwise would seek to develop or commercialize ourselves.

In addition, if BIO89-100 receives approval and is commercialized, we will be required to make milestone and royalty payments to Teva, from whom we acquired certain patents and intellectual property relating to BIO89-100, and from whom we licensed patents and know-how related to glycoPEGylation technology that is used in the manufacture of BIO89-100. For additional information regarding this license agreement, please see "Business—Agreements with Teva."

Raising additional capital may cause dilution to stockholders purchasing shares in this offering, restrict our operations or require us to relinquish rights to our technologies.

Stockholders purchasing shares in this offering could suffer dilution or be negatively affected by fixed payment obligations we may incur if we raise additional funds through the issuance of additional equity securities or debt. Furthermore, these securities may have rights senior to those of our common stock and could contain covenants or protective rights that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we need to secure additional financing, such additional fundraising efforts may divert our management and research efforts from our day-to-day activities, which may adversely affect our ability to develop and commercialize BIO89-100 and any future product candidates.

To the extent we obtain additional funding through product collaborations, these arrangements would generally require us to relinquish rights to some of our technologies, product candidates or products, and we may not be able to enter into such agreements, on acceptable terms, if at all. If we are unable to obtain additional funding on a timely basis, we may be required to curtail or terminate some or all of our development programs or product candidates.

Our financial condition raises substantial doubt as to our ability to continue as a going concern.

Our consolidated financial statements have been prepared assuming that we will continue to operate as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. Based on our current forecast, and without accounting for the proceeds from this offering or any other offering, we do not have sufficient resources for at least the next year following the date that the consolidated financial statements appearing elsewhere in this prospectus were issued. To date, we have not generated revenues from our activities and have incurred substantial operating losses. We expect that we will continue to generate substantial operating losses for the foreseeable future until we complete development of BIO89-100 or our other product candidates and seek regulatory approvals to market such product candidates. We will continue to fund our operations primarily through utilization of our current financial resources and additional raises of capital.

These conditions raise substantial doubt about our ability to continue as a going concern. Additionally, our independent registered public accounting firm has included in its audit opinion for the period from January 18, 2018 (inception) to December 31, 2018 an explanatory paragraph that there is substantial doubt as to our ability to continue as a going concern. We plan to address these conditions by raising funds from our current investors as well as potential outside investors. However, there is no assurance that such funding will be available to us, will be obtained on terms favorable to us or will provide us with sufficient funds to meet our objectives. The reaction of investors to the inclusion of a going concern statement by our auditors and our potential inability to continue as a going concern may materially adversely affect our share price and our ability to raise new capital or enter into partnerships. If we become unable to continue as a going concern, we may have to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our consolidated financial statements.

Our business depends on the success of BIO89-100, our only product candidate under clinical development, which is in the early stages of clinical development and has not completed a pivotal trial. If we are unable to obtain regulatory approval for and successfully commercialize BIO89-100 or other future product candidates, or we experience significant delays in doing so, our business will be materially harmed.

To date, the primary focus of our product development has been BIO89-100 for the treatment of patients with NASH. Currently, BIO89-100 is our only product candidate under clinical development. This may make an investment in our company riskier than similar companies that have multiple product candidates in active development and that therefore may be able to better sustain a failure of a lead candidate. Successful continued development and ultimate regulatory approval of BIO89-100 for the treatment of NASH or other indications, including SHTG, is critical to the future success of our business. We have invested, and will continue to invest, a significant portion of our time and financial resources in the clinical development of BIO89-100. If we cannot successfully develop, obtain regulatory approval for and commercialize BIO89-100, we may not be able to continue our operations. The future regulatory and commercial success of BIO89-100 is subject to a number of risks, including the following:

- we may not have sufficient financial and other resources to complete the necessary clinical trials for BIO89-100, including, but not limited to, the clinical trials needed to obtain drug approval;
- the mechanism of action of BIO89-100 is complex, and we do not know the degree to which it will translate into a therapeutic benefit, if any, in NASH or any other indication, and we do not know the degree to which the complex mechanism of action may contribute to long-term safety issues or adverse events, if any, when BIO89-100 is taken for prolonged periods such as in the treatment of NASH or any other indication;
- we may not be able to obtain adequate evidence from clinical trials of efficacy and safety for BIO89-100 for the treatment of NASH or other indications;
- in our clinical trials for BIO89-100, we may need to adjust our clinical trial procedures and may need additional clinical trial sites, which could delay our clinical trial progress;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA or comparable foreign regulatory authorities for marketing approval;
- patients in our clinical trials may suffer serious adverse effects for reasons that may or may not be related to BIO89-100, which could delay or prevent further clinical development;
- the standards implemented by clinical or regulatory agencies may change at any time and we cannot be certain what efficacy endpoints the FDA or foreign clinical or regulatory agencies may require in pivotal clinical trials with respect to NASH or any other indication for the approval of BIO89-100;
- the results of later stage clinical trials may not be as favorable as the results we have observed to date in our preclinical studies and Phase 1a clinical trial;
- if we obtain accelerated approval of BIO89-100 or any other product candidate based on a surrogate endpoint, we may be required to conduct a post-approval clinical outcomes trial to confirm the clinical benefit of the product candidate; if any such post-approval trial is not successful we may not be able to continue marketing the product;
- we cannot be certain of the number and type of clinical trials and non-clinical studies that the FDA or other regulatory agencies will require in order to approve BIO89-100 for the treatment of NASH or any other indication, including SHTG;

- if approved for NASH or SHTG, BIO89-100 will likely compete with products that may reach approval for the treatment of NASH prior to BIO89-100, products that are currently approved for the treatment of SHTG and the off-label use of currently marketed products for NASH and SHTG; and

- we may not be able to obtain, maintain or enforce our patents and other intellectual property rights.

Of the large number of drugs in development in the pharmaceutical industry, only a small percentage results in the submission of a new drug application or a new BLA to the FDA and even fewer are approved for commercialization. Furthermore, even if we do receive regulatory approval to market BIO89-100, any such approval may be subject to limitations on the indicated uses or patient populations for which we may market the products. Accordingly, even if we are able to obtain the requisite financing to continue to fund our development programs, we may be unable to successfully develop or commercialize BIO89-100. If we or any of our future development collaborators are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize BIO89-100, we may not be able to generate sufficient revenue to continue our business.

Clinical drug development involves a lengthy and expensive process with uncertain timelines and uncertain outcomes, and the results of prior preclinical or clinical trials are not necessarily predictive of our future results. Our clinical trials may fail to adequately demonstrate the safety and efficacy of BIO89-100 or any future product candidates.

BIO89-100 and any future product candidates will be subject to rigorous and extensive clinical trials and extensive regulatory approval processes implemented by the FDA and comparable foreign regulatory authorities before obtaining marketing approval from these regulatory authorities. The drug development and approval process is lengthy and expensive, and approval is never certain. Investigational new drugs, such as BIO89-100, may not prove to be safe and effective in clinical trials. We have no direct experience as a company in conducting later stage clinical trials required to obtain regulatory approval. We may be unable to conduct clinical trials at preferred sites, enlist clinical investigators, enroll sufficient numbers of participants or begin or successfully complete clinical trials in a timely fashion, if at all. In addition, the design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. Because we have limited experience as a company designing clinical trials, we may be unable to design and execute a clinical trial to support regulatory approval. Even if our current clinical trial is successful, it will be insufficient to demonstrate that BIO89-100 is safe or effective for registration purposes.

There is a high failure rate for drugs and biologic products proceeding through clinical trials. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of BIO89-100 or any future product candidate may not be predictive of the results of later-stage clinical studies or trials and the results of studies or trials in one set of patients or line of treatment may not be predictive of those obtained in another. In fact, many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late stage clinical trials even after achieving promising results in preclinical studies and earlier stage clinical trials. In addition, data obtained from preclinical and clinical activities is subject to varying interpretations, which may delay, limit or prevent regulatory approval. It is impossible to predict when or if BIO89-100 or any future product candidate will prove effective or safe in humans or will receive regulatory approval. Owing in part to the complexity of biological pathways, BIO89-100 or any future product candidate may not demonstrate in patients the biochemical and pharmacological properties we anticipate based on laboratory studies or earlier stage clinical trials, and they may interact with human biological systems or other drugs in unforeseen, ineffective or harmful ways. The number of patients exposed to product candidates and the average exposure time in the clinical development programs may be inadequate to detect rare adverse events or findings that may only be detected once a product candidate is administered to more patients and for greater periods of time. To date, our Phase 1a clinical trial has involved a small patient population of healthy volunteers and, because of the small sample size in such trial, the results of this clinical trial may be subject to substantial

variability and may not be indicative of either future interim results or final results in patients with liver or cardio-metabolic diseases. If we are unable to successfully demonstrate the safety and efficacy of BIO89-100 or other future product candidates and receive the necessary regulatory approvals, our business will be materially harmed.

If we experience delays in clinical testing, our commercial prospects will be adversely affected, our costs may increase and our business may be harmed.

Conducting clinical studies for any product candidates for approval in the United States requires filing an investigational new drug ("IND") application and reaching agreement with the FDA on clinical protocols, finding appropriate clinical sites and clinical investigators, securing approvals for such studies from the institutional review board at each such site, manufacturing clinical quantities of product candidates and supplying drug product to clinical sites. Currently, we have an active IND with the FDA in the United States for BIO89-100. Because our IND is with the gastrointestinal division of the FDA, we may be required to file an additional IND with another division for any future indications, including SHTG. If any such future IND is not approved by the FDA, our clinical development timeline may be negatively impacted and any future clinical programs may be delayed or terminated.

We cannot guarantee that we will be able to successfully accomplish required regulatory activities or all of the other activities necessary to initiate and complete clinical trials. As a result, our preclinical studies and clinical trials may be extended, delayed or terminated, and we may be unable to obtain regulatory approvals or successfully commercialize our products. We do not know whether any other clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Our product development costs will increase if we experience delays in clinical testing. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize BIO89-100 and any future product candidates or allow our competitors to bring products to market before we do, which would impair our ability to successfully commercialize BIO89-100 or any future product candidates and may harm our business, results of operations and prospects. Events that may result in a delay or unsuccessful completion of clinical development include:

- delays in reaching agreement on acceptable terms with prospective CROs and clinical trial sites;
- ongoing discussions with the FDA or comparable foreign authorities regarding the scope or design of our clinical trials;
- deviations from the trial protocol by clinical trial sites and investigators, or failures to conduct the trial in accordance with regulatory requirements;
- the need to repeat clinical trials as a result of inconclusive or negative results or poorly executed testing or changes in required endpoints by the FDA or comparable foreign authorities;
- unfavorable FDA inspection and review of a clinical trial site or records of any clinical or preclinical investigation;
- the placement of a clinical hold on a clinical trial by the FDA or comparable foreign authorities;
- delays in obtaining, or the inability to obtain, required approvals from institutional review boards or other governing entities at clinical sites selected for participation in our clinical trials;
- failure of third parties, such as CROs, to satisfy their contractual duties to us or meet expected deadlines;

- delays in the testing, validation, manufacturing and delivery of the product candidates to the clinical sites;
- insufficient supply or deficient quality of product candidate materials or other materials necessary to conduct our clinical trials;
- for clinical trials in selected patient populations, delays in identification and auditing of central or other laboratories and the transfer and validation of assays or tests to be used to identify selected patients;
- delays in enrolling participants into our clinical trials;
- delays in patients completing a trial or returning for post-treatment follow-up;
- delays caused by patients dropping out of a trial due to side effects, disease progression or otherwise;
- serious and unexpected drug-related adverse effects experienced by participants in our clinical trials;
- implementation of new, or changes to, guidance or interpretations from the FDA or comparable foreign authorities with respect to approval pathways for any product candidates we are pursuing, such as the draft guidance documents from the FDA and the European Medicines Agency for the development of NASH that were issued in 2018 and 2019;
- withdrawal of clinical trial sites from our clinical trials as a result of changing standards of care or the ineligibility of a site to participate in our clinical trials; or
- changes in government regulations or administrative actions or lack of adequate funding to continue the clinical trials.

Our or our future collaborators' inability to timely complete clinical development could result in additional costs to us as well as impair our ability to generate product revenue, continue development, commercialize BIO89-100 and any future product candidates, reach sales milestone payments and receive royalties on product sales. In addition, if we make changes to a product candidate, we may need to conduct additional nonclinical studies or clinical trials to bridge or demonstrate the comparability of our modified product candidate to earlier versions, which could delay our clinical development plan or marketing approval for our current product candidate and any future product candidates.

If we encounter difficulties in enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

The timely completion of clinical trials largely depends on patient enrollment. We may encounter delays in enrolling, or be unable to enroll, a sufficient number of patients to complete any of our clinical trials, and even once enrolled, we may be unable to retain a sufficient number of patients to complete any of our trials. Furthermore, as a result of the inherent difficulties in diagnosing NASH, which can currently only be definitively diagnosed through a liver biopsy, and the significant competition for recruiting NASH patients in clinical trials, we or our future collaborators may be unable to enroll the patients we need to complete clinical trials on a timely basis, or at all.

Many factors affect patient enrollment, including:

- the size and nature of the patient population, which may be limited due to diagnostic requirements;

- the number and location of clinical sites;
- competition with other companies for clinical sites or patients;
- the availability and amount of any patient stipend;
- the eligibility and exclusion criteria for the trial, including any potential requirement for a biopsy;
- the design of the clinical trial;
- inability to obtain and maintain patient consents;
- significant adverse events or other side effects observed, if any;
- risk that enrolled participants will drop out before completion; and
- competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies (oral versus injectables, like BIO89-100), including any new drugs that may be approved for the indications we are investigating.

In addition, our competitors, some of whom have significantly greater resources than we do, are conducting clinical trials for the same indications and seek to enroll patients in their studies that may otherwise be eligible for our clinical studies or trials, which could lead to slow recruitment and delays in our clinical programs. Further, since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which could further reduce the number of patients who are available for our clinical trials in these sites.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. If we are unable to enroll a sufficient number of patients that will complete clinical testing, we will be unable to seek or gain marketing approval for BIO89-100 and any future product candidates and our business will be harmed. Even if we are able to enroll a sufficient number of patients in our clinical studies or trials, delays in patient enrollment may result in increased costs or may affect the timing or outcome of our clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of BIO89-100 and any future product candidates.

We are initially developing BIO89-100 for the treatment of NASH, an indication for which there are no approved products. This makes it difficult to predict the timing and costs of the clinical development of BIO89-100 for the treatment of NASH.

Our current research and development efforts are focused on developing BIO89-100 for the treatment of NASH, an indication for which there are no approved products. The regulatory approval process for novel product candidates such as BIO89-100 can be more expensive and take longer than for other, better known or extensively studied product candidates. As other companies are in later stages of clinical trials for their potential NASH therapies, we expect that the path for regulatory approval for NASH therapies may continue to evolve in the near term as these other companies refine their regulatory approval strategies and interact with regulatory authorities. Such evolution may impact our future clinical trial designs, including trial size and endpoints, in ways that we cannot predict today. Our anticipated development costs would likely increase if development of BIO89-100 or any future product candidate is delayed because we are required by the FDA to perform studies or trials in addition to, or different from, those that we currently anticipate. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to predict the timing or amount of any increase in our anticipated development costs.

BIO89-100 and any future product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval or limit the commercial profile of an approved label.

Undesirable side effects caused by BIO89-100 or any future product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities. Additional clinical studies may be required to evaluate the safety profile of BIO89-100 or any future product candidates. While no serious adverse events were reported in our Phase 1a clinical trial of BIO89-100, the following treatment-related adverse events were reported in at least two subjects in the treatment cohort: injection site reactions and headaches.

Future results of our trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. In such an event, we could suspend or terminate our trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of BIO89-100 or any future product candidates for any or all targeted indications. Drug-related side effects could affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences could materially and adversely affect our business, financial condition, results of operations and prospects.

It may be difficult to discern whether certain events or symptoms observed during our clinical trials or by patients using our approved products are related to BIO89-100 or any future product candidates or approved products or some other factor. As a result, we and our development programs may be negatively affected even if such events or symptoms are ultimately determined to be unlikely related to BIO89-100 or any future product candidates or approved products. We cannot assure you that additional or more severe adverse side effects related to BIO89-100 or any future product candidates will not be observed in our clinical trials or in the commercial setting. Further, we expect that BIO89-100 will require multiple administrations vis subcutaneous injection in the course of a clinical trial, and this chronic administration increases the risk that our clinical drug development programs may not uncover all possible adverse events that may eventually be experienced by patients treated with BIO89-100, such as rare adverse events or chance findings that may only be detected once product candidates are administered to ore patients or for greater periods of time. If observed, such adverse side effects could delay or preclude regulatory approval of BIO89-100 or any future product candidates, limit commercial use or result in the withdrawal of previously granted marketing approvals. If we or others identify undesirable or unacceptable side effects caused by BIO89-100 or any future product candidates or products:

- we may be required to modify, suspend or terminate our clinical trials;
- we may be required to modify or include additional dosage and administration instructions, warnings and precautions, contraindications, boxed warnings, limitations, restrictions or other statements in the product label for our approved products, or issue field alerts to physicians and pharmacies;
- we may be required to conduct costly additional clinical trials;
- we may be subject to limitations on how we may promote our approved products;
- sales of our approved products may decrease significantly;
- regulatory authorities may require us to take our approved products off the market;
- we may be subject to regulatory investigations, government enforcement actions, litigation or product liability claims; and
- our products may become less competitive or our reputation may suffer.

Any of these results could decrease or prevent any sales of our approved product or substantially increase the costs and expenses of commercializing and marketing our product.

We face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than us.

The biopharmaceutical industry is intensely competitive and subject to rapid innovation and significant technological advancements. We believe the key competitive factors that will affect the development and commercial success of BIO89-100 and any future product candidates are efficacy, safety and tolerability profile, reliability, convenience of dosing, price, the level of generic competition and reimbursement. Our competitors include multinational pharmaceutical companies, specialized biotechnology companies, universities and other research institutions. A number of biotechnology and pharmaceutical companies are pursuing the development or marketing of pharmaceuticals that target the same diseases that we are targeting. Smaller or earlier-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Given the high incidence of NASH and SHTG, it is likely that the number of companies seeking to develop products and therapies for the treatment of liver and cardio-metabolic diseases, such as NASH and SHTG, will increase. For additional information regarding our competition, please see “Business—Competition.”

There are no currently approved therapies for the treatment of NASH. Although there are no approved therapies that specifically target the signaling pathways that BIO89-100 is designed to affect, there are numerous currently approved therapies for treating diseases other than NASH and some of these currently approved therapies may exert effects that could be similar to BIO89-100. Many of these approved drugs are well-established therapies or products and are widely accepted by physicians, patients and third-party payors. Some of these drugs are branded and subject to patent protection, and others are available on a generic basis. Insurers and other third-party payors may also encourage the use of generic products or specific branded products. We expect that if BIO89-100 or any future product candidates are approved, they will be priced at a significant premium over competitive generic products, including branded generic products. This may make it difficult for us to differentiate our products from currently approved therapies, which may adversely impact our business strategy. In addition, many companies are developing new therapeutics, and we cannot predict what the standard of care will be as BIO89-100 or any future product candidates progress through clinical development. In addition, to the extent BIO89-100 or any future product candidates are approved for cardio-metabolic indications, such as SHTG, the commercial success of our products will also depend on our ability to demonstrate benefits over the then-prevailing standard of care, including diet, exercise and lifestyle modifications.

Further, if BIO89-100 or any future product candidates are approved for the treatment of SHTG, we will compete with currently approved therapies and therapies further along in development. Our competitors both in the United States and abroad include large, well-established pharmaceutical and generic companies with significantly greater name recognition. Our competitors may be able to charge lower prices than we can, which may adversely affect our market acceptance. Many of these competitors have greater resources than we do, including financial, product development, marketing, personnel and other resources. Clinical trials for the treatment of SHTG may be relatively costly and time consuming. The requirements for approval by the FDA and comparable foreign regulatory authorities may change over time and this may require changes to ongoing or future clinical trial designs that could impact timelines and cost.

If our competitors market products that are more effective, safer or cheaper than our products or that reach the market sooner than our products, we may not achieve commercial success. In addition, the biopharmaceutical industry is characterized by rapid technological change. Because our research approach integrates many technologies, it may be difficult for us to stay abreast of the rapid changes in other technologies. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies, products or product candidates obsolete, less competitive or not economical.

Many of our competitors have substantially greater financial, technical, human and other resources than we do and may be better equipped to develop, manufacture and market technologically superior products. In addition, many of these competitors have significantly longer operating histories and greater experience than we have in undertaking nonclinical studies and human clinical trials of new pharmaceutical products and in obtaining regulatory approvals of human therapeutic products. Many of our competitors have established distribution channels for the commercialization of their products, whereas we have no such channel or capabilities. In addition, many competitors have greater name recognition and more extensive collaborative relationships.

As a result, our competitors may obtain regulatory approval of their products more rapidly than we do or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidate or any future product candidates. Our competitors may also develop and succeed in obtaining approval for drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile than our products and these competitors may also be more successful than we are in manufacturing and marketing their products. If we are unable to compete effectively against these companies, then we may not be able to commercialize our product candidate or any future product candidates or achieve a competitive position in the market. This would adversely affect our ability to generate revenue. Our competitors also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and enrolling patients for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our inability to compete effectively in any of these aspects of our business could harm our business, financial condition, results of operations and prospects.

Lack of efficacy, adverse events or undesirable side effects may emerge in clinical trials conducted by third parties developing FGF product candidates, which could adversely affect our stock price, our ability to attract additional capital and our development program.

Lack of efficacy, adverse events or undesirable side effects may emerge in clinical trials conducted by third parties developing FGF product candidates like ours. For example, Bristol-Myers Squibb Company and Akero Therapeutics, Inc. are also developing FGF21 product candidates for the treatment of NASH. We have no control over their clinical trials or development program, and lack of efficacy, adverse events or undesirable side effects experienced by subjects in their clinical trials could adversely affect our stock price, our ability to attract additional capital and our development of BIO89-100 or even the viability of BIO89-100 as a product candidate, including by creating a negative perception of FGF therapeutics by healthcare providers or patients.

Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or topline data from our clinical trials, which are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical trials. In addition, we may report interim analyses of only certain endpoints rather than all endpoints. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available.

In addition, adverse changes between interim data and final data could significantly harm our business and prospects. Additional disclosure of interim data by us or by our competitors in the future could also result in volatility in the price of our common stock after this offering. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug, drug candidate or our business. If the topline data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, BIO89-100 or any future product candidates may be harmed, which could harm our business, financial condition, results of operations and prospects.

We may encounter difficulties in managing our growth, which could adversely affect our operations.

We are in the early stages of building the full management team and employee base that we anticipate we will need to complete the development BIO89-100 and other future product candidates. As of June 30, 2019, we had 14 employees, some of whom are based in the United States and some of whom are based in Israel. As we advance our preclinical and clinical development programs for product candidates, seek regulatory approval in the United States and elsewhere and increase the number of ongoing product development programs, we anticipate that we will need to increase our product development, scientific and administrative headcount. We will also need to establish commercial capabilities in order to commercialize any product candidates that may be approved. Such an evolution may impact our strategic focus and our deployment and allocation of resources. Our management, personnel and systems may experience difficulty in adjusting to our growth and strategic focus.

Our ability to manage our operations and growth effectively depends upon the continual improvement of our procedures, reporting systems and operational, financial and management controls. We may not be able to implement administrative and operational improvements in an efficient or timely manner and may discover deficiencies in existing systems and controls. If we do not meet these challenges, we may be unable to execute our business strategies and may be forced to expend more resources than anticipated addressing these issues.

We may acquire additional technology and complementary businesses in the future. Acquisitions involve many risks, any of which could materially harm our business, including the diversion of management's attention from core business concerns, failure to effectively exploit acquired technologies, failure to successfully integrate the acquired business or realize expected synergies or the loss of key employees from either our business or the acquired businesses.

In addition, in order to continue to meet our obligations as a public company and to support our anticipated long-term growth, we will need to increase our general and administrative capabilities. Our management, personnel and systems may not be adequate to support this future growth.

If we are unable to successfully manage our growth and the increased complexity of our operations, our business, financial position, results of operations and prospects may be materially and adversely affected.

We must attract and retain highly skilled employees in order to succeed. If we are not able to retain our current senior management team and our scientific advisors or continue to attract and retain qualified scientific, technical and business personnel, our business will suffer.

We may not be able to attract or retain qualified personnel and consultants due to the intense competition for such individuals among in the biotechnology and pharmaceutical industries. If we are not able to

attract and retain necessary personnel and consultants to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development and commercial objectives, our ability to raise additional capital and our ability to implement our business strategy.

Our industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on the development, regulatory, commercialization and business development expertise of the members of our executive team, as well as other key employees and consultants. If we lose one or more of our executive officers or other key employees or consultants, our ability to implement our business strategy successfully could be seriously harmed. Any of our executive officers or other key employees or consultants may terminate their employment at any time and replacing such individuals may be difficult and time-consuming because of the limited number of individuals in our industry with the necessary breadth of skills and experience. Competition to hire and retain employees and consultants from this limited pool is intense, and we may be unable to hire, train, retain or motivate such individuals. Additionally, we do not currently maintain “key person” life insurance on the lives of our executives or any of our employees. This lack of insurance means that we may not receive adequate compensation for the loss of the services of these individuals. If we are unable to continue to attract and retain high-quality personnel, the rate and success with which we can discover and develop product candidates and our business will be limited.

We have relied on, and expect to continue to rely on, third-party manufacturers to produce BIO89-100 or any future product candidates. Any failure by a third-party manufacturer to produce acceptable product candidates for us pursuant to our specifications and regulatory standards may delay or impair our ability to initiate or complete our clinical trials, obtain and maintain regulatory approvals or commercialize approved products.

The manufacturing of biologic drugs such as BIO89-100 is complex and the process of identifying the qualifying suppliers takes a significant investment of time and money. We do not own or operate manufacturing facilities for the production of clinical or commercial quantities of our product candidates, and we lack the resources and the capabilities to do so. As a result, we currently rely, and expect to rely for the foreseeable future, on third-party manufacturers to supply us with BIO89-100 and any future product candidates.

We currently have a sole source relationship with Northway Biotechpharma (“BTPH”) pursuant to which they supply us with BIO89-100. If there should be any disruption in our supply arrangement with BTPH, including any adverse events affecting BTPH, it could have a negative effect on the clinical development of BIO89-100 and other operations while we work to identify and qualify an alternate supply source.

We do not have a long-term supply agreement with any third-party manufacturer. Reliance on third-party manufacturers entails risks to which we would not be subject if we manufacture product candidates or products ourselves. For example, if we do not maintain our key manufacturing relationships, we may fail to find replacement manufacturers or develop our own manufacturing capabilities in a timely manner or at all, which could delay or impair our ability to obtain regulatory approval for our products and substantially increase our costs or deplete profit margins, if any. If we do find replacement manufacturers, we may not be able to enter into agreements with them on terms and conditions favorable to us, and there could be a substantial delay before new facilities could be qualified and registered with the FDA and other comparable foreign regulatory authorities. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the possible failure of the third party to manufacture product candidates according to our schedule, or at all, including if our third-party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;

- the possible breach of the manufacturing agreement by the third party because of factors beyond our control (including a failure to manufacture product candidates in accordance with our product specifications);
- the possible mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;
- the possibility of clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how;
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us; and
- reliance on the third party for regulatory compliance, quality assurance and safety and pharmacovigilance reporting.

Certain raw materials necessary for the manufacture of BIO89-100 under our current manufacturing process, such as reagents that are needed for the glycoPEGylation, are available only from a single supplier. In April 2018, we entered into a Reagent Supply and Technology Transfer Agreement with Teva under which Teva agreed to supply us several reagents required for the glycoPEGylation process until December 31, 2022 and transfer the know-how required for our production of these reagents. We expect the manufacture of these reagents will be transferred to a new supplier prior to expiration of the agreement with Teva. Any complications arising under our agreement with Teva, with the subsequent transfer of know-how to us, or any difficulties securing a new supplier could considerably delay the manufacture of BIO89-100. Any significant delay in the acquisition or decrease in the availability of these raw materials from Teva or any new supplier could considerably delay the manufacture of BIO89-100, which could adversely impact the timing of any planned trials or the regulatory approvals of BIO89-100.

The FDA and other comparable foreign regulatory authorities require manufacturers to register manufacturing facilities. The FDA and other comparable foreign regulatory authorities also inspect these facilities to confirm compliance with current good manufacturing practices (“cGMP”). Contract manufacturers may face manufacturing or quality control problems causing drug substance production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP requirements. We may have little to no control regarding the occurrence of third-party manufacturer incidents. Any failure to comply with cGMP requirements or other FDA or comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to develop BIO89-100 or any future product candidates and market our products following approval. Our sole source supplier, BTPH, has not yet manufactured a commercial product, and as a result, has not been subject to inspection by the FDA and other comparable foreign regulatory authorities.

If BIO89-100 or any future product candidates are approved by the FDA or other comparable foreign regulatory authorities for commercial sale, we may need to manufacture such product candidate in larger quantities. We intend to use third-party manufacturers for commercial quantities of BIO89-100 to the extent we advance this product candidate and other product candidates. Our manufacturers may not be able to successfully increase the manufacturing capacity for any of our product candidates in a timely or efficient manner, or at all. If we are unable to successfully increase the manufacturing capacity for a product candidate, the regulatory approval or commercial launch of that product candidate may be delayed or there may be a shortage in the supply of the product candidate.

In addition, the operations of our third-party manufacturers may be subject to earthquakes, power shortages, telecommunications failures, failures or breaches of information technology systems, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics, and other natural or man-made disasters or business interruptions. Damage or extended periods of interruption to our facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development of some or all of our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

Our current and anticipated future dependence upon others for the manufacture of our product candidates may adversely affect our future profit margins and our ability to develop our product candidates and commercialize any products that receive regulatory approval on a timely basis.

In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer, we may have difficulty transferring such skills or technology to another third party and a feasible alternative many not exist. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to have another third party manufacture our product candidates. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. For example, in the event that we need to switch our third-party manufacturer of BIO89-100 from BTPH, which is our sole manufacturing source for BIO89-100, we anticipate that the complexity of the glycoPEGylation manufacturing process may materially impact the amount of time it may take to secure a replacement manufacturer. The delays associated with the verification of a new manufacturer, if we are able to identify an alternative source, could negatively affect our ability to develop product candidates in a timely manner or within budget.

The manufacture of biologic products is complex and we are subject to many manufacturing risks, any of which could substantially increase our costs and limit supply of our products.

To date, BIO89-100 has been manufactured by a single third-party manufacturer, BTPH, solely for preclinical studies and clinical trials. This manufacturer may not be able to scale production to the larger quantities required for large clinical trials and to commercialize BIO89-100. The process of manufacturing BIO89-100 is complex, highly regulated and subject to several risks, including:

- the process of manufacturing biologics is susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error and improper storage conditions. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our products or in the manufacturing facilities in which our products are made, the manufacturing facilities may need to be closed for an extended period of time to investigate and eliminate the contamination;

- the manufacturing facilities in which our products are made could be adversely affected by equipment failures, labor and raw material shortages, financial difficulties of our contract manufacturers, natural disasters, power failures, local political unrest and numerous other factors; and

- any adverse developments affecting manufacturing operations for our products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls or other interruptions in the supply of our products. We may also have to record inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek costlier manufacturing alternatives.

The manufacture of biologic products, and in particular, the glycoPEGylation process, is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of biologic products often encounter difficulties in production, particularly in scaling up and validating initial production and ensuring the avoidance of contamination. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error and shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. We cannot assure you that any stability or other issues relating to the manufacture of BIO89-100 will not occur in the future.

We have limited process development capabilities and have access only to external manufacturing capabilities. We do not have and we do not currently plan to acquire or develop the facilities or capabilities to manufacture bulk drug substance or filled drug product for use in human clinical trials or commercialization. Any delay or interruption in the supply of clinical trial materials, including as a result of breach by us or BTPH of our agreement with BTPH, or our inability to agree to the terms of supply or related services in any statement of work, could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely.

We plan to develop a new drug product formulation for BIO89-100 and we may be unsuccessful. Any changes in methods of product candidate manufacturing or formulation may result in the need to perform new clinical trials, which would require additional costs and cause delay.

We plan to develop a new drug product formulation of BIO89-100 for late stage clinical trials and commercialization. Our current drug product is stored as a frozen liquid and is therefore not well-suited to larger clinical trials or commercialization. We have engaged a formulation development company to explore both a new refrigerated liquid formulation and a freeze-dried, or lyophilized formulation. We also plan to begin development of a pen-type autoinjector for the new drug product formulation. There is no assurance that we will be successful in developing a new drug product formulation or an autoinjector on a timely basis or at all, which could impede our development and commercialization strategy for BIO89-100. The FDA or other comparable foreign regulatory authorities could require nonclinical studies or clinical trials to support introduction of any new formulation and autoinjector, which could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase our clinical trial costs, delay approval of BIO89-100 and jeopardize our ability to commence product sales and generate revenue from BIO89-100, if approved.

We rely on third parties to conduct our clinical trials and some aspects of our research and preclinical testing, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research or testing.

We currently rely on, and expect to continue to rely on, third parties, such as CROs, clinical data management organizations, medical institutions, consultants and clinical investigators, to conduct our clinical trials and certain aspects of our research and preclinical testing. Any of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements, it would delay our product development activities and such alternative arrangements may not be available on terms acceptable to us.

Our reliance on these third parties for research and development activities will reduce our control over these activities, but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as current Good Clinical Practices, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We also are required to register ongoing clinical trials and post the results of completed clinical

trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for BIO89-100 or any future product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our medicines.

We also expect to rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development, marketing approval and/or commercialization of BIO89-100 or any future product candidates, producing additional losses and depriving us of potential revenue.

In addition, while we have received the majority of the knowledge with regard to our current product candidate from Teva, we may still depend on Teva to provide information and documentation regarding certain aspects of BIO89-100 or any future product candidates. If Teva delays providing or fails to provide such information or documentation, we may also be delayed in our efforts to successfully commercialize BIO89-100 or any future product candidates. We also depend on Teva to support our efforts to transfer the manufacturing process to a contract manufacturer. If Teva is unable to or otherwise fails to support such transfer, we may incur significant delay and increased costs in commercializing BIO89-100 or any future product candidates.

We may not be able to obtain and maintain the third-party relationships that are necessary to develop, commercialize and manufacture some or all of our product candidates.

We expect to depend on collaborators, partners, licensees, clinical investigators, CROs, manufacturers and other third parties to support our discovery efforts, to formulate product candidates, to conduct clinical trials for some or all of our product candidates, to manufacture clinical and commercial scale quantities of our drug substance and drug product and to market, sell and distribute any products we successfully develop. Any problems we experience with any of these third parties could delay the development, commercialization and manufacturing of our product candidates, which could harm our results of operations.

We cannot guarantee that we will be able to successfully negotiate agreements for, or maintain relationships with, collaborators, partners, licensees, clinical investigators, CROs, manufacturers and other third parties on favorable terms, if at all. If we are unable to obtain or maintain these agreements, we may not be able to clinically develop, formulate, manufacture, obtain regulatory approvals for or commercialize BIO89-100 and any future product candidates, which will in turn adversely affect our business.

We expect to expend substantial management time and effort to enter into relationships with third parties and, if we successfully enter into such relationships, to manage these relationships. In addition, substantial amounts will be paid to third parties in these relationships. However, we cannot control the amount or timing of resources our future contract partners will devote to our research and development programs, product candidates or potential product candidates, and we cannot guarantee that these parties will fulfill their obligations to us under these arrangements in a timely fashion, if at all. In addition, while we manage the relationships with third parties, we cannot control all of the operations of and any outsourcing used by such third parties. We rely on third parties' knowledge regarding specific local laws and regulatory requirements in foreign jurisdictions, where applicable.

If we fail to develop and commercialize additional product candidates, we may be unable to grow our business.

Although the development and commercialization of BIO89-100 is currently our primary focus, as part of our longer-term growth strategy, we plan to evaluate the development and commercialization of other

therapies related to NASH and other liver and cardio-metabolic diseases. The success of this strategy depends primarily upon our ability to identify and validate new therapeutic candidates, and to identify, develop and commercialize new drugs and biologics. Our research efforts may initially show promise in discovering potential new drugs and biologics, yet fail to yield product candidates for clinical development for a number of reasons, including:

- we may need to rely on third parties to generate molecules for some of our product candidate programs;
- we may encounter product manufacturing difficulties that limit yield or produce undesirable characteristics that increase the cost of manufacturing our product candidates, cause delays or make our product candidates unmarketable;
- product candidates may cause adverse effects in patients or subjects, even after successful initial toxicology studies, which may make the product candidates unmarketable;
- product candidates may not demonstrate a meaningful benefit to patients or subjects; and
- our future collaboration partners may change their development profiles or plans for potential product candidates or abandon a therapeutic area or the development of a partnered product.

If any of these events occur, we may be forced to abandon our development efforts for one or more programs, which could have a material adverse effect on our business, operating results and prospects and could potentially cause us to cease operations. Future research programs to identify new product candidates may require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful.

Product candidates may require additional, time-consuming development efforts prior to commercial sale, including preclinical studies, clinical trials and approval by the FDA and/or comparable foreign regulatory authorities. All product candidates are prone to the risks of failure that are inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot assure you that any such products that are approved will be manufactured or produced economically, be successfully commercialized, be widely accepted in the marketplace, or be more effective than other commercially available alternatives.

We may use our limited financial and human resources to pursue a particular research program or product candidate that is ultimately unsuccessful or less successful than other programs or product candidates that we may have forgone or delayed.

Because we have limited personnel and financial resources, we may forego or delay the development of certain programs or product candidates that later prove to have greater commercial potential than the programs or product candidates that we do pursue. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs for product candidates may not yield any commercially viable products. Similarly, our decisions to delay or terminate drug development programs may also be incorrect and could cause us to miss valuable opportunities. If we fail to accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic collaboration, licensing or other arrangements or we may allocate our limited internal resources to that product candidate when it would have been more advantageous to enter into such an arrangement. Any such failure could have a material adverse effect on our business, financial condition, results of operations or prospects.

As we evolve from a company that is primarily involved in clinical development to a company that is also involved in commercialization, we may encounter difficulties in expanding our operations successfully.

As we advance our product candidates through clinical trials, we will need to expand our development, regulatory, manufacturing, and marketing and sales capabilities and may need to further contract with third parties to provide these capabilities, such as collaborators, distributors, marketers and additional suppliers. We currently have no experience as a company in or infrastructure for sales, marketing and distribution, and our operations are currently limited to clinical development activities and as our operations expand, we likely will need to manage additional relationships with such third parties.

If BIO89-100 or any future product candidate is approved, we intend either to establish a sales and organization with technical expertise and supporting distribution capabilities to commercialize BIO89-100 or any future product candidate or to outsource such functions to one or more third parties. Either of these options would be expensive and time-consuming. Some or all of these costs may be incurred in advance of any approval of BIO89-100 or any future product candidate. In addition, we may not be able to hire a sales force that is sufficient in size or has adequate expertise in the medical markets that we intend to target. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely affect the commercialization of BIO89-100 and other future product candidates.

Maintaining third-party relationships for these purposes will impose significant added responsibilities on members of our management and other personnel. We must be able to effectively manage our development efforts, recruit and train sales and marketing personnel, effectively manage our participation in the clinical trials in which our product candidates are involved and improve our managerial, development, operational and finance systems, all of which may impose a strain on our administrative and operational infrastructure.

If we enter into arrangements with third parties to perform sales, marketing or distribution services, any product revenues that we receive, or the profitability of these product revenues to us, are likely to be lower than if we were to market and sell any products that we develop without the involvement of these third parties. In addition, we may not be successful in entering into arrangements with third parties to sell and market our products or in doing so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our products.

We may seek to establish commercial collaborations for our product candidates, and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

Our drug development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. We may decide to collaborate with other pharmaceutical and biotechnology companies for the development and potential commercialization of our product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator’s resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator’s evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or comparable foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products and the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborators may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate.

Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

BIO89-100 and any future product candidates may not achieve adequate market acceptance among physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

Even if our product candidates receive regulatory approval, they may not gain adequate market acceptance among physicians, patients, healthcare payors and others in the medical community. Given the number of drugs in development for the treatment of NASH, if we are unsuccessful in achieving a differentiated profile with BIO89-100 based on efficacy, safety and tolerability, dosing and administration, market acceptance will be limited. Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may not be successful. Demonstrating the safety and efficacy of our product candidates and obtaining regulatory approvals will not guarantee future revenue. Our commercial success also depends on coverage and adequate reimbursement of our product candidates by third-party payors, including government payors, which may be difficult or time-consuming to obtain, may be limited in scope and may not be obtained in all jurisdictions in which we may seek to market our products. Governments and private insurers closely examine medical products to determine whether they should be covered by reimbursement and, if so, the level of reimbursement that will apply. We cannot be certain that third-party payors will sufficiently reimburse sales of our products, or otherwise enable us to sell our products at profitable prices. Similar concerns could also limit the reimbursement amounts that health insurers or government agencies in other countries are prepared to pay for our products. In many countries or regions where we may market our products, either directly or with collaborators, the pricing of prescription drugs is controlled by the government or regulatory agencies. Regulatory agencies in these countries could determine that the pricing for our products should be based on prices of other commercially available drugs for the same disease, rather than allowing us to market our products at a premium as new drugs. This may be particularly true for drugs that treat NASH or SHTG, which some healthcare providers and payors may deem to be a “lifestyle” disease that could be ameliorated by changes in diet and exercise. The degree of market acceptance of any of our approved product candidates will depend on a number of factors, including:

- the efficacy, safety and dosing profile of the product candidate as demonstrated in clinical trials;
- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which the product candidate is approved;
- acceptance of the product candidate as a safe and effective treatment by physicians and patients;
- the potential and perceived advantages of the product candidate over alternative treatments, including any similar generic treatments;
- the cost of treatment in relation to alternative treatments;

- the availability of coverage and adequate reimbursement and pricing by third parties and government authorities, including any requirements for biopsy-proven NASH prior to being approved for reimbursement;
- patients' willingness to pay out-of-pocket in the absence of coverage and/or adequate reimbursement from third-party payors;
- the relative convenience and ease of administration;
- the frequency and severity of adverse events;
- the effectiveness of sales and marketing efforts; and
- unfavorable publicity relating to the product candidate.

Sales of medical products also depend on the willingness of physicians to prescribe the treatment, which is likely to be based on a determination by these physicians that the products are safe, therapeutically effective and cost effective. In addition, the inclusion or exclusion of products from treatment guidelines established by various physician groups and the viewpoints of influential physicians can affect the willingness of other physicians to prescribe the treatment. We cannot predict whether physicians, physicians' organizations, hospitals, other healthcare providers, government agencies or private insurers will determine that our products are safe, therapeutically effective and cost effective as compared with competing treatments. If any product candidate is approved but does not achieve an adequate level of acceptance by such parties, we may not generate or derive sufficient revenue from that product candidate and may not become or remain profitable.

Even if we commercialize BIO89-100 or any future product candidate, we may face challenges to achieving profitability such as our products becoming subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which could harm our business.

The regulations that govern marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay or limit our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenue we generate from the sale of the product in that particular country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval.

Our ability to commercialize any products successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third-party payors, including government health care programs and private health insurers. Such third-party payors determine which medications they will cover and establish reimbursement levels. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that coverage and reimbursement will be available for any product that we or our future collaborators commercialize and, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we or our future collaborators obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we and our future collaborators may not be able to successfully commercialize any product candidate for which marketing approval is obtained.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

To become and remain profitable, we or any potential future collaborator must develop and eventually commercialize BIO89-100 or any future product candidates with significant market potential at an adequate profit margin after cost of goods sold and other expenses. Commercialization of BIO89-100 or any future product candidates may entail a substantial cost of goods sold and there can be no assurance that we will be able to achieve a suitable gross margin with respect to sales of BIO89-100 or any future product candidates.

Healthcare reform in the United States may negatively impact our ability to profitably sell our product candidates, if approved, and to recoup the upfront investment needed to obtain regulatory approval of our product candidates.

Third-party payors, whether domestic or foreign, or governmental or commercial, are continually developing and advancing new methods of controlling healthcare costs. The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product for which we obtain marketing approval.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the “Affordable Care Act”) was enacted, which includes measures that have significantly changed the way health care is financed by both governmental and private insurers. Among the provisions of the Affordable Care Act of particular importance include:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, which is apportioned among these entities according to their market share in certain government healthcare programs;
- a Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- a methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;

- a licensure framework for follow-on biologic products;
- an extension of a manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and
- establishment of a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services ("CMS") to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Some of the provisions of the Affordable Care Act have yet to be implemented, and there have been judicial and congressional challenges to certain aspects of the Affordable Care Act which could potentially void or significantly modify the Affordable Care Act in part or in whole. For example, since January 2017, President Trump signed two Executive Orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the Affordable Care Act. On December 22, 2017, President Trump signed into law The Tax Cuts and Jobs Act of 2017 (the "Tax Act"), which includes a provision repealing the individual mandate to maintain health insurance coverage under the Affordable Care Act effective January 1, 2019. Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain mandated fees under the Affordable Care Act, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans and the annual fee imposed on certain health insurance providers based on market share. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas ruled that the individual mandate is a critical and inseverable feature of the Affordable Care Act, and because it was repealed as part of the Tax Act, the remaining provisions of the Affordable Care Act are invalid as well. While neither the Texas District Court Judge, the Trump administration nor CMS have stated that the ruling will have an immediate effect, it is unclear how this decision, subsequent appeals, if any, and other efforts will impact the Affordable Care Act.

At the same time, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration's budget proposals for fiscal years 2019 and 2020 contain further drug price control measures that could be enacted during the budget process or in other future legislation. The Trump administration released a "Blueprint," or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. We expect that the healthcare reform measures that have been adopted and may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate product revenue, attain profitability or commercialize our products.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate product revenue, attain profitability, or commercialize our products. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for

which we may obtain regulatory approval and may affect our overall financial condition, including our ability to recoup the upfront investment needed to obtain regulatory approval for our product candidates.

Our international operations may expose us to business, regulatory, political, operational, financial, pricing and reimbursement risks associated with doing business outside of the United States.

Our use of our international facilities subject us to U.S. and foreign governmental trade, import and export, and customs regulations and laws. Compliance with these regulations and laws is costly and exposes us to penalties for non-compliance. Furthermore, if we succeed in developing any products, we intend to market them in other jurisdictions in addition to the United States. If approved, we may hire sales representatives and conduct physician and patient association outreach activities outside of the United States.

Doing business internationally potentially involves a number of risks, including but not limited to:

- multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements, and other governmental approvals, permits and licenses;
- failure by us to obtain and maintain regulatory approvals for the use of our products in various countries;
- rejection or qualification of foreign clinical trial data by the competent authorities of other countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining, maintaining, protecting and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- a shortage of high-quality employees;
- laws and business practices favoring local companies;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- limits in our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions;
- the imposition of restrictions on the activities of foreign agents and representatives;
- certain expenses including, among others, expenses for travel, translation and insurance; and
- regulatory and compliance risks that relate to anti-corruption compliance and record-keeping that may fall within the purview of the U.S. Foreign Corrupt Practices Act, its accounting provisions or its anti-bribery provisions or provisions of anti-corruption or anti-bribery laws in other countries.

Any of these factors could harm our ongoing international clinical operations and supply chain, as well as any future international expansion and operations and, consequently, our business, financial condition, prospects and results of operations.

If we fail to comply with foreign regulatory requirements governing human clinical trials and marketing approval for drugs, we could be prevented from selling our product candidates in foreign markets, which may adversely affect our operating results and financial condition.

The requirements governing the conduct of clinical trials, product licensing, pricing, and reimbursement for marketing our product candidates outside the United States vary greatly from country to country and may require additional testing. We expect that our future clinical development of our product candidates will involve a number of clinical trials in foreign jurisdictions. We have no direct experience as a company in obtaining foreign regulatory approvals. The time required to obtain approvals outside the United States may differ from that required to obtain FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not guarantee approval by comparable foreign regulatory authorities, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other countries or by the FDA. Failure to comply with these regulatory requirements or obtain required approvals could impair our ability to develop foreign markets for our product candidates and may have a material adverse effect on our results of operations and financial condition.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercialize any resulting products. Product liability claims may be brought against us by subjects enrolled in our clinical trials, patients, or others using our products. If we cannot successfully defend ourselves against claims that our product candidates or products that we may develop caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- product recalls or a change in the indications for which products may be used;
- termination of clinical trial sites or entire trial programs;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial subjects or patients;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize any products that we may develop.

Our clinical trial liability insurance coverage may not adequately cover all liabilities that we may incur. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any

liability that may arise. Our inability to obtain product liability insurance at an acceptable cost or to otherwise protect against potential product liability claims could prevent or delay the commercialization of any products or product candidates that we develop. We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain marketing approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. If we are sued for any injury caused by our products, product candidates or processes, our liability could exceed our product liability insurance coverage and our total assets. Claims against us, regardless of their merit or potential outcome, may also generate negative publicity or hurt our ability to obtain physician endorsement of our products or expand our business.

Our employees, contractors, vendors, principal investigators, consultants and future partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, contractors, vendors, principal investigators, consultants or future partners. Misconduct by these parties could include failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with federal and state healthcare fraud and abuse laws and regulations, to report financial information or data timely, completely or accurately, or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Third-party misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. Although we intend to adopt a Code of Business Conduct and Ethics, which will be effective prior to the consummation of this offering, it is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us resulting from this misconduct and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions. If we or our future partners market products in a manner that violates fraud and abuse and other healthcare laws, or if we or our future partners violate government price reporting laws, we or our future partners may be subject to administrative civil and/or criminal penalties, among other sanctions.

Most states also have statutes or regulations similar to these federal laws, which may apply to items such as pharmaceutical products and services reimbursed by private insurers. We and/or our future partners may be subject to administrative, civil and criminal sanctions for violations of any of these federal and state laws. Pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of promotional and marketing activities, such as: providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates. Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations.

Our business operations and relationships with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers are subject to broadly applicable healthcare regulatory laws, which could expose us to penalties.

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any product candidate for which we obtain regulatory approval. Our current and future arrangements may expose us to broadly applicable fraud and abuse and other healthcare laws that may constrain the business or financial arrangements and relationships through which we would market, sell and distribute our products. Even though we will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, federal and state healthcare laws pertaining to fraud and abuse are and will be applicable to our business. Such laws include, but are not limited to, the following:

- Federal false claims, false statements and civil monetary penalties laws, including the federal civil False Claims Act ("FCA"), which can be enforced through civil whistleblower or qui tam actions, prohibit, among others, any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid.

- The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers, on the one hand, and prescribers, purchasers and formulary managers, on the other. Although there are several statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. In addition, the intent standard under the federal Anti-Kickback Statute was amended by the Affordable Care Act to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Moreover, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA.

- The federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme or artifice to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious or fraudulent statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

- Patient data privacy and security regulation, including, in the United States, HIPAA, as amended by the Health Information Technology for Clinical Health Act of 2009 ("HITECH"), and their respective implementing regulations, which impose specified requirements on "covered entities," including healthcare providers, health plans, and healthcare clearinghouses, as well as their respective "business associates" that perform services for them that involve the use, or disclosure of, individually identifiable health information relating to the privacy, security and transmission of individually identifiable health information.

- The federal transparency requirements under the Physician Payments Sunshine Act, enacted as part of the Affordable Care Act, that require applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to track and annually report to CMS payments and other transfers of value provided to physicians and teaching hospitals and certain ownership and investment interests held by physicians or their immediate family members in the applicable manufacturer, and disclosure of such information will be made by CMS on a publicly available website.

- Analogous state, local or foreign laws, such as state anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state and local marketing and/or transparency laws applicable to manufacturers that may be broader in scope than the federal requirements; state laws that require biopharmaceutical companies to comply with the biopharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state and local laws that require licensure or registration by sales and marketing agents of a pharmaceutical company; state laws that require disclosure of information related to drug pricing; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect as HIPAA.

Pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of promotional and marketing activities, such as: providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates. Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations.

The global data protection landscape is rapidly evolving, and we may be affected by or subject to new, amended or existing laws and regulations in the future, including as our operations continue to expand or if we operate in foreign jurisdictions. For example, in June 2018, California enacted the California Consumer Privacy Act of 2018 (the "CCPA"), which takes effect on January 1, 2020. The CCPA gives California residents the right to access and require deletion of their personal information, the right to opt out of certain personal information sharing, and the right to detailed information about how their personal information is collected, used and shared. The CCPA provides civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Although the CCPA includes exemptions for certain clinical trials data, the law may increase our compliance costs and potential liability with respect to other personal information we collect about California residents. The CCPA has prompted a wave of proposals for new federal and state privacy legislation that, if passed, could increase our potential liability, increase our compliance costs and adversely affect our business. Several foreign jurisdictions, including the European Union (EU), its member states, the United Kingdom, Japan and Australia, among others, have adopted legislation and regulations that increase or change the requirements governing the collection, use, disclosure and transfer of the personal information of individuals in these jurisdictions. Additionally, certain countries have passed or are considering passing laws that require local data residency and/or restrict the international transfer of data. These laws have the potential to increase costs of compliance, risks of noncompliance and penalties for noncompliance.

If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, disgorgement, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, additional oversight and reporting obligations, contractual damages, reputational harm, diminished

profits and future earnings, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, that person or entity may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

We depend on our information technology systems and those of our third-party collaborators, service providers, contractors or consultants. Our internal computer systems, or those of our third-party collaborators, service providers, contractors or consultants, may fail or suffer security breaches, disruptions, or incidents, which could result in a material disruption of our development programs or loss of data or compromise the privacy, security, integrity or confidentiality of sensitive information related to our business and have a material adverse effect on our reputation, business, financial condition or results of operations.

In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. Our internal technology systems and infrastructure, and those of our current or future third-party collaborators, service providers, contractors and consultants are vulnerable to damage from computer viruses, unauthorized access or use resulting from malware, natural disasters, terrorism, war and telecommunication and electrical failures, denial-of-service attacks, cyber-attacks or cyber-intrusions over the Internet, hacking, phishing and other social engineering attacks, persons inside our organizations (including employees or contractors), loss or theft, or persons with access to systems inside our organization. Attacks on information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and they are being conducted by increasingly sophisticated and organized foreign governments, groups and individuals with a wide range of motives and expertise. In addition to extracting or accessing sensitive information, such attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the security, confidentiality, integrity and availability of information. The prevalent use of mobile devices that access sensitive information also increases the risk of data security incidents which could lead to the loss of confidential information or other intellectual property. While to our knowledge we have not experienced any material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations or the operations of third-party collaborators, service providers, contractors and consultants, it could result in a material disruption of our development programs and significant reputational, financial, legal, regulatory, business or operational harm. The costs to us to mitigate, investigate and respond to potential security incidents, breaches, disruptions, network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position.

For example, the loss of clinical trial data from completed, ongoing or planned clinical trials for our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any real or perceived security breach affects our systems (or those of our third-party collaborators, service providers, contractors or consultants), or results in the loss of or accidental, unlawful or unauthorized access to, use of, release of, or other processing of personally identifiable information or damage to our data or applications or other data or applications relating to our technology or product candidates, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and the further development of our product candidates could be delayed. Such a breach may require notification to governmental agencies, the media or individuals pursuant to various foreign, domestic (federal and state) privacy and security laws, if applicable, including HIPAA, as amended by HITECH, and its implementing rules and regulations, as well as regulations promulgated by the Federal Trade Commission and state breach notification laws. In addition, our liability insurance may not be sufficient in type or amount to cover us against claims related to security breaches, cyberattacks and other related incidents.

Any failure or perceived failure by us or any third-party collaborators, service providers, contractors or consultants to comply with our privacy, confidentiality, data security or similar obligations, or any data security

incidents or other security breaches that result in the accidental, unlawful or unauthorized access to, use of, release of, processing of, or transfer of sensitive information, including personally identifiable information, may result in negative publicity, harm to our reputation, governmental investigations, enforcement actions, regulatory fines, litigation or public statements against us, could cause third parties to lose trust in us or could result in claims by third parties, including those that assert that we have breached our privacy, confidentiality, data security or similar obligations, any of which could have a material adverse effect on our reputation, business, financial condition or results of operations. To the extent we maintain individually identifiable health information, we could be subject to fines and penalties (including civil and criminal) under HIPAA for any failure by us or our business associates to comply with HIPAA's requirements. Moreover, data security incidents and other security breaches can be difficult to detect, and any delay in identifying them may lead to increased harm. While we have implemented data security measures intended to protect our information, data, information technology systems, applications and infrastructure, there can be no assurance that such measures will successfully prevent service interruptions or data security incidents.

European data collection is governed by restrictive regulations governing the collection, use, processing and cross-border transfer of personal information.

We may collect, process, use or transfer personal information from individuals located in the European Economic Area in connection with our business, including in connection with conducting clinical trials in the European Economic Area (the "EEA"). Additionally, if any of our product candidates are approved, we may seek to commercialize those products in the European Economic Area. The collection and use of personal health data in the European Economic Area is governed by the provisions of the General Data Protection Regulation ((EU) 2016/679) (the "GDPR"), along with other European Union and country-specific laws and regulations. The United Kingdom and Switzerland have also adopted data protection laws and regulations. These legislative acts (together with regulations and guidelines) impose requirements relating to having legal bases for processing personal data relating to identifiable individuals and transferring such data outside of the European Economic Area, including to the United States, providing details to those individuals regarding the processing of their personal data, keeping personal data secure, having data processing agreements with third parties who process personal data, responding to individuals' requests to exercise their rights in respect of their personal data, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers or corporate representatives, conducting data protection impact assessments and record-keeping. The GDPR imposes additional responsibilities and liabilities in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. Failure to comply with the requirements of the GDPR and related national data protection laws of the member states of the European Economic Area and other states in the European Economic Area may result in substantial fines, other administrative penalties and civil claims being brought against us, which could have a material adverse effect on our business, financial condition and results of operations. European data protection authorities may interpret the GDPR and national laws differently and may impose additional requirements, which adds to the complexity of processing personal data in or from the EEA or United Kingdom. Guidance on implementation and compliance practices are often updated or otherwise revised.

Our insurance policies are expensive and only protect us from some business risks, leaving us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. We believe that we maintain insurance customary for businesses of our size and type, including clinical trial liability insurance. However, there are types of losses we may incur that cannot be insured against or that we believe are not economically reasonable to insure. Moreover, any loss incurred could exceed policy limits and policy payments made to us may not be made on a timely basis. Such losses could adversely affect our business prospects, results of operations, cash flows and financial condition. We do not know if our current levels of coverage are adequate or if we will be able to obtain insurance with adequate levels of coverage in the future, if at all. Any significant uninsured liability may require us to pay substantial amounts, which could materially and adversely affect our financial position and results of operations.

Disputes under key agreements or conflicts of interest with our scientific advisors or clinical investigators could delay or prevent development or commercialization of our product candidates.

Any agreements we have or may enter into with third parties, such as collaboration, license, formulation supplier, manufacturing, clinical research organization or clinical trial agreements, may give rise to disputes regarding the rights and obligations of the parties. Disagreements could develop over contract interpretation, rights to ownership or use of intellectual property, the scope and direction of research and development, the approach for regulatory approvals or commercialization strategy. We intend to conduct research programs in a range of therapeutic areas, but our pursuit of these opportunities could result in conflicts with the other parties to these agreements that may be developing or selling pharmaceuticals or conducting other activities in these same therapeutic areas. Any disputes or commercial conflicts could lead to the termination of our agreements, delay progress of our product development programs, compromise our ability to renew agreements or obtain future agreements, lead to the loss of intellectual property rights, result in increased financial obligations for us or result in costly litigation.

We work with outside scientific advisors and collaborators at academic and other institutions that assist us in our research and development efforts. Our scientific advisors are not our employees and may have other commitments that limit their availability to us. If a conflict of interest between their work for us and their work for another entity arises, we may lose their services.

If the market opportunities for any product that we or our strategic collaborators develop are smaller than we believe they are, our revenue may be adversely affected and our business may suffer.

We intend to initially focus our product candidate development on therapies for the treatment of liver and cardio-metabolic diseases. Our projections of addressable patient populations that have the potential to benefit from treatment with our product candidates are based on estimates. These estimates have been derived from a variety of sources, including the scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our product candidates may not ultimately be amenable to treatment with our product candidates. Our market opportunity may also be limited by future competitor treatments that enter the market. If any of our estimates are inaccurate, the market opportunities for any of our product candidates could be significantly diminished and have an adverse material impact on our business.

Monitoring safety of patients receiving our product candidates is challenging, which could adversely affect our ability to obtain regulatory approval and commercialize.

For our ongoing clinical trial and planned clinical trials, we have and expect to contract with CROs and clinical trial sites experienced in the assessment and management of toxicities arising during clinical trials. Nonetheless, these CROs and clinical trial sites may have difficulty observing patients and treating toxicities, which may be more challenging due to personnel changes, inexperience, shift changes, house staff coverage or related issues. This could lead to more severe or prolonged toxicities or even patient deaths, which could result in us or the FDA delaying, suspending or terminating one or more of our clinical trials, and which could jeopardize regulatory approval. We also expect the centers using our product candidates, if approved, on a commercial basis could similarly have difficulty in managing adverse events. Medicines used at centers to help manage adverse side effects of our product candidates may not adequately control the side effects and/or may have a detrimental impact on the efficacy of the treatment. Use of these medicines may increase with new physicians and centers administering our product candidates.

Unstable market and economic conditions may have serious adverse consequences on our business and financial condition.

Global credit and financial markets have experienced extreme disruptions at various points over the last few decades, characterized by diminished liquidity and credit availability, declines in consumer confidence,

declines in economic growth, increases in unemployment rates and uncertainty about economic stability. If another such disruption in credit and financial markets and deterioration of confidence in economic conditions occurs, our business may be adversely affected. If the equity and credit markets were to deteriorate significantly in the future, it may make any necessary debt or equity financing more difficult to complete, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and share price and could require us to delay or abandon development or commercialization plans. In addition, there is a risk that one or more of our service providers, manufacturers or other partners would not survive or be able to meet their commitments to us under such circumstances, which could directly affect our ability to attain our operating goals on schedule and on budget.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties to sell our products sell our products outside the United States, to conduct clinical trials, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

Changes in our effective income tax rate could adversely affect our results of operations.

We are subject to income taxes in the United States and various foreign jurisdictions. Various factors may have favorable or unfavorable effects on our effective income tax rate. These factors include, but are not limited to, interpretations of existing tax laws, changes in tax laws and rates, the accounting for stock options and other stock-based compensation, changes in accounting standards, future levels of research and development spending, changes in the mix and level of pre-tax earnings in different jurisdictions, the outcome of audits or other examinations by the U.S. Internal Revenue Service and tax regulators in other jurisdictions, the accuracy of our estimates for unrecognized tax benefits, the realization of deferred tax assets and changes to our ownership or capital structure. The impact of the above-mentioned factors and others on our effective income tax rate may be significant and could adversely affect our results of operations.

Risks Related to Regulatory Approvals

BIO89-100 has not received regulatory approval. If we are unable to obtain regulatory approvals to market BIO89-100 or any future product candidates, our business will be adversely affected.

We do not expect BIO89-100 or any future product candidate to be commercially available for several years, if at all. BIO89-100 is and any future product candidate will be subject to strict regulation by regulatory

authorities in the United States and in other countries. We cannot market any product candidate until we have completed all necessary preclinical studies and clinical trials and have obtained the necessary regulatory approvals. We do not know whether regulatory agencies will grant approval for BIO89-100 or any future product candidate. Even if we complete preclinical studies and clinical trials successfully, we may not be able to obtain regulatory approvals or we may not receive approvals to make claims about our products that we believe to be necessary to effectively market our products. Data obtained from preclinical studies and clinical trials is subject to varying interpretations that could delay, limit or prevent regulatory approval, and failure to comply with regulatory requirements or inadequate manufacturing processes are examples of other problems that could prevent approval. The regulatory authorities in the United States and the EU have not approved any products for the treatment of NASH, and while there are recent guidelines issued by the FDA for the development of drugs for the treatment of NASH and a FDA surrogate endpoint table for drug approval that includes SHTG, it is unclear whether the requirements for approval will change in the future. Any such changes may require us to conduct new trials that could delay our timeframe and increase the costs of our programs related to BIO89-100 or any future product candidate for the treatment of NASH or SHTG. While the FDA has approved reduction in triglycerides levels as a surrogate endpoint for the full approval of drugs for the treatment of SHTG, it is unclear whether this endpoint will apply to any product candidates that we develop. If such endpoint is not deemed to apply to our product candidates, it would delay our development timeline and increase the costs of our programs for the treatment of SHTG. We have not had any discussions with the FDA regarding a surrogate endpoint or accelerated approval regulations. However, we currently expect that our SHTG program would be subject to smaller clinical trials and that we may expect a relatively quick overall development timeline for this indication. These expectations are based on a published FDA surrogate endpoint table for drug approval that includes SHTG, as well as the development path followed by other companies that developed an SHTG therapy. However, we do not have a Special Protocol Assessment or other agreement with the FDA on the required clinical trials needed to support an application for approval of BIO89-100 in SHTG, and the overall clinical requirements and development timeline may be greater than expected. In addition, we may encounter delays or rejections due to additional government regulation from future legislation, administrative action or changes in the policies of the FDA or comparable foreign regulatory authorities. Even if the FDA or a comparable foreign regulatory authority approves a product, the approval will be limited to those indications covered in the approval.

Even if we are able to obtain regulatory approvals for BIO89-100 or any future product candidate, if they exhibit harmful side effects after approval, our regulatory approvals could be revoked or otherwise negatively impacted, and we could be subject to costly and damaging product liability claims.

Even if we receive regulatory approval for BIO89-100 or any future product candidates, we will have tested them in only a small number of patients during our clinical trials. If our applications for marketing are approved and more patients begin to use our product, new risks and side effects associated with our products may be discovered. As a result, regulatory authorities may revoke their approvals. We have not had any discussions with the FDA regarding a surrogate endpoint or accelerated approval regulations. However, based on recent guidelines issued by the FDA for the development of drugs for the treatment of NASH, if BIO89-100 is approved by the FDA based on a surrogate endpoint pursuant to section 506(c) of the Federal Food, Drug, and Cosmetic Act and the accelerated approval regulations (21 C.F.R. part 314, subpart H; 21 C.F.R. part 601, subpart E), consistent with FDA guidance, we will be required to conduct additional clinical trials establishing clinical benefit on the ultimate outcome of NASH. If BIO89-100 is approved by the FDA for the treatment of SHTG based on an endpoint of the reduction of triglycerides, the FDA may still require a cardiovascular outcomes study as part of a post-marketing authorization commitment. Such a study would be time consuming and costly and we cannot guarantee that we will see positive results, which could result in the revocation of the approval. Additionally, we may be required to conduct additional clinical trials, make changes in labeling of our product, reformulate our product or make changes and obtain new approvals for our and our suppliers' manufacturing facilities for BIO89-100 and any future product candidates. We might have to withdraw or recall our products from the marketplace. We may also experience a significant drop in the potential sales of our product if and when regulatory approvals for such product are revoked. As a result, we may experience harm to our reputation in the marketplace or become subject to

lawsuits, including class actions. Any of these results could decrease or prevent any sales of our approved product or substantially increase the costs and expenses of commercializing and marketing our product.

The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable. Our inability to obtain regulatory approval for BIO89-100 or any future product candidates would substantially harm our business.

Currently, we do not have any product candidates that have received regulatory approval. The time required to obtain approval from the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's development and may vary among jurisdictions. It is possible that none of BIO89-100 or any future product candidates will ever obtain regulatory approval.

BIO89-100 or any future product candidate could fail to receive regulatory approval from the FDA or comparable foreign regulatory authorities for many reasons, including:

- disagreement with the design or implementation of our clinical trials;
- failure to demonstrate that a product candidate is safe and effective for its proposed indication;
- failure of clinical trials to meet the level of statistical significance required for approval;
- failure to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- the insufficiency of data collected from clinical trials of a product candidate to support the submission and filing of a BLA or other submission or to obtain regulatory approval;
- failure to obtain approval of the manufacturing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies; or
- changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval.

The FDA or comparable foreign regulatory authorities may require more information, including additional preclinical or clinical data to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program for other reasons. If we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may grant approval contingent on the performance of costly post-marketing clinical trials or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate.

Our failure to obtain regulatory approval in international jurisdictions would prevent us from marketing our product candidates outside the United States.

If we succeed in developing any products, we intend to market them in foreign jurisdictions in addition to the United States. In order to market and sell our products in other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. We may not obtain foreign

regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions. Approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. If we fail to obtain approval of any of our product candidates by regulatory authorities in another country we will be unable to commercialize our product in that country, and the commercial prospects of that product candidate and our business prospects could decline. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, we must secure product reimbursement approvals before regulatory authorities will approve the product for sale in that country. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries and regulatory approval in one country does not ensure approval in any other country, while a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. Also, regulatory approval for any of our product candidates may be withdrawn if we fail to comply with regulatory requirements, if problems occur after the product candidate reaches the market or for other reasons. If we fail to comply with the regulatory requirements in international markets and fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business will be adversely affected.

Even if BIO89-100 or any future product candidate receives regulatory approval, it may still face future development and regulatory difficulties.

Even if we obtained regulatory approval for a product candidate, it would be subject to ongoing requirements by the FDA and comparable foreign regulatory authorities governing the manufacture, quality control, further development, labeling, packaging, storage, distribution, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-market information. The FDA and comparable foreign regulatory authorities will continue to closely monitor the safety profile of any product even after approval. If the FDA, or comparable foreign regulatory authorities, become aware of new safety information after approval of any of our product candidates, it may require labeling changes or establishment of a risk evaluation and mitigation strategy or similar strategy, impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance.

In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP, regulations and standards. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, or undesirable side effects caused by such products are identified, a regulatory agency may:

- issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings about such product;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require that we conduct post-marketing studies;

- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend marketing of, withdraw regulatory approval of or recall such product;
- suspend any ongoing clinical studies;
- refuse to approve pending applications or supplements to applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of products or require us to initiate a product recall.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our products and generate product revenue.

Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by the FDA, the Department of Justice, the Department of Health and Human Services' Office of Inspector General, state attorneys general, members of Congress and the public. Violations, including promotion of our products for unapproved (or off-label) uses, are subject to enforcement letters, inquiries and investigations, and significant civil and criminal sanctions by the government. In the United States, engaging in the impermissible promotion of our products for off-label uses can also subject us to false claims litigation under federal and state statutes, which can lead to significant civil and criminal penalties. Additionally, comparable foreign regulatory authorities will heavily scrutinize advertising and promotion of any product candidate that obtains approval outside of the United States.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

Risks Relating to Intellectual Property

Our success depends upon our ability to obtain and maintain intellectual property protection for our products and technologies.

Our success will depend in significant part on our and our current or future licensors', licensees' or collaborators' ability to establish and maintain adequate protection of our owned and licensed intellectual property covering the product candidates we plan to develop, and the ability to develop these product candidates and commercialize the products resulting therefrom, without infringing the intellectual property rights of others. In addition to taking other steps to protect our intellectual property, we hold issued patents, we have applied for patents, and we intend to continue to apply for, patents with claims covering our technologies, processes and product candidates when and where we deem it appropriate to do so. We have filed numerous patent applications both in the United States and in certain foreign jurisdictions to obtain patent rights to inventions we have discovered, with claims directed to compositions of matter, methods of use and other technologies relating to our programs. There can be no assurance that any of these patent applications will issue as patents or, for those applications that do mature into patents, that the claims of the patents will exclude others from making, using or

selling our product candidates or products that compete with or are similar to our product candidates. In countries where we have not sought and do not seek patent protection, third parties may be able to manufacture and sell our product candidates without our permission, and we may not be able to stop them from doing so.

With respect to patent rights, we do not know whether any of the pending patent applications for any of our product candidates will result in the issuance of patents that effectively protect our technologies, processes and product candidates, or if any of our issued patents or our current or future licensors', licensees' or collaborators' issued patents will effectively prevent others from commercializing competitive technologies, processes and products. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or in some cases not at all, until they are issued as a patent. Therefore, we cannot be certain that we or our current or future licensors, licensees or collaborators were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our current or future licensors, licensees or collaborators were the first to file for patent protection of such inventions. For a description of our patent portfolio, see "Business—Intellectual Property."

Any changes we make to our BIO89-100 or any future product candidates to cause them to have what we view as more advantageous properties may not be covered by our existing patents and patent applications, and we may be required to file new applications and/or seek other forms of protection for any such altered product candidates. The patent landscape surrounding the technology underlying our product candidates is crowded, and there can be no assurance that we would be able to secure patent protection that would adequately cover an alternative to BIO89-100 or any future product candidates.

The patent prosecution process is expensive and time-consuming, and we and our current or future licensors, licensees or collaborators may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our current or future licensors, licensees or collaborators will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection for them. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain or enforce the patents, covering technology that we license from or license to third parties and may be reliant on our current or future licensors, licensees or collaborators to perform these activities, which means that these patent applications may not be prosecuted, and these patents enforced, in a manner consistent with the best interests of our business. If our current or future licensors, licensees or collaborators fail to establish, maintain, protect or enforce such patents and other intellectual property rights, such rights may be reduced or eliminated. If our current or future licensors, licensees or collaborators are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised.

Similar to the patent rights of other biotechnology companies, the scope, validity and enforceability of our owned and licensed patent rights generally are highly uncertain and involve complex legal and factual questions. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. In recent years, these areas have been the subject of much litigation in the industry. As a result, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors', licensees' or collaborators' patent rights are highly uncertain. Our and our current or future licensors', licensees' or collaborators' pending and future patent applications may not result in patents being issued that protect our technology or product candidates, or products resulting therefrom, in whole or in part, or that effectively prevent others from commercializing competitive technologies and products. The patent examination process may require us or our current or future licensors, licensees or collaborators to narrow the scope of the claims of pending and future patent applications, which would limit the scope of patent protection that is obtained, if any. Our and our current or future licensors', licensees' or collaborators' patent applications cannot be enforced against third parties practicing the technology that is currently claimed in such applications unless and until a patent issues from such

applications, and then only to the extent the claims that issue are broad enough to cover the technology being practiced by those third parties.

Furthermore, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after the resulting products are commercialized. As a result, our owned and in-licensed patents may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. We expect to seek extensions of patent terms for our issued patents, where available. This includes in the United States under the Hatch-Waxman Act, which permits a patent term extension of up to five years beyond the original expiration date of the patent as compensation for regulatory delays. However, such a patent term extension cannot lengthen the remaining term of a patent beyond a total of 14 years from the product's approval date. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. During the period of patent term extension, the claims of a patent are not enforceable for their full scope, but are instead limited to the scope of the approved product. In addition, the applicable authorities, including the FDA in the United States, and any comparable foreign regulatory authorities, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. In addition, we may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to the expiration of relevant patents or otherwise failing to satisfy applicable requirements. If this occurs, any period during which we have the right to exclusively market our product will be shorter than we would otherwise expect, and our competitors may obtain approval of and launch products earlier than might otherwise be the case.

We may not be able to protect our intellectual property rights throughout the world.

The legal protection afforded to inventors and owners of intellectual property in countries outside of the United States may not be as protective or effective as that in the United States and we may, therefore, be unable to acquire and enforce intellectual property rights outside the United States to the same extent as in the United States. Whether filed in the United States or abroad, our patent applications may be challenged or may fail to result in issued patents.

In addition, our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing or commercializing competing products. Furthermore, others may independently develop or commercialize similar or alternative technologies or drugs, or design around our patents. Our patents may be challenged, invalidated, circumvented or narrowed, or fail to provide us with any competitive advantages. In many foreign countries, patent applications and/or issued patents, or parts thereof, must be translated into the native language. If our patent applications or issued patents are translated incorrectly, they may not adequately cover our technologies; in some countries, it may not be possible to rectify an incorrect translation, which may result in patent protection that does not adequately cover our technologies in those countries.

Filing, prosecuting, enforcing and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States are less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and certain state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with BIO89-100 or any future product candidates and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals. This could make it difficult for us to stop the infringement of our patents or the marketing of competing products in violation of our proprietary rights, generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could place our patent applications at risk of not issuing and could provoke third parties to assert claims against us or our collaborator. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful.

The requirements for patentability differ and certain countries have heightened requirements for patentability, requiring more disclosure in the patent application. In addition, certain countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. Accordingly, our efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

We rely on a license from Teva and a sublicense from ratiopharm to patents and know-how related to glycoPEGylation technology that are used in the development, manufacture and commercialization of BIO89-100. Any termination or loss of significant rights, including the right to glycoPEGylation technology, or breach, under these agreements or any future license agreement related to our product candidates, would materially and adversely affect our ability to continue the development and commercialization of the related product candidates.

In April 2018, we entered into an Asset Transfer and License Agreement (the "FGF21 Agreement") with Teva under which we acquired certain patents, intellectual property and other assets relating to Teva's glycoPEGylated FGF21 program, including BIO89-100. Under this agreement, we were granted a perpetual, non-exclusive (but exclusive as to BIO89-100), non-transferable, worldwide license to patents and know-how related to glycoPEGylation technology used in the development, manufacture and commercialization of BIO89-100 and products containing BIO89-100. The FGF21 Agreement also contains numerous covenants with which we must comply, including the utilization of commercially reasonable efforts to develop and ultimately commercialize BIO89-100, as well as certain reporting covenants and the obligation to make royalty payments, if and when BIO89-100 is approved for commercialization. Our failure to satisfy any of these covenants could result in the termination of the FGF21 Agreement. In addition, we entered into a Sublicense Agreement with ratiopharm (the "ratiopharm Sublicense"), under which we were granted a perpetual, exclusive, worldwide sublicense to patents and know-how related to glycoPEGylation technology used in the development, manufacture and commercialization of BIO89-100 and products containing BIO89-100. Termination of the FGF21 Agreement or the ratiopharm Sublicense will impact our rights under the intellectual property licensed to us by Teva and ratiopharm, respectively, including our license to glycoPEGylation technology, but will not affect our rights under the assets assigned to us.

Beyond this agreement, our commercial success will also depend upon our ability, and the ability of our licensors, to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. A third party may hold intellectual property rights, including patent rights, that are important or necessary to the development of our product candidates. As a result, we may enter into additional license agreements in the future. If we fail to comply with the obligations under these agreements, including payment and diligence obligations, our licensors may have the right to terminate these agreements, in which event we may not be able to develop, manufacture, market or sell any product that is

covered by these agreements or to engage in any other activities necessary to our business that require the freedom to operate afforded by the agreements, or we may face other penalties under the agreements.

Any of the foregoing could materially and adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or amended agreements, which may not be available to us on equally favorable terms, or at all, or cause us to lose our rights under these agreements, including our rights to intellectual property or technology important to our development programs.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect BIO89-100 and any future product candidates.

As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on intellectual property rights, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves technological and legal complexity, and obtaining and enforcing biopharmaceutical patents is costly, time-consuming and inherently uncertain. The U.S. Supreme Court in recent years has issued rulings either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations or ruling that certain subject matter is not eligible for patent protection. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the federal courts, the USPTO and equivalent bodies in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce existing patents and patents we may obtain in the future.

Patent reform laws, such as the Leahy-Smith America Invents Act (the "Leahy-Smith Act"), as well as changes in how patent laws are interpreted, could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith Act made a number of significant changes to U.S. patent law. These include provisions that affect the filing and prosecution strategies associated with patent applications, including a change from a "first-to-invent" to a "first-inventor-to-file" patent system, and a change allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, *inter partes* review and derivation proceedings. The USPTO has developed regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act and, in particular, the "first-inventor-to-file" provisions, became effective in 2013. The Leahy-Smith Act and its implementation may increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition and results of operations.

We may be unable to obtain intellectual property rights or technology necessary to develop and commercialize BIO89-100 and any future product candidates.

The patent landscape around our programs is complex, and we are aware of several third-party patents and patent applications containing subject matter that might be relevant to BIO89-100. Depending on what claims ultimately issue from these patent applications, and how courts construe the issued patent claims, as well as depending on the ultimate formulation and method of use of BIO89-100 or any future product candidates, we may need to obtain a license to practice the technology claimed in such patents. There can be no assurance that such licenses will be available on commercially reasonable terms, or at all. If a third party does not offer us a necessary license or offers a license only on terms that are unattractive or unacceptable to us, we might be unable to develop and commercialize one or more of our product candidates, which would have a material adverse effect on our business, financial condition and results of operations. Moreover, even if we obtain licenses to such intellectual property, but subsequently fail to meet our obligations under the relevant license agreements, or such

license agreements are terminated for any other reasons, we may lose our rights to the technologies licensed under those agreements.

The licensing or acquisition of third-party intellectual property rights is an area in which many companies operate that have interests that are in conflict with ours, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment, or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may become involved in lawsuits or other proceedings to protect or enforce our intellectual property, which could be expensive, time-consuming and unsuccessful and have a material adverse effect on the success of our business.

Third parties may infringe our patents or misappropriate or otherwise violate our intellectual property rights. In the future, we may initiate legal proceedings to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity or scope of intellectual property rights we own or control. Also, third parties may initiate legal proceedings against us to challenge the validity or scope of intellectual property rights we own, control or to which we have rights. For example, generic or biosimilar drug manufacturers or other competitors or third parties may challenge the scope, validity or enforceability of our patents, requiring us to engage in complex, lengthy and costly litigation or other proceedings. These proceedings can be expensive and time-consuming and many of our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating intellectual property rights we own, control or have rights to, particularly in countries where the laws may not protect those rights as fully as in the United States. Litigation could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, if we initiated legal proceedings against a third party to enforce a patent covering a product candidate, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendants usually assert counterclaims alleging invalidity or unenforceability. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. In an infringement or declaratory judgment proceeding, a court may decide that a patent owned by or licensed to us is invalid or unenforceable, or may refuse to stop the other party from using the subject matter alleged to be infringing on the grounds that our patents do not cover that subject matter. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, narrowed, held unenforceable or interpreted in such a manner that would not preclude third parties from entering the market with competing products.

Third-party pre-issuance submission of prior art to the USPTO, or opposition, derivation, revocation, reexamination, *inter partes* review or interference proceedings, or other pre-issuance or post-grant proceedings or other patent office proceedings or litigation in the United States or other jurisdictions provoked by third parties or brought by us, may be necessary to determine the inventorship, priority, patentability or validity of inventions with respect to our patents or patent applications. An unfavorable outcome could leave our technology or product candidates without patent protection, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or could require us to obtain license rights from the prevailing party in order to be able to manufacture or commercialize our product candidates without infringing

third-party patent rights. Our business could be harmed if the prevailing party in such a case does not offer us a license on commercially reasonable terms, or at all. Even if we obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Even if we successfully defend such litigation or proceeding, we may incur substantial costs and our defense may distract our management and other employees.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, many foreign jurisdictions have rules of discovery that are different than those in the United States and that may make defending or enforcing our patents extremely difficult. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock.

Third parties may initiate legal proceedings against us alleging that we infringe their intellectual property rights or we may initiate legal proceedings against third parties to challenge the validity or scope of intellectual property rights controlled by third parties, the outcome of which would be uncertain and could have a material adverse effect on our business.

Our commercial success depends upon our ability to develop, manufacture, market and sell BIO89-100 and any future product candidates that we may develop and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of third parties. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. Third parties may initiate legal proceedings against us alleging that we infringe their intellectual property rights or we may initiate legal proceedings against third parties to challenge the validity or scope of intellectual property rights controlled by third parties, including in oppositions, interferences, revocations, reexaminations, *inter partes* review or derivation proceedings before the USPTO or its counterparts in other jurisdictions. These proceedings can be expensive and time-consuming and many of our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can.

We could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent of a third party. A finding of infringement could prevent us from commercializing our BIO89-100 or any future product candidates or force us to cease some of our business operations, which could materially harm our business.

We may not be aware of all third-party intellectual property rights potentially relating to BIO89-100 or any future product candidates and technologies. We are not aware of any facts that would lead us to conclude that the valid and enforceable claims of any third-party patents would reasonably be interpreted to cover our product candidates. As to pending third-party applications, we cannot predict with any certainty which claims will issue, if any, or the scope of such issued claims. Even if we believe third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability or priority. A court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could materially and adversely affect our ability to commercialize any product candidates we may develop and any other product candidates or technologies covered by the asserted third-party patents. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. If any such third-party patents (including those that may issue from such applications) were successfully asserted against us or other commercialization partners

and we were unable to successfully challenge the validity or enforceability of any such asserted patents, then we and other commercialization partners may be prevented from commercializing our product candidates, or may be required to pay significant damages, including treble damages and attorneys' fees if we are found to willfully infringe the asserted patents, or obtain a license to such patents, which may not be available on commercially reasonable terms, or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. Any of the foregoing would have a material adverse effect on our business, financial condition and operating results.

Although we have reviewed certain third-party patents and patent filings that we believe may be relevant to our therapeutic candidates or products, we have not conducted a freedom-to-operate search or analysis for any of our therapeutic candidates or products, and we may not be aware of patents or pending or future patent applications that, if issued, would block us from commercializing our therapeutic candidates or products. Thus, we cannot guarantee that our therapeutic candidates or products, or our commercialization thereof, do not and will not infringe any third party's intellectual property.

We may be subject to claims by third parties asserting misappropriation of intellectual property, or claiming ownership of what we regard as our own intellectual property.

Although we seek to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed confidential information or intellectual property, including trade secrets or other proprietary information, of any such employee's former employer, or that third parties have an interest in our patents as an inventor or co-inventor. Litigation may be necessary to defend against these claims. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or the services of personnel or sustain other damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms, or at all. Even if we successfully prosecute or defend against such claims, litigation could result in substantial costs and distract management.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our inability to protect our confidential information and trade secrets would harm our business and competitive position.

In addition to seeking patents for some of our technology and product candidates, we also rely substantially on trade secrets, including unpatented know-how, technology and other proprietary materials and information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. However, these steps may be inadequate, we may fail to enter into agreements with all such parties or any of these parties may breach the agreements and disclose our trade secrets and there may be no adequate remedy available for such breach of an agreement. We cannot assure you that our trade secrets will not be disclosed or that we can meaningfully protect our trade secrets. Enforcing a claim that a party illegally

disclosed or misappropriated a trade secret is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, some courts both within and outside the United States may be less willing, or unwilling, to protect trade secrets. If a competitor lawfully obtained or independently developed any technology or information that we protect as trade secret, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to BIO89-100 and any future product candidates we may develop or utilize similar technology but that are not covered by the claims of the patents that we exclusively license or may own in the future;
- we, or our future collaborators, might not have been the first to make the inventions covered by the issued patents and pending patent applications that we exclusively license or may own in the future;
- we, or our future collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or exclusively licensed intellectual property rights;
- it is possible that our pending patent applications or those that we may file in the future will not result in issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in major commercial markets in which we do not have sufficient patent rights to stop such sales;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may be asserted against our product candidates and technologies in a manner that harms our business; and
- we may choose not to file a patent application in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such trade secrets or know-how.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

If our trademarks and trade names are not maintained and adequately protected, we may not be able to build name recognition in our markets of interest, and our business may be adversely affected.

Failure to obtain trademark registrations in the future, could limit our ability to protect and enforce our trademarks and impede our marketing efforts in the countries in which we operate. We may not be able to protect our rights to trademarks and trade names which we may need to build name recognition with potential partners or

customers in our markets of interest. As a means to enforce any future trademark rights and prevent infringement, we may be required to file trademark claims against third parties or initiate trademark opposition proceedings. This can be expensive, and strain the financial resources of a company of our size, and time-consuming, and we may not be successful in enforcing our trademark rights. In addition, our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks.

Future trademark applications in the United States and in other foreign jurisdictions where we may file may not be allowed or may subsequently be opposed. Even if these applications result in registration of trademarks, third parties may challenge our use or registration of these trademarks in the future. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected.

Risks Related to this Offering and Ownership of Our Common Stock

There is no existing market for our common stock and we do not know if one will develop, which may make it difficult for you to sell shares of our common stock. Even if a market does develop, the price of shares of our common stock in the market may not exceed the offering price.

Prior to this offering, there has not been a public market for our common stock or any of our equity interests. We cannot predict the extent to which investor interest in our company will lead to the development of an active trading market on The Nasdaq Global Market or how liquid that market may become. An active public market for our common stock may not develop or be sustained after this offering. If an active trading market does not develop or is not sustained, you may have difficulty selling any shares of our common stock that you buy. An inactive market may also impair our ability to raise additional capital or use our shares of common stock to acquire companies, products or technologies.

The initial public offering price for our common stock will be determined by negotiations among us and the representatives of the underwriters and may not be indicative of prices that will prevail in the open market following this offering. Consequently, you may not be able to sell shares of our common stock at prices equal to or greater than the price you pay in this offering.

The price of our common stock may be volatile, and you may lose all or part of your investment.

The market price of our common stock could fluctuate significantly, and you may not be able to resell your shares at or above the offering price. Those fluctuations could be based on various factors in addition to those otherwise described in this prospectus, including those described in these “Risk Factors.” Any of these factors may result in large and sudden changes in the volume and trading price of our common stock. In the past, following periods of volatility in the market price of a company’s securities, stockholders have often instituted securities class action litigation against that company. If we were involved in a class action suit, it could divert the attention of management, result in negative press reports and, if adversely determined, have a material adverse effect on our results of operations and financial condition.

In addition, the stock market, in general, and the stocks of many small healthcare and biotechnology companies, in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. Further, a decline in the broader financial markets and related factors beyond our control may cause the price of our common stock to decline rapidly and unexpectedly.

Future sales of our common stock, or the perception that such sales may occur, could depress the price of our common stock.

Sales of a substantial number of shares of our common stock in the public market, or the perception that such sales may occur, following this offering could depress the market price of our common stock. Our principal

stockholders, executive officers and directors and certain other equity holders have agreed with the underwriters not to offer, sell, dispose of or hedge any shares of our common stock or securities convertible into or exchangeable for shares of our common stock, subject to specified limited exceptions and extensions described elsewhere in this prospectus, during the period ending 180 days after the date of the final prospectus, except with the prior written consent of BofA Securities, Inc., SVB Leerink LLC and RBC Capital Markets, LLC.

Our Amended Certificate will authorize us to issue up to shares of common stock, of which shares will be outstanding and shares will be issuable upon the exercise of outstanding stock options and vesting of restricted stock units. Of the outstanding shares, shares will be freely tradable after the expiration date of the lock-up agreements, excluding any acquired by persons who may be deemed to be our affiliates. Shares of our common stock held by our affiliates will continue to be subject to the volume and other restrictions of Rule 144 under the Securities Act. BofA Securities, Inc., SVB Leerink LLC and RBC Capital Markets, LLC may, in their discretion and at any time without notice, release all or any portion of the shares subject to the lock-up. Sales of a substantial number of such shares upon expiration of the lock-up and market stand-off agreements, the perception that such sales may occur or early release of these agreements, could cause our market price to fall or make it more difficult for you to sell your common stock at a time and price that you deem appropriate. See “Underwriting.”

Moreover, after this offering, holders of an aggregate of shares of our common stock will have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders.

In addition, promptly following this offering, we intend to file a registration statement registering under the Securities Act the shares of our common stock reserved for issuance under our 2019 Plan, including shares issuable upon exercise of outstanding options. See “Shares Eligible for Future Sale” for a more detailed description of the shares that will be available for future sales upon completion of this offering. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements described above.

Further, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt or equity securities. If we issue common stock or securities convertible into our common stock, our common stockholders would experience additional dilution and, as a result, the price of our common stock may decline.

Our directors, executive officers and current holders of 5% or more of our capital stock will continue to have substantial control over our company after this offering, which could limit your ability to influence the outcome of matters subject to stockholder approval, including a change of control.

Our directors and executive officers will beneficially own approximately % of our outstanding common stock after this offering. Other holders of 5% or more of our common stock will beneficially own approximately % of our outstanding common stock after this offering. Without giving effect to any shares they may purchase in this offering, our current directors, officers and stockholders who own greater than 5% of our outstanding common stock (on an as-converted basis), together with their affiliates, will beneficially own, in the aggregate, approximately % of our outstanding common stock after this offering. As a result, after this offering, our executive officers, directors and other holders of 5% or more of our common stock, if they act, will be able to influence or control matters requiring approval by our stockholders, including the election of directors and the approval of mergers, acquisitions or other extraordinary transactions. In addition, our current directors, executive officers and other holders of 5% or more of our common stock, acting together, would have the ability to control the management and affairs of our company. They may also have interests that differ from yours and may vote in a way with which you disagree and that may be adverse to your interests. This concentration of ownership may have the effect of delaying, preventing or deterring a change of control of our company, could deprive our stockholders of an opportunity to receive a premium for their shares of our common stock as part of a sale of our company and could affect the market price of our common stock.

If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our stock or business, the price of our common stock and trading volume could decline.

The trading market for our common stock will depend, in part, on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on our company. If no securities or industry analysts commence coverage of our company or if they cease to cover our company, the trading price for our stock would likely be negatively impacted. In the event that securities or industry analysts initiate coverage, if one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, demand for our common stock could decrease and the price of our common stock could decline. In addition, if our operating results fail to meet the forecast of analysts, the price of our common stock would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause the price of our common stock and trading volume to decline.

We have identified material weaknesses in our internal control over financial reporting. If our remediation of the material weaknesses is not effective, or if we experience additional material weaknesses or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial information and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 (“Section 404”) of the Sarbanes-Oxley Act of 2002, as amended (the “Sarbanes-Oxley Act”), or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our consolidated financial statements or identify other areas for further attention or improvement. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements will not be prevented or detected on a timely basis.

In connection with our financial statement close process for 2018, we identified material weaknesses in the design and operating effectiveness of our internal control over financial reporting.

These material weaknesses related to the following:

- We did not have an internal finance department. Consequently, we lacked sufficient personnel with an appropriate level of knowledge and requisite U.S. generally accepted accounting principles expertise to identify, evaluate and account for complex and non-routine transaction and an adequate supervisory review structure that is needed to comply with financial reporting requirements.

- We did not have an adequate assessment of risks that could significantly impact internal control over financial reporting and did not effectively design controls in response to the risks of material misstatement.

We are taking steps to remediate these material weaknesses through the implementation of appropriate segregation of duties, formalization of accounting policies and controls, hiring of our Chief Financial Officer and additional qualified accounting and finance personnel and engagement of financial consultants to enable the implementation of internal controls over financial reporting. We also plan to implement certain accounting systems to automate manual processes. However, we are still in the process of implementing these steps and cannot assure you that we will be successful in doing so or that these measures will significantly improve or remediate the material weaknesses described above. We, and our independent registered public accounting firm,

were not required to perform an evaluation of our internal control over financial reporting as of December 31, 2018 in accordance with the provisions of the Sarbanes-Oxley Act. Accordingly, we cannot assure you that we have identified all material weaknesses or that there will not be additional material weaknesses or deficiencies that we will identify.

Upon becoming a public company, we will be required to comply with Section 404, which will require management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of our internal control over financial reporting commencing with our second annual report. To achieve compliance with Section 404 within the prescribed period, we will need to continue to dedicate internal resources, outside consultants and continue to execute a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes, as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404 and material weaknesses may still exist. We also cannot assure you that there will not be additional material weaknesses or significant deficiencies in our internal controls in the future. In the event that we are not able to successfully remediate the existing material weaknesses in our internal control over financial reporting or demonstrate compliance with the Sarbanes-Oxley Act, that our internal control over financial reporting is perceived as inadequate or that we are unable to produce timely or accurate consolidated financial statements, investors may lose confidence in our operating results, the price of our common stock could decline and we may not be able to remain listed on The Nasdaq Global Market.

We will incur increased costs as a result of operating as a public company, and our management will devote substantial time to new compliance initiatives.

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company, and these expenses may increase even more after we are no longer an “emerging growth company.” As a public company, we will be subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Protection Act, as well as rules adopted, and to be adopted, by the SEC and Nasdaq. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. The increased costs will increase our net loss. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be forced to accept reduced policy limits or incur substantially higher costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

We are an emerging growth company, as defined in the Securities Act, and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an emerging growth company, as defined in Section 2(a) of the Securities Act, as modified by the JOBS Act, and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including relief from the auditor attestation requirements of Section 404 less extensive disclosure obligations regarding executive compensation in our registration statements, periodic reports and proxy statements, exemptions from the requirements to hold a nonbinding advisory vote on executive compensation, and exemptions from stockholder approval of any golden parachute payments not previously approved. As a result, our stockholders may not have access to certain information that they may deem important. We could be an emerging growth company for up to five years, although circumstances could cause us to lose that status earlier.

In addition, the JOBS Act also provides that an emerging growth company can take advantage of the extended transition period provided in the Securities Act for complying with new or revised accounting standards. An emerging growth company can therefore delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, as a result, will not be subject to the same implementation timing for new or revised accounting standards as for other public companies that are not emerging growth companies, which may make comparison of our consolidated financial statements to those of other public companies more difficult.

We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and the price of our common stock may be more volatile.

We have broad discretion as to the use of proceeds from this offering and may not use the proceeds effectively.

Our management will retain broad discretion as to the application of the proceeds of this offering and may spend these proceeds in ways in which you may not agree. You will not have the opportunity, as part of your investment decision, to assess whether we are using the proceeds appropriately. Our management might not apply our net proceeds in ways that ultimately increase the value of your investment. We cannot specify with certainty all of the particular uses for the net proceeds to be received upon the closing of this offering. Until the net proceeds are used, they may be placed in investments that do not produce significant income or that may lose value. The failure of our management to apply these funds effectively could result in unfavorable returns and uncertainty about our prospects, each of which could cause the price of our common stock to decline.

Because we do not expect to pay dividends in the foreseeable future, you must rely on price appreciation of our common stock for return on your investment.

We intend to retain most, if not all, of our available funds and earnings to fund the development and growth of our business. As a result, we do not expect to pay any cash dividends in the foreseeable future. Therefore, you should not rely on an investment in our common stock as a source for any future dividend income.

Our board of directors has significant discretion as to whether to distribute dividends and in what amounts. Even if our board of directors decides to declare and pay dividends, the timing, amount and form of future dividends, if any, will depend on, among other matters, our future results of operations and cash flow, our capital requirements and surplus, the amount of distributions, if any, received by us from our subsidiaries, our financial condition, contractual restrictions and other factors deemed relevant by our board of directors.

If you purchase shares of our common stock sold in this offering, you will incur immediate and substantial dilution.

If you purchase shares of our common stock in this offering, you will incur immediate and substantial dilution in the amount of $ per share because the assumed public offering price of $ per share, the midpoint of the range set forth on the cover of this prospectus, is substantially higher than the as adjusted net tangible book value per share of our outstanding common stock. This dilution is due in large part to the fact that our earlier investors paid substantially less than the initial public offering price when they purchased their shares. In addition, you may also experience additional dilution upon future equity issuances or the issuance of stock options to purchase our common stock granted to our employees, directors and consultants under our stock option plan after this offering. To the extent we raise additional capital by issuing equity securities, our stockholders may experience additional dilution. In addition, as of June 30, 2019, we had outstanding stock options to purchase 4,482,991 shares of our common stock, all of which have exercise prices below the assumed initial offering price. To the extent these outstanding options are ultimately exercised, you will experience further dilution. See “Dilution.”

Our Amended Certificate, Amended Bylaws and Delaware law could prevent a third party from acquiring us (even if an acquisition would benefit our stockholders), may limit the ability of our stockholders to replace our management and limit the price that investors might be willing to pay for shares of our common stock.

Our Amended Certificate and our Amended Bylaws could have the effect of making it more difficult for a third party to acquire, or of discouraging a third party from attempting to acquire, control of us. These provisions could delay or prevent a change in control of the company and could limit the price that investors might be willing to pay in the future for shares of our common stock. These provisions, among other things:

- establish a staggered board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- authorize our board of directors to issue new series of preferred stock without stockholder approval and create, subject to applicable law, a series of preferred stock with preferential rights to dividends or our assets upon liquidation, or with superior voting rights to our existing common stock;
- eliminate the ability of our stockholders to call special meetings of stockholders;
- eliminate the ability of our stockholders to fill vacancies on our board of directors;
- establish advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon by stockholders at our annual stockholder meetings;
- permit our board of directors to establish the number of directors;
- provide that our board of directors is expressly authorized to make, alter or repeal our Amended Bylaws;
- provide that shareholders can remove directors only for cause and only upon the approval of not less than 66⅔ of all outstanding shares of our voting stock;
- require the approval of not less than 66⅔ of all outstanding shares of our voting stock to amend our bylaws and specific provisions of our certificate of incorporation; and
- limit the jurisdictions in which certain stockholder litigation may be brought.

As a Delaware corporation, we will be subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which prohibits a Delaware corporation from engaging in a business combination specified in the statute with an interested stockholder (as defined in the statute) for a period of three years after the date of the transaction in which the person first becomes an interested stockholder, unless the business combination is approved in advance by a majority of the independent directors or by the holders of at least two-thirds of the outstanding disinterested shares. The application of Section 203 of the Delaware General Corporation Law could also have the effect of delaying or preventing a change of control of us.

Our Amended Certificate provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our Amended Certificate to be in effect upon the completion of this offering provides that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: any derivative action or proceeding brought on our behalf; any action

asserting a breach of a fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our Amended Certificate or our Amended Bylaws; or any action asserting a claim against us that is governed by the Delaware internal affairs doctrine. This provision would not apply to claims brought to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Our Amended Certificate provides further that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, subject to and contingent upon a final adjudication in the State of Delaware of the enforceability of such exclusive forum provision. These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees. If a court were to find the choice of forum provision contained in our Amended Certificate to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business. For example, under the Securities Act, federal courts have concurrent jurisdiction over all suits brought to enforce any duty or liability created by the Securities Act, and investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder, and the Court of Chancery of the State of Delaware recently determined that the exclusive forum provision of federal district courts of the United States for resolving any complaint asserting a cause of action arising under the Securities Act is not enforceable. However, this decision may be reviewed and ultimately overturned by the Delaware Supreme Court. If the Court of Chancery's decision were to be overturned, we would enforce the federal district court exclusive forum provision in our Amended Certificate.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains "forward-looking statements" within the meaning of the federal securities laws, which statements are subject to substantial risks and uncertainties and are based on estimates and assumptions. All statements, other than statements of historical facts included in this prospectus, including statements concerning our plans, objectives, goals, strategies, future events, future revenues or performance, financing needs, plans or intentions relating to product candidates, estimates of market size, business trends, the anticipated timing, costs, design and conduct of our planned clinical trials for BIO89-100, our only product candidate, the timing and likelihood of regulatory filings and approvals for BIO89-100, our ability to commercialize BIO89-100, if approved, the pricing and reimbursement of BIO89-100, if approved, the potential to develop future product candidates, our ability to scale up manufacturing, the potential benefits of strategic collaborations and our intent to enter into any strategic arrangements, the timing and likelihood of success, plans and objectives of management for future operations, future results of anticipated product development efforts and the anticipated use of the net proceeds from this offering, are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "design," "estimate," "predict," "potential," "plan" or the negative of these terms, and similar expressions intended to identify forward-looking statements.

These statements involve known and unknown risks, uncertainties and other factors that could cause our actual results to differ materially from the forward-looking statements expressed or implied in this prospectus. Such risks, uncertainties and other factors include, among others, the factors disclosed in the sections in this prospectus entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this prospectus.

We caution you that the risks, uncertainties and other factors referred to above and elsewhere in this prospectus may not contain all of the risks, uncertainties and other factors that may affect our future results and operations. Moreover, new risks will emerge from time to time. It is not possible for our management to predict all risks. In addition, we cannot assure you that we will realize the results, benefits or developments that we expect or anticipate or, even if substantially realized, that they will result in the consequences or affect us or our business in the way expected. Forward-looking statements are not historical facts, and reflect our current views with respect to future events. Given the significant uncertainties, you should evaluate all forward-looking statements made in this prospectus in the context of these risks and uncertainties and not place undue reliance on these forward-looking statements as predictions of future events.

All forward-looking statements in this prospectus apply only as of the date made and are expressly qualified in their entirety by the cautionary statements included in this prospectus. We disclaim any intent to publicly update or revise any forward-looking statements to reflect subsequent events or circumstances, except as required by law.

INDUSTRY AND MARKET DATA

We obtained the industry, market and competitive position data used throughout this prospectus from our own internal estimates and research, as well as from industry and general publications, and research, surveys and studies conducted by third parties. Internal estimates are derived from publicly available information released by industry analysts and third-party sources, our internal research and our industry experience, and are based on assumptions made by us based on such data and our knowledge of the industry and market, which we believe to be reasonable. In addition, while we believe the industry, market and competitive position data included in this prospectus is reliable and based on reasonable assumptions, we have not independently verified any third-party information, and all such data involve risks and uncertainties and are subject to change based on various factors, including those discussed in “Risk Factors.” These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

USE OF PROCEEDS

We estimate that we will receive net proceeds of approximately $ million (or approximately $ million if the underwriters' option to purchase additional shares is exercised in full) from the issuance and sale of the shares of common stock offered by us in this offering, assuming an initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Each $1.00 increase (decrease) in the assumed initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the net proceeds to us from this offering by $ million, assuming the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1,000,000 shares in the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, would increase (decrease) our net proceeds from this offering by $ million, assuming the assumed initial public offering price remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

We intend to use the net proceeds of this offering, together with our existing cash and cash equivalents, primarily as follows:

- approximately $ million to complete our ongoing POC Phase 1b/2a clinical trial and initiate our subsequent Phase 2b clinical trial of BIO89-100 in patients with NASH;
- approximately $ million to fund our Phase 2 trial of BIO89-100 in patients with SHTG, as well as evaluate potential new indications for BIO89-100;
- approximately $ million for BIO89-100 manufacturing and scale up; and
- the remainder for working capital and general corporate purposes.

Our expected use of proceeds from this offering represents our current intentions based on our present plans and business condition. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the proceeds to be received upon the completion of this offering or the amounts that we will actually spend on the uses set forth above. We may also use a portion of the proceeds to license, acquire or invest in complementary businesses, technology, products or assets, however we have no current commitments to do so. As a result, our management will have broad discretion over the use of the proceeds from this offering.

Based on our current business plans, we believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will be sufficient to fund our planned operations through . The expected net proceeds from this offering will not be sufficient for us to fund BIO89-100 or any future product candidate through regulatory approval, and we will need to raise substantial additional capital to complete the development and commercialization of BIO89-100 and any future product candidates. The amount and timing of our actual expenditures will depend on numerous factors, including the pace and results of our research and development efforts, the timing and success of clinical trials, the timing and costs associated with the manufacture and supply of product candidates, the timing of regulatory submissions and any unforeseen cash needs. For additional information regarding our potential capital requirements, including factors that could cause actual costs to vary from the estimates set forth above, see "Risk Factors."

Pending the use of the proceeds from this offering, we may invest the proceeds in interest-bearing, investment-grade securities, certificates of deposit or government securities.

DIVIDEND POLICY

We have never declared or paid cash dividends on our capital stock and have no present intention to pay cash dividends on our common stock for the foreseeable future. Any determination to pay dividends to holders of our common stock will be at the discretion of our board of directors and will depend on many factors, including our financial condition, results of operations, liquidity, earnings, projected capital and other cash requirements, legal requirements, restrictions in the agreements governing any indebtedness we may enter into, business prospects and other factors that our board of directors deems relevant.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and our capitalization as of June 30, 2019:

- on an actual basis after giving effect to the Reorganization;
- on a pro forma basis to give effect to (i) the Reorganization, (ii) the issuance in July 2019 of 1,173,611 shares of our convertible preferred stock and (iii) the automatic conversion of all outstanding shares of our convertible preferred stock into 44,000,000 shares of our common stock; and
- on a pro forma as adjusted basis giving effect to (i) the Reorganization; (ii) the other pro forma items described immediately above and (iii) the issuance and sale of shares of our common stock in this offering, at the assumed initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma as adjusted information below is illustrative only and our capitalization following the completion of this offering will be based on the actual initial public offering price and other terms of this offering. You should read the following table in conjunction with "Use of Proceeds," "Selected Consolidated Financial Data," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes included elsewhere in this prospectus.

	As of June 30, 2019		
	Actual	Pro Forma	Pro Forma As Adjusted(1)
		(in thousands, except share and per share amounts)	
Cash and cash equivalents	$ 21,919	$ 23,093	$
Convertible preferred shares, $0.001 par value; 60,000,000 shares authorized as of June 30, 2019; 42,826,389 shares issued and outstanding as of June 30, 2019 actual; no shares authorized, issued and outstanding, pro forma and pro forma as adjusted	$ 48,168	$ —	$ —
Shareholders' (deficit) equity:			
Preferred shares, $0.001 par value, no shares authorized, issued or outstanding, actual; shares authorized and no shares issued or outstanding, pro forma and pro forma as adjusted	—	—	—
Common stock, $0.001 par value, 72,882,353 shares authorized, 3,800,000 shares issued and outstanding, actual; shares authorized, 47,800,000 shares issued and outstanding, pro forma; and shares authorized, shares issued and outstanding, pro forma as adjusted	11	48	
Additional paid-in capital	219	49,524	
Accumulated deficit	(35,588)	(35,588)	
Total shareholders' (deficit) equity	(35,358)	13,984	
Total capitalization	$ 12,810	$ 13,984	$

(1) Each $1.00 increase (decrease) in the assumed initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) each of our pro forma as adjusted cash and cash equivalents, additional paid-in capital, total shareholders' (deficit) equity and total capitalization by approximately $ million, assuming the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1,000,000 shares in the number of shares of common stock offered by us would increase (decrease) each of our pro forma as adjusted cash and cash

equivalents, additional paid-in capital, total shareholders' (deficit) equity and total capitalization by approximately $ million, assuming the assumed initial public offering price remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The number of shares of common stock to be outstanding following this offering (i) is based on 3,800,000 shares of our common stock and 42,826,389 shares of our convertible preferred stock outstanding as of June 30, 2019, (ii) includes 1,173,611 shares of our convertible preferred stock issued in July 2019, (iii) gives effect to the Reorganization and the automatic conversion immediately prior to the completion of this offering of all outstanding shares of our convertible preferred stock into 44,000,000 shares of our common stock, and (iv) excludes the following:

- 4,482,991 shares of our common stock issuable upon the exercise of stock options outstanding as of June 30, 2019 under our 2019 Plan at a weighted-average exercise price of $0.31 per share;
- 3,300,101 options to purchase shares of our common stock granted subsequent to June 30, 2019 at an exercise price of $0.50 per share;
- shares of our common stock reserved for future issuance under our 2019 Plan as of June 30, 2019, as well as any automatic increase in the number of shares of common stock reserved for future issuance thereunder; and
- shares of our common stock to be reserved for future issuance under our 2019 Employee Stock Purchase Plan, which we expect to enter into and which will become effective immediately prior to the completion of this offering, as well as any automatic increase in the number of shares of common stock reserved for future issuance thereunder.

DILUTION

If you invest in the shares of our common stock in this offering, your ownership interest will be immediately diluted. Dilution represents the difference between the amount per share paid by investors in this offering and the pro forma as adjusted net tangible book value per share of our common stock immediately after the completion of this offering. The data in this section are derived from our consolidated balance sheet as of June 30, 2019. Our historical net tangible book value per share is equal to our total tangible assets less the amount of our total liabilities, divided by the sum of the number of shares of our common stock outstanding on June 30, 2019 (assuming the conversion of all outstanding shares of preferred stock into shares of common stock). Our historical net tangible book value (deficit) as of June 30, 2019 was $ million, or $ per share of common stock. Pro forma net tangible book value, before the issuance and sale of shares in this offering, gives effect to the conversion of all outstanding shares of our convertible preferred stock as of June 30, 2019 and all shares of our convertible preferred stock issued in July 2019 into an aggregate of 44,000,000 shares of common stock.

After giving effect to our receipt of the estimated net proceeds from the issuance and sale of our common stock in this offering at an assumed initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of June 30, 2019 would have been $ million, or $ per share of our common stock. This represents an immediate increase in net tangible book value to our existing stockholders of $ per share and an immediate dilution to new investors in this offering of $ per share. The following table illustrates this per share dilution:

Assumed initial public offering price per share		$
Historical net tangible book value (deficit) per share as of June 30, 2019	$	
Increase per share attributable to the pro forma adjustments described above		
Pro forma net tangible book value per share as of June 30, 2019		
Increase in net tangible book value per share attributable to new investors participating in this offering		
Pro forma as adjusted net tangible book value per share after this offering		
Dilution in pro forma net tangible book value per share to new investors participating in this offering		$

The pro forma as adjusted dilution information discussed above is illustrative only and will change based on the actual initial public offering price and other terms of this offering. Each $1.00 increase or decrease in the assumed initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) our pro forma as adjusted net tangible book value by $ per share and increase (decrease) the dilution to new investors by $ per share, in each case assuming the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1,000,000 shares in the number of shares offered by us would increase (decrease) our pro forma as adjusted net tangible book value by $ per share and increase (decrease) the dilution to new investors by $ per share, in each case assuming the assumed initial public offering price remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters exercise their option to purchase additional shares of our common stock in full, our pro forma as adjusted net tangible book value after this offering would be $ per share, and there would be an immediate dilution of approximately $ per share to new investors.

The following table presents on a pro forma as adjusted basis, as described above, the differences between the existing stockholders and the purchasers of shares in this offering with respect to the number of shares purchased from us, the total consideration paid, and the average price paid per share at an assumed initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus:

	Shares Purchased		Total Consideration		Weighted-Average Price Per Share
	Number	Percent	Amount (in thousands)	Percent	
Existing stockholders before this offering		%	$	%	$
New investors participating in this offering					$
Total		100.0%	$	100.0%	

If the underwriters were to fully exercise their option to purchase additional shares of our common stock from us, the percentage of shares of our common stock held by existing investors would be %, and the percentage of shares of our common stock held by new investors would be %.

The number of shares of common stock to be outstanding following this offering (i) is based on 3,800,000 shares of our common stock and 42,826,389 shares of our convertible preferred stock outstanding as of June 30, 2019, (ii) includes 1,173,611 shares of our convertible preferred stock issued in July 2019, (iii) gives effect to the Reorganization and the automatic conversion immediately prior to the completion of this offering of all outstanding shares of our convertible preferred stock into 44,000,000 shares of our common stock, and (iv) excludes the following:

- 4,482,991 shares of our common stock issuable upon the exercise of stock options outstanding as of June 30, 2019 under our 2019 Plan at a weighted-average exercise price of $0.31 per share;
- 3,300,101 options to purchase shares of our common stock granted subsequent to June 30, 2019 at an exercise price of $0.50 per share;
- shares of our common stock reserved for future issuance under our 2019 Plan as of June 30, 2019, as well as any automatic increase in the number of shares of common stock reserved for future issuance thereunder; and
- shares of our common stock to be reserved for future issuance under our 2019 Employee Stock Purchase Plan, which we expect to enter into and which will become effective immediately prior to the completion of this offering, as well as any automatic increase in the number of shares of common stock reserved for future issuance thereunder.

To the extent that outstanding options are exercised, new options or other securities are issued under our equity incentive plans, or we issue additional shares of common stock in the future, there will be further dilution to investors participating in this offering. In addition, we may choose to raise additional capital because of market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

SELECTED CONSOLIDATED FINANCIAL DATA

The following tables set forth selected historical consolidated financial data as of and for the periods indicated. The historical consolidated statement of operations data for the period from January 18, 2018 (inception) to December 31, 2018 and the consolidated balance sheet data as of December 31, 2018 are derived from our audited consolidated financial statements included elsewhere in this prospectus. The historical consolidated statement of operations data for the period from January 18, 2018 (inception) to June 30, 2018 and the six months ended June 30, 2019 and the consolidated balance sheet data as of June 30, 2019 are derived from our unaudited interim condensed consolidated financial statements included elsewhere in this prospectus. Our unaudited interim condensed consolidated financial statements were prepared on the same basis as our audited consolidated financial statements and, in our opinion, reflect all adjustments, consisting only of normal recurring adjustments, that are necessary for the fair statement of our unaudited interim condensed consolidated financial statements.

Our historical results presented below are not necessarily indicative of the results to be expected for any future period, and our interim results are not necessarily indicative of the results to be expected for the full year or any future period. This information should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes included elsewhere in this prospectus.

	Period from January 18, 2018 (inception) to December 31, 2018	Period from January 18, 2018 (inception) to June 30, 2018	Six Months Ended June 30, 2019
	(in thousands, except share and per share data)		
Consolidated Statement of Operations Data:			
Operating expenses:			
Research and development	$ 13,681	$ 6,700	$ 7,474
General and administrative	1,481	268	1,357
Total operating expenses	15,162	6,968	8,831
Loss from operations	15,162	6,968	8,831
Other (income) expenses, net	986	405	10,552
Net loss before tax	16,148	7,373	19,383
Income tax expense	28	—	29
Net loss and comprehensive loss	$ 16,176	$ 7,373	$ 19,412
Net loss per share, basic and diluted[1]	$ 5.86	$ 4.34	$ 5.11
Weighted-average shares used to compute net loss per share, basic and diluted[1]	2,758,904	1,700,552	3,800,000
Pro forma net loss per share, basic and diluted (unaudited)[1]	$ 1.22		$ 0.68
Weighted-average shares used to compute pro forma net loss per share, basic and diluted (unaudited)[1]	13,224,780		28,496,861

(1) See Notes 2 and 11 to our audited consolidated financial statements and Notes 2 and 10 to our unaudited interim condensed consolidated financial statements included elsewhere in this prospectus for an explanation of the calculations of our historical and pro forma net loss per share, basic and diluted, and weighted-average number of shares used in the computation of the per share amounts.

	As of December 31, 2018	As of June 30, 2019
	(in thousands)	
Consolidated Balance Sheet Data:		
Cash and cash equivalents	$ 11,234	$ 21,919
Total assets	11,369	22,347
Total current liabilities	4,353	9,537
Convertible preferred shares	23,073	48,168
Accumulated deficit	(16,176)	(35,588)
Total shareholders' deficit	(16,057)	(35,358)

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes and other financial information included elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those described in or implied by these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those discussed in the section titled "Risk Factors" included elsewhere in this prospectus. Unless the context requires otherwise, references to "we," "us," "our," "89bio" or the "company" refer to (i) 89Bio Ltd. for the periods prior to the Reorganization and (ii) 89bio, Inc. for the periods after completion of the Reorganization, in each case together with its consolidated subsidiaries.

Overview

We are a clinical-stage biopharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of liver and cardio-metabolic diseases. Our lead product candidate, BIO89-100, a specifically engineered glycoPEGylated analog of FGF21, is currently being developed for the treatment of NASH. NASH is a severe form of NAFLD, characterized by inflammation and fibrosis in the liver that can progress to cirrhosis, liver failure, HCC and death. There are currently no approved products for the treatment of NASH. FGF21 is a clinically-validated mechanism that has been shown in humans to reduce steatosis and address cardio-metabolic dysregulation. We believe BIO89-100 may be a differentiated FGF21 therapy based on its robust and durable biological effects and a favorable tolerability profile, as well as its potential for a longer dosing interval. Combining these characteristics with the ability to address the key liver pathologies in NASH, as well as the underlying metabolic dysregulation in NASH patients, BIO89-100 has the potential to become a mainstay of NASH therapy. We successfully completed a Phase 1a, first-in-human, SAD clinical trial with 58 healthy volunteers. The magnitude and significance of BIO89-100's biological effects after a single dose on lipid parameters were robust and durable. In July 2019, we initiated our POC Phase 1b/2a clinical trial in patients with NASH or patients with NAFLD and a high risk of NASH and we expect to report topline data in the second half of 2020. We also intend to develop BIO89-100 for the treatment of SHTG, a condition identified by severely elevated levels of triglycerides (greater than or equal to 500 mg/dL), which is associated with an increased risk of NASH, cardiovascular events and acute pancreatitis. We expect to initiate our Phase 2 trial in SHTG patients in the first half of 2020 in order to evaluate the ability of BIO89-100 to reduce fasting plasma triglyceride levels compared to baseline levels and to report topline data in the first half of 2021. Based on FDA guidance for the development of SHTG treatments, as well as the regulatory path followed by other companies that have successfully developed SHTG therapies, we believe that a combination of smaller clinical trials and shorter development timelines could mean that SHTG potentially represents a quicker path to market for BIO89-100. We believe BIO89-100 has the potential to address multiple drivers underlying metabolic dysregulation, which would make it an ideal candidate for selected liver and cardio-metabolic diseases.

We commenced operations in 2018 and have devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, acquiring our initial product candidate, BIO89-100, and licensing certain related technology, conducting research and development activities, including preclinical studies and early clinical trials, and providing general and administrative support for these operations. We have funded our operations since our inception to June 30, 2019 through the issuance and sale of capital stock, from which we have raised aggregate net proceeds of $42.5 million. Additionally, in July 2019, we issued and sold capital stock from which we raised aggregate net proceeds of $1.2 million. As of June 30, 2019, our cash and cash equivalents totaled $21.9 million. Based on our current operating plan, we believe that our cash and cash equivalents, together with the estimated net proceeds from this offering, will be sufficient to meet our anticipated cash requirements through at least the next months.

We do not have any products approved for sale and have incurred net losses since our inception. Our net losses for the period from January 18, 2018 (inception) to December 31, 2018 were $16.2 million. Our net loss for the six months ended June 30, 2019 was $19.4 million. As of June 30, 2019, we had an accumulated deficit of $35.6 million. We expect to continue to incur significant expenses and increasing operating losses as we advance BIO89-100 and any future product candidates through clinical trials, seek regulatory approval for BIO89-100 and any future product candidates, expand our clinical, regulatory, quality, manufacturing and commercialization capabilities, protect our intellectual property, prepare for and, if approved, proceed to commercialization of BIO89-100 and any future product candidates, expand our general and administrative support functions, including hiring additional personnel, and incur additional costs associated with operating as a public company. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and our expenditures on other research and development activities.

We have never generated revenue and do not expect to generate revenue from product sales unless and until we successfully complete development and obtain regulatory approval for BIO89-100, which we expect will not be for at least several years, if ever. Accordingly, until such time as we can generate significant revenue from sales of BIO89-100, if ever, we expect to finance our cash needs through a combination of public or private equity offerings, debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements when needed would have a negative impact on our financial condition and could force us to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Reorganization

We were incorporated in January 2018 in Israel under the name 89Bio Ltd. 89bio, Inc., the registrant whose name appears on the cover page of this prospectus, was incorporated in June 2019 for the purpose of an internal reorganization transaction. In September 2019, all of the equity holders of 89Bio Ltd. exchanged 100% of the equity of 89Bio Ltd. for 100% of the equity of 89bio, Inc. Following the Reorganization, 89Bio Ltd. became a wholly owned subsidiary of 89bio, Inc. and 89bio, Inc. owns the business described and for which historical financial information is included elsewhere in this prospectus. Shares of the common stock of 89bio, Inc. are being offered by this prospectus.

Agreements with Teva

In April 2018, we entered into the FGF21 Agreement with Teva, under which we acquired certain patents, intellectual property and other assets relating to Teva's glycoPEGylated FGF21 program, including BIO89-100. Under the FGF21 Agreement, Teva also granted us a perpetual, non-exclusive (but exclusive as to BIO89-100), non-transferable, worldwide license to patents and know-how related to glycoPEGylation technology for use in the research, development, manufacture and commercialization of BIO89-100 and products containing BIO89-100. We also entered into an Asset Transfer and License Agreement with Teva under which we acquired from Teva certain patents, intellectual property and other assets relating to Teva's development program of small molecule inhibitors of FASN (the "FASN Agreement" and collectively with the FGF21 Agreement, the "Teva Agreements").

Pursuant to the Teva Agreements, we paid Teva a nonrefundable upfront payment of $6.0 million. See "Business—Agreements with Teva." In addition, we are required to make certain payments to Teva under each of the Teva Agreements of up to $2.5 million for the achievement of certain development milestones, and additional payments of up to $65.0 million upon achievement of certain commercial milestones, for a total under both Teva Agreements of up to $135.0 million. We are also obligated to pay Teva tiered royalties at percentages in the low-to-mid single-digits on worldwide net sales of products containing BIO89-100 or FASN.

The assets acquired from Teva did not meet the definition of a business and therefore, this acquisition was treated as an asset acquisition for accounting purposes. In addition, we recorded the total consideration transferred to Teva in connection with this acquisition as research and development expense because the acquired technology represented in-process research and development and had no alternative future use.

Components of Results of Operations

Research and Development

Research and development expenses consist primarily of costs incurred for the development of our lead product candidate, BIO89-100. Our research and development expenses consist primarily of external costs related to preclinical and clinical development, including costs related to acquiring patents and intellectual property, expenses incurred under license agreements and agreements with contract research organizations and consultants, costs related to acquiring and manufacturing clinical trial materials, including under agreements with contract manufacturing organizations and other vendors, costs related to the preparation of regulatory submissions and expenses related to laboratory supplies and services, as well as personnel costs. Personnel costs consist of salaries, employee benefits and share-based compensation for individuals involved in research and development efforts.

We expense all research and development expenses in the periods in which they are incurred. We accrue for costs incurred as the services are being provided by monitoring the status of specific activities and the invoices received from our external service providers. We adjust our accrual as actual costs become known. Payments associated with licensing agreements to acquire licenses to develop, use, manufacture and commercialize products that have not reached technological feasibility and do not have alternate commercial use are expensed as incurred. Where contingent milestone payments are due to third parties under research and development arrangements or license agreements, the milestone payment obligations are expensed when the milestone results are probable and estimable, which is generally upon achievement of milestones.

We expect our research and development expenses to increase substantially for the foreseeable future as we continue the development of BIO89-100 and continue to invest in research and development activities. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time consuming, and the successful development of BIO89-100 and any future product candidates is highly uncertain. To the extent that BIO89-100 continues to advance into larger and later stage clinical trials, our expenses will increase substantially and may become more variable. The actual probability of success for BIO89-100 or any future product candidate may be affected by a variety of factors, including the safety and efficacy of our product candidates, investment in our clinical programs, manufacturing capability and competition with other products. As a result, we are unable to determine the timing of initiation, duration and completion costs of our research and development efforts or when and to what extent we will generate revenue from the commercialization and sale of BIO89-100 or any future product candidate.

Our future clinical development costs may vary significantly based on factors such as:

- the cost and timing of manufacturing BIO89-100 and any future product candidates;
- per-patient trial costs;
- the number of trials required for approval;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;

- the number of patients that participate in the trials;
- the number of doses evaluated in the trials;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up;
- the phase of development of BIO89-100 and any future product candidates; and
- the efficacy and safety profile of BIO89-100 and any future product candidates.

General and Administrative

Our general and administrative expenses consist primarily of personnel costs, expenses for outside professional services, including legal, human resource, audit and accounting services, consulting costs and allocated facilities costs. Personnel and related costs consist of salaries, benefits and share-based compensation for personnel in executive, finance and other administrative functions. Facilities costs consist of rent and maintenance of facilities. We expect our general and administrative expenses to increase for the foreseeable future as we increase the size of our administrative function to support the growth of our business and support our continued research and development activities. We also anticipate increased expenses as a result of operating as a public company, including increased expenses related to audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums and investor relations costs.

Other (Income) Expenses, Net

Other (income) expenses, net primarily consists of the revaluation of our convertible preferred share liability.

Results of Operations

Period from January 18, 2018 (inception) to June 30, 2018 and the Six Months Ended June 30, 2019

The following table summarizes our results of operations for the periods presented (in thousands):

	Period from January 18, 2018 (inception) to June 30, 2018	Six Months Ended June 30, 2019	Increase/ (Decrease)
Operating expenses:			
Research and development	$ 6,700	$ 7,474	$ 774
General and administrative	268	1,357	1,089
Total operating expenses	6,968	8,831	1,863
Loss from operations	6,968	8,831	1,863
Other (income) expenses, net	405	10,552	10,147
Income tax expense	—	29	29
Net loss and comprehensive loss	$ 7,373	$ 19,412	$ 12,039

Research and Development Expenses

The following table summarizes the period-over-period changes in research and development expenses for the periods indicated:

	Period from January 18, 2018 (inception) to June 30, 2018	Six Months Ended June 30, 2019	Increase/ (Decrease)
Up-front license payment to Teva	$ 6,000	$ —	$ (6,000)
Clinical development	120	2,451	2,331
Contract manufacturing	284	2,679	2,395
Pre-clinical costs	7	418	411
Personnel-related expenses	248	1,540	1,292
Other expenses	41	386	345
Total research and development expenses	$ 6,700	$ 7,474	$ 774

Research and development expenses increased by $0.8 million, or 12%, from $6.7 million during the period from January 18, 2018 (inception) to June 30, 2018 to $7.5 million during the six months ended June 30, 2019. The increase was primarily due to an increase of $2.4 million in contract manufacturing costs, an increase of $2.3 million in clinical development costs, and an increase of $0.4 million in pre-clinical costs, related to advancing our current clinical programs with our lead product candidate, BIO89-100. In addition, personnel-related costs, including share-based compensation, increased by $1.3 million and other expenses increased by $0.3 million due to increased headcount and other costs as we ramped up our operations. These increases were partially offset by a $6.0 million decrease due to a one time up-front license payment to Teva in the period from January 18, 2018 (inception) to June 30, 2018.

General and Administrative Expenses

General and administrative expenses increased by $1.1 million, or 406%, from $0.3 million during the period January 18, 2018 (inception) to June 30, 2018 to $1.4 million during the six months ended June 30, 2019. The increase was primarily due to an increase of $0.7 million in personnel-related costs, including share-based compensation, driven by an increase in headcount and an increase of $0.4 million in professional and accounting consulting service fees, incurred in connection with our preparation to become a public company.

Other (Income) Expenses, Net

Other (income) expenses, net increased by $10.1 million, from $0.4 million during the period from January 18, 2018 (inception) to June 30, 2018 to $10.6 million during the six months ended June 30, 2019. The increase was primarily due to the revaluation of our convertible preferred share liability.

Period from January 18, 2018 (inception) to December 31, 2018

The following table summarizes our results of operations for the period presented (in thousands):

	Period from January 18, 2018 (inception) to December 31, 2018
Operating expenses:	
Research and development	$ 13,681
General and administrative	1,481
Total operating expenses	15,162
Loss from operations	15,162
Other (income) expenses, net	986
Income tax expense	28
Net loss and comprehensive loss	$ 16,176

Research and Development Expenses

Research and development expenses were $13.7 million for the period presented (in thousands):

	Period from January 18, 2018 (inception) to December 31, 2018
Up-front license payment to Teva	$ 6,000
Clinical development	1,826
Contract manufacturing	3,379
Pre-clinical costs	1,207
Personnel-related expenses	1,013
Other expenses	256
Total research and development expenses	$ 13,681

General and Administrative Expenses

General and administrative expenses were $1.5 million for the period from January 18, 2018 (inception) to December 31, 2018. General and administrative expenses consisted primarily of $0.9 million in payroll and related expenses and $0.5 million in legal fees and professional consulting service fees, each related to the establishment of our company.

Other (Income) Expenses, Net

Other (income) expenses, net was $1.0 million for the period from January 18, 2018 (inception) to December 31, 2018, which was primarily due to the revaluation of our convertible preferred share liability.

Liquidity and Capital Resources

As of September 30, 2019, we estimate that our cash and cash equivalents were approximately $ million. Our independent registered public accounting firm, Brightman Almagor Zohar & Co., a Firm in the Deloitte Global Network, has not reviewed, and does not express an opinion with respect to, these estimates. Our actual cash and cash equivalents as of September 30, 2019 may differ from these estimates due to the completion of our financial closing procedures, final adjustments and other developments that may arise between now and the time the financial results for our third fiscal quarter are finalized. Our financial statements for the quarter ended September 30, 2019 will not be available until after this offering is completed, and consequently will not be available to you prior to investing in this offering.

Since our inception to June 30, 2019, we have funded our operations from the issuance and sale of capital stock, from which we have raised aggregate net proceeds of $42.5 million. As of June 30, 2019, we had available cash and cash equivalents of $21.9 million and an accumulated deficit of $35.6 million. Additionally, in July 2019, we received aggregate net proceeds of $1.2 million in connection with the issuance of Series A convertible preferred shares.

Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures related to our lead product candidate, BIO89-100. We plan to increase our research and development expenses substantially for the foreseeable future as we continue the clinical development of our current and future product candidates. At this time, due to the inherently unpredictable nature of clinical development, we cannot reasonably estimate the costs we will incur and the timelines that will be required to complete development, obtain marketing approval, and commercialize our current product candidate or any future product candidates. For the same reasons, we are also unable to predict when, if ever, we will generate revenue from product sales or our current or any future license agreements which we may enter into or whether, or when, if ever, we may achieve profitability. Clinical and preclinical development timelines, the probability of success, and development costs can differ materially from expectations. In addition, we cannot forecast the timing and amounts of milestone, royalty and other revenue from licensing activities, which future product candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

Based on our research and development plans, we expect that the net proceeds from this offering, together with our existing cash and cash equivalents will be sufficient to fund our operations through at least the next months from the date of this offering. However, our operating plans and other demands on our cash resources may change as a result of many factors, and we may seek additional funds sooner than planned. There can be no assurance that we will be successful in acquiring additional funding at levels sufficient to fund our operations or on terms favorable to us.

Our future funding requirements will depend on many factors, including the following:

- the progress, timing, scope, results and costs of our clinical trials of BIO89-100 and preclinical studies or clinical trials of other potential product candidates we may choose to pursue in the future, including the ability to enroll patients in a timely manner for our clinical trials;
- the costs and timing of obtaining clinical and commercial supplies and validating the commercial manufacturing process for BIO89-100 and any other product candidates we may identify and develop;
- the cost, timing and outcomes of regulatory approvals;
- the timing and amount of any milestone, royalty or other payments we are required to make pursuant to current or any future collaboration or license agreements;
- costs of acquiring or in-licensing other product candidates and technologies;
- the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements;
- the costs associated with attracting, hiring and retaining additional qualified personnel as our business grows;
- our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company, including enhanced internal controls over financial reporting; and

- the cost of preparing, filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

We expect to continue to generate substantial operating losses for the foreseeable future as we expand our research and development activities. We will continue to fund our operations primarily through utilization of our current financial resources and through additional raises of capital. These conditions, and our cash and cash equivalents balances, raise substantial doubts about our ability to continue as a going concern for at least a year after the filing date of the interim condensed consolidated financial statements, included elsewhere in this prospectus. We plan to address these conditions by raising funds from our current investors as well as outside potential investors. However, there is no assurance that such funding will be available to us or that it will be obtained on terms favorable to us or will provide us with sufficient funds to meet our objectives. The interim condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of assets, carrying amounts or the amount or classification of liabilities that may be required should we be unable to continue as a going concern.

To the extent that we raise additional capital through partnerships or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, future revenue streams or research programs or to grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings, the ownership interest of our then-existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of or suspend one or more of our clinical trials or preclinical studies, research and development programs or commercialization efforts or grant rights to develop and market our product candidates even if we would otherwise prefer to develop and market such product candidates ourselves.

Pursuant to a share purchase agreement (the "Series A SPA") entered into with investors in April 2018, subject to the satisfaction, as determined in good faith by our board of directors, of certain milestones set forth in the Series A SPA, we may sell additional shares of Series A convertible preferred stock to our investors for aggregate gross proceeds of up to $16.0 million. We do not expect to fully satisfy these milestones prior to this offering and do not anticipate selling any additional shares of Series A convertible preferred stock prior to this offering. The Series A SPA will terminate upon consummation of this offering and no shares of Series A convertible preferred stock will be issued under the Series A SPA after this offering. See Note 7 to our interim condensed consolidated financial statements appearing elsewhere in this prospectus for more information about the Series A SPA.

Cash Flows

The following table summarizes our cash flows for the periods presented (in thousands):

	Period from January 18, 2018 (inception) to December 31, 2018	Period from January 18, 2018 (inception) to June 30, 2018	Six Months Ended June 30, 2019
Net cash used in operating activities	$ (12,469)	$ (6,644)	$ (8,131)
Net cash used in investing activities	(39)	(31)	(20)
Net cash provided by financing activities	23,765	14,772	18,837
Net increase in cash and cash equivalents, and restricted cash	$ 11,257	$ 8,097	$ 10,686

Net Cash Used in Operating Activities

During the six months ended June 30, 2019, net cash used in operating activities was $8.1 million, which consisted of a net loss of $19.4 million, partially offset by non-cash charges of $10.6 million and a net

change of $0.7 million in our net operating assets and liabilities. The non-cash charges are primarily comprised of the revaluation of our convertible preferred share liability of $10.5 million and $0.1 million in share-based compensation. The change in our operating assets and liabilities was primarily due to a $1.3 million increase in accrued expenses as we grew our operations, offset in part by a $0.5 million decrease in accounts payable due to the timing of payments.

During the period from January 18, 2018 (inception) to June 30, 2018, net cash used in operating activities was $6.6 million, which consisted of a net loss of $7.4 million, partially offset by non-charges of $0.4 million and a net change of $0.4 million in our net operating assets and liabilities. The non-cash charges are primarily comprised of the revaluation of our convertible preferred share liability of $0.4 million. The change in our operating assets and liabilities was primarily due to a $0.4 million increase in accounts payable and accrued expenses as we grew our operations.

During the period from January 18, 2018 (inception) to December 31, 2018, net cash used in operating activities was $12.5 million, which consisted of a net loss of $16.2 million, partially offset by non-cash charges of $1.1 million and a net change of $2.6 million in our net operating assets and liabilities. The non-cash charges are primarily comprised of the revaluation of our convertible preferred share liability of $1.0 million and $0.1 million in share-based compensation. The change in our net operating assets and liabilities was primarily due to a $2.7 million increase in accounts payable and accrued expenses as we grew our operations.

Net Cash Used in Investing Activities

During the six months ended June 30, 2019, the period from January 18, 2018 (inception) to June 30, 2018, and the period from January 18, 2018 (inception) to December 31, 2018, net cash used in investing activities primarily consisted of purchases of fixed assets.

Net Cash Provided by Financing Activities

During the six months ended June 30, 2019 net cash provided by financing activities was $18.8 million, which consisted of net proceeds of $18.8 million from the issuance and sale of our convertible preferred shares.

During the period from January 18 (inception) to June 30, 2018 net cash provided by financing activities was $14.8 million, which primarily consisted of net proceeds of $14.7 million from the issuance and sale of our convertible preferred shares.

During the period from January 18, 2018 (inception) to December 31, 2018, net cash provided by financing activities was $23.8 million, which primarily consisted of net proceeds of $23.7 million from the issuance and sale of our convertible preferred shares.

Contractual Obligations and Other Commitments

The following table summarizes our contractual obligations as of December 31, 2018 (in thousands):

	Payments Due by Period				
	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years	Total
Operating lease obligations	$ 18	$ —	$ —	$ —	$ 18
Total contractual obligations	$ 18	$ —	$ —	$ —	$ 18

In addition, under the Teva Agreements, we have milestone and royalty payment obligations if and when we achieve certain milestones and commercialize products developed under the agreements. Because these obligations are uncertain, and their timing and amount are not known, they are not included in the table above. See “Business—Agreements with Teva.”

The amounts in the table above do not include: (a) a non-cancellable purchase commitment entered into in July 2019 related to the supply of reagents in the amount of €1.2 million, or $1.4 million (using the exchange rate as of June 30, 2019), pursuant to a purchase order issued to Teva; or (b) non-cancellable purchases commitments entered into in June, July and August 2019 amounting in total to €4.1 million, or $4.7 million (using the exchange rate as of June 30, 2019), that we will be responsible to pay in connection with multiple statements of work with a contract manufacturer related to scale-up activities of BIO89-100 and the production of material for preclinical and clinical studies, and for the technology transfer related to the manufacturing of certain enzymes.

We also enter into agreements in the normal course of business with contract research organizations for clinical trials, preclinical studies, manufacturing and other services and products, which are generally cancelable upon written notice. These obligations and commitments are also not included in the table above.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements, as defined in the rules and regulations of the SEC, and do not have any holdings in variable interest entities.

Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities. We held cash and cash equivalents of $11.2 million and $21.9 million as of December 31, 2018 and June 30, 2019, respectively, which consist of bank deposits. Historical fluctuations in interest rates have not had a significant impact on our financial condition or results of operations, and a hypothetical future 10% relative increase or decrease in interest rates would not have a material impact on the value of our cash and cash equivalents or on our future financial condition or results of operations.

Foreign Currency Risk

Our expenses are generally denominated in the currencies in which our operations are located, which is primarily in the United States and Israel. We make payments to vendors for research and development services with payments denominated in foreign currencies, including the Israeli New Shekel and Euro. We are subject to foreign currency transaction gains or losses on our payments denominated in foreign currencies. To date, foreign currency transaction gains and losses have not been material and we have not had a formal hedging program with respect to foreign currency. A 10% increase or decrease in currency exchange rates would not have a material effect on our financial results.

Critical Accounting Polices and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities as of the date of the consolidated financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Accrued Research and Development Expenditures

We record accrued expenses for estimated preclinical and clinical trial and research expenses related to the services performed but not yet invoiced pursuant to contracts with research institutions, contract research organizations and clinical manufacturing organizations that conduct and manage preclinical studies, and clinical trials, and research services on our behalf. Payments for these services are based on the terms of individual agreements and payment timing may differ significantly from the period in which the services were performed. Our estimates are based on factors such as the work completed, including the level of patient enrollment. We monitor patient enrollment levels and related activity to the extent reasonably possible and make judgments and estimates in determining the accrued balance in each reporting period. Our estimates of accrued expenses are based on the facts and circumstances known at the time. If we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates. As actual costs become known, we adjust our accrued expenses. To date, we have not experienced significant changes in our estimates of preclinical studies and clinical trial accruals.

Convertible Preferred Share Liability

The freestanding instruments related to the commitments by the Series A convertible preferred shareholders to purchase and by us to sell our Series A convertible preferred shares in subsequent closings, contingent upon the achievement of certain developmental milestones and approval by the board of directors, at a fixed price per share, are considered a liability (or an asset) measured at fair value as the shares underlying the rights contain liquidation preferences upon certain "deemed liquidation events" that are not solely within the Company's control and which are considered in-substance contingent redemption features. The instruments are subject to revaluation at each balance sheet date until settlement, with revaluations recognized as a component of other (income) expenses, net in the consolidated statement of operations and comprehensive loss.

Share-Based Compensation

We recognize compensation expense related to share-based awards granted to employees, directors, and non-employee service providers, including stock options, based on the estimated fair value of the awards on the date of grant. We estimate the grant date fair value, and the resulting share-based compensation, using the Black-Scholes option-pricing model. The grant date fair value of the share-based awards, which have graded vesting, is recognized using the straight-line method over the requisite service period of each award, which is generally the vesting period of the respective awards. We recognize forfeitures as they occur.

We use the Black-Scholes option-pricing model to estimate the fair value of stock option awards that requires the use of subjective assumptions to determine the fair value of share-based awards. These assumptions include:

- *Expected volatility*—Since we are privately held and do not have any trading history for our shares of common stock, the expected volatility is based on the historical volatilities of the shares of common stock of similar publicly traded companies in the biotechnology sector. The historical volatility data was computed using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of the share-based awards.

- *Risk-free interest rate*—The risk-free interest rate is based on the U.S. Treasury zero coupon bonds in effect at the time of grant for periods corresponding with the expected term of the option.

- *Expected term*—The expected term of options granted to employees and directors is determined using the "simplified" method. Under this approach, the expected term is presumed to be the mid-point between the weighted-average vesting term and the contractual term of the option. The simplified method makes the assumption that the employee will exercise share options evenly over the period when the share options are vested and ending on the date when the share options would expire. The expected option term for options granted to non-employees is based on the contractual term.

- *Expected dividend*—We have never paid dividends on our shares of common stock and have no plans to pay dividends on our shares of common stock. Therefore, we used an expected dividend of zero.

We will continue to use judgment in evaluating the expected volatility and expected term utilized for our share-based compensation calculations on a prospective basis.

Given the absence of a public trading market for our shares of common stock, our board of directors exercised their judgment and considered a number of objective and subjective factors to determine the best estimate of the fair value of our shares of common stock, including timely valuations of our shares of common stock prepared by an unrelated third-party valuation firm, important developments in our operations, sales of convertible preferred shares, actual operating results and financial performance, the conditions in the biotechnology industry and the economy in general, the stock price performance and volatility of comparable public companies, and the lack of liquidity of our shares of common stock, among other factors. After the closing of this offering, our board of directors will determine the fair value of each share of common stock based on the closing price of our shares of common stock as reported on the date of grant. Our board of directors intended all options granted to be exercisable at a price per share not less than the estimated per share fair value of shares of common stock underlying those options on the date of grant.

For the six months ended June 30, 2019 and during the period from January 18, 2018 (inception) to December 31, 2018, share-based compensation was $111,000 and $108,000, respectively. As of June 30, 2019, there was $682,000 of unrecognized share-based compensation related to stock options granted, which is expected to be recognized over a weighted average period of 3.0 years.

Based on the assumed initial offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, the aggregate intrinsic value of outstanding stock options as of June 30, 2019 was $ million, of which $ million related to vested options and $ million related to unvested options.

Recent Accounting Pronouncements

See Note 2 to our consolidated financial statements included elsewhere in this prospectus for more information about recent accounting pronouncements, the timing of their adoption, and our assessment, to the extent we have made one yet, of their potential impact on our financial condition of results of operations.

JOBS Act Accounting Election

We are an “emerging growth company,” as defined in the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies.

We have elected to use this extended transition period to enable us to comply with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our consolidated financial statements and our interim condensed consolidated financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

BUSINESS

Overview

We are a clinical-stage biopharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of liver and cardio-metabolic diseases. Our lead product candidate, BIO89-100, a specifically engineered glycoPEGylated analog of FGF21, is currently being developed for the treatment of NASH. NASH is a severe form of NAFLD, characterized by inflammation and fibrosis in the liver that can progress to cirrhosis, liver failure, HCC and death. There are currently no approved products for the treatment of NASH. FGF21 is a clinically-validated mechanism that has been shown in humans to reduce steatosis and address cardio-metabolic dysregulation. We believe BIO89-100 may be a differentiated FGF21 therapy based on its robust and durable biological effects and a favorable tolerability profile, as well its potential for a longer dosing interval. Combining these characteristics with the ability to address the key liver pathologies in NASH, as well as the underlying metabolic dysregulation in NASH patients, BIO89-100 has the potential to become a mainstay of NASH therapy. We successfully completed a Phase 1a, first-in-human, SAD clinical trial with 58 healthy volunteers. The magnitude and significance of BIO89-100's biological effects after a single dose on lipid parameters were robust and durable. In July 2019, we initiated our POC Phase 1b/2a clinical trial in patients with NASH or patients with NAFLD and a high risk of NASH and we expect to report topline data in the second half of 2020. We also intend to develop BIO89-100 for the treatment of SHTG, a condition identified by severely elevated levels of triglycerides (greater than or equal to 500 mg/dL), which is associated with an increased risk of NASH, cardiovascular events and acute pancreatitis. We expect to initiate our Phase 2 trial in SHTG patients in the first half of 2020 in order to evaluate the ability of BIO89-100 to reduce fasting plasma triglyceride levels compared to baseline levels and to report topline data in the first half of 2021. Based on FDA guidance for the development of SHTG treatments, as well as the regulatory path followed by other companies that have successfully developed SHTG therapies, we believe that a combination of smaller clinical trials and shorter development timelines could mean that SHTG potentially represents a quicker path to market for BIO89-100. We believe BIO89-100 has the potential to address multiple drivers underlying metabolic dysregulation, which would make it an ideal candidate for selected liver and cardio-metabolic diseases.

The prevalence of NAFLD, which affects approximately 25% of the global population, and NASH, which develops in approximately 20% to 25% of NAFLD patients, is growing and is driven primarily by the worldwide obesity epidemic. NAFLD and NASH patients have an excessive accumulation of fat in the liver resulting primarily from a caloric intake above and beyond energy needs. In NAFLD patients, this abnormal liver fat contributes to the progression to NASH, a liver necro-inflammatory state, that can lead to scarring, also known as fibrosis, and, for some, can progress to cirrhosis and liver failure. The critical pathophysiologic mechanisms underlying the development and progression of NASH include reduced ability to handle lipids, increased insulin resistance, injury to hepatocytes and liver fibrosis in response to hepatocyte injury. Patients with NASH frequently have other significant metabolic co-morbidities such as obesity, hyperglycemia, dyslipidemia and systemic hypertension (a constellation of which is commonly referred to as metabolic syndrome) and these further contribute to the risk of cardiovascular disease. The number of NASH cases in the United States is projected to expand from 16.5 million in 2015 to 27 million in 2030, with similar prevalence growth expected in Europe. Diet and exercise are currently the standard of care for NAFLD and NASH, but adherence to this treatment regimen is poor and there remains a high unmet need in the treatment of NASH.

BIO89-100 is a specifically engineered FGF21 analog that we believe has the potential to address the critical pathophysiologic mechanisms underlying NASH. FGF21 is a metabolic hormone that regulates energy expenditure and glucose and lipid metabolism. FGF21 has been clinically shown to reduce steatosis in the liver. It is also thought to exert effects on liver fibrosis by improving metabolic regulation, which reduces ongoing liver injury thus giving the liver time to heal. FGF21 also generates an on-target effect to increase adiponectin, a hormone released from adipose tissue that, among other functions, can suppress development and progression of hepatic fibrosis. However, FGF21 in its native form suffers from a short half-life and a tendency to aggregate in solution, both of which impact its suitability as a viable drug. To address these challenges, we have specifically engineered

BIO89-100 to maintain the clinical benefits of FGF21, while extending half-life in vivo, protecting against proteolysis, reducing renal clearance, minimizing susceptibility to aggregate in solution and optimizing potency.

BIO89-100 has been evaluated in seven animal studies of NASH, diabetes and obesity, including studies in mice and non-human primates. Each study was customized to assess endpoints relevant to liver and metabolic diseases and conducted according to standard practices at experienced CROs. In these preclinical studies, consistent beneficial effects across a range of endpoints were observed, including improvements in hepatic steatosis, injury and fibrosis in a diet-induced NASH study of 50 mice (see "BIO89-100—Results of DIN Mouse Studies" Figure 11 which illustrates that statistically significant mean changes with respect to hepatic steatosis and fibrosis were each observed and Figure 12 which illustrates that statistically significant mean changes with respect to injury were observed) and improved glycemic resistance and lipid handling in a study of 24 spontaneously diabetic obese cynomolgus monkeys with elevated triglycerides (see "BIO89-100—Results of Spontaneously Diabetic Obese Cynomolgus Monkey Studies" Figures 20 and 21, respectively, which illustrate that statistically significant mean changes with respect to glycemic control and lipid handling were each observed). We believe this demonstrates BIO89-100's potential to simultaneously address the multiple drivers of NASH pathogenesis. The histological endpoints assessed in these preclinical studies, NAFLD activity score ("NAS") and fibrosis score, mirror the endpoints we expect to assess in our clinical development. In addition, treatment with BIO89-100 in animal models demonstrated consistent reductions in body weight.

In May 2019, we announced positive topline data from our Phase 1a, first-in-human, SAD clinical trial of BIO89-100 in 58 healthy volunteers. In this SAD study, BIO89-100 demonstrated a favorable tolerability profile in the 43 volunteers who received BIO89-100 with a half-life of 55 to 100 hours. At single doses of 9.1 mg and higher, BIO89-100 demonstrated significant improvements in key lipid parameters measured at Day 8 and Day 15 after dosing on Day 1. The mean changes versus baseline include reductions in triglycerides (up to 51%) and LDL-C (up to 37%) and increase in HDL-C (up to 36%) despite the baseline values being in the normal range. As compared to placebo treatment, these mean changes were all statistically significant ($p < 0.001$). BIO89-100 demonstrated rapid (beginning from Day 2), sustained and durable improvements in lipid parameters for two weeks or more after single dose administration. Based on these findings and results from our animal studies, we believe such a lengthy duration of effect may confer longer dosing intervals to BIO89-100. We are currently enrolling our POC Phase 1b/2a trial with 83 total patients randomized to receive once weekly or once every two weeks subcutaneous dosing of either BIO89-100 or placebo, in each case, for up to 12 weeks. This trial is designed to assess the safety, tolerability and PK properties of BIO89-100, as well as changes in liver steatosis and key biomarker assessments.

We also intend to develop BIO89-100 for the treatment of SHTG, a condition identified by severely elevated levels of triglycerides (greater than or equal to 500 mg/dL) and which is associated with an increased risk of NASH, cardiovascular events and acute pancreatitis. SHTG accounts for up to 10% of all acute pancreatitis episodes. It is estimated that there are 2.5 million to 4 million patients in the United States with TG ^{3} 500 mg/dL and up to 50% of SHTG patients treated with certain approved drugs are refractory to current standard of care. In a study of 24 diabetic obese cynomolgus monkeys with elevated triglycerides, BIO89-100 showed significant effects on triglycerides at doses as low as 0.1 mg/kg/week, with a 78% reduction from baseline (range of 52% reduction to 94% reduction) observed at the highest dose level of 1.0 mg/kg/week on Day 56. In our Phase 1a SAD study, BIO89-100 showed a significant reduction in triglycerides of up to 51% after a single dose in healthy volunteers. While currently approved SHTG therapies decrease TG levels, they generally do not have broader metabolic benefits. To the extent that we are able to show in subsequent human clinical trials that BIO89-100 significantly decreases both TG and LDL-C levels and improve other metabolic parameters, we believe that BIO89-100 could be a differentiated therapy in this indication. We expect to initiate our Phase 2 trial in SHTG patients in the first half of 2020 in order to evaluate the ability of BIO89-100 to reduce fasting plasma triglyceride levels compared to baseline levels and to report topline data in the first half of 2021.

We retain exclusive worldwide rights to BIO89-100. BIO89-100 is protected by a family of issued patents with claims directed to composition of matter and methods of use. The first of our patents for BIO89-100

are projected to expire in the United States in 2028, with the final composition-of-matter patent projected to expire in the United States in 2038, in each case, without patent term extensions. Because BIO89-100 is a biologic drug, marketing approval is also expected to provide 12 years of market exclusivity in the United States from the approval date of a BLA. We license the patents and know-how related to the glycoPEGylation technology for use in the research, development, manufacture and commercialization of BIO89-100 from Teva and ratiopharm.

Our management team has extensive drug development, manufacturing and commercialization experience, having brought many successful drugs to market, including biologic agents. We are also supported by a group of directors and leading investors whose collective experience will assist us in realizing our corporate strategy. Our existing investors include OrbiMed, Longitude Capital, RA Capital and Pontifax.

Strategy

Our goal is to become a leading biopharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of liver and cardio-metabolic diseases. The key components of our strategy are to:

- **Rapidly advance BIO89-100 through clinical development for the treatment of NASH.** We believe BIO89-100 may be a differentiated FGF21 therapy based on its robust and durable biological effects and a favorable tolerability profile, as its potential for a longer dosing interval, and is well positioned to address the complex pathophysiology of NASH. We are currently enrolling patients in our POC Phase 1b/2a clinical trial to evaluate the safety and efficacy of BIO89-100. We believe that our trial design and the use of well-established surrogate clinical endpoints can contribute meaningfully to the rapid advancement of BIO89-100 through its clinical development. With potential for BIO89-100 to be established as a mainstay monotherapy for NASH, we continue to explore opportunities to combine BIO89-100 with products targeting other pathways within NASH for possible development as a combination therapy.

- **Expand the breadth of indications for BIO89-100 with an initial focus on SHTG.** While we are focused on becoming a leader in the treatment of NASH, the mechanism of action of our FGF21 analog supports evaluation across a spectrum of liver and cardio-metabolic diseases. We believe BIO89-100's mechanism and potentially robust and durable biological effects and favorable tolerability profile, as well as its potential for a longer dosing interval make it an ideal candidate for selected liver and cardio-metabolic diseases. We intend to develop BIO89-100 for the treatment of SHTG. Based on FDA guidance for the development of SHTG treatments, as well as the regulatory path followed by other companies that have successfully developed SHTG therapies, we believe that a combination of smaller clinical trials and shorter development timelines could mean that SHTG potentially represents a quicker path to market for BIO89-100.

- **Scale-up and optimize the manufacturing of BIO89-100.** We currently use an external contract manufacturing organization ("CMO") to manufacture BIO89-100 for our ongoing and planned clinical trials. While these trials are ongoing, we plan to work with our CMO to optimize and scale-up the manufacturing process for BIO89-100 to support the increased production that will be needed for later-stage clinical trials and commercialization, if BIO89-100 is approved.

- **Establish a commercial infrastructure in key geographies.** We have worldwide rights to BIO89-100 and intend to develop the sales infrastructure required for commercialization in the United States. We also plan to evaluate options, including strategic collaborations, for commercializing BIO89-100, if approved, in other key markets, such as Europe and China.

- **Construct a diversified multi-asset pipeline of novel therapies.** We intend to employ a value-driven strategy to identify, acquire, develop and commercialize product candidates for liver and

cardio-metabolic diseases. We intend to focus on product candidates that we believe have attractive profiles in early clinical testing, address a clear unmet medical need and can advance quickly and efficiently into late-stage development.

Our Focus on Liver and Cardio-Metabolic Disease

We are focused on developing and commercializing therapeutic interventions that have a clinically meaningful impact on patients with liver and cardio-metabolic diseases. These diseases, including NASH and SHTG, represent leading global causes of morbidity and mortality. Despite a wave of public health campaigns to promote better diet and exercise habits and a range of treatment options available for many of these diseases, there is a significant unmet medical need for more effective therapies to improve patient outcomes and reduce the burden on global healthcare systems.

We are currently developing our lead product candidate, BIO89-100, a specifically engineered glycoPEGylated analog of FGF21, for the treatment of NASH. We believe BIO89-100 is an ideal candidate for the treatment of NASH based on:

- its ability to address the key liver pathologies in NASH;
- its ability to address the underlying metabolic dysregulation in NASH patients;
- its balance of its robust and durable biological effects and favorable tolerability profile; and
- its potential for a longer dosing interval.

Given the potential of BIO89-100 to meaningfully reduce triglycerides, we also intend to develop BIO89-100 for the treatment of SHTG. There is regulatory precedence for the approval of a therapy for the treatment of patients with SHTG in the United States and the reduction in triglycerides from baseline is recognized by the FDA as the primary endpoint for full approval. Based on FDA guidance for the development of SHTG treatments, as well as the regulatory path followed by other companies that have successfully developed SHTG therapies, we believe that a combination of smaller clinical trials and shorter development timelines could mean that SHTG potentially represents a quicker path to market for BIO89-100.

NASH Overview

NAFLD is emerging as the most common chronic liver disorder, driven primarily by the global obesity epidemic. NAFLD affects approximately 25% of the population globally and is often referred to as the hepatic manifestation of metabolic syndrome. Patients with NAFLD have an excessive accumulation of fat in the liver resulting from a caloric intake above and beyond energy needs. This abnormal fat in the liver contributes to the progression of NAFLD to NASH, a necro-inflammatory state in the liver that ultimately leads to scarring, also known as fibrosis; and for certain patients, progression to cirrhosis and liver failure.

Patients with NASH exhibit suboptimal lipid handling, increased insulin resistance, caloric overload and inadequate fat burning, all of which contribute to the increased risk of cardiovascular disease. Due to an increase in obesity and Type 2 diabetes, which predispose individuals to more significant liver disease, the number of NASH cases in the United States is projected to expand from 16.5 million in 2015 to 27 million in 2030. Currently, there are no approved products for the treatment of NASH and diet and exercise is established as the standard of care.

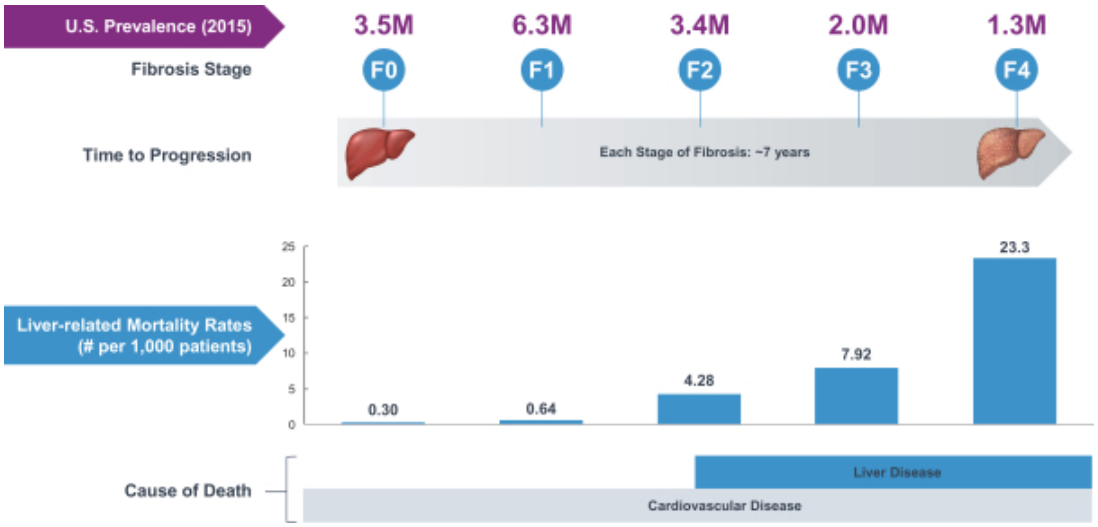
Disease Overview

NAFLD is a condition of excess fat accumulation, or steatosis, of more than 5% in liver cells, also known as hepatocytes. NASH, a severe form of NAFLD, is characterized histologically by the additional presence of inflammation and hepatocellular injury such as visible ballooning and has a significantly worse

prognosis, with the potential to progress to liver fibrosis, cirrhosis or HCC. Steatohepatitis is a key catalyst in fibrosis development, and there is a substantial collinearity between the presence of NASH and fibrosis severity. While NAFLD has historically been viewed as benign in terms of liver-related outcomes, recent studies have challenged this notion since patients with NAFLD may develop NASH and fibrosis over time.

Figure 1 below shows the increase in prevalence liver-related mortality rates by fibrosis stage.

Figure 1: Prevalence and Liver-Related Mortality Rate by Fibrosis Stage



It is estimated that 20% to 25% of NAFLD patients progress to NASH. Of those with NASH, cirrhosis develops in approximately 20% and 45% of patients and in some cases, cirrhosis progresses to decompensated cirrhosis, which results in permanent liver damage that can lead to liver failure. In addition, it is estimated that 8% of patients with advanced fibrosis will develop HCC.

There is a high unmet need in the treatment of NASH, and there are currently no approved therapies. In the United States, the number of NASH cases is projected to expand from 16.5 million in 2015 (5.1% of the population) to 27 million in 2030. The expected lifetime economic burden of all patients with NASH in the United States in 2017 is estimated at $223 billion. NASH is currently the second leading cause of liver transplants behind hepatitis C, and is expected to become the leading cause of liver transplants by 2020. Additionally, multiple epidemiological studies have linked NAFLD to increased cardiovascular disease, concluding that the majority of deaths among NAFLD patients are attributable to cardiovascular disease. As a result, we believe it is important that new therapeutics options for NASH also address the underlying cardiovascular and metabolic dysregulations in these patients.

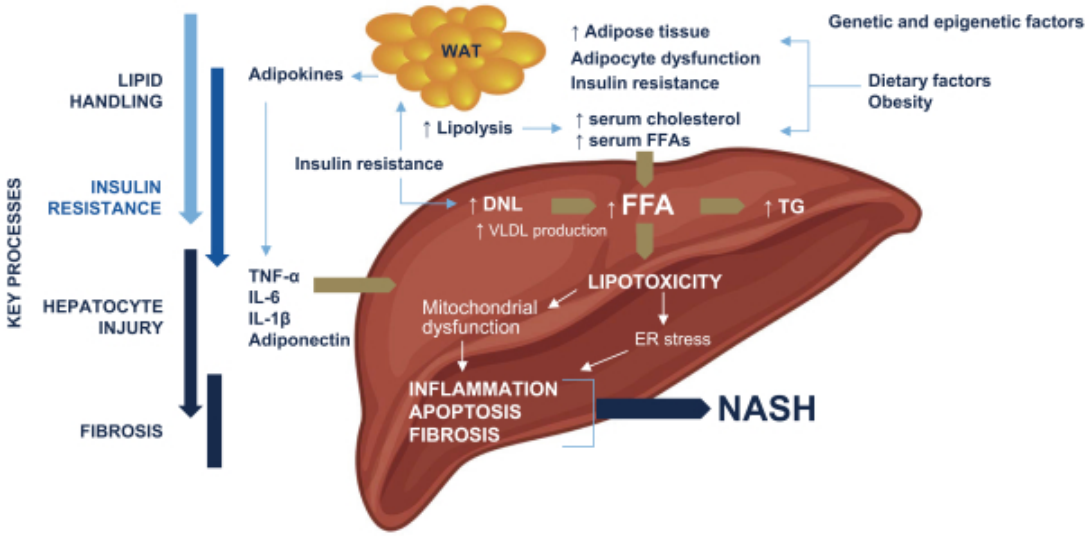
Etiology

Understanding of the pathophysiologic mechanisms that lead to NASH has evolved in recent years. Excessive caloric overload, metabolic dysregulation, cardio-metabolic co-morbidities and genetic risk factors increase the likelihood of developing NASH, with a multitude of potential mechanistic contributors to pathophysiology. In NASH, the liver's capacity to handle the primary metabolic energy substrates, carbohydrates and fatty acids, is overwhelmed. This occurs when there is an excess of free fatty acids deposited in the liver or their disposal from the liver is impaired. The accumulation of surplus free fatty acids leads to the formation of toxic lipid species. These toxic lipids then induce endoplasmic reticulum stress, oxidative stress and an

inflammatory response, which can result in hepatocellular injury and death. This may lead to fibrosis and genomic instability, which may worsen over time to cirrhosis and HCC, respectively.

As shown in Figure 2 below, the critical pathophysiologic mechanisms underlying development and progression of NASH include (1) reduced ability to handle lipids, (2) increased insulin resistance, (3) injury to hepatocytes and (4) development and progression of liver fibrosis in response to hepatocyte injury.

Figure 2: Mechanisms Underlying Development and Progression of NASH



Reduced Ability to Handle Lipids

Excess consumption of calories, poor diet and a sedentary lifestyle, each often associated with obesity, can burden the body with a surplus of carbohydrates and lipids. This burden can be progressively more difficult for the liver to handle thereby resulting in steatosis in the liver. The problem is compounded further as insulin resistance develops.

Free fatty acids (“FFA”) accumulate in the liver primarily from three sources, namely, through (1) the transfer from peripheral adipose tissues where triglycerides are mobilized, (2) de-novo lipogenesis (“DNL”), and (3) direct dietary intake. The FFA that lead to NASH are believed to arise primarily from the peripheral tissue pool and secondarily through DNL. The increase in the influx of FFA to the liver from the peripheral tissues is driven by excessive caloric intake greater than the body’s demand and increased insulin resistance resulting in deposition of fat to the liver for processing. DNL is a distinct process in the liver by which hepatocytes convert excess carbohydrates, especially fructose, to fatty acids.

The three main fates of fatty acids in the liver are (1) mitochondrial beta-oxidation (to release ATP, or energy), (2) re-esterification to form triglyceride, which can then be exported into the blood as very low density lipoproteins, or (3) stored in lipid droplets, resulting in liver steatosis and ultimately NASH. Adiponectin, a hormone derived from adipose tissue, appears to have a pivotal role in improving fatty acid oxidation and decreasing fatty acid synthesis, components of lipid handling.

An increase in cholesterol accumulation in the liver can also contribute to NASH, though its role is not as clearly defined as in the case of triglycerides. The dysregulation of the cholesterol pathway can result in an

increase in the cholesterol levels in the liver. The increased cholesterol can accumulate in the liver cell membranes and activate Kupffer cells (activated stellate macrophages), thereby triggering inflammatory pathways and resulting in the progression of NASH.

Increased Insulin Resistance

Insulin resistance, which typically develops in obese individuals, is considered to be a fundamental underlying mechanism in the majority of NASH patients. Fatty acids are primarily delivered to the liver from blood following lipolysis of triglycerides in adipose tissue, a process that is regulated by the actions of insulin on adipocytes. Insulin resistance in adipose tissue manifests as dysregulated lipolysis resulting in excessive delivery of FFA to the liver. The liver tries to cope with the large influx of FFA; however, the build-up of metabolic intermediates interferes with signaling, resulting in hepatic insulin resistance and the inability of the liver to process this excess FFA influx. The state of hepatic insulin resistance further exacerbates the problem by triggering DNL and the build-up of excess fat in the liver.

Injury to Hepatocytes

When the disposal of fatty acids through beta-oxidation or the formation of triglycerides is chronically overwhelmed, fatty acids can form lipotoxic species that lead to stress on the endoplasmic reticulum, oxidative stress and inflammation, all of which are pivotal processes in the development of NASH. Liver inflammation may be an important link between the initial metabolic stress and subsequent hepatocyte death and stimulation of fibrogenesis in NASH by promotion of the expression of pro-inflammatory cytokines and of apoptosis (cell death). These processes are core to the steatohepatitis that gives NASH its name. For example, hepatocyte apoptosis results in the ballooning of cells, a classic pathological feature of NASH. While hepatocytes are the primary and major target of toxic lipids, other cells such as Kupffer cells and hepatic stellate cells are also affected by lipotoxicity and contribute to the development of NASH pathology.

Additional factors, including dysregulation of cytokines and adipokines, energy depletion, anti-oxidant deficiencies, products of the gut microbiome and iron load may modulate hepatocyte vulnerability to the development of lipotoxic stress, injury and inflammation.

Development and Progression of Liver Fibrosis in Response to Hepatocyte Injury

Signaling from stressed or injured hepatocytes and Kupffer cells leads to activation of quiescent hepatic stellate cells. Upon activation, hepatic stellate cells release collagen and other factors. When the production of collagen and matrix proteins is faster than their degradation, accumulation of these proteins in the extracellular matrix can lead to progressive fibrosis. As the lipotoxicity and inflammation continue to damage the liver, the hepatic stellate cells continue to be activated resulting in greater collagen deposition that ultimately leads to fibrosis and cirrhosis.

Co-morbidities Associated with NASH

Patients with NASH frequently have other significant co-morbidities—hypertriglyceridemia, obesity, hyperlipidemia/dyslipidemia, hyperglycemia (including Type 2 diabetes) and systemic hypertension, a constellation of which is commonly referred to as metabolic syndrome—which also increase the risk of developing cardiovascular disease. Figure 3 below shows certain co-morbidities associated with NASH.

Figure 3: NASH Co-morbidities

Selected Co-morbidities	Prevalence in NASH Population
Hypertriglyceridemia	83%
Obesity	82%
Hyperlipidemia / Dyslipidemia	72%
Metabolic syndrome	71%
Type 2 diabetes	44%

The association between NASH and features of metabolic syndrome appears to be bidirectional. Metabolic syndrome increases the risk of NASH and NASH may also exacerbate several features and co-morbidities of metabolic syndrome. Type 2 diabetes, hypertriglyceridemia, obesity and other features of metabolic syndrome have all been shown to be associated with an increased risk for NASH and advanced liver fibrosis. In addition, it is estimated that approximately 30% of obese patients and approximately 30% of patients with Type 2 diabetes have NASH.

In addition, NASH was found to independently increase the risk of non-liver-related adverse outcomes, including cardiovascular risk and malignancy. Multiple epidemiological studies have linked NASH to increased cardiovascular morbidity, concluding that the majority of deaths among NASH patients are attributable to cardiovascular disease (cardiovascular death is four times higher than death related to liver disease).

In considering therapeutic options to treat NASH, we believe it is important to address the underlying metabolic co-morbidities in addition to the liver pathology.

Diagnosis

Most people with NASH are asymptomatic and their disease is often discovered incidentally following a liver imaging procedure, such as an ultrasound, prescribed for other reasons or as part of an investigation for elevated liver enzymes. Once suspected clinically, a liver biopsy is required to definitively diagnose NASH, which necessitates the joint presence of steatosis, ballooning and lobular inflammation. Once pathologically confirmed, the severity of NAFLD and NASH is determined using the histologically validated NAS, which grades disease activity on a scale of 0 to 8. The NAS is the sum of the individual scores for steatosis (0 to 3), lobular inflammation (0 to 3), and hepatocellular ballooning (0 to 2) but does not include a score for fibrosis. Fibrosis staging (F0-F4) relies on the Kleiner classification (F0 = no fibrosis; F1 = perisinusoidal or periportal fibrosis (not both); F2 = both perisinusoidal and periportal fibrosis; F3 = bridging fibrosis; F4 = cirrhosis).

Histological diagnosis remains the gold standard for assessment of NASH and fibrosis. However, given that liver biopsy is associated with risks of pain, bleeding and other morbidity, as well as significant cost, the procedure is not practical for general patient screening. Several non-invasive tools such as clinical risk scores and imaging techniques are increasingly used to assess NASH patients. Clinical risk scores such as the NAFLD fibrosis score, Fibrosis-4 index, the Enhanced Liver Fibrosis score and vibration-controlled transient elastography (“VCTE”), have been validated and are increasingly used. These tools have an excellent negative

predictive value and an acceptable positive predictive value for detection of advanced (³ F3) fibrosis, and are increasingly used in clinical settings. Additionally, evidence is emerging that shows a correlation between reduction in steatosis as measured by magnetic resonance imaging proton density fat fraction ("MRI-PDFF") and improvement histological changes in the liver. Extensive efforts are also under way to develop non-invasive means to identify patients with NAS ³4 or fibrosis ³ F2 patients without a need for a liver biopsy. In a recent draft guidance, the FDA encouraged sponsors to identify biochemical or noninvasive imaging biomarkers that, once characterized and agreed by the FDA, could replace liver biopsies for patient selection and efficacy assessment in clinical trials.

We expect that the validation and subsequent adoption of these new tools will result in an increase in the diagnosis and treatment rates for NASH in the future.

Prevalence

The prevalence of NASH has increased significantly in recent decades, paralleling similar trends in the prevalence of obesity, insulin resistance and Type 2 diabetes. Alarmingly, the prevalence of these conditions is expected to increase further in view of the unhealthy nutrition habits, such as consumption of a diet high in fructose, sucrose and saturated fats, and sedentary behavior that characterize modern lifestyle. In the United States, the number of NASH cases is projected to expand from 16.5 million in 2015 (5.1% of the population) to 27 million in 2030. Approximately 20% of the 16.5 million NASH cases in 2015 had F3/F4 fibrosis, a number that is expected to increase to 7.9 million by 2030, which will be approximately 30% of the total NASH population. Similar growth trends for NASH cases are expected in Europe (12.6 million in 2016 to 18.3 million in 2030 within France, Germany, Italy, Spain and the United Kingdom) as well as China (32.6 million in 2016 to 48.3 million in 2030).

Since no approved drugs exist currently, NASH is emerging as a major economic issue. Lifetime costs of all NASH patients in the United States in 2017 was estimated at $223 billion, and the cost of the advanced NASH population was estimated at $95 billion with estimated increase in NASH cases (as mentioned above) further expected to drive costs upwards. Progression of patients along the NASH continuum further adds to costs as mean health care costs (per month) were 32% and 247% higher for patients with compensated cirrhosis ($1,870) and end-stage liver disease ($4,931), respectively, compared to those without cirrhosis ($1,420) and these results were independent of age. The economic burden of NASH is expected to continue to increase, as NASH is anticipated to become the leading cause of liver transplants by 2020 in conjunction with the significant increase in liver transplant costs ($577,000 in 2013 to $812,500 in 2017).

Overview of NASH Treatment Options

There are currently no approved therapies for the treatment of NASH. We believe four key attributes are essential for successful NASH therapies: (1) robust efficacy with respect to liver pathologies; (2) ability to address underlying co-morbidities associated with the disease; (3) limited tolerability issues at effective doses; and (4) patient convenience. Figure 4 below summarizes the primary interventional and therapeutic approaches to NASH that are in existence or under development and their key advantages and limitations.

Figure 4: Primary Interventional and Therapeutic Approaches to NASH

Approach	Advantages	Limitations
Diet and exercise	■ Reduction in continuing injury to the liver allowing liver to regenerate ■ Inexpensive and widely available	■ Poor adherence
Farnesoid X receptor (FXR) agonism	■ Statistically significant but modest reduction in liver fibrosis ■ Liver fat reduction with some agents	■ Increase in LDL-C and pruritus with some agents ■ Limited impact on NASH resolution by histology
Peroxisome proliferator-activated receptor (PPAR) agonism	■ Improvement in glycemic control with some agents ■ Anti-inflammatory ■ Reduction in triglycerides and liver fat with some agents	■ Weight gain with certain agents ■ Safety issues with certain agents (cancer, heart failure, edema) and renal adverse events ■ No effect on liver fat with certain agents
Thyroid receptor-ß (THR-ß) agonism	■ Reduction in LDL-C and triglycerides ■ Reduction in liver fat	■ Potential for drug-drug interactions ■ Potential risk of hypothyroidism ■ Questionable effect on fibrosis
Acetyl-CoA (ACC) inhibition	■ Reduction in DNL from inhibition	■ Increase in triglycerides, risk of thrombocytopenia
Fibroblast growth factors (FGFs)	■ Reduction in liver fat and fibrosis ■ Improvements in lipid parameters with certain agents	■ FGF19 is associated with increases in LDL-C; impact on HDL and glucose unclear ■ Daily injections with some agents likely to be poorly received by patients ■ Native FGF21 is rapidly broken down by the body and is difficult to formulate in solution
GLP1	■ Reduction in body weight ■ Well-established glycemic control agent	■ No impact on lipid parameters ■ Injectable formulation in testing for NASH has burdensome dosing regime ■ Questionable impact on fibrosis and liver fat reduction

We believe that the market for NASH treatments will evolve to be similar to the multi-billion dollar markets for diabetes and dyslipidemia treatments and has the potential to support multiple successful commercial products across different therapeutic classes as well as within the same class. Further, we believe potent injectable therapies have the potential to be a preferred treatment option for some patient populations.

Our Solution

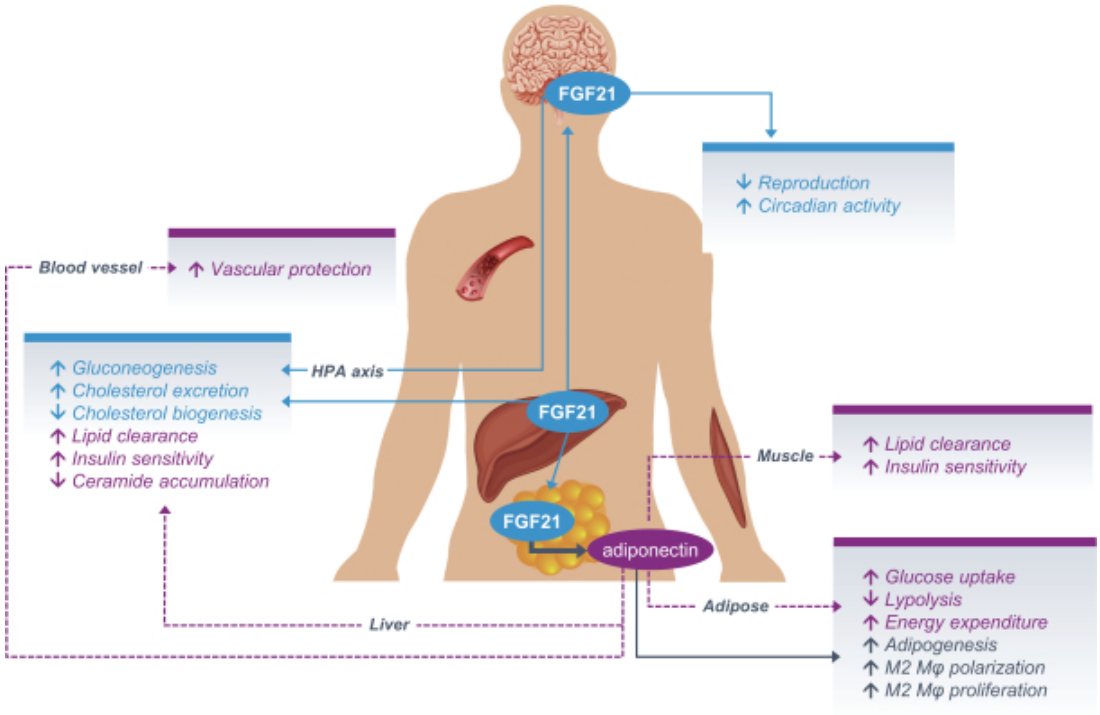
Summary

We are developing BIO89-100, a specifically engineered glycoPEGylated analog of FGF21, for the treatment of NASH and other liver and cardio-metabolic indications. FGF21 is an endogenous metabolic hormone that is naturally found as a monomeric, non-glycosylated protein and is known to play a key role in regulating energy expenditure, and glucose and lipid metabolism. FGF21 has been clinically shown to reduce steatosis in the liver. It is also thought to exert effects on liver fibrosis by improving metabolic regulation, which reduces ongoing liver injury thus giving the liver time to heal. FGF21 also generates an on-target effect to increase adiponectin, a hormone released from adipose tissue that, among other functions, can suppress development and progression of hepatic fibrosis. Given the relevant and broad-based effects of FGF21, we believe it is a compelling pharmaceutical target for treating NASH, which may offer benefits and/or address the limitations relative to the therapeutic approaches described in Figure 4 above. We believe FGF21 analogs such as ours have the potential to be the mainstay of therapies for NASH because they can address liver pathologies and the underlying metabolic dysregulation which result in NASH progression. However, FGF21 in its native form is not suitable as a pharmacological product given it is rapidly broken down by the body and it is unstable in soluble formulation. BIO89-100 is specifically engineered to overcome these challenges while maintaining the efficacious properties of the endogenous molecule. We believe BIO89-100 may be a differentiated FGF21 therapy based on its robust and durable biological effects and a favorable tolerability profile, as well its potential for a longer dosing interval. We are currently evaluating BIO89-100 in a POC Phase 1b/2a clinical trial in patients with NASH or patients with NAFLD and high risk of NASH.

FGF21 Overview

Fibroblast growth factors ("FGFs"), including FGF21 and FGF19, are a large family of cell-signaling proteins involved in the regulation of many processes within the body. FGF21 is an endogenous metabolic hormone that regulates energy homeostasis, glucose-lipid-protein metabolism and insulin sensitivity, and modulates the pathways that mitigate against intracellular stress. FGF21 is secreted primarily by the liver but is also secreted by the white adipose tissue ("WAT"), skeletal muscle and the pancreas. FGF21 exerts its biological benefits through the activation of three fibroblast growth factor receptors ("FGFRs"), FGFR1c, FGFR2c and FGFR3c, and requires co-activation of the transmembrane protein cofactor beta Klotho ("ß-Klotho"). FGF21 is not believed to activate FGFR4, which has been associated with adverse effects. FGF21 can act directly or indirectly on target organs by mediating downstream regulators, such as adiponectin, and upstream regulators that induce FGF21, such as nutritional stress or transcription factors. Figure 5 below shows effects of FGF21 on the body.

Figure 5: Biological Effects of FGF21



Reducing Liver Steatosis by Improving Lipid Handling and Insulin Sensitivity

FGF21 has been clinically shown to reduce liver steatosis. FGF21 reduces liver steatosis by (1) increasing fatty acid oxidation in the liver, (2) reducing the deposition of free fatty acids from peripheral tissue to the liver and (3) reducing DNL in the liver. FGF21 exerts its systemic effects by reducing the serum levels of lipids (e.g., triglycerides, LDL cholesterol) and increasing insulin sensitivity. Increasing insulin sensitivity reduces lipolysis and can also reduce serum levels of lipids. In particular, FGF21 has been demonstrated to reduce liver fat in patients with NASH and has also shown beneficial effects in obese diabetic patients on both serum levels of lipids and insulin resistance.

Improving Liver Inflammation and Fibrosis

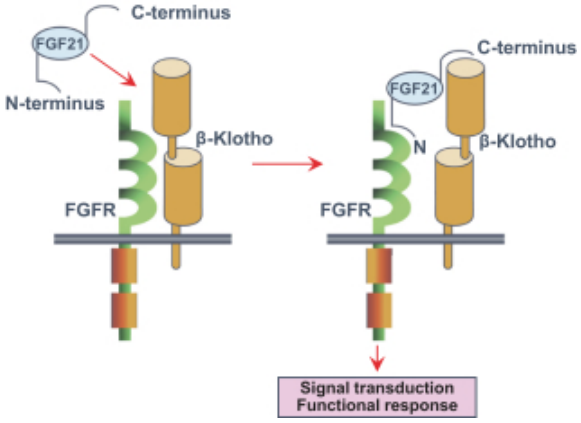
FGF21 is believed to reduce liver fibrosis, the pathological change mostly clearly linked to liver-related morbidity in NASH patients via two potential pathways. One pathway is through the metabolic benefits of FGF21 described above. Long-term improvements in metabolic regulation reduce the ongoing liver injury that drives fibrosis and thus allows the liver time to heal. The other pathway is a direct anti-fibrotic effect mediated via adiponectin, an adipokine that is upregulated by FGF21. Increased adiponectin downregulates the hepatic stellate cells that are activated upon hepatic injury and responsible for collagen deposition and subsequent fibrosis.

FGF21 Signaling

As noted above, FGF21 exerts its biological benefits through the co-activation of FGFRs and ß-Klotho. FGFRs are expressed widely throughout the body whereas ß-Klotho is primarily expressed in metabolic tissues such as adipose tissue, liver, and pancreas, thereby providing organ specificity to FGF21.

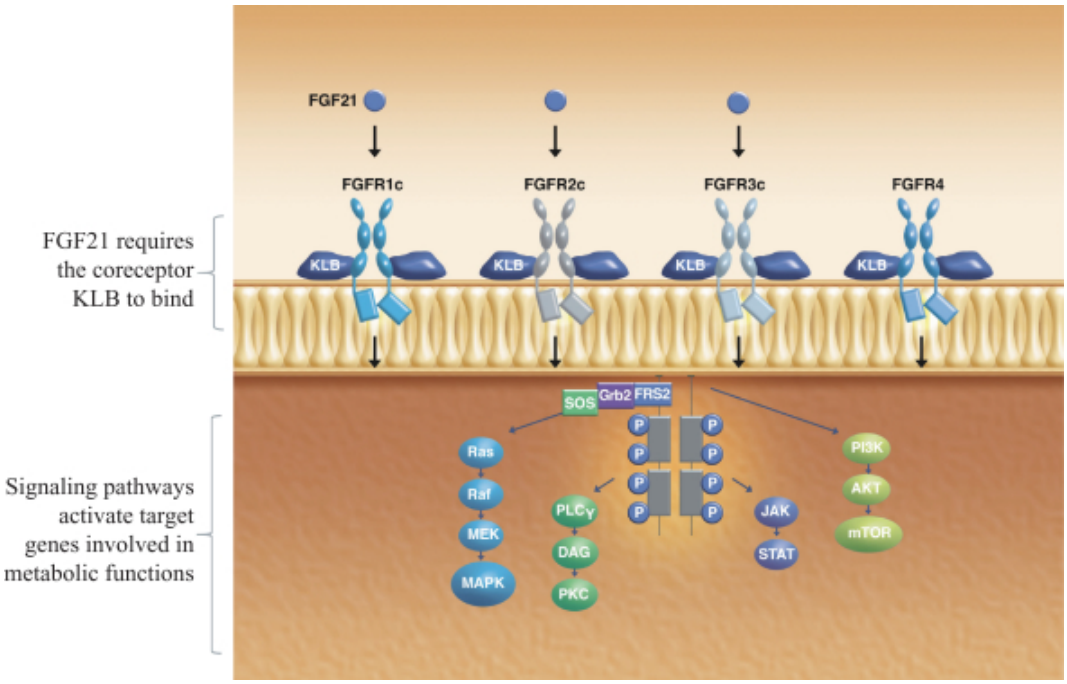
As illustrated in Figure 6 below, the binding of FGF21 is a two-step process. The C-terminus of FGF21 initially binds to ß-Klotho enabling the N-terminus to form an expanded complex with one of the FGFRs. Once the co-receptor complex has formed with ß-Klotho and one of the FGFRs, a series of intracellular signaling cascades is initiated. These signaling cascades enable FGF21 to exert its biological functions.

Figure 6: FGF21's two-step receptor binding with ß-Klotho and FGFRs



FGF21 activates three specific FGFRs (FGFR1c, FGFR2c and FGFR3c), which based on nonclinical studies and clinical trials, appear to be responsible for mediating the desired therapeutic actions of FGF21 in NASH. FGF19 activates these receptors and acts upon another FGFR known as FGFR4. Activation of FGFR4 results in an increase in LDL cholesterol and has been implicated in the etiology or progression of HCC. The activation and downstream signaling pathways of FGF21 are shown in Figure 7 below.

Figure 7: FGF21 Receptor Activation



Overcoming the Challenges of Developing FGF21 as a Pharmaceutical Product

While the observed pharmacological effects of recombinant human FGF21 in preclinical disease models clearly highlight its therapeutic potential, FGF21 in its native form is not suitable for commercialization for two key reasons:

- **Native FGF21 is rapidly broken down in the bloodstream and cleared through the kidneys.** The native form of FGF21 is a 19.4 kDa protein with a half-life estimated to be less than two hours. Reducing renal clearance and protecting both ends of the protein from proteolysis remains key to extending half-life and thereby extending the duration of its effect. If the N-terminus is not intact, signaling activity of FGF21 is significantly reduced. However, if the C-terminus is not intact, FGF21's ability to bind with ß-Klotho is impaired, thereby rendering it inactive.

- **Native FGF21 is unstable and has a tendency to aggregate in solution.** Hence, it is operationally challenging to develop a stable liquid formulation at high concentration with low viscosity, which is required to achieve good bioavailability via subcutaneous injection.

Clinical Validation of FGF21

We believe FGF21 has the potential to be the mainstay monotherapy for NASH because it addresses multiple facets of the disease. Specifically, it has the potential to reduce steatosis, improve fibrosis and importantly, impact the metabolic dysregulation which continues to promote disease progression. The potential for FGF21 analogs in the treatment for NASH has been demonstrated by clinical trial data with pegbelfermin, a pegylated form of FGF21. In a third-party Phase 1b study, pegbelfermin was observed to result in reductions in triglycerides, LDL-C and HDL. In addition, a third-party Phase 2a study conducted in patients with biopsy-proven NASH, pegbelfermin showed a significant reduction in absolute hepatic fat fraction measured by MRI-PDFF, a significant increase in adiponectin concentration, a decrease in mean liver stiffness and a significant decrease in concentration of PRO-C3, a biomarker of fibrosis. Clinical outcomes were better when dosed as a daily injection versus a weekly injection. The compound was deemed generally well tolerated, although a higher frequency of gastrointestinal adverse events was reported in treated patients versus placebo.

A second compound, selectively activating the FGFR1c and its co-receptor ß-Klotho, reported reductions in liver fat content and improvements in metabolic parameters in a study in NAFLD patients.

BIO89-100

Overview

We are developing BIO89-100, a specifically engineered glycoPEGylated analog of FGF21, for the treatment of NASH with fibrosis and other cardio-metabolic indications. BIO89-100 has successfully completed a Phase 1a study, and we are currently evaluating BIO89-100 in a POC Phase 1b/2a clinical trial in patients with NASH or NAFLD with a high risk of NASH. BIO89-100 has been specifically engineered to: (1) protect against proteolysis and reduce renal clearance, (2) have an extended half-life, (3) minimize susceptibility to aggregate in solution and (4) optimize its potency, enabling the potential use of lower dosage/doses. Additionally, we believe that BIO89-100 may enhance binding affinity for ß-Klotho, by altering the conformation of the C-terminus which could have a positive impact on efficacy.

Primary Structure and Protein Engineering of BIO89-100

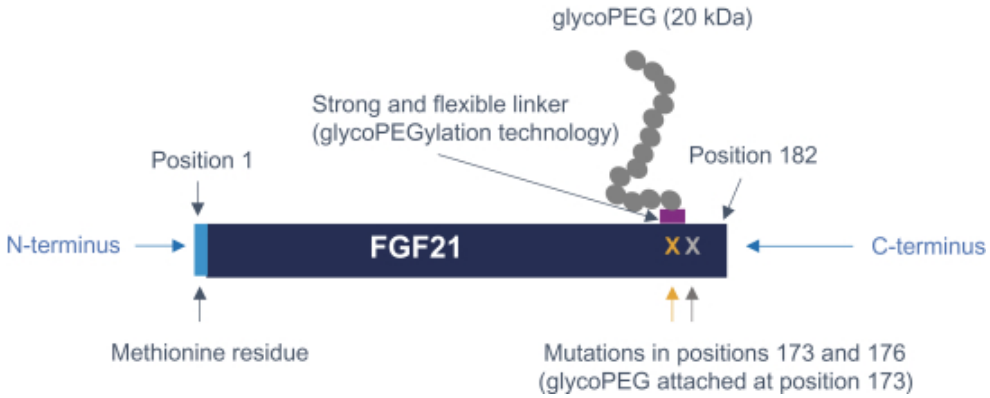
BIO89-100 has been optimally constructed with two mutations via substitutions with natural amino acids at site-specific positions (173 and 176) toward the C-terminus end of the hormone. The mutations were incorporated into the FGF21 sequence after existing proline to create a consensus sequence for glycosylation. Subsequently, the glycosyl linker and a single 20 kDa glycoPEG moiety were enzymatically introduced at the O-linked glycosylation consensus site (position 173) via the proprietary glycoPEGylation technology. Our glycoPEG moiety is an activated form of the PEG molecule with the use of Sialic Acid, CMP-SA-PEG. The proximity of the mutations ensures consistent and efficient attachment of the glycoPEG moiety.

BIO89-100 has two modified natural amino acid residues:

- S173T: Serine modified to Threonine at position 173; and
- R176A: Arginine modified to Alanine at position 176.

In addition, a Methionine residue was introduced at the N-terminus which acts as the translation initiation signal. A single 20 kDa linear glycoPEG moiety is attached to the Threonine in position 173 via the proprietary glycoPEGylation technology. Figure 8 below shows the structure of BIO89-100.

Figure 8: Structure of BIO89-100



The increase in the size of the molecule from 19.4 kDa to 40 kDa together with the site-specific mutations adjacent to the primary cleavage site of FGF21 (by the FAP enzyme between positions 171 and 172 on the native amino acid chain, which would be represented by positions 172 and 173 in our molecule starting with Methionine in position 1) are designed to prolong the half-life of the molecule. Additionally, we believe that the use of glycoPEGylation technology produces a comparatively stronger and more flexible structure, which aids in the development of a stable formulation. PEGylation technology has been used successfully in many pharmaceutical products including products that have been marketed for more than 10 years.

BIO89-100 uses a proprietary glycoPEGylation technology that has been previously validated by a third party, as this technology is incorporated in another pharmaceutical product (Lonquex® by Teva) that has received regulatory approval and is currently commercialized in the European Union.

The Development and Selection of BIO89-100

The discovery program that led to the selection of BIO89-100 was directed towards achieving an optimal PK and efficacy profile. It has been shown that the in vivo half-life of FGF21 can be extended by covalently linking a single glycoPEG moiety to the molecule. We performed extensive screening of FGF21 analogs with mutations at different positions including close to the N-terminus, as well as different glycoPEGylations to select an optimized molecule based on its potency, PK and in-vivo efficacy.

Stage I—Optimizing Selection of Mutation Sites—In Vitro Potency Testing

Mutations were inserted at different sites for both non-PEGylated FGF21 analogs and corresponding glycoPEGylated analogs and screened in a cell-based potency assay to select analogs that did not lose potency relative to the native hormone. Amongst the multiple glycoPEGylated analogs tested, only mutations at sites towards either N-terminus or C-terminus showed potency comparable to that of native FGF21 hormone and were selected for further development.

Stage II—Optimizing for glycoPEG (20 kDa vs 30 kDa)—In Vitro Potency Testing

Analogs selected in Stage I were prepared with either a 20 kDa or a 30 kDa glycoPEG moiety and tested for potency in mouse adipocytes (3T3-L1) and human embryonic kidney (HEK-293) cell lines. Minimal

differences in potencies were observed between the 20 kDa and 30 kDa glycoPEGylated analogs. However, only the glycoPEGylated analogs that had mutations and a glycoPEG attachment at the C-terminus, as distinct from those with mutations at the N-terminus, maintained their potency in both mouse and human cell lines. These analogs were selected for future development.

Stage III—Optimizing for PK Properties and Efficacy—In Vivo Testing

Selected analogs from Stage II with either a 20 kDa or a 30 kDa glycoPEG moiety, were chosen for in vivo testing in a diabetic mouse model. In addition to PK, changes from baseline in glucose, triglycerides and insulin were measured. The data showed that the circulating half-life of the glycoPEGylated analogs for both glycoPEG sizes was extended (range 15 to 30 hours) as compared to native FGF21 (2 hours). As expected, all analogs were observed to cause a reduction in blood glucose levels. However, the 20 kDa glycoPEGylated analogs were observed to outperform the 30 kDa analogs by improving triglycerides at lower doses and across broader dose ranges. BIO89-100 resulted in the greatest reduction of insulin and was selected as the candidate for clinical development.

In summary, the mutations made to the native FGF21 molecule and the addition of the 20 kDA glycoPEG moiety via the use of the glycoPEGylation technology were observed to significantly improve the PK properties of the molecule while retaining the therapeutic benefits. We believe that BIO89-100 is a well-balanced molecule with a unique profile, which has the potential to have therapeutic benefits in NASH and cardio-metabolic diseases. Figure 9 below sets forth what we believe are the key features and potential benefits of BIO89-100:

Figure 9: Summary of BIO89-100 Attributes and Benefits

Features	Description	Potential Benefit
Use of PEG (via glycoPEGylation)	■ Increases protein size and hydrodynamic volume that reduces renal filtration ■ Prevents degradation by endocytosis and proteolytic enzymes	■ Prolongs half-life
	■ Protects antigenic sites present on the protein surface (i.e. antigenic epitopes)	■ Reduces immunogenicity
	■ Steric repulsion between the PEGylated surfaces increases water solubility and reduces aggregates	■ Results in more stable formulation
Site-Specific Mutations	■ Mutation at position 173 is immediately adjacent to the primary cleavage (FAP enzyme) site of FGF21	■ Prolongs half-life
GlycoPEGylation Technology	■ Allows site specific linkage (glycoPEG moiety to position 173) ■ Proximity of the glycoPEG moiety to the C-terminus induces conformational changes to the molecule	■ Retains potency against receptor to improve efficacy
	■ Provides a strong and flexible glycosyl bond that helps the glycoPEG moiety remain intact, further reducing degradation	■ Further enhances half-life

Therapeutic Potential of BIO89-100 Supported by Preclinical Animal Models of NASH, Diabetes and Obesity

BIO89-100 was evaluated in multiple distinct animal models of NASH, diabetes and obesity, including non-human primate studies. In each of these studies, consistent and significant beneficial effects were observed

across a range of endpoints, specifically, robust improvements in lipid handling, glycemic control and insulin resistance as well as significant improvements in hepatic steatosis, injury and fibrosis. We believe these results demonstrate the potential of BIO89-100 to simultaneously address the multiple drivers of NASH pathogenesis. The histological endpoints, NAS and fibrosis score, mirror the endpoints we expect to assess in our clinical development. In addition, treatment with BIO89-100 in animal models was observed to result in consistent reductions in body weight.

BIO89-100 has been evaluated in three animal models of direct relevance to NASH. These included: (1) Stelic Animal Model ("STAM"), (2) Diet-induced NASH ("DIN") model and (3) spontaneous diabetic obese cynomolgus monkey model. Additional studies done in diabetes mouse model and diet induced obesity mouse model showed benefits in key markers of relevance in NASH.

A wide range of doses were tested in these studies as well as weekly and once every two week dosing regimen was tested in a cynomolgus monkey study. The key outcomes of these studies are summarized in Figure 10 below.

Figure 10: Summary of NASH Pharmacology Studies

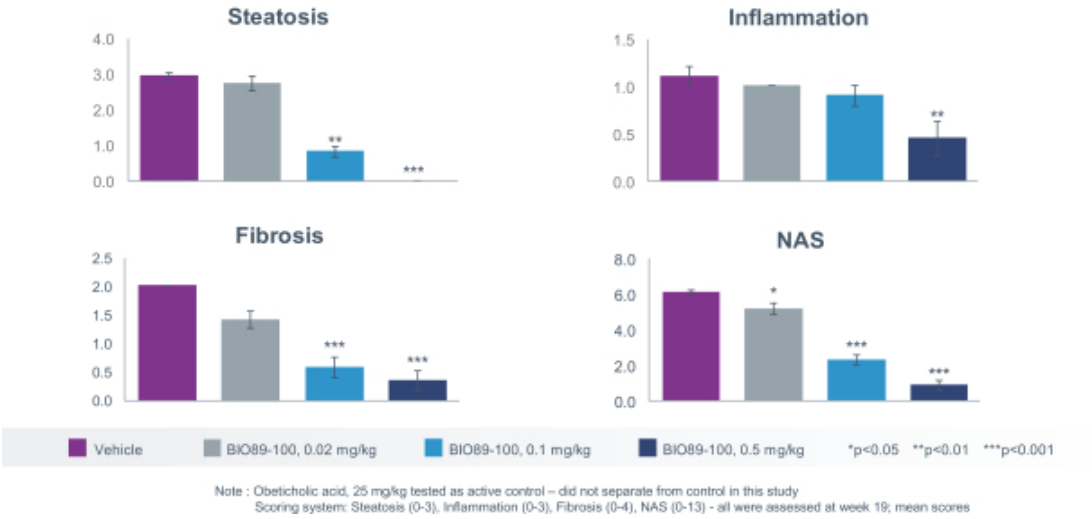
Preclinical pharmacology study with BIO89-100	Improved Insulin Sensitivity	Improved Lipid Handling	Reduced Hepatocyte Injury	Reduced Fibrosis
STAM mouse model	✓	✓	✓	*
DIN mouse model I (10 weeks)	✓	✓	✓	✓
DIN mouse model II (19 weeks)	✓	✓	✓	✓
Diabetic obese cynomolgus monkey study 1 (8 weeks; weekly dosing)	✓	✓	✓	Not evaluated
Diabetic obese cynomolgus monkey study 2 (4 weeks; QW or Q2W dosing)	✓	✓	✓	Not evaluated

Legend:
✓ Statistically significant benefit observed
* Improvement observed, but did not achieve statistical significance.

Results of DIN Mouse Studies

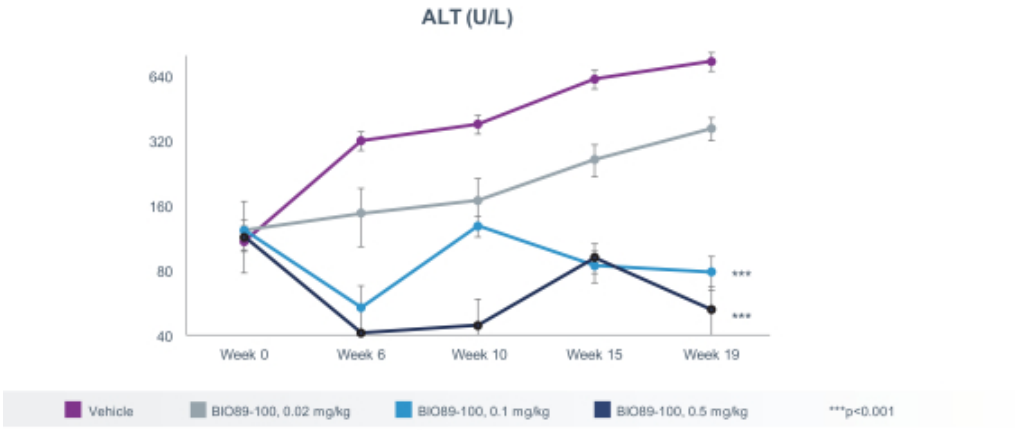
Two pharmacology studies were conducted in a DIN mouse model. In the first study of 40 mice (10 per treatment group), the animals received BIO89-100 via a subcutaneous injection at 0.5 and 2 mg/kg every 3 days for 10 weeks, and a detailed assessment of liver parameters was performed to evaluate the effectiveness of the dosing regimen. Both doses of BIO89-100 were observed to reduce the total NAS significantly based on histological evaluation and improved measures with respect to both lipid handling and insulin sensitivity. In addition, expression of hepatic genes involved in inflammation and fibrosis were significantly reduced following administration of BIO89-100. In the second DIN mouse study of 50 mice (10 per treatment group), lower dose levels of BIO89-100 were tested (0.02, 0.1 and 0.5 mg/kg every 3 days) but the treatment duration was longer at 19 weeks. In this study too, BIO89-100 was observed to result in significant reductions in the liver damage induced by the diet in a dose-dependent manner. Specifically, treatment with BIO89-100 was observed to result in a significant mean reduction of the histological markers of NASH (Figure 11), as well as a reduction in the marker of hepatic injury (alanine amino transaminase ("ALT")) (Figure 12), in liver lipids (Figure 13), and in inflammatory and fibrotic markers (Figure 14), each in a dose dependent manner compared to vehicle treatment. In addition to the beneficial effects on the liver, treatment with BIO89-100 demonstrated significant improvements in glycemic control and weight loss. As NAS and measures of fibrosis are histological endpoints for the assessment of NASH in clinical studies, we believe that the observations in the STAM and DIN mouse models suggest that BIO89-100 is a compelling candidate for the treatment of NASH.

Figure 11: Improvement in Histology with BIO89-100 in a DIN Mouse Model



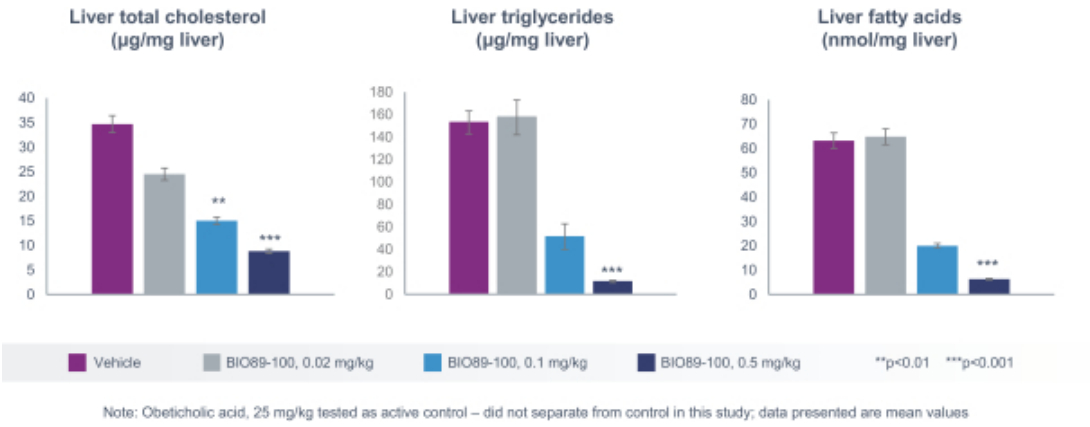
Note : Obeticholic acid, 25 mg/kg tested as active control – did not separate from control in this study
Scoring system: Steatosis (0-3), Inflammation (0-3), Fibrosis (0-4), NAS (0-13) - all were assessed at week 19; mean scores

Figure 12: Changes in ALT with BIO89-100 in a DIN Mouse Model



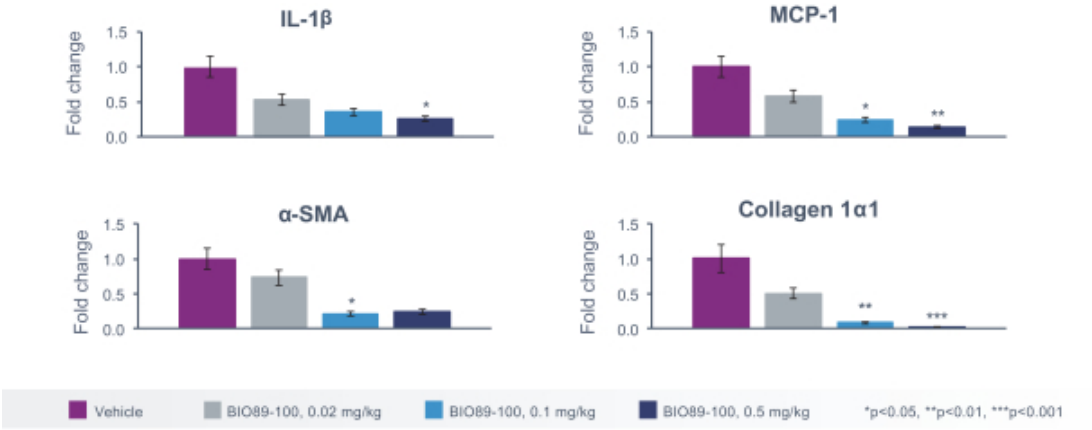
Note: Obeticholic acid, 25 mg/kg tested as active control – did not separate from control in this study; data presented are mean values

Figure 13: Reduction in Liver Lipids with BIO89-100 in a DIN Mouse Model



Note: Obeticholic acid, 25 mg/kg tested as active control – did not separate from control in this study; data presented are mean values

Figure 14: Changes in Inflammatory and Fibrotic Markers with BIO89-100 in a DIN Mouse Model



Note: Obeticholic acid, 25 mg/kg tested as active control – did not separate from control in this study; data presented are mean values

Results of Spontaneously Diabetic Obese Cynomolgus Monkey Studies

BIO89-100 efficacy was evaluated in 24 spontaneously diabetic obese cynomolgus monkeys (six per treatment group) after multiple subcutaneous doses. In the first study, BIO89-100 was administered at doses of 0.1, 0.3 and 1 mg/kg once per week for 8 weeks followed by a 6-week washout phase. Administration of BIO89-100 showed significant effects on triglycerides at all doses tested, with a highly robust 78% reduction observed at the highest dose level of 1 mg/kg/week (Figure 15). Statistically significant mean reductions were observed in total cholesterol (Figure 16), glucose (Figure 17), insulin, glycated hemoglobin (HbA1c) and ALT (Figure 18), along with improvement in oral glucose test results.

Figure 15: Changes in Triglycerides with BIO89-100 in Diabetic Monkey Study 1

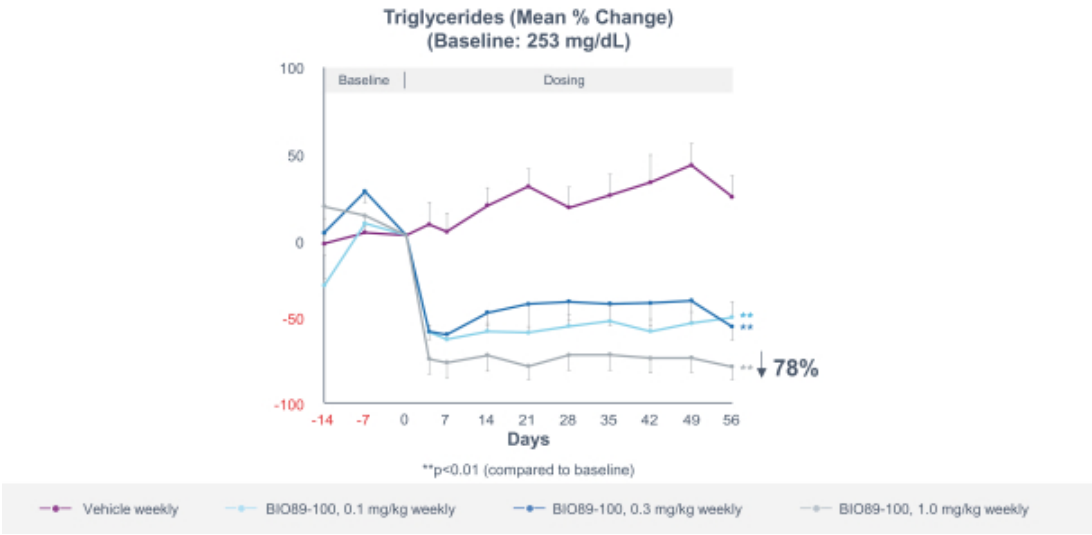


Figure 16: Changes in Total Cholesterol with BIO89-100 in Diabetic Monkey Study 1

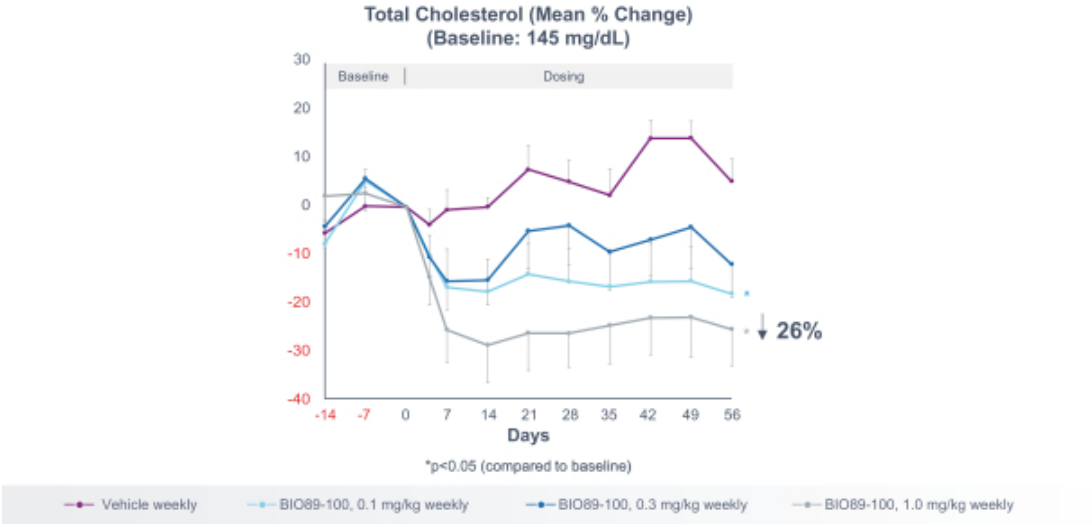


Figure 17: Changes in Blood Glucose with BIO89-100 in Diabetic Monkey Study 1

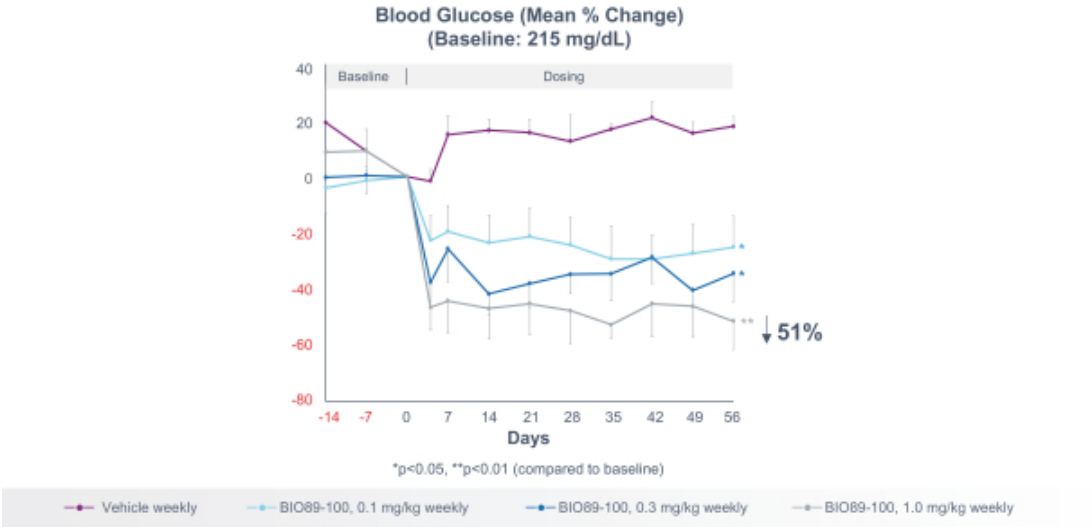
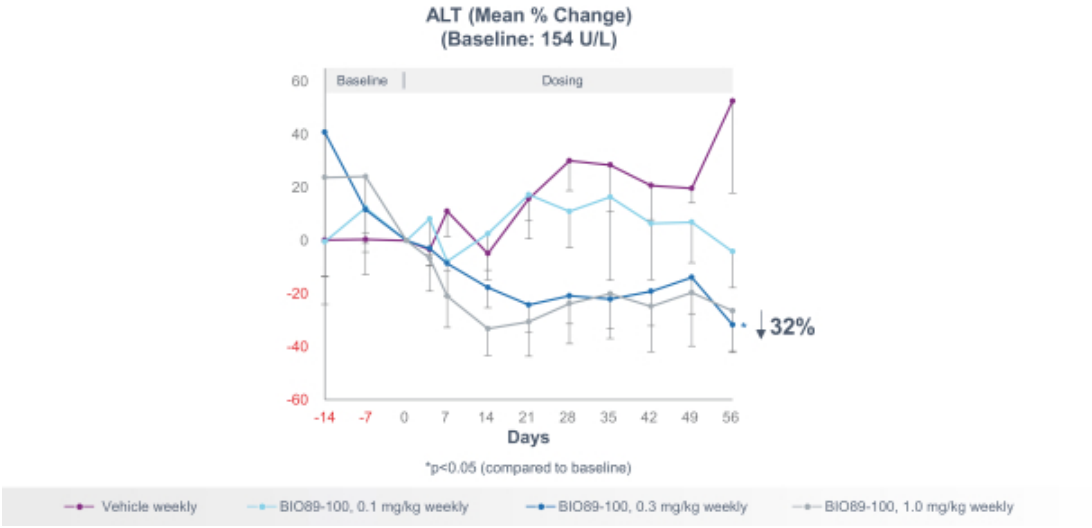


Figure 18: Changes in ALT with BIO89-100 in Diabetic Monkey Study 1



In a second multiple-dose study in 24 spontaneously diabetic obese cynomolgus monkeys (six per treatment group), BIO89-100 was administered for 4 weeks at 1 mg/kg once weekly or 1 or 2 mg/kg given once every 2 weeks. A rapid and dramatic reduction in triglycerides (Figure 21), up to 76%, was observed with BIO89-100. Statistically significant mean reductions were also observed in body weight (Figure 19), HbA1c (Figure 20), glucose, and insulin, along with increased adiponectin levels (Figure 22) and improvement in oral glucose test results in all BIO89-100-treated groups (both once weekly and every 2 weeks) in comparison to the vehicle group. The robust effect on body weight and HbA1c over the 4-week treatment period were particularly unexpected. The PD effects were relatively similar across all three dosing groups suggesting that once every two weeks could be a viable clinical dosing strategy.

Figure 19: Changes in Body Weight with BIO89-100 in Diabetic Monkey Study 2

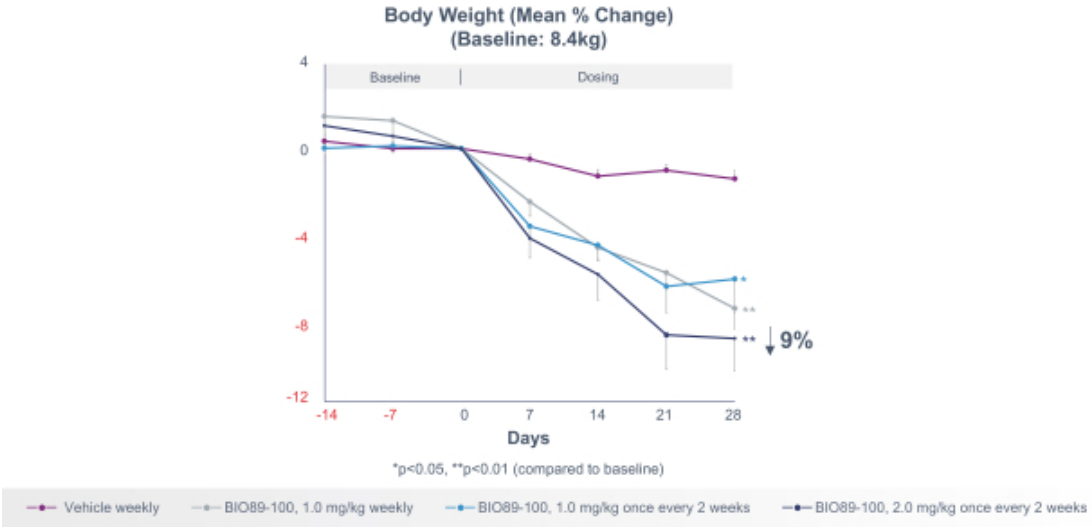


Figure 20: Changes in HbA1c with BIO89-100 in Diabetic Monkey Study 2

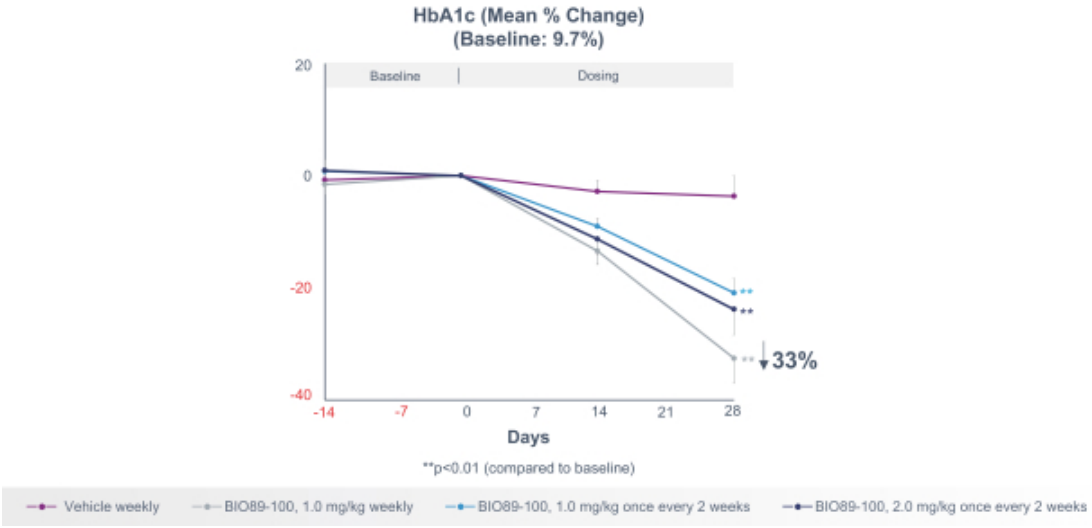


Figure 21: Changes in Triglycerides with BIO89-100 in Diabetic Monkey Study 2

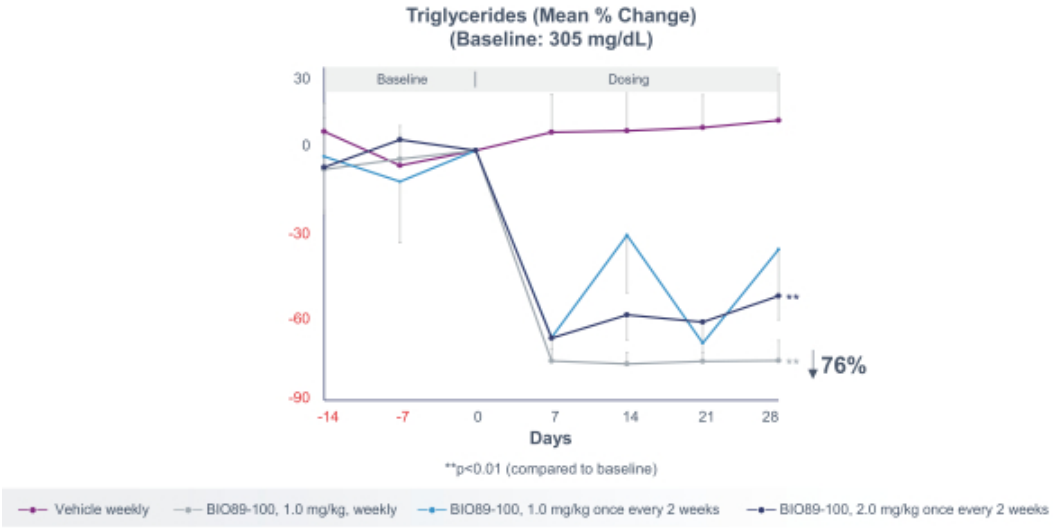
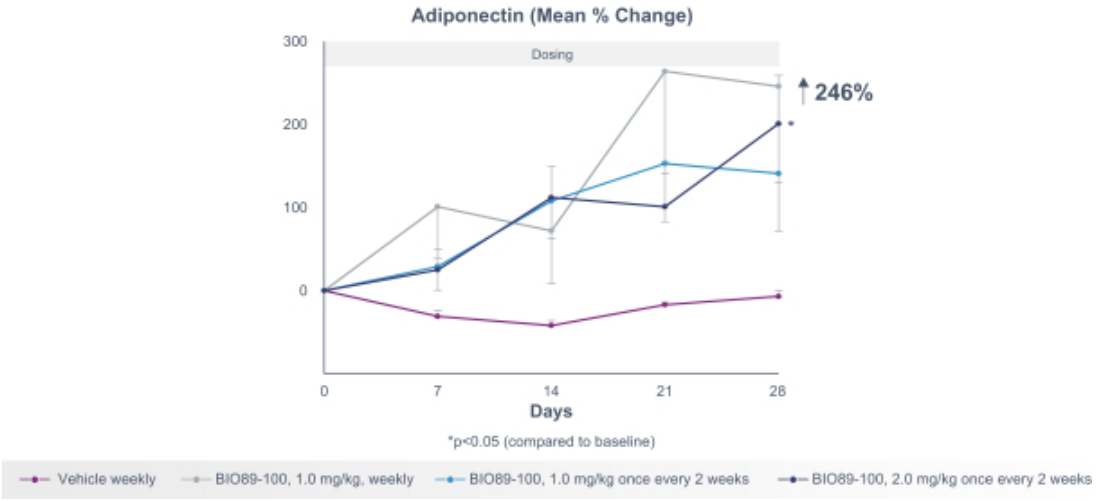


Figure 22: Changes in Adiponectin with BIO89-100 in Diabetic Monkey Study 2



We believe the PD effects observed in the animal studies suggest that BIO89-100 is a potent molecule that may address the key pathways in NASH by (1) improving lipid handling and resultant steatosis, (2) improving insulin resistance, (3) reducing hepatocyte injury and inflammation and (4) improving fibrosis.

Additionally, the data from the cynomolgus monkey studies suggest that the molecule may be amenable to an extended dosing interval.

BIO89-100 Clinical Development

We are developing BIO89-100 for the indication of NASH with fibrosis. In our randomized, double-blind, placebo-controlled, Phase 1a, first-in-human, SAD clinical trial of BIO89-100 of 58 healthy volunteers, 43 healthy volunteers received BIO89-100 with a half-life of 55 to 100 hours and 15 received placebo treatment. In this SAD study, BIO89-100 was well tolerated, with all treatment related adverse events reported as mild; there were no serious adverse events reported. At single doses of 9.1 mg and higher, we observed significant improvements in key lipid parameters measured at Day 8 and Day 15 after dosing on Day 1. The mean changes versus baseline include reductions in triglycerides (up to 51%) and LDL-C (up to 37%) and increase in HDL-C (up to 36%) despite the baseline values being in the normal range. As compared to placebo treatment, these mean changes were all statistically significant ($p < 0.001$). BIO89-100 demonstrated rapid (starting from Day 2), sustained and durable improvements on lipid parameters for two weeks or more after single dose administration. We believe this duration of effect further supports the possibility of an extended dosing interval, as observed in our preclinical studies.

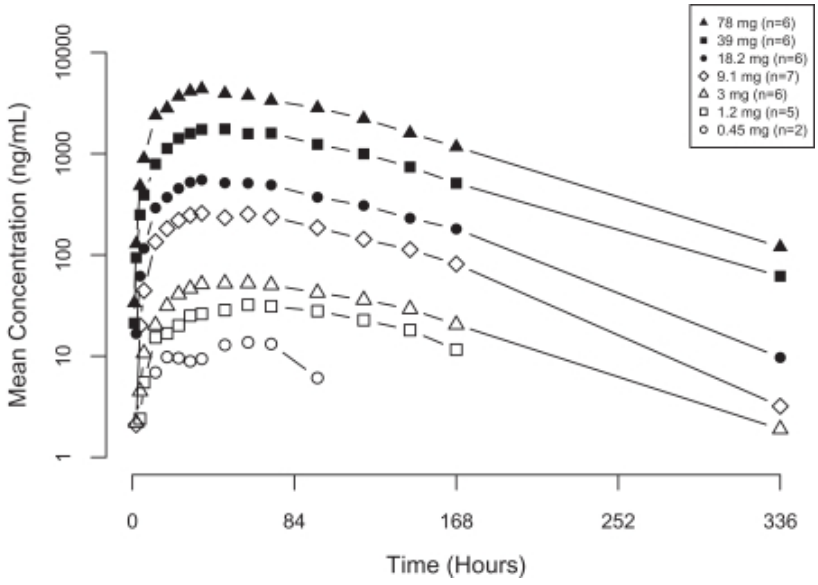
Phase 1a Clinical Trial of Single Dose of BIO89-100 in Healthy Volunteers

We conducted a Phase 1a clinical trial to evaluate the safety, tolerability and PK of BIO89-100 in healthy volunteers. We enrolled a total of 58 healthy volunteers into one of seven cohorts and randomized to receive a single dose of BIO89-100 or a placebo. Forty-three healthy subjects received BIO89-100 at the following doses: 0.45 mg, 1.2 mg, 3 mg, 9.1 mg, 18.2 mg, 39 mg and 78 mg.

BIO89-100 Exhibited Generally Linear, Dose-proportional PK

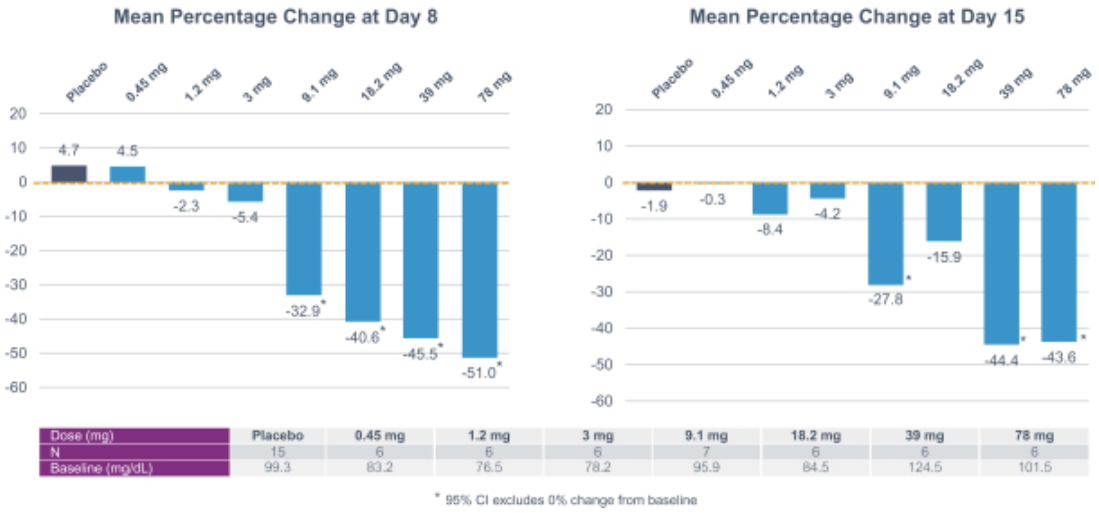
The PK profile of BIO89-100 was generally dose-proportional or slightly more than dose-proportional with T1/2 range from approximately 55 to 100 hours. As shown in Figure 23 below, the observed median time of maximum serum concentration ranged from 36 to 60 hours.

Figure 23: Single-dose PK of BIO89-100



Our Phase 1a clinical trial enrolled healthy volunteers with a mean (SD) age and BMI of 39.3 (9.7) years and 26.7 (3.1) kg/m2 respectively, with laboratory parameters in the normal range at baseline (mean values: TG 94.0 mg/dL; LDL 124.1 mg/dL; HDL 47.7 mg/dL). Even in this healthy study population, after a single dose administration of BIO89-100 at doses 9.1 mg and higher, robust and durable PD effects were observed across key lipid parameters, including triglycerides (Figures 24 and 25), LDL (Figure 26) and HDL (Figure 27), over two weeks. The changes in lipids parameters started from Day 2 with maximal effects typically observed at Day 8 or Day 15. The effect on lipid parameters was generally dose-dependent, with single doses of BIO89-100 at 9.1 mg and higher, demonstrating significant improvements versus baseline in key lipid parameters measured at Day 8 and Day 15 following dosing. The BIO89-100 effects appeared to plateau at 39 mg with minimal additional effect observed in 78 mg.

Figure 24: Changes in Triglycerides after Single Dose of BIO89-100



Dose (mg)	Placebo	0.45 mg	1.2 mg	3 mg	9.1 mg	18.2 mg	39 mg	78 mg
N	15	6	6	6	7	6	6	6
Baseline (mg/dL)	99.3	83.2	76.5	78.2	95.9	84.5	124.5	101.5

* 95% CI excludes 0% change from baseline

Figure 25: Changes in Triglycerides after Single Dose of BIO89-100

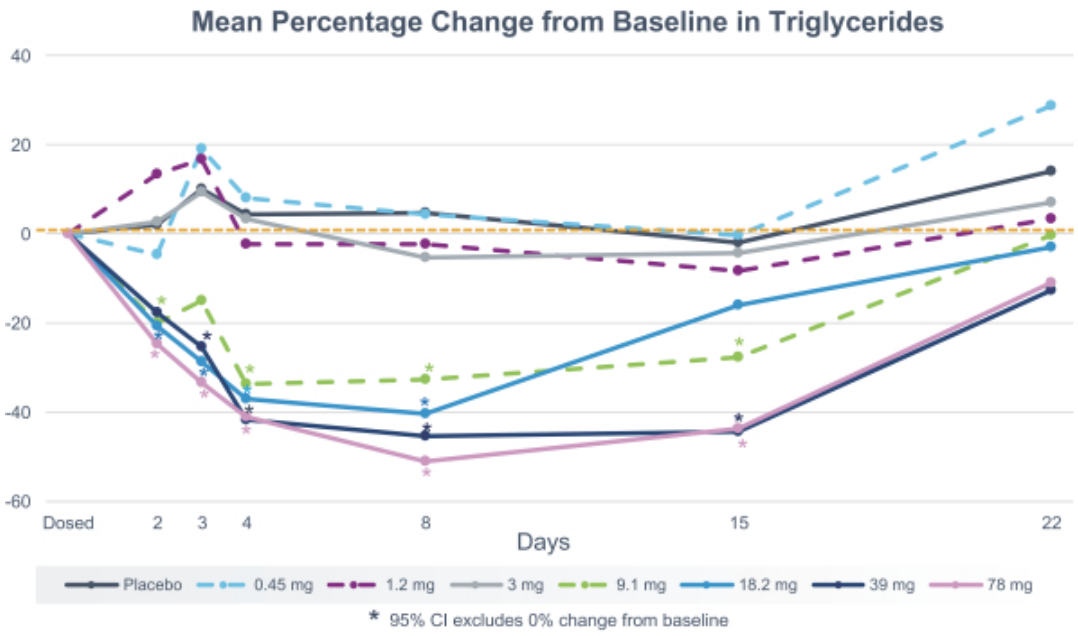


Figure 26: Changes in LDL Cholesterol after Single Dose of BIO89-100

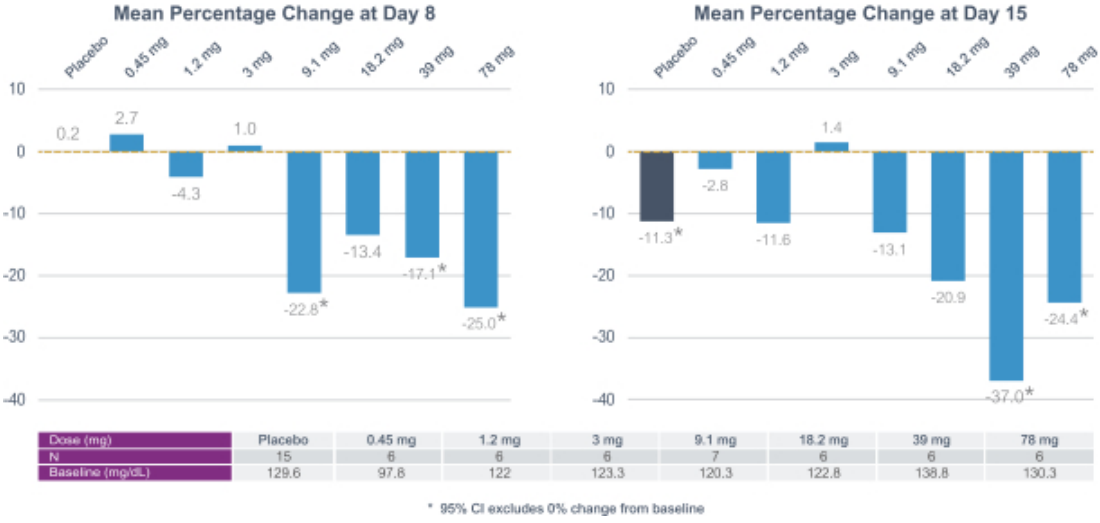
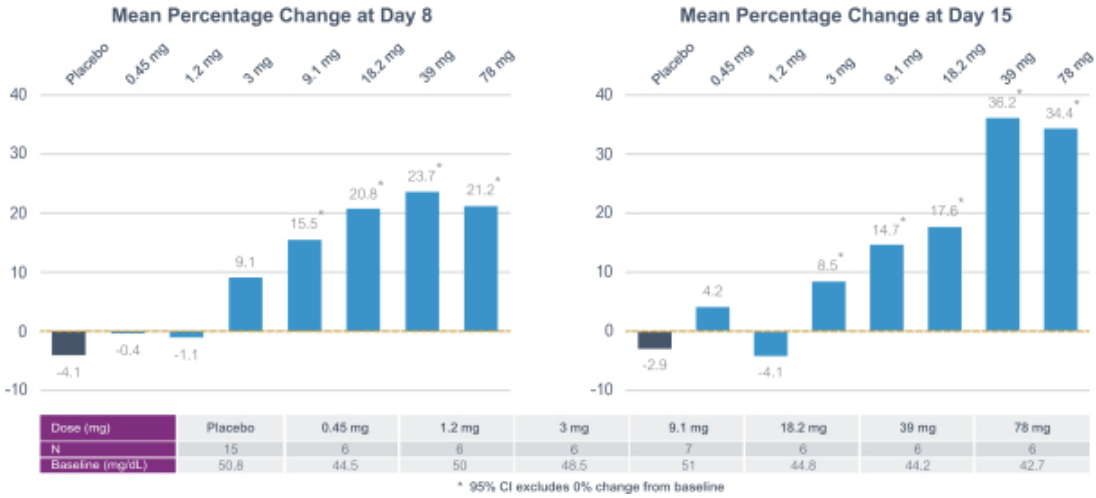


Figure 27: Changes in HDL Cholesterol after Single Dose of BIO89-100



BIO89-100 was well tolerated across the dose range in our Phase 1a clinical trial. There were no deaths, serious adverse events or discontinuations due to adverse events. The most commonly observed treatment-related adverse events, occurring in at least two subjects in the pooled BIO89-100 group, were injection site reactions and headache, all of which were reported as mild. Injection site reactions were more frequent in the 39 mg cohort, likely due to a larger injection volume administered at one time in that cohort. No clinically meaningful trends were observed in gastrointestinal events, laboratories or vital signs including blood pressure or heart rate changes. No tremors were reported. Five of 43 BIO89-100 treated subjects tested positive for anti-drug antibodies (“ADA”); however, all titers were low (£ 16) and did not appear to affect the PK or safety profile. Treatment-related treatment emergent adverse events (“TEAE”) reported in two subjects or more in pooled BIO89-100 treatment group are shown in Figure 28 below.

Figure 28: Treatment-Related TEAE Reported in ³ 2 Subjects in Pooled BIO89-100 Treatment Group

	Placebo	BIO89-100						Pooled
	(N=15)	0.45 mg	1.2 mg	3 mg	9.1 mg	18.2 mg	39 mg	78 mg	BIO89-100
n (%)		(N=6)	(N=6)	(N=6)	(N=7)	(N=6)	(N=6)	(N=6)	(N=43)
Any Treatment Related TEAE	3 (20.0)	0	0	0	1	3	6	3	13 (30.2)
Injection site induration	1 (6.7)	0	0	0	1	0	5	1	7 (16.3)
Injection site erythema	1 (6.7)	0	0	0	0	0	3	2	5 (11.6)
Injection site pain	0	0	0	0	0	0	2	0	2 (4.7)
Headache	1 (6.7)	0	0	0	0	2	0	0	2 (4.7)

Note: All adverse events reported in table were Grade 1.

These data supported the advancement of BIO89-100 into a study in patients with NASH or patients with NAFLD and a high risk of NASH to evaluate BIO89-100’s potential as a treatment of NASH. Based on PK/PD modeling and drug exposure analysis, we have identified BIO89-100 doses in the range of 9 mg to 36 mg weekly (“QW”) or every other week (“Q2W”) as the target dose range for evaluation in future clinical trials in patients with NASH or patients with NAFLD and a high risk of NASH.

We believe that the totality of the data from our Phase 1a study, the preclinical data with BIO89-100 and the clinical data from third parties collectively support the hypothesis that BIO89-100 has the potential to address the complex nature of NASH, especially given the frequency of metabolic co-morbidities in NASH patients. The magnitude and significance of BIO89-100's biological effects after a single dose on lipid parameters in healthy volunteers were observed to be robust and durable, and the magnitude of these reductions appear to be comparable or better than data reported to date in Phase 1 clinical trials of other FGF analogs, although no head-to-head studies have been conducted.

Phase 1b/2a POC Clinical Trial

We are currently enrolling patients in our Phase 1b/2a POC clinical trial. Our clinical trial is a multicenter, randomized, double-blind, placebo-controlled, multiple ascending dose-ranging trial in patients with NASH or patients with NAFLD and a high risk of NASH, with 83 total patients randomized to receive QW or Q2W subcutaneous dosing of BIO89-100 or placebo for up to 12 weeks. This clinical trial is designed to assess the safety, tolerability and PK properties of BIO89-100 as well as change in liver fat measured by MRI-PDFF and key biomarker assessments. These data are aimed at providing proof-of-concept for BIO89-100 in NASH and help inform dose selection for larger, longer-term paired-biopsy trials. At our meeting with the FDA in June 2019, the FDA concurred with our overall trial design, including study population, dose selection and study treatment duration.

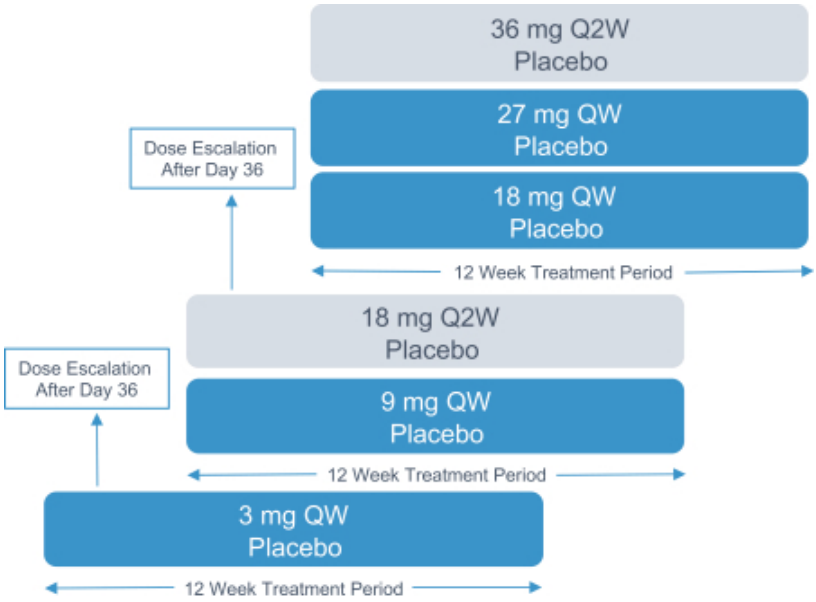
Our POC study is enrolling patients with NASH or patients with NAFLD and a high risk of NASH, defined as patients with steatosis greater than 10% who have central obesity and Type 2 diabetes or central obesity and evidence of liver injury. NAFLD patients, especially the subset of NAFLD patients we will enroll, have similar disease characteristics as patients with biopsy-proven NASH, and we expect that the data from these NAFLD patients will be informative regarding the potential of BIO89-100 as treatment for NASH. The trial will include a set number of patients with biopsy confirmed NASH with fibrosis (F1-F3) to help inform the design of subsequent clinical trials.

The key objectives of the trial are to:

- evaluate the safety and tolerability of multiple ascending doses of BIO89-100;
- assess change from baseline in liver fat (measured via MRI-PDFF);
- assess changes from baseline in lipids, glycemic control parameters, fibrosis and inflammation markers;
- characterize the PK properties of BIO89-100; and
- evaluate the immunogenicity of BIO89-100 as measured by presence of ADA.

The design of the trial is presented in Figure 29 below:

Figure 29: POC Clinical Trial Design



Our planned active treatment groups are: 3 mg, 9 mg 18 mg and 27 mg QW, and 18 mg and 36 mg Q2W. As this is a multiple ascending dose study, we expect to have two dose escalation decision points during the study. The first decision point will be to move from the 3 mg QW dose cohort to both the 9 mg QW and 18 mg Q2W dose cohorts. The second decision point will be to move from those two dose cohorts to the final three dose cohorts. We expect dose escalation decisions after Day 36 assessment in the relevant cohorts. We have designed the trial to detect differences on MRI-PDFF between BIO89-100 at different dose levels and the pooled placebo group. We expect to report topline data in the second half of 2020. In addition, we anticipate initiating a Phase 2b trial in the first half of 2021.

BIO89-100 Differentiation

We believe BIO89-100 could have a differentiated profile relative to other therapies targeting FGF21 and FGFR1c that are in development.

A PEGylated form of FGF21 is currently in two third-party Phase 2b studies in NASH. The compound has a reported half-life of 19 to 24 hours and includes mutations with non-native amino acid substitutions. In this third party's Phase 2a study, the molecule showed a significant reduction in absolute liver fat measured by MRI-PDFF and a significant decrease in concentration of PRO-C3 (a biomarker of fibrosis), but no significant changes on lipid markers. Study outcomes were better when dosed as a daily injection versus a weekly injection. The compound was deemed generally well tolerated, although a higher frequency of gastrointestinal adverse events was reported in treated patients. Sixty-three percent to 92% of treated patients in the Phase 2a study tested positive for anti-drug and anti-FGF21 antibodies.

A second compound, a long-acting Fc-FGF21 fusion protein with extended half-life of approximately three to four days, has completed third-party Phase 1 studies in which patients with Type 2 diabetes demonstrated decreases in triglycerides and increases in HDL-C, with improvements in insulin sensitivity, but modest to no

changes in LDL in doses approximating those advancing to further development. The highest doses tested in the single and multiple-ascending dose study were not well-tolerated with adverse events of significance being gastrointestinal disorders and tremors. The compound is currently in a Phase 2a study in NASH with weekly dosing.

A third compound, an agonistic antibody selectively activating FGFR1c and its co-receptor ß-Klotho, has completed a third-party Phase 1 study as a once-monthly injectable insulin sensitizer for the treatment of NASH. Reductions in liver fat content and improvements in metabolic parameters were reported in a clinical trial evaluating a high single dose in obese, insulin-resistant, non-diabetic subjects with NAFLD. The most common adverse events reported were injection site reaction and increased appetite. Subjects gained an average of 1.6 kg body weight 36 days after dosing compared to baseline. The compound agonizes only the FGFR1c receptor and is not believed to have any activity on the FGFR2c and FGFR3c receptors.

We believe BIO89-100 may be a differentiated FGF21 therapy based on its robust and durable biological effects and a favorable tolerability profile. In addition, BIO89-100 has the potential for a once every two-weeks dosing interval that could provide significant value to asymptomatic patients who will be taking the product chronically. In market research that we conducted amongst obese diabetic subjects (n=150), respondents were asked for their preference when selecting an injectable product with different dosing regimens for the treatment of a chronic liver condition. In this study, 63% of respondents expressed a preference or strong preference for a product injected once every two weeks versus a product injected every week, and 68% of respondents expressed similar preferences for a product injected once every two weeks versus a product injected daily. Further, we believe that BIO89-100 may have a differentiated tolerability profile and that tolerability issues may influence physician and patient preference in NASH, a chronic and generally asymptomatic disease. We believe the risk of CNS effects, significant gastrointestinal tolerability issues and weight gain could significantly impact adoption by physicians and patients. Finally, based on the non-human primate study results and the human SAD study results across different lipid markers (triglyceride reduction up to 51% and LDL reduction up to 37%), we believe BIO89-100 may offer robust and durable biological effects. We believe that activation of the FGFR1c, 2c and 3c receptors may confer benefits versus activation of a single receptor (FGFR1c) given the expression of the receptors in the key organs of interest (FGFR1c in adipose tissue and FGFR2c and FGFR3c in the liver) and provide a more balanced approach.

Severe Hypertriglyceridemia

We also intend to develop BIO89-100 for the treatment of SHTG. Hypertriglyceridemia (“HTG”) is characterized by elevated fasting plasma triglyceride levels higher than 200 mg/dL and SHTG is typically defined as triglyceride levels of greater than or equal to 500 mg/dL. SHTG is associated with an increased risk of NAFLD, NASH and cardiovascular diseases, as well as acute pancreatitis, accounting for up to 10% of all acute pancreatitis episodes. A recent third-party study utilizing an omega-3 fatty acid (“omega-3 FA”) demonstrated the linkage between a reduction in triglycerides and favorable cardiovascular clinical outcomes.

It is estimated that there are 2.5 million to 4 million patients in the United States with triglyceride levels of greater than or equal to 500 mg/dL. Of these patients, it is estimated that 42% have dyslipidemia and 27% have diabetes. This patient population is expected to increase due to the triple epidemic of obesity, metabolic syndrome and Type 2 diabetes. In addition, the addressable market has the potential to expand as a result of increasing awareness of the importance of treating elevated TG levels, similar to the focus today of physicians on managing LDL levels, as well as due to third party commercial efforts expected to promote TG reduction.

The treatment regimen for SHTG includes dietary restrictions and lipid-lowering drug treatment such as fibrates, omega-3 fish oils and niacin. Some statins are indicated in HTG but do not have an indication for use in SHTG. In third-party studies, up to 50% of treated SHTG patients were unable to reduce their triglyceride levels to < 500 mg/dL despite using approved drugs and are considered refractory patients. These refractory patients have substantial unmet medical need and represent a significant market opportunity as there are no approved therapies for the treatment of refractory SHTG.

Despite multiple agents approved for the treatment of SHTG, these agents have limitations that may not make them ideal for all patients. For example, fibrates have demonstrated reductions in triglycerides of up to approximately 55% at 12 weeks of treatment. However, they have also shown increases in LDL-C (up to 45%), a detrimental effect in this patient population, risk of drug-drug interactions and increases in transaminases, as well as tolerability issues including myopathy. Omega 3 fish oils have shown more modest benefits in reduction of triglycerides from baseline of approximately 25% to 45%. However, fish oils with a higher percentage reduction in triglycerides have also showed major increases in LDL-C (up to 45%). Fish oils also have a significant pill burden given the high daily doses required. In addition, these agents fail to meaningfully address the related co-morbidities of SHTG, including glycemic control, which, when left untreated, may further exacerbate the condition. Yet, despite these limitations, the existing drugs have achieved commercial success with two third parties each generating peak sales of approximately $1 billion or greater.

Given the continuing unmet need in SHTG and limitations of current treatments, there are several agents in development for the treatment of SHTG, including a fish oil product, a fibrate, and novel drugs primarily targeting rare, genetically defined subsets of SHTG, including ANGPTL3 and ApoC III inhibitors. Dyslipidemia apart from SHTG also continues to be a very active area for pharmaceutical development. We believe BIO89-100 may be a differentiated SHTG therapy due to its pleiotropic metabolic benefits and its potential to target a broader patient population versus those therapies primarily targeting rare, genetically defined subsets of SHTG.

BIO89-100 has demonstrated significant reduction in triglyceride levels in both its non-human primate studies and our Phase 1a clinical study. In diabetic obese cynomolgus monkeys with elevated triglyceride levels, BIO89-100 showed significant effects on triglycerides with a maximal reduction of 78% and 76% at doses of 1 mg/kg (see Figures 15 and 21). In monkeys treated with baseline levels of triglycerides > 500mg/dL (n=4), the three monkeys treated with BIO89-100 1 mg/kg weekly had TG reductions > 90% at study end. In our Phase 1a clinical study, in patients with baseline triglyceride values in the normal range (mean baseline 94 mg/dL), BIO89-100 demonstrated reductions of triglycerides from baseline up to 51% at Day 8 after a single dose in healthy volunteers. While currently approved SHTG therapies decrease TG levels, they generally do not have broader metabolic benefits. In our Phase 1a study, BIO89-100 demonstrated a reduction in LDL of up to 37% (see Figure 26) and to the extent that we are able to show in subsequent human clinical trials that BIO89-100 significantly decreases both TG and LDL-C levels and improves other metabolic parameters, such as glycemic control, we believe that BIO89-100 could be a differentiated therapy in this indication. Based on a mechanism of action that is distinct from the currently approved therapies, we believe that BIO89-100 has the potential to be used as a monotherapy agent or in combination with other agents. Another FGF21 analog developed by a third party has also demonstrated a statistically significant reduction in triglycerides in obese, Type 2 diabetes patients. We intend to initiate a Phase 2 trial in SHTG patients in the first half of 2020 in order to evaluate the ability of BIO89-100 to reduce triglyceride levels compared to baseline levels and to report topline data in the first half of 2021. We expect this Phase 2 trial to enroll 80 to 100 patients with triglyceride levels greater than or equal to 500 mg/dL, who will be randomized to receive multiple doses of BIO89-100 or placebo for six to eight weeks.

There is regulatory precedence in the United States for the approval of therapies to treat SHTG based on such therapies demonstrating a reduction in triglycerides from baseline at 12 weeks. The FDA surrogate endpoint table for drug approval lists a reduction in triglycerides from baseline as the endpoint for full approval of a therapy in SHTG. A clinical outcome study was not required for certain third-party approvals in SHTG or as a post-marketing commitment. The SHTG Phase 3 trial for some of these products consisted of a single study of a 12-week duration with 75 to 100 patients per treatment group. Based on current plans, we anticipate initiating Phase 3 trials in SHTG patients by the end of 2021, which we expect will follow existing SHTG regulatory precedence.

Based on FDA guidance for the development of SHTG treatments, as well as the regulatory path followed by other companies that have successfully developed SHTG therapies, we believe that a combination of smaller clinical trials and shorter development timelines could mean that SHTG potentially represents a quicker path to market for BIO89-100.

Agreements with Teva

Agreements Relating to FGF21 Program

On April 16, 2018, we entered into the FGF21 Agreement with Teva, under which we acquired certain patents, intellectual property and other assets relating to Teva's glycoPEGylated FGF21 program. Under this agreement, Teva also granted a perpetual, non-exclusive (but exclusive as to BIO89-100), non-transferable, worldwide license to patents and know-how related to glycoPEGylation technology for use in the research, development, manufacture and commercialization of the compound BIO89-100 and products containing BIO89-100. In addition, we entered into the ratiopharm Sublicense, under which we were granted a perpetual, exclusive, worldwide sublicense to patents and know-how related to glycoPEGylation technology used in the development, manufacture and commercialization of BIO89-100 and products containing BIO89-100.

Under the FGF21 Agreement, we are obligated to use commercially reasonable efforts to develop and commercialize BIO89-100 in each of the United States and five major European countries. We have the right to sublicense all rights licensed to us by Teva under the FGF21 Agreement.

Pursuant to the FGF21 Agreement and the FASN Agreement (as described below), we paid Teva a nonrefundable upfront payment of $6.0 million. In addition, under the FGF21 Agreement, we are required to make certain payments to Teva totaling $2.5 million for the achievement of certain clinical development milestones, and additional payments totaling up to $65.0 million upon achievement of certain commercial milestones. We are also obligated to pay Teva tiered royalties at percentages in the low-to-mid single-digits on worldwide net sales of products containing BIO89-100. Our royalty obligations will terminate, on a product-by-product and country-by-country basis, at the later of: (1) the date of expiration of the last to expire valid claim in the assigned patents that covers BIO89-100 in such country, (2) the expiration of data or regulatory exclusivity for BIO89-100 in such country and (3) 10 years from the first commercial sale of BIO89-100 in such country. We are not required to make any payments to ratiopharm pursuant to the ratiopharm Sublicense.

The term of the FGF21 Agreement will continue, on a product-by-product and country-by-country basis, until the royalty term with respect to BIO89-100 in such country expires. The ratiopharm Sublicense will continue until terminated in accordance with its terms. We may terminate the FGF21 Agreement and the ratiopharm Sublicense for any reason. Either party may terminate the FGF21 Agreement for cause for the other party's uncured material breach. ratiopharm may terminate the ratiopharm Sublicense for certain material breaches by us. Either party may terminate the FGF21 Agreement or the ratiopharm Sublicense in the event of bankruptcy of the other party. Teva may terminate the FGF21 Agreement if we challenge the validity of any patent licensed to us under the FGF21 Agreement. Termination of the FGF21 Agreement or the ratiopharm Sublicense will impact our rights under the intellectual property licensed to us by Teva and ratiopharm, respectively, but will not affect our rights under the assets assigned to us.

On April 16, 2018, we also entered into a Reagent Supply and Technology Transfer Agreement, under which Teva will supply us with certain regents required for the glycoPEGylation process that are necessary for our development and commercialization of BIO89-100, and transfer to us certain know-how required for the production of such reagents. The term of this agreement was recently extended by mutual agreement until December 31, 2022.

FASN Agreements

On April 16, 2018, we entered into the FASN Agreement with Teva under which we acquired from Teva patents, intellectual property and other assets relating to Teva's development program of small molecule inhibitors of FASN.

Under the FASN Agreement, we are obligated to use commercially reasonable efforts to develop and commercialize FASN in the United States and five major European countries. We have the right to sublicense all rights licensed to us by Teva under the FASN Agreement.

Pursuant to the FASN Agreement and the FGF21 Agreement (as described above), we paid Teva a nonrefundable upfront payment of $6.0 million. In addition, under the FASN Agreement, we are required to make certain payments to Teva totaling $2.5 million for the achievement of certain clinical development milestones, and additional payments totaling up to $65.0 million upon achievement of certain commercial milestones. We are also obligated to pay Teva tiered royalties at percentages in the low-to-mid single-digits on worldwide net sales of products arising from the FASN program. Our royalty obligations will terminate, on a product-by-product and country-by-country basis, at the later of: (1) the date of expiration of the last to expire valid claim in the assigned patents that covers FASN in such country, (2) the expiration of data or regulatory exclusivity for such product arising from the FASN program in such country and (3) 10 years from the first commercial sale of a product arising from the FASN program in such country.

The term of the FASN Agreement will continue, on a product-by-product and country-by-country basis, until the royalty term with respect to the product arising from the FASN program in such country expires. We may terminate the FASN Agreement for any reason. Either party may terminate the agreement for cause for the other party's uncured material breach, or in the event of bankruptcy of the other party.

Government Regulation and Product Approval

The FDA and other regulatory authorities at federal, state and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of biologics, such as those we are developing. We, along with third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates.

The process required by the FDA before biologic product candidates may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's current Good Laboratory Practice regulation;
- submission to the FDA of an IND, which must become effective before clinical trials may begin and must be updated annually or when significant changes are made;
- approval by an independent Institutional Review Board ("IRB") or ethics committee at each clinical site before the trial is commenced;
- performance of adequate and well-controlled human clinical trials to establish the safety, purity and potency of the proposed biologic product candidate for its intended purpose;
- preparation of and submission to the FDA of a BLA after completion of all pivotal clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMP and to assure that the

facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency, and of selected clinical investigation sites to assess compliance with current Good Clinical Practices ("cGCP"); and

- FDA review and approval of the BLA to permit commercial marketing of the product for particular indications for use in the United States.

Preclinical and Clinical Development

Prior to beginning the first clinical trial with a product candidate, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is the general investigational plan and the protocol(s) for clinical studies. The IND also includes results of animal and in vitro studies assessing the toxicology, PK, pharmacology and PD characteristics of the product; chemistry, manufacturing and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with cGCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site, and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

For purposes of BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

- ***Phase 1***—The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.

- ***Phase 2***—The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

- ***Phase 3***—The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so called Phase 4 studies may be made a condition to approval of the BLA. Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate, and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product, or for biologics, the safety, purity and potency. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

BLA Submission and Review

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from pertinent preclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. The submission of a BLA requires payment of a substantial application user fee to FDA, unless a waiver or exemption applies.

Once a BLA has been submitted, the FDA's goal is to review standard applications within ten months after it accepts the application for filing, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process is often significantly extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may convene an advisory committee to provide clinical insight on application review questions. Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with cGCP. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response letter will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response letter without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the Complete Response letter, the FDA may recommend actions that the applicant might take to place the BLA in

condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a Risk Evaluation and Mitigation Strategy ("REMS") to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 postmarket studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies.

Expedited Programs for Serious Conditions

The FDA maintains several programs intended to facilitate and expedite development and review of new drugs and biologics to address unmet medical needs in the treatment of serious or life- threatening diseases or conditions. These programs include Fast Track designation, Breakthrough Therapy designation, Priority Review and Accelerated Approval. These programs can significantly reduce the time it takes for the FDA to review a BLA, but they do not guarantee that a product will receive FDA approval. Even if a product qualifies initially, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review will not be shortened. In May 2018, the Right to Try Act also established a program to increase access to unapproved, investigational treatments for patients diagnosed with life-threatening diseases or conditions who have exhausted approved treatment options and who are unable to participate in a clinical trial.

A new drug or biologic is eligible for Fast Track designation if it is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address unmet medical needs for such disease or condition. Fast Track designation provides increased opportunities for sponsor interactions with the FDA during preclinical and clinical development, in addition to the potential for rolling review once a marketing application is filed, meaning that the agency may review portions of the marketing application before the sponsor submits the complete application, as well as Priority Review, discussed below. In addition, a new drug or biologic may be eligible for Breakthrough Therapy designation if it is intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Breakthrough Therapy designation provides all the features of Fast Track designation in addition to intensive guidance on an efficient drug development program beginning as early as Phase 1, and FDA organizational commitment to expedited development, including involvement of senior managers and experienced review staff in a cross-disciplinary review, where appropriate.

Any product submitted to the FDA for approval, including a product with Fast Track or Breakthrough Therapy designation, may also be eligible for additional FDA programs intended to expedite the review and approval process, including Priority Review designation and accelerated approval. A product is eligible for Priority Review if it has the potential to provide a significant improvement in safety or effectiveness in the treatment, diagnosis or prevention of a serious disease or condition. Under priority review, FDA will review an application in six months compared to ten months for a standard review. Products are eligible for accelerated

approval if they can be shown to have an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or an effect on a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality which is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatment. Accelerated approval is usually contingent on a sponsor's agreement to conduct additional post-approval studies to verify and describe the product's clinical benefit. In addition, unless otherwise informed by the FDA, the FDA currently requires, as a condition for accelerated approval, that all advertising and promotional materials that are intended for dissemination or publication be submitted to FDA for review before the initial dissemination or publication.

Post-Approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing user fee requirements, under which FDA assesses an annual program fee for each product identified in an approved BLA. Biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result

in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

Biosimilars and Reference Product Exclusivity

The Patient Protection and Affordable Care Act, as amended by the Affordable Care Act, signed into law in 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-approved reference biological product. To date, a number of biosimilars have been licensed under the BPCIA, and numerous biosimilars have been approved in Europe. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. Complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, recent government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation, and impact of the BPCIA is subject to significant uncertainty.

Other U.S. Healthcare Laws and Compliance Requirements

In the United States, our current and future operations are subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, the CMS, other divisions of the U.S. Department of Health and Human Services ("HHS") (such as the Office of Inspector General, Office for Civil Rights and the Health Resources and Service Administration), the U.S. Department of Justice ("DOJ"), and state and local governments. For example, our clinical research, sales, marketing and scientific/educational grant programs may have to comply with the anti-fraud and abuse provisions of the Social Security Act, the false claims laws, the privacy and security provisions of HIPAA, and similar state laws, each as amended, as applicable.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between therapeutic product manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor. The statutory exceptions and regulatory safe harbors are also subject to change.

Additionally, the intent standard under the Anti-Kickback Statute was amended by the Affordable Care Act, to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the Affordable Care Act also codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal FCA (discussed below).

The federal false claims and civil monetary penalty laws, including the FCA, which imposes significant penalties and can be enforced by private citizens through civil qui tam actions, prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to, or approval by, the federal government, including federal healthcare programs, such as Medicare and Medicaid; knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government; or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government. A claim includes “any request or demand” for money or property presented to the U.S. government. Although we would not submit claims directly to payors, manufacturers can be held liable under these laws if they are deemed to “cause” the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. In addition, our future activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state, and third-party reimbursement for our products, and the sale and marketing of our products, are subject to scrutiny under this law. For example, pharmaceutical companies have been prosecuted under the FCA in connection with their alleged off-label promotion of drugs, purportedly concealing price concessions in the pricing information submitted to the government for government price reporting purposes, and allegedly providing free product to customers with the expectation that the customers would bill federal health care programs for the product.

HIPAA created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the Anti-Kickback Statute, the Affordable Care Act amended the intent standard for certain healthcare fraud statutes under HIPAA such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Also, many states have similar, and typically more prohibitive, fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

In addition, we may be subject to data privacy, data security and data breach notification laws, regulations, standards, and codes of conduct by both the U.S. federal government and the states. These laws, regulations, standards, and codes of conduct may govern the collection, use, disclosure and protection of health-related and other personal information. HIPAA, as amended by the HITECH, imposes requirements relating to the privacy, security and transmission of individually identifiable health information. HIPAA requires covered entities to limit the use and disclosure of protected health information to specifically authorized situations, and requires covered entities to implement security measures to protect health information that they maintain in electronic form. The federal government may impose civil, criminal, and administrative fines and penalties and/or additional reporting or oversight obligations for a violation of HIPAA's requirements. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition to HIPAA and HITECH, many state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways, are often not pre-empted by federal law, and may have a more prohibitive effect than federal law, thus complicating compliance efforts.

We may develop products that, once approved, may be administered by a physician. Under currently applicable U.S. law, certain products not usually self-administered (including injectable drugs) may be eligible for coverage under Medicare through Medicare Part B. Medicare Part B is the part of Medicare that covers outpatient services and supplies, including certain pharmaceutical products, that are medically necessary to treat a beneficiary's health condition. As a condition of receiving Medicare Part B reimbursement for a manufacturer's eligible drugs, the manufacturer is required to participate in other government healthcare programs, including the Medicaid Drug Rebate Program and the 340B Drug Pricing Program. The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of HHS as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. Under the 340B Drug Pricing Program, the manufacturer must extend discounts to entities that participate in the program.

In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely.

Additionally, the federal Physician Payments Sunshine Act (the "Sunshine Act") within the Affordable Care Act, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) report annually to CMS information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members. This information is made publicly available on a CMS website, and failure to report accurately could result in penalties. In addition, many states also govern the reporting of payments or other transfers of value, many of which differ from each other in significant ways, are often not pre-empted, and may have a more prohibitive effect than the Sunshine Act, thus further complicating compliance efforts.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in

certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several state and local laws have been enacted requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. In addition, all of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

Ensuring business arrangements with third parties comply with applicable healthcare laws and regulations is a costly endeavor. If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other current or future governmental regulations that apply to us, we may be subject to significant penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private "qui tam" actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we may obtain regulatory approval. In the United States and in foreign markets, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the extent to which third-party payors provide coverage and establish adequate reimbursement levels for such products. In the United States, third-party payors include federal and state healthcare programs, private managed care providers, private health insurers and other organizations. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid in the United States, and commercial payors are critical to new product acceptance.

Our ability to commercialize any products successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which therapeutics they will pay for and establish reimbursement levels. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a therapeutic is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

We cannot be sure that reimbursement will be available for any product that we commercialize and, if coverage and reimbursement are available, what the level of reimbursement will be. Coverage may also be more limited than the purposes for which the product is approved by the FDA or comparable foreign regulatory authorities. Reimbursement may impact the demand for, or the price of, any product for which we obtain regulatory approval.

Third-party payors are increasingly challenging the price, examining the medical necessity, and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with branded drugs and drugs administered under the supervision of a physician. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. Obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our product on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize any product candidate that we successfully develop.

Different pricing and reimbursement schemes exist in other countries. In the European Union, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care, the increasing influence of health maintenance organizations, and additional legislative changes in the United States has increased, and we expect will continue to increase, the pressure on healthcare pricing. The downward pressure on the rise in healthcare costs in general, particularly prescription medicines, medical devices and surgical procedures and other treatments, has become very intense. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Healthcare Reform

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect the ability to profitably sell product candidates for which marketing approval is obtained. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States,

the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

For example, the Affordable Care Act has substantially changed healthcare financing and delivery by both governmental and private insurers. The Affordable Care Act and its implementing regulations, among other things, revised the methodology for calculating rebates for covered outpatient drugs and certain biologics owed by manufacturers to the state and federal government under the Medicaid Drug Rebate Program, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected manufacturers to new annual fees and taxes for certain branded prescription drugs, and expanded programs designed to test innovative payment models, service delivery models, or value-based arrangements, and fund comparative effectiveness research.

Some of the provisions of the Affordable Care Act have yet to be implemented, and there have been legal and political challenges to certain aspects of the Affordable Care Act. Since January 2017, President Trump has signed two executive orders and other directives designed to delay, circumvent or loosen certain requirements mandated by the Affordable Care Act. On December 22, 2017, President Trump signed into law the Tax Cuts and Jobs Act of 2017, or Tax Act which included a provision that repealed the tax penalty for an individual's failure to maintain Affordable Care Act-mandated health insurance, effective January 1, 2019. Further, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain Affordable Care Act-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Moreover, the Bipartisan Budget Act of 2018, or the BBA, among other things, amended the Affordable Care Act, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." Additionally, in December 2018, CMS published a final rule permitting further collections and payments to and from certain Affordable Care Act qualified health plans and health insurance issuers under the Affordable Care Act risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment.

On December 14, 2018, a United States District Court judge in Texas ruled that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. The decision has been appealed to the United States Court of Appeals for the Fifth Circuit. On March 25, 2019, the DOJ submitted a filing to the Fifth Circuit stating that the district court's judgment should be affirmed and, on May 1, 2019, filed a brief in the Fifth Circuit arguing that the Affordable Care Act should be struck down in its entirety. While this U.S. District Court judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals and other efforts to repeal and replace the Affordable Care Act will impact the Affordable Care Act.

We anticipate that the Affordable Care Act, if substantially maintained in its current form, will continue to result in additional downward pressure on coverage and the price that we receive for any approved product, and could seriously harm our business. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

In addition, further legislation or regulation could be passed that could harm our business, financial condition and results of operations. Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, in August 2011, President Obama signed into law the Budget

Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction of at least $1.2 trillion for fiscal years 2012 through 2021, triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect beginning on April 1, 2013 and will stay in effect through 2027 unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration's budget proposals for fiscal years 2019 and 2020 contain further drug price control measures that could be enacted during the budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Further, the Trump administration released a "Blueprint," or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. While some proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs.

Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. For example, after some pharmacy benefit managers and insurers adopted policies stating that the amount of a copay coupon would not be applied to the enrollee's deductible or out-of-pocket maximum (referred to as "accumulator adjustment programs"), some states passed legislation banning these policies. Based on a rule that will take effect in the 2020 plan year, CMS will allow accumulator adjustment programs only when used for a branded drug that has a generic equivalent. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates, if approved.

Additional Regulation

In addition to the foregoing, local, state and federal laws, including in the United States and Israel, regarding such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous or biohazardous substances, we could be liable for damages, environmental remediation, and/or governmental fines. We believe that we are in material compliance with applicable environmental laws and occupational health and safety laws that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations. We may incur significant costs to comply with such laws and regulations now or in the future.

Competition

The biopharmaceutical industry is intensely competitive and subject to rapid innovation and significant technological advancements. We believe the key competitive factors that will affect the development and commercial success of BIO89-100 and any future product candidates are efficacy, safety and tolerability profile, reliability, convenience of dosing, price, the level of generic competition and reimbursement. Our competitors include multinational pharmaceutical companies, specialized biotechnology companies, universities and other research institutions. A number of biotechnology and pharmaceutical companies are pursuing the development or marketing of pharmaceuticals that target the same diseases that we are targeting. Smaller or earlier-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Given the high incidence of NASH, it is likely that the number of companies seeking to develop products and therapies for the treatment of liver and cardio-metabolic diseases, such as NASH, will increase.

If BIO89-100 is approved for the treatment of NASH, future competition could also arise from products currently in development, including: cenicriviroc, an immunomodulator that blocks CCR2 and CCR5 from Allergan plc; GS-0976, an ACC inhibitor, and GS-9674, an FXR agonist, from Gilead Sciences, Inc.; PF-05221304, an ACC inhibitor, and PF-06835919, a KHK inhibitor, from Pfizer Inc.; Ocaliva, an FXR agonist from Intercept Pharmaceuticals, Inc.; MGL-3196, a beta-thyroid hormone receptor agonist from Madrigal Pharmaceuticals, Inc.; VK2809, a beta-thyroid hormone receptor agonist from Viking Therapeutics, Inc.; NGM-282, an FGF19 analog from NGM Biopharmaceuticals, Inc.; MK-3655, an FGFR1c/KLB agonist antibody from Merck & Co., Inc.; pegbelfermin, a PEGylated FGF21 analog from Bristol-Myers Squibb Company; AKR-001, a FGF21 fusion protein from Akero Therapeutics, Inc.; elobixibat, an IBAT-inhibitor from Albireo Pharma, Inc.; a Galectin-3 inhibitor from Galectin Therapeutics Inc.; a synthetic conjugate of cholic acid and arachidic acid from Galmed Pharmaceuticals Ltd.; an FXR agonist from Metacrine, Inc.; FXR agonists from Novartis AG; a mitochondrial pyruvate complex modulator from Cirius Therapeutics, Inc.; seladelpar, a PPAR delta agonist from CymaBay Therapeutics, Inc.; semaglutide, a GLP-1 receptor agonist from Novo Nordisk A/S; tirzepatide, a dual IP/GLP-1 receptor agonist from Eli Lilly and Company; and elafibranor, a PPAR alpha/delta agonist from Genfit S.A.

If BIO89-100 is approved for the treatment of SHTG, we would face competition from currently approved and marketed products, including statins, fibrates, Vascepa, Epanova and Lovaza, as well as generic products. Further competition could arise from products currently in development, including: AKCEA-APOCIII-LRx, an ApoC III inhibitor from Akcea Therapeutics, Inc.; evinacumab, an Anti-ANGPTL3 from Regeneron Pharmaceuticals, Inc.; pemafibrate, a PPAR alpha agonist from Kowa Research Institute, Inc.; gemcabene; CaPre, an omega-3 fatty acid from Acasti Pharma Inc.; and ARO-APOC3, an ApoC III inhibitor from Arrowhead Pharmaceuticals, Inc.

Many of our competitors have substantially greater financial, technical, human and other resources than we do and may be better equipped to develop, manufacture and market technologically superior products. In addition, many of these competitors have significantly longer operating histories and greater experience than we have in undertaking nonclinical studies and human clinical trials of new pharmaceutical products and in obtaining regulatory approvals of human therapeutic products. Many of our competitors have established distribution channels for the commercialization of their products, whereas we have no such channel or capabilities. In addition, many competitors have greater name recognition and more extensive collaborative relationships. As a result, our competitors may obtain regulatory approval of their products more rapidly than we do or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidate or any future product candidates. Our competitors may also develop and succeed in obtaining approval for drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile than our products and these competitors may also be more successful than we are in manufacturing and marketing their products. If we are unable to compete effectively against these companies, then we may not be able to commercialize our product candidate or any future product candidates or

achieve a competitive position in the market. This would adversely affect our ability to generate revenue. Our competitors also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and enrolling patients for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Manufacturing and Supply

We do not own or operate manufacturing facilities for the production of BIO89-100, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently rely, and expect to continue to rely, on third parties for the manufacturing of our product candidates for preclinical and clinical testing, as well as for commercial manufacturing if BIO89-100 or any future product candidate receives marketing approval.

BIO89-100 drug substance is manufactured by fermentation of a recombinant strain of the bacterium E. coli. Product accumulates as insoluble particles (inclusion bodies) within the cells and is recovered by cell disruption, followed by solubilization of the inclusion bodies, protein refolding and purification with two chromatographic separation columns. Purified material is glycoPEGylated in a 2-step enzymatic reaction where a 20kDa linear glycoPEG moiety is attached to the protein through GalNAc and Sialic Acid linkers. GlycoPEGylated protein is purified with two chromatographic columns to yield product with target quality attributes. Purified glycoPEGylated protein is concentrated and then formulated to a target concentration with formulation buffer as drug product.

BTPH is our sole source supplier for BIO89-100. While any reduction or halt in supply of drug product from BTPH could limit our ability to develop BIO89-100 until a replacement contract manufacturer is found and qualified, we have recently produced several batches to support toxicology and clinical studies. We currently have material available to support our ongoing Phase POC 1b/2a trial of BIO89-100 for the treatment of NASH and for the initiation of our SHTG trial.

We are working with BTPH on process optimization to support large-scale production for future trials and commercialization. In parallel, we have entered into a contract with a formulation development company to explore the potential for a new refrigerated liquid formulation and/or a freeze-dried, or lyophilized product.

BTPH Agreement

On May 7, 2018, we entered into a master services agreement with BTPH, under which BTPH agreed to provide us certain services, including the manufacturing, packaging, labeling and storing of BIO89-100, under statements of work for such services to be agreed by the parties from time to time. The master services agreement will continue for the duration of time that BTPH is providing services to us, unless earlier terminated by either party upon its terms. We may terminate the agreement at any time after a specified notice period and subject to the payment of certain agreed upon fees where such termination results in cancellation of manufacturing scheduled within a certain period. In addition, either party may terminate the agreement for cause for the other party's uncured material breach, in the event of bankruptcy of the other party, in the event of the commission of fraud by the other party or in the event of a force majeure.

Sales and Marketing

We currently have no marketing, sales or distribution capabilities. In order to commercialize any products that are approved for commercial sale, we must either develop a sales and marketing infrastructure or collaborate with third parties that have sales and marketing experience.

We may elect to establish our own sales force to market and sell a product for which we obtain regulatory approval if we expect that the geographic market for a product we develop on our own is limited or

that the prescriptions for the product will be written principally by a relatively small number of physicians. If we decide to market and sell any products ourselves, we do not expect to establish direct sales capability until shortly before the products are approved for commercial sale.

We plan to seek third-party support from established pharmaceutical and biotechnology companies for those products that would benefit from the promotional support of a large sales and marketing force. In these cases, we might seek to promote our products in collaboration with marketing partners or rely on relationships with one or more companies with large established sales forces and distribution systems.

Intellectual Property

Our success depends in part upon our ability to protect our core technology and intellectual property. To protect our intellectual property rights, we rely on patents, trademarks, copyrights and trade secret laws, confidentiality procedures, and employee disclosure and invention assignment agreements. Our intellectual property is critical to our business and we strive to protect it through a variety of approaches, including by obtaining and maintaining patent protection in the United States and internationally for our product candidates, novel biological discoveries, new targets and applications, and other inventions that are important to our business. For our product candidates, we generally intend to pursue patent protection covering compositions of matter, methods of making and methods of use. As we continue the development of our product candidates, we plan to identify additional means of obtaining patent protection that would potentially enhance commercial success, including pursuit of claims directed to new therapeutic indications.

FGF21 Patents

Our FGF21 patent portfolio includes two families: the first is entitled “Remodeling and GlycoPEGylation of Fibroblast Growth Factor (FGF)” and the second is entitled “Mutant FGF-21 Peptide Conjugate and Uses Thereof.” The first family provides granted patent protection in 39 countries around the globe, including the United States (USPN 9,200,049; expiry June 25, 2028), Canada, Europe (broadly), and Japan (latter three expire October 31, 2025) for FGF21 conjugates comprising a variety of modifying groups that can be attached at several different amino acid positions. GlycoPEGylated FGF21 is specifically claimed. The granted claims broadly protect our lead drug candidate BIO89-100 and pharmaceutical compositions thereof, as well as methods for making and using BIO89-100 to treat FGF21 deficiency in a patient in need thereof. One U.S. application is pending in this family.

The second family is specifically directed to BIO89-100. The progenitor PCT Application for this family was filed on September 4, 2018 (PCT/US18/49379; projected expiry September 4, 2038). A U.S. Prioritized Examination Continuation Patent Application (Application Serial No. 16/225,640) was filed in parallel with PCT/US18/49379 on September 4, 2018 and from which U.S. Patent Number 10,407,479 issued on September 10, 2019. The issued claims are directed to BIO89-100 and a defined genus specifically encompassing BIO89-100 and compositions thereof (including site-specific mutations at positions 173 and 176), as well as methods for making and using BIO89-100 for a variety of therapeutic indications. Such indications include methods for treating NASH or metabolic syndrome. Subjects wherein there is a need to reduce blood glucose or to reduce HbA1C include those afflicted with diabetes Type 2, NASH and metabolic syndrome. The claims encompass different therapeutic regimens for administering BIO89-100 (e.g., once a week or once every two weeks), which regimens are based on BIO89-100’s surprisingly long half-life in vivo.

National phase entry of this PCT Application in March of 2020 provides the opportunity to pursue global protection of specific mutant FGF21 peptide conjugates, and particularly BIO89-100. National phase entry is envisioned in at least Europe, China, Japan, Canada, Israel and Korea.

FASN Patents

Our FASN patent portfolio currently consists of three patent families, including patents and/or patent applications in the United States, the European Patent Convention, Canada, Mexico, Israel and Japan.

The first patent family, directed to TEV-48317, which we acquired from Teva under the FASN Agreement, and other 1,4-substituted piperidine-based FASN inhibitors, is currently protected by two granted U.S. patents that cover these compounds, pharmaceutical compositions comprising these compounds, and methods of treating FASN-mediated disorders using these compounds. The non-extended term for these patents would expire on June 17, 2036. A pending U.S. application is directed to additional methods of treatment using these compounds. The second patent family is directed to other 1,4-substituted piperidine-based FASN inhibitors, pharmaceutical compositions, and methods of treating FASN-mediated disorders. The third patent family is directed to spiropiperidine FASN inhibitors, pharmaceutical compositions containing these compounds, and methods of treating FASN-mediated disorders using these compounds.

Employees

As of June 30, 2019, we had 13 full-time employees and 14 total employees. 11 employees are engaged in research and development activities. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Facilities

We lease office space, which consists of approximately 1,600 square feet located at 6 Hamada Street, Herzliya, 4673340, Israel. The lease expires on April 30, 2020. We also lease access to shared office space at 535 Mission Street, San Francisco, California 94105 on a month-to-month basis. We believe that our current spaces are adequate for our needs. We also believe we will be able to obtain additional space, as needed, on commercially reasonable terms.

Legal Proceedings

We are currently not a party to any material legal proceedings. From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors, and there can be no assurances that favorable outcomes will be obtained.

MANAGEMENT

Executive Officers and Directors

The following table sets forth certain information regarding our executive officers and directors as of October 11, 2019.

Name	Age	Position
Executive Officers		
Rohan Palekar	53	Chief Executive Officer and Director
Ram Waisbourd	52	Chief Operating Officer and Chief Business Officer
Ryan Martins	42	Chief Financial Officer
Hank Mansbach, M.D.	54	Chief Medical Officer
Quoc Le-Nguyen	51	Chief Technical Operations Officer and Head of Quality
Non-Employee Directors		
Derek DiRocco, Ph.D.(1)(3)	39	Director
Gregory Grunberg, M.D.(2)(3)	47	Director
Michael Hayden, M.B. Ch.B., Ph.D.(1)(2)	67	Director
Tomer Kariv(1)	58	Director
Anat Naschitz(2)(3)	52	Director

(1) Member of the Audit Committee
(2) Member of the Compensation Committee
(3) Member of the Nominating and Corporate Governance Committee

The following is a biographical summary of the experience of our executive officers and directors:

Executive Officers

Rohan Palekar has served as our Chief Executive Officer and a member of our board of directors since June 2018. Prior to joining our company, Mr. Palekar served as the president and Chief Executive Officer of Avanir Pharmaceuticals, Inc., a specialty pharmaceutical company, from December 2015 to July 2017, where he led the company following its acquisition by Otsuka Pharmaceutical Co., Ltd. in 2015. Mr. Palekar also served as Executive Vice President and Chief Operating Officer of Avanir in 2015 and as Senior Vice President and Chief Commercial Officer of Avanir from March 2012 to March 2015. Prior to Avanir, Mr. Palekar served as Chief Commercial Officer for Medivation, Inc., a biopharmaceutical company, from 2008 to 2011, where he was responsible for all commercial activities, chemistry, manufacturing and controls, medical affairs and public relations functions. Prior to Medivation, Mr. Palekar spent over 16 years at Johnson & Johnson, a diversified healthcare company, in various senior commercial and strategic management roles. Mr. Palekar earned his M.B.A. from the Tuck School of Business at Dartmouth College, his B.Com. in Accounting from the University of Mumbai and his L.L.B. in Law from the University of Mumbai.

We believe Mr. Palekar is qualified to serve on our board of directors because of his broad and long experience in the biopharmaceutical industry.

Ram Waisbourd has served as our Chief Operating Officer and Chief Business Officer since May 2018. Prior to joining our company, Mr. Waisbourd served as Vice President of Strategy and Transformation, Global Research and Development, at Teva Pharmaceutical Industries Ltd., a pharmaceutical company, from November 2016 to April 2018, where he was responsible for Teva research and development strategy, novel pipeline funding transactions and digital initiatives. Mr. Waisbourd also served as Vice President of Transformational Initiatives and Operations, Global Research and Development at Teva from September 2015 to October 2016 and Senior Director, Chief of the Research and Development Office from August 2012 to August 2015. Previously,

Mr. Waisbourd served as Vice President of Business Development of XTL Biopharmaceuticals Ltd., a biotechnology company, and as Vice President of Biomedical Investments, an investment fund. Mr. Waisbourd earned his M.B.A from Tel-Aviv University and his B.Sc. in Economics from The Wharton School at the University of Pennsylvania.

Ryan Martins has served as our Chief Financial Officer since July 2019 and previously served as our consultant since April 2019. Prior to joining our company, Mr. Martins was Chief Financial Officer at Revolution Medicines, Inc., from March 2018 to October 2018, where he was responsible for all aspects of the finance function including financial accounting, capital planning, audit, tax and investor relations. Before Revolution Medicines, Mr. Martins was Vice President and Head of Corporate Strategy and Investor Relations at Ultragenyx Pharmaceutical, Inc., from September 2015 to March 2018, where he was responsible for strategic planning, capital raising, investor relations and assisting business development. Prior to Ultragenyx, Mr. Martins spent nearly 10 years as a biotechnology analyst at Jefferies, Lazard, and Barclays/Lehman Brothers after holding operating roles at Chiron Corporation from 2001 to 2006. Mr. Martins earned his B.Sc. in Life Sciences from St. Xavier's College, a M.S. degree in Biology from Virginia Tech and an M.B.A. from the Haas School of Business at U.C. Berkeley.

Hank Mansbach, M.D. has served as our Chief Medical Officer since December 2018. Prior to joining our company, Dr. Mansbach was at Ultragenyx Pharmaceutical Inc., a biotechnology company where he served Head of Global Clinical Development for Metabolic and Neurologic Diseases from June 2018 to December 2018, Vice President of Global Clinical Development and Ultra Programs from March 2017 to June 2018 and Vice President of Medical Affairs from May 2015 to March 2017. During his time at Ultragenyx, Dr. Mansbach was responsible for leading clinical development programs for metabolic disorders and building and leading the Medical Affairs team. Before Ultragenyx, Dr. Mansbach served as Vice President of Medical Affairs at Medivation, Inc., a biopharmaceutical company, from August 2009 to April 2015, where he played a key role in the development and commercialization of enzalutamide for the treatment of advanced prostate cancer. Earlier in his career, Dr. Mansbach served as Senior Vice President of Global Drug Development at Valeant Pharmaceuticals and Chief Medical Officer at Cortex Pharmaceuticals, Inc., a pharmaceutical company. Dr. Mansbach began his industry career at Glaxo Wellcome after clinical practice and research in neurology. He earned his M.D. from Duke University and a B.A. in Philosophy from Yale University.

Quoc Le-Nguyen has served as our Chief Technical Operations Officer and Head of Quality since March 2019. Prior to joining our company, Mr. Le-Nguyen was Senior Vice President, Global Head of Technical Operations & Quality for Aduro BioTech, Inc., a biotechnology company, from September 2015 to July 2018, where he was responsible for clinical supply including analytical and process development, manufacturing, supply chain and quality for cell therapy, small molecule and antibody platforms. Prior to Aduro, Mr. Le-Nguyen was the Vice President of Manufacturing Operations for Bayer AG from September 2007 to September 2013, where he was responsible for the Betaferon/Betaseron franchise. Prior to Bayer, Mr. Le-Nguyen worked in biologics manufacturing for Novartis International AG, Chiron Corporation and BioMarin Pharmaceutical Inc. Mr. Le-Nguyen earned his B.S. in Biochemistry from the University of California, Davis.

Non-Employee Directors

Derek DiRocco, Ph.D. has served as a member of our board of directors since April 2018. Dr. DiRocco has been a principal at RA Capital Management, LLC, an investment advisory firm that invests in healthcare and life science companies, since December 2017 and was previously an analyst from June 2015 to December 2017 and an associate from July 2013 to June 2015. Dr. DiRocco earned his Ph.D. in Pharmacology from the University of Washington and his B.A. in Biology from College of the Holy Cross.

We believe Dr. DiRocco is qualified to serve on our board of directors because of his experience as an investor in biotechnology companies and role in early stage companies.

Gregory Grunberg, M.D. has served as a member of our board of directors since April 2018. Dr. Grunberg has been a Managing Director at Longitude Capital Management Co., LLC, a venture capital firm, since February 2012. Prior to joining Longitude, Dr. Grunberg was a Principal at Rho Ventures, a venture capital firm, where he worked from May 2007 to January 2012. Dr. Grunberg maintains a limited clinical practice in internal medicine and affiliations with University of California, San Francisco and Kaiser Permanente. Dr. Grunberg has served on the boards of Kala Pharmaceuticals Inc., a pharmaceutical company, since April 2016, and WelbeHealth LLC, a private healthcare services company, since April 2018. He has served as a board observer at Sydnexis, Inc., an private biotechnology company, since September 2017. He previously served on the board of California Cryobank (acquired by GI Partners) from August 2014 to August 2018 and led Longitude's investment in Practice Fusion (acquired by Allscripts Healthcare Solutions, Inc.). While at Rho Ventures he served on the board of AqueSys Inc. (acquired by Allergan plc) from June 2010 to December 2011 and was a board observer at both SARCode Bioscience Inc. (acquired by Shire plc) from June 2011 to February 2012 and PHT Corporation (acquired by eResearchTechnology, Inc.) from November 2010 to November 2012. Dr. Grunberg earned his M.D. and M.B.A. from Duke University and his A.B. in Economics and English from Amherst College.

We believe Dr. Grunberg is qualified to serve on our board of directors because of his extensive experience investing in and guiding early phase companies.

Michael Hayden, M.B. Ch.B., Ph.D. has served as a member of our board of directors since April 2018. Dr. Hayden is currently a Killam Professor at the University of British Columbia and the director of the Translational Laboratory in Genetic Medicine at the National University of Singapore and A*STAR. Dr. Hayden was the President of Global Research and Development and Chief Scientific Officer at Teva Pharmaceutical Industries Ltd., a pharmaceutical company, from May 2012 to December 2017, and served as an advisor to Teva from December 2017 to August 2018. During this time approximately 35 new products were approved in major markets with many for diseases of the CNS such as migraine. He led the development of the first deuterated drug to be approved by the FDA and the second drug ever to be approved for Huntington disease. He is also the Founder and a Senior Scientist of the Centre for Molecular Medicine and Therapeutics at the University of British Columbia. Dr. Hayden has served on the boards of Aurinia Pharmaceuticals Inc., a biopharmaceutical company, since February 2018, Ionis Pharmaceuticals, Inc., a biopharmaceutical company, since September 2018, and Xenon Pharmaceuticals, Inc., a pharmaceutical company, since November 1996. Dr. Hayden received his M.B. Ch.B. in Medicine, Ph.D. in Genetics and Diploma in Child Health from the University of Cape Town. He received his American Board Certification in both internal medicine and clinical genetics from Harvard Medical School and an FRCPC in internal medicine from the University of British Columbia.

We believe Dr. Hayden is qualified to serve on our board of directors because of his extensive experience as a senior executive and member of the board of other life science companies.

Tomer Kariv has served as a member of our board of directors since May 2018. Mr. Kariv has served as co-founder and managing partner of the Pontifax Group, a venture capital firm, since December 2004. He serves on the boards of Eloxx Pharmaceuticals, Inc., a pharmaceutical company, since December 2017, and Logicbio Therapeutics, Inc., a pharmaceutical company, since June 2017. He previously served on the board of VBI Vaccines Inc., a pharmaceutical company, from January 2018 to June 2019, Medical Compression Systems Ltd, a pharmaceutical company, from August 2012 to April 2015, Macrocure Ltd, a pharmaceutical company, from March 2008 to January 2017, Arno Therapeutics Inc., a pharmaceutical company, from September 2010 to August 2017, and Check-Cap Ltd, a medical diagnostics company, from March 2008 to June 2018. Mr. Kariv earned his B.A. in Economics from Harvard University and a J.D. from Harvard Law School.

We believe Mr. Kariv is qualified to serve on our board of directors of his extensive experience in investing in, guiding and leading start-up companies and experience as a director in similar stage companies.

Anat Naschitz has served as a member of our board of directors since January 2018, and played a key role in creating 89Bio, Ltd. as a spinout from a pharmaceutical company. Ms. Naschitz has served as Managing

Director at OrbiMed, a global healthcare investment firm, since January 2010. Ms. Naschitz has over 20 years of healthcare experience. Previously, Ms. Naschitz created, invested in and advised healthcare companies across stages and substance. She was an Associate Partner with McKinsey in London from 1995 to 2002, where she managed strategy, company formation through spinouts and mergers and acquisitions projects for senior management of the world's leading pharmaceutical and biotechnology companies. Subsequently Ms. Naschitz was a Principal at Apax Partners, where she invested in healthcare companies. She currently serves on the boards of biotech and digital health companies and served on the board of Medigus Ltd., a medical device company, from March 2013 to June 2017. Ms. Naschitz earned her M.B.A. at INSEAD and her L.L.B. at Tel Aviv University.

We believe Ms. Naschitz is qualified to serve on our board of directors because of her long industry experience and experience as an investor in biotechnology companies.

Family Relationships

There are no family relationships among any of our directors or executive officers.

Composition of our Board of Directors

Our board of directors currently consists of six members, each of whom are members pursuant to the board composition provisions of our current certificate of incorporation and agreements with our stockholders. Our current certificate of incorporation and agreements among our stockholders provide for two directors to be appointed by entities affiliated with OrbiMed, one director to be appointed by Longitude, one director to be appointed by RA Capital and two directors (only one of which has been appointed to date) to be appointed by the holders of at least 50% of our Series A convertible preferred shares, including either OrbiMed IL or OrbiMed US (the "Requisite Preferred"), and one director who shall be the presiding Chief Executive Officer of our company, currently Mr. Palekar. Ms. Naschitz is the designee of OrbiMed IL, Mr. Kariv is the designee of OrbiMed US, Dr. DiRocco is the designee of RA Capital, Dr. Grunberg is the designee of Longitude and Dr. Hayden is an industry director who has been appointed by the Requisite Preferred. These board composition provisions will terminate upon the completion of this offering. Upon the termination of these provisions, there will be no further contractual obligations regarding the election of our directors, although no changes to our board composition are expected at that time. Our board of directors may therefore consider a broad range of factors relating to the qualifications and background of nominees, including the identification of persons who will further the interests of our stockholders through their established record of professional accomplishment, the ability to contribute positively to the collaborative culture among board members, knowledge of our business, understanding of the competitive landscape, and professional and personal experiences and expertise relevant to our growth strategy. We have no formal policy regarding board diversity. Our Amended Certificate and Amended Bylaws, both to become effective upon the completion of this offering, provide that the number of directors shall be fixed from time to time by a resolution of the majority of our board of directors.

Director Independence

Our board of directors has determined that all members of our board of directors, except Mr. Palekar, are independent directors for purposes of applicable Nasdaq listing rules. In making such independence determination, our board of directors considered the relationships that each non-employee director has with us and all other facts and circumstances that our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director. In considering the independence of the directors listed above, our board of directors considered the association of our directors with the holders of more than 5% of our common stock and other affiliations, including family and other relationships.

Upon the completion of this offering, we expect that the composition and functioning of our board of directors and each of our committees will comply with all applicable requirements of the Nasdaq listing rules and

the rules and regulations of the SEC. Mr. Palekar is not an independent director under these rules because he is currently employed as the chief executive officer of our company.

Term of Office, Removal and Vacancies

Our directors hold office until their successors have been elected and qualified or until the earlier of their resignation or removal. Our Amended Certificate and Amended Bylaws provide that our directors may be removed only for cause by the affirmative vote of the holders of at least 66⅔% of the votes that all our stockholders would be entitled to cast in an annual election of directors, and that any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office.

Election of Directors

Our Amended Certificate provides that our board of directors will be divided into three staggered classes of directors and each will be assigned to one of the three classes. At each annual meeting of the stockholders, a class of directors will be elected for a three-year term to succeed the directors of the same class whose terms are then expiring. The terms of the directors will expire upon the election and qualification of successor directors at the annual meeting of stockholders to be held during the years 2020 for Class I directors, 2021 for Class II directors and 2022 for Class III directors.

- Our Class I directors will be Mr. Palekar and Dr. Grunberg;
- Our Class II directors will be Dr. Hayden and Mr. Kariv; and
- Our Class III directors will be Dr. DiRocco and Ms. Naschitz.

The division of our board of directors into three classes with staggered three-year terms may delay or prevent stockholder efforts to effect a change of our management or a change in control.

Board Leadership Structure and the Role of our Board in Risk Oversight

Board Leadership Structure

The positions of our chairman of the board and chief executive officer are currently separated. Separating these positions allows our chief executive officer to focus on our day-to-day business, while allowing the chairman of the board to lead our board of directors in its fundamental role of providing advice to and oversight of management.

Although our Amended Bylaws do not require that we separate the chief executive officer and board leadership positions, our board of directors believes that having separate positions is the appropriate leadership structure for us at this time. Our board of directors recognizes that, depending on the circumstances, other leadership models, such as combining the role of executive chairman of the board with the role of chief executive officer, might be appropriate. Accordingly, our board of directors may periodically review its leadership structure. Our board of directors believes its administration of its risk oversight function has not affected its leadership structure.

Our independent directors will meet alone in executive session regularly throughout each year. The purpose of these executive sessions is to promote open and candid discussion among independent directors.

Role of our Board in Risk Oversight

We face a number of risks, including those described under the section titled “Risk Factors” included elsewhere in this prospectus. Our board of directors believes that risk management is an important part of

establishing, updating and executing on the company's business strategy. Our board of directors, as a whole and at the committee level, has oversight responsibility relating to risks that could affect the corporate strategy, business objectives, compliance, operations and the financial condition and performance of the company. Our board of directors focuses its oversight on the most significant risks facing the company and on its processes to identify, prioritize, assess, manage and mitigate those risks. Our board of directors and its committees receive regular reports from members of the company's senior management on areas of material risk to the company, including strategic, operational, financial, legal and regulatory risks. While our board of directors has an oversight role, management is principally tasked with direct responsibility for management and assessment of risks and the implementation of processes and controls to mitigate their effects on the company.

Committees of our Board of Directors

Our board of directors has established an audit committee, a compensation committee, and a nominating and corporate governance committee, each of which will operate pursuant to a charter that will be effective upon the completion of this offering. The composition and functioning of all of our committees will comply with all applicable requirements of the Sarbanes-Oxley Act of 2002, The Nasdaq Global Market and SEC rules and regulations. A current copy of the charters of the committees of our board of directors will be posted on our website, which is located at *www.89bio.com*.

Audit Committee

Dr. DiRocco and Dr. Hayden serve on the audit committee, which is chaired by Mr. Kariv. Our board of directors has determined that each member of the audit committee is "independent" for audit committee purposes as that term is defined in the rules of the SEC and the applicable Nasdaq listing rules, and has sufficient knowledge in financial and auditing matters to serve on the audit committee. Our board of directors has designated Mr. Kariv as an "audit committee financial expert," as defined under the applicable rules of the SEC as a result of his more than 25 years of experience in identifying and managing investments in, and evaluating financial statements of, both private and public companies, including 15 years serving as founder and chief executive officer of a healthcare-focused venture capital firm, as well as his service on other public company audit committees. In order to be considered independent for purposes of Rule 10A-3 under the Exchange Act, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors or any other board committee: (1) accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries; or (2) be an affiliated person of the listed company or any of its subsidiaries.

The primary responsibilities of the audit committee are to oversee the accounting and financial reporting processes and the internal and external audit processes. The audit committee also assists our board of directors in fulfilling its oversight responsibilities by reviewing the financial information provided to stockholders and others and the system of internal controls established by management and our board of directors. The audit committee oversees the independent auditors, including their independence and objectivity. However, committee members will not act as professional accountants or auditors, and their functions are not intended to duplicate or substitute for the activities of management and the independent auditors. The audit committee is empowered to retain independent legal counsel and other advisors as it deems necessary or appropriate to assist it in fulfilling its responsibilities, and to approve the fees and other retention terms of the advisors.

Compensation Committee

Dr. Grunberg and Dr. Hayden serve on the compensation committee, which is chaired by Ms. Naschitz. Our board of directors has determined that each member of the compensation committee is "independent" as defined in the applicable Nasdaq listing rules, including the additional independence requirements set forth in Nasdaq Rule 5605(d)(2). In order to be considered independent for purposes of Nasdaq Rule 5605(d)(2), a member of a compensation committee of a listed company may not, other than in his or her capacity as a member

of the compensation committee, our board of directors or any other board committee, accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries.

The primary responsibilities of the compensation committee are to periodically review and approve the compensation and other benefits for our employees, officers and independent directors. This includes reviewing and approving corporate goals and objectives relevant to the compensation of our executive officers in light of those goals and objectives, and setting compensation for these officers based on those evaluations.

Nominating and Corporate Governance Committee

Ms. Naschitz and Dr. DiRocco serve on the nominating and corporate governance committee, which is chaired by Dr. Grunberg. Our board of directors has determined that each member of the nominating and corporate governance committee is "independent" as defined in the applicable Nasdaq listing rules. The primary responsibilities of the nominating and corporate governance committee are to develop and recommend to our board of directors criteria for identifying and evaluating qualified candidates for directorships and recommend candidates for election or reelection to our board of directors at each annual stockholders' meeting. The nominating and corporate governance committee also is responsible for making recommendations to our board of directors concerning the structure, composition and function of our board of directors and its committees.

Our board of directors may from time to time establish other committees.

Other Governance Matters

Compensation Committee Interlocks and Insider Participation

None of the members of our compensation committee has at any time during the prior three years been one of our officers or employees. None of our executive officers currently serves, or in the past fiscal year has served, as a member of our board of directors or compensation committee of any entity that has one or more executive officers serving on our board of directors or compensation committee.

Code of Business Conduct and Ethics

Our board of directors has adopted a written code of business conduct and ethics, effective upon the completion of this offering, that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A current copy of the code will be posted on the investor relations section of our website, which is located at *www.89bio.com*. If we make any substantive amendments to, or grant any waivers from, the code of business conduct and ethics for any officer or director, we will disclose the nature of such amendment or waiver on our website or in a current report on Form 8-K.

Director Compensation

The following table sets forth the total cash and equity compensation paid to our non-employee directors for service on our board of directors during 2018:

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)(1)	Total ($)
Michael Hayden	26,700(2)	112,860	129,560
Derek DiRocco	—	—	—
Gregory Grunberg	—	—	—
Tomer Kariv	—	—	—
Anat Naschitz	—	—	—

(1) Amounts shown in this column represent the aggregate grant date fair value (calculated in accordance with FASB Accounting Standards Codification Topic 718) of stock options granted during the year. A description of the methodologies and assumptions we use to value equity awards and the manner in which we recognize the related expense are described in Note 8 to our consolidated financial statements included elsewhere in this prospectus, Share-Based Compensation. These amounts may not correspond to the actual value eventually realized by the director because the value depends on the market value of our common stock at the time the award is exercised. As of December 31, 2018, Dr. Hayden held 550,000 outstanding stock options.

(2) Dr. Hayden is party to a letter agreement with the Company pursuant to which the Company pays him a monthly fee of $3,334 for service on the Board. Includes $10,000 paid in 2019 for services rendered in 2018.

Other than as set forth in the Director Compensation Table above, we did not compensate our non-employee directors for 2018. We have also reimbursed directors for their reasonable out-of-pocket expenses, including travel, food and lodging, incurred in attending meetings of our board of directors and/or its committees. We did not compensate Mr. Palekar for his service on our board of directors during 2018 and we do not expect to compensate our employee directors for their service on our board of directors in the future.

Outside Director Compensation Policy

After the completion of this offering, we anticipate that each of our non-employee directors will be eligible to receive compensation for his or her service on our board of directors consisting of . Our board of directors may revise the compensation arrangements for our directors from time to time.

Indemnification Agreements

We have entered into indemnification agreements with our officers and directors. The indemnification agreements and our Amended Bylaws, to be effective upon the completion of this offering, require us to indemnify these individuals to the fullest extent permitted by Delaware law.

EXECUTIVE COMPENSATION

Our named executive officers ("NEOs") for 2018, which consist of our principal executive officer and the next most highly-compensated executive whose total compensation did not exceed $100,000 in 2018, are:

- Rohan Palekar, our Chief Executive Officer; and
- Ram Waisbourd, our Chief Operating Officer and Chief Business Officer.

2018 Summary Compensation Table

The following table summarizes the compensation awarded to, earned by or paid to our NEOs for 2018.

Name and Principal Position(1)	Year	Salary ($)	Bonus ($)(2)	Option Awards ($)(3)	All Other Compensation ($)	Total ($)
Rohan Palekar, *Chief Executive Officer*	2018	194,792	97,396	414,908	1,065(4)	708,161
Ram Waisbourd, *Chief Operating Officer and Chief Business Officer*(5)	2018	115,522	36,288	130,383	35,809(6)	318,002

(1) Messrs. Palekar and Waisbourd commenced employment as of July 16, 2018 and May 1, 2018, respectively.
(2) Following the end of the fiscal year, we awarded Messrs. Palekar and Waisbourd bonuses in respect of our performance in fiscal year 2018.
(3) Amounts shown in this column represent the aggregate grant date fair value (calculated in accordance with FASB Accounting Standards Codification Topic 718) of stock options granted during the year. A description of the methodologies and assumptions we use to value equity awards and the manner in which we recognize the related expense are described in Note 9 to our consolidated financial statements included elsewhere in this prospectus, Share-Based Compensation. These amounts may not correspond to the actual value eventually realized by each NEO because the value depends on the market value of our common stock at the time the award is exercised.
(4) Represents 401(k) employer matching contribution.
(5) We paid the amounts reported for Mr. Waisbourd in New Israeli Shekels. We have translated amounts paid in New Israeli Shekels into U.S. dollars based on the foreign exchange rate as of December 31, 2018.
(6) Includes a $9,623 contribution by us to Mr. Waisbourd's severance fund, a $6,444 contribution by us for Israeli social insurance and $11,185 in aggregate contributions to pension and Israeli educational funds and a car allowance of $8,557.

Outstanding Equity Awards at 2018 Fiscal-Year End

The following table sets forth information regarding outstanding equity awards at the end of 2018 for each of our NEOs.

	Option Awards (1)			
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date
Rohan Palekar	—	2,021,967	0.31	11/09/2028
Ram Waisbourd	—	635,397	0.31	11/09/2028

(1) Each option award expires on the tenth anniversary of the date of grant. Twenty-five percent of each outstanding stock option award vests on the one-year anniversary of the employee's start date (July 16, 2018, in the case of Mr. Palekar and May 1, 2018, in the case of Mr. Waisbourd) and the remainder vests in equal quarterly installments thereafter, subject to continued service through each such vesting date.

Employment Agreements

During 2018, we were party to an offer letter agreement with Mr. Palekar, effective as of July 16, 2018, pursuant to which he serves as our Chief Executive Officer. The agreement provides for a base salary, eligibility

to receive an annual performance bonus and eligibility to participate in employee benefit or group insurance plans maintained from time to time by the Company. The agreement also provided for the grant of a stock option award as described in the 2018 Summary Compensation Table. The agreement provides for employment on an at-will basis and thus either party may terminate at any time for any or no reason, subject to the severance provisions described below in the section titled "Post-Employment Compensation and Change in Control Payments and Benefits."

During 2018, we were party to an employment agreement with Ram Waisbourd, effective as of May 1, 2018, pursuant to which he serves as our Chief Operating Officer and Chief Business Officer. The employment agreement provides for employment on an at-will basis and thus either party may terminate the agreement by providing 90 days prior written notice; provided, however, that we may terminate earlier and without prior notice, or with shorter notice, provided that we make payment in lieu of such notice and further provided that we may terminate the agreement immediately upon written notice in the event of "cause" (as defined therein). The agreement provides for a base salary, global overtime remuneration (collectively, the "Salary"), eligibility to receive an annual performance bonus, vacation, sick leave, car allowance and convalescence pay. Pursuant to the agreement, we have effected a manager's insurance policy for Mr. Waisbourd pursuant to which we make contributions on his behalf as well as the required statutory deductions from Salary and any other amounts payable under the agreement on his behalf to the relevant authorities in accordance with Israeli law. We contribute an amount equal to 8.5% of his Salary toward the policy for the severance pay component and 6.5% of his Salary toward the policy for pension and disability insurance. We also make the required statutory deductions on behalf of Mr. Waisbourd equal to 6% of his Salary and contribute an amount equal to 7.5% of his Salary to an education fund. The agreement also provided for the grant of a stock option award as described in the 2018 Summary Compensation Table.

For 2018, Mr. Palekar's annualized base salary was $425,000 and Mr. Waisbourd's annualized Salary was $173,283.

Incentive Compensation

For fiscal year 2018, Mr. Palekar and Mr. Waisbourd had target bonus opportunities equal to 45% of base salary and 20% of Salary, respectively, pro-rated for the length of time employed during the year.

Following the end of the fiscal year, our board of directors evaluated the performance of Messrs. Palekar and Waisbourd and based on Company performance in 2018, determined to award bonuses equal to $97,396 and $36,288, respectively.

Post-Employment Compensation and Change in Control Payments and Benefits

Severance

Mr. Palekar

Pursuant to the terms of the employment agreement with Mr. Palekar, upon a termination without cause (as defined in the agreement) not in connection with a change in control (as defined in the agreement), Mr. Palekar will receive, subject to execution and non-revocation of a release of claims in favor of the Company (the "release condition"), severance equal to six months of the base salary as then in effect, a pro-rata amount of the target bonus opportunity based on the number of months employed during the year of termination and payment or reimbursement of COBRA premiums for up to six months, or, if sooner, until eligible for similar coverage through another employer.

If Mr. Palekar is terminated without cause or for good reason (as defined in the agreement) within 90 days prior to, or 12 months following, the consummation of a change in control, then, subject to the release condition, the benefits described above will be provided for 12 months and all outstanding equity awards will vest in full.

Mr. Waisbourd

Pursuant to the terms of his employment agreement, as well as in accordance with Israeli law, upon a termination of Mr. Waisbourd's employment, Mr. Waisbourd is entitled to the payments we have made on his behalf to the Manager's Insurance Policy. If Mr. Waisbourd is terminated without cause within 12 months following a change of control transaction, all outstanding equity awards will vest in full. Further, upon the completion of 12 months of employment with the Company or any successor following a change of control transaction, all unvested options granted pursuant to his employment agreement will vest in full.

Employee Benefit Plans

2019 Equity Incentive Plan

In 2018, our board of directors adopted and our shareholders approved the 89Bio Ltd. 2018 Equity Incentive Plan (the "2018 Plan"). In connection with the Reorganization, in September 2019, our board of directors adopted and our stockholders approved the 2019 Plan, the successor to the 2018 Plan. From and after the effective date of the 2019 Plan, no additional stock awards can be made under the 2018 Plan. In addition, all stock awards granted under the 2018 Plan prior to the effective time of the 2019 Plan that were outstanding as of the effectiveness of the 2019 Plan were canceled and replaced with equivalent awards under the 2019 Plan.

Purpose. The 2019 Plan is intended to help us secure and retain the services of eligible award recipients, provide incentives for such persons to exert maximum efforts for our success and the success of our affiliates and provide a means by which the eligible recipients may benefit from increases in the value of our common stock.

Eligibility. Awards may be granted to our and our affiliates' employees, including officers, non-employee directors and consultants. Only our employees and those of our affiliates are eligible to receive incentive stock options.

Types of Awards. The 2019 Plan provides for the grant of incentive stock options within the meaning of Section 422 of the Code, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance stock awards and performance cash awards.

Authorized Shares. Subject to adjustment for certain dilutive or related events, the aggregate maximum number of shares of our common stock that may be issued pursuant to stock awards under the 2019 Plan (the "Share Reserve") is 9,082,353 shares of common stock.

The Share Reserve will not be reduced if an award or any portion thereof (i) expires, is cancelled or forfeited or otherwise terminates without all of the shares covered by such award having been issued or (ii) is settled in cash. If any shares of common stock issued under an award are forfeited back to or repurchased by us, such shares will revert to and again be made available for issuance under the 2019 Plan. Any shares retained or not issued by us in satisfaction of tax withholding obligations or as consideration for the exercise or purchase price of an award will also again become available for issuance under the 2019 Plan.

The aggregate maximum number of shares of common stock that may be issued on the exercise of incentive stock options is 9,082,353.

Shares issued under the 2019 Plan may consist of our authorized but unissued or reacquired common stock, including shares repurchased by us on the open market or otherwise or shares classified as treasury shares.

Plan Administration. Our board of directors has the authority to administer the 2019 Plan, including the powers to: (i) determine who will be granted awards and what type of award, when and how each award will be granted, the provisions of each award (which need not be identical), the number of shares or cash value subject to

an award and the fair market value applicable to an award; (ii) construe and interpret the 2019 Plan and awards granted thereunder and establish, amend and revoke rules and regulations for administration of the 2019 Plan and awards, including the ability to correct any defect, omission or inconsistency in the 2019 Plan or any award document; (iii) settle all controversies regarding the 2019 Plan and awards granted thereunder; (iv) accelerate or extend, in whole or in part, the time during which an award may be exercised or vested or at which cash or shares may be issued; (v) suspend or terminate the 2019 Plan; (vi) amend the 2019 Plan; (vii) submit any amendment to the 2019 Plan for stockholder approval; (viii) approve forms of award documents for use under the 2019 Plan and to amend the terms of any one or more outstanding awards; (ix) generally exercise such powers and perform such acts as our board of directors may deem necessary or expedient to promote our best interests and that are not in conflict with the provisions of the 2019 Plan or any award documents; and (x) adopt procedures and sub-plans as are necessary or appropriate.

Subject to the provisions of the 2019 Plan, our board of directors may delegate all or some of the administration of the 2019 Plan to a committee of one or more directors and may delegate to one or more officers the authority to designate employees who are not officers to be recipients of options and stock appreciation rights (and, to the extent permitted by applicable law, other stock awards) and, to the extent permitted by applicable law, to determine the terms of such awards and the number of shares of common stock to be subject to such stock awards granted to such employees. Unless otherwise provided by our board of directors, delegation of authority by our board of directors to a committee or an officer will not limit the authority of our board of directors. All determinations, interpretations and constructions made by our board of directors (or another authorized committee or officer exercising powers delegated by our board of directors) in good faith will be final, binding and conclusive on all persons.

Stock Options. A stock option may be granted as an incentive stock option or a nonqualified stock option. The option exercise price may not be less than the fair market value of the stock subject to the option on the date the option is granted (or, with respect to incentive stock options, less than 110% of the fair market value if the recipient owns stock possessing more than 10% of the total combined voting power of all classes of our stock or the stock of any affiliate (a "Ten Percent Stockholder") unless the option was granted pursuant to an assumption or substitution for another option in a manner satisfying the provisions of Section 409A and, if applicable, Section 424(a) of the Code, including, for avoidance of doubt, the options granted in substitution for awards outstanding under the 2018 Plan). Options will not be exercisable after the expiration of ten years from the date of grant (or five years, in the case of an incentive stock option issued to a Ten Percent Stockholder). Each award agreement will set forth the number of shares subject to each option. The purchase price of any shares acquired pursuant to an option may be payable in cash, check, bank draft, money order, net exercise or as otherwise determined by our board of directors and set forth in the award agreement, including through an irrevocable commitment by a broker to pay over such amount from a sale of the shares issuable under the option and the delivery of previously owned shares. The vesting schedule applicable to any option, including any performance conditions, will be as set forth in the award agreement.

Stock Appreciation Rights. A stock appreciation right ("SAR") is a right that entitles the participant to receive, in cash or shares of stock or a combination thereof, as determined by our board of directors, value equal to or otherwise based on the excess of (i) the fair market value of a specified number of shares at the time of exercise over (ii) the exercise price of the right, as established by our board of directors on the date of grant. Upon exercising a SAR, the participant is entitled to receive the amount by which the fair market value of the stock at the time of exercise exceeds the exercise price of the SAR. The exercise price of each SAR may not be less than the fair market value of the stock subject to the award on the date the SAR is granted, unless the SAR was granted pursuant to an assumption of or substitution for another option in a manner satisfying the provisions of Section 409A of the Code. SARs will not be exercisable after the expiration of ten years from the date of grant. Each award agreement will set forth the number of shares subject to the SAR. The vesting schedule applicable to any SAR, including any performance conditions, will be as set forth in the award agreement.

Provisions Applicable to Both Options and SARs.

Transferability. Our board of directors may, in its sole discretion, impose limitations on the transferability of options and SARs. Unless our board of directors provides otherwise, an option or SAR will not be transferable except by will or the laws of descent and distribution and will be exercisable during the lifetime of a participant only by such participant. Our board of directors may permit transfer of an option or SAR in a manner not prohibited by applicable law. Subject to approval by our board of directors, an option or SAR may be transferred pursuant to the terms of a domestic relations order or similar instrument or pursuant to a beneficiary designation.

Termination of Service. Except as otherwise provided in an applicable award document or other agreement between us or any affiliate and a participant, upon a termination for any reason other than for cause or due to death or disability, a participant may exercise his or her option or SAR (to the extent such award was exercisable as of the date of termination) for a period of three months following the termination date or, if earlier, until the expiration of the term of such award. Upon a termination due to a participant's disability, unless otherwise provided in an applicable award or other agreement, the participant may exercise his or her option or SAR (to the extent that such award was exercisable as of the date of termination) for a period of twelve months following the termination date or, if earlier, until the expiration of the term of such award. Upon a termination due to a participant's death, unless otherwise provided in an applicable award or other agreement, the participant's estate may exercise the option or SAR (to the extent such award was exercisable as of the termination date) for a period of eighteen months following the termination date or, if earlier, until the expiration of the term of such award. Unless provided otherwise in an award or other agreement, an option or SAR will terminate on the date that a participant is terminated for cause and the participant will not be permitted to exercise such award.

Awards Other Than Options and SARs.

Restricted Stock and Restricted Stock Units. Restricted shares are awards of shares, the grant, issuance, retention, vesting and/or transferability of which is subject during specified periods of time to such conditions (including continued employment) and terms as our board of directors deems appropriate. Restricted stock units ("RSUs") are an award denominated in units under which the issuance of shares (or cash payment in lieu thereof) is subject to such conditions (including continued employment) and terms as our board of directors deems appropriate. Each award document evidencing a grant of restricted stock or RSUs will set forth the terms and conditions of each award, including vesting and forfeiture provisions, transferability and, if applicable, right to receive dividends or dividend equivalents.

Performance Awards. A performance award is a stock or cash award that is payable contingent upon the attainment during a performance period of certain performance goals. A performance award may, but need not, require the completion of a specified period of service. The length of any performance period, the applicable performance goals and the measurement of whether and to what degree such performance goals have been attained will be as determined by the compensation committee, our board of directors or an authorized officer. We retain the discretion to reduce or eliminate the compensation or economic benefit upon the attainment of any performance goals and to define the manner of calculating the performance criteria it selects to use for a performance period.

Certain Adjustments. In the event of any change in our capitalization, our board of directors will appropriately and proportionately adjust: (i) the class(es) and maximum number of securities subject to the 2019 Plan; (ii) the class(es) and maximum number of securities that may be issued pursuant to the exercise of incentive stock options; and (iii) the class(es) and number of securities or other property and value (including price per share of stock) subject to outstanding stock awards. Our board of directors will make such adjustments, and its determination will be final, binding and conclusive. Unless provided otherwise in an award or other agreement, in the event of our dissolution or liquidation, all outstanding stock awards (other than stock awards consisting of

vested and outstanding shares of our common stock not subject to a forfeiture condition or the our right of repurchase) will terminate immediately prior to the completion of such dissolution or liquidation, and the shares of common stock subject to the our repurchase rights or subject to forfeiture may be repurchased or reacquired by us notwithstanding the fact that the holder of such stock award is providing continuous service; provided, however, that our board of directors may, in its sole discretion, provide that some or all stock awards will become fully vested, exercisable and/or no longer subject to repurchase or forfeiture (to the extent not already expired or terminated) before the dissolution or liquidation is completed but contingent upon its completion.

Change in Control. Unless provided otherwise in an award agreement or other agreement between us or an affiliate and the participant, in the event of Change in Control (as defined in the 2019 Plan), our board of directors will take one or more of the following actions with respect to each outstanding award, contingent upon the closing or completion of the Change in Control:

(i) arrange for the surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company) to assume or continue the award or to substitute a similar stock award for the award (including, but not limited to, an award to acquire the same consideration per share paid to the stockholders of the company pursuant to the Change in Control);

(ii) arrange for the assignment of any reacquisition or repurchase rights held by us in respect of common stock issued pursuant to the award to the surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company);

(iii) accelerate the vesting, in whole or in part, of the award (and, if applicable, the time at which the award may be exercised) to a date prior to the effective time of such Change in Control as determined by our board of directors, with such award terminating if not exercised (if applicable) at or prior to the effective time of the Change in Control, and with such exercise reversed if the Change in Control does not become effective;

(iv) arrange for the lapse, in whole or in part, of any reacquisition or repurchase rights held by us with respect to the award;

(v) cancel or arrange for the cancellation of the award, to the extent not vested or not exercised prior to the effective time of the Change in Control, in exchange for such cash consideration, if any, as our board of directors, in its reasonable determination, may consider appropriate as an approximation of the value of the canceled award; and

(vi) cancel or arrange for the cancellation of the award, to the extent not vested or not exercised prior to the effective time of the Change in Control, in exchange for a payment equal to the excess, if any, of (A) the value in the Change in Control of the property the participant would have received upon the exercise of the award immediately prior to the effective time of the Change in Control, over (B) any exercise price payable by such holder in connection with such exercise.

Our board of directors need not take the same action or actions with respect to all awards or portions thereof or with respect to all participants and may take different actions with respect to the vested and unvested portions of an award.

In the absence of any affirmative determination by our board of directors at the time of a Change in Control, each outstanding award will be assumed or an equivalent award will be substituted by such successor corporation or a parent or subsidiary of such successor corporation, referred to as a Successor Corporation, unless the Successor Corporation does not agree to assume the award or to substitute an equivalent award, in which case the vesting of such award will accelerate in its entirety (along with, if applicable, the time at which the award may be exercised) to a date prior to the effective time of such Change in Control as our board of directors will determine (or, if our board of directors does not determine such a date, to the date that is five days prior to the

effective date of the Change in Control), with such award terminating if not exercised (if applicable) at or prior to the effective time of the Change in Control, and with such exercise reversed if the Change in Control does not become effective.

Acceleration of Awards upon a Change in Control. An award may be subject to additional acceleration of vesting and exercisability upon or after a Change in Control as may be provided in the award agreement for such award or as may be provided in any other written agreement between us or an affiliate and the participant, but in the absence of such provision, no such acceleration will occur.

Termination and Amendment. Our board of directors or the compensation committee may suspend or terminate the 2019 Plan at any time. No incentive stock options may be granted under the 2019 Plan after the tenth anniversary of the date our board of directors adopted the 2019 Plan. No awards may be granted under the 2019 Plan while the 2019 Plan is suspended or after it is terminated.

401(k) Plan

The Company offers eligible employees, including its NEO based in the United States, the opportunity to participate in its tax-qualified 401(k) plan. Employees can contribute 1%-100% of their eligible earnings up to the Internal Revenue Service's annual limits on a before-tax basis. For every dollar an employee contributes up to 6% of their compensation, the Company may contribute 25 cents per dollar, provided that there are no matching contributions in excess of 1.5% of eligible IRS compensation. The Company match provided to our Chief Executive Officer in 2018 is reflected in the "All Other Compensation" column of the 2018 Summary Compensation Table above. The Company funds are 100% vested after the completion of one year of service.

Other Retirement Benefits

We do not maintain any defined benefit pension plans or any nonqualified deferred compensation plans.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following is a summary of each transaction or series of similar transactions since January 18, 2018, our inception, or any currently proposed transaction, to which we were or are a party in which:

- the amount involved exceeded or exceeds $120,000 or one percent of our total assets at December 31, 2018; and
- any of our directors or executive officers or any beneficial owners of 5% of any class of our voting capital stock or and affiliate or immediate family member thereof, had or will have a direct or indirect material interest, other than compensation and other arrangements that are described under the section titled “Executive Compensation” or that were approved by our compensation committee.

Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to such securities.

Related Party Transactions

Sales of Securities

In April 2018, with subsequent closings in December 2018 and June and July 2019, we issued an aggregate of 44,000,000 shares of our Series A convertible preferred shares at a purchase price of $1.00 per share pursuant to a share purchase agreement entered into with investors, for an aggregate purchase price of approximately $44.0 million. Each share of our Series A convertible preferred shares will automatically convert into one share of our common stock immediately prior to the completion of this offering. Additionally, in April 2018, we issued 3,797,750 shares of our ordinary shares to OrbiMed Israel Partners II, L.P. and OrbiMed Private Investments VI, L.P., for total proceeds of $10,994. All purchasers of our convertible preferred shares are entitled to specified registration rights. See “Description of Capital Stock—Registration Rights” for more information regarding these registration rights. The following table summarizes purchases of our Series A convertible preferred shares by related persons:

Participant	Shares of Series A Convertible Preferred Shares		Total Purchase Price
Entities affiliated with OrbiMed(1)	15,888,888	$	15,888,888
Entities affiliated with Pontifax(2)	5,500,001	$	5,500,001
Entities affiliated with RA Capital(3)	10,327,777	$	10,327,777
Longitude Venture Partners III, L.P.(4)	11,916,667	$	11,916,667
Genworks 2 Consulting Inc.(5)	366,667	$	366,667

(1) OrbiMed Israel Partners II, L.P. (“OrbiMed Israel”) together with its affiliate fund OrbiMed Private Investments VI, L.P. is a holder of 5% or more of our capital stock. Anat Naschitz is a managing director at OrbiMed Israel and a member of our board of directors.
(2) Pontifax (Israel) V L.P., together with its affiliate funds Pontifax (Cayman) V L.P. and Pontifax (China) V L.P., is a holder of 5% or more of our capital stock. Tomer Kariv is co-founder and managing partner of the Pontifax Group and a member of our board of directors.
(3) RA Capital Healthcare Fund, L.P. together with its affiliate funds Blackwell Partners LLC - Series A and RA Capital Nexus Fund, L.P. is a holder of 5% or more of our capital stock. Derek DiRocco is a principal at RA Capital Management, LLC and a member of our board of directors.
(4) Longitude Venture Partners III, L.P. is a holder of 5% or more of our capital stock. Gregory Grunberg, M.D. is a Managing Director at Longitude Capital Management Co., LLC and a member of our board of directors.
(5) Dr. Michael Hayden, a member of our board of directors, is affiliated with Genworks 2 Consulting Inc.

Investors' Rights Agreement

We are a party to an investors' rights agreement, effective as of September 17, 2019 (the "IRA"), with the holders of our Series A convertible preferred shares, including our 5% stockholders and entities affiliated with our directors. The IRA provides these holders the right, following the completion of this offering, to demand that we file a registration statement or request that their shares be covered by a registration statement that we are otherwise filing. See "Description of Capital Stock—Registration Rights" for additional information regarding these registration rights. The IRA also provides such holders a right of first offer to purchase future securities sold by us, which such right shall terminate immediately prior to the consummation of this offering and do not apply to the shares of common stock issued pursuant to this registration statement. See "Description of Capital Stock—Registration Rights" for additional information regarding these registration rights.

Voting Agreement

We are party to a voting agreement, effective as of September 17, 2019 (the "Voting Agreement"), with the holders of our Series A convertible preferred shares, including our 5% stockholders and entities affiliated with our directors. Each of our 5% stockholders have appointed representatives to our board of directors. The voting agreement will terminate upon the completion of this offering, and members previously elected to our board of directors pursuant to this agreement will continue to serve as directors until they resign, are removed or their successors are duly elected by the holders of our common stock. The composition of our board of directors after this offering is described in more detail under "Management—Composition of Our Board of Directors."

Right of First Refusal and Co-Sale Agreement

We are a party to a right of first refusal and co-sale agreement, effective as of September 17, 2019 (the "ROFR Agreement"), with the holders of our Series A convertible preferred shares, including our 5% stockholders and entities affiliated with our directors. The ROFR Agreement will terminate upon completion of this offering.

Employment Agreements

We have entered into employment agreements with our named executive officers. For more information regarding the agreements with our named executive officers, see "Executive Compensation—Employment Agreements."

Director Compensation

See "Director Compensation" for information regarding compensation of our directors.

Indemnification Agreements

In connection with this offering, we entered into agreements to indemnify our directors and executive officers. These agreements will, among other things, require us to indemnify these individuals for certain expenses (including attorneys' fees), judgments, fines and settlement amounts reasonably incurred by such person in any action or proceeding, including any action by or in our right, on account of any services undertaken by such person on behalf of our company or that person's status as a member of our board of directors to the maximum extent allowed under Delaware law.

Stock Option Grants to Executive Officers and Directors

We have granted stock options to our executive officers and certain of our directors as more fully described in the sections entitled "Executive Compensation" and "Management—Director Compensation."

PRINCIPAL STOCKHOLDERS

The following table presents information regarding beneficial ownership of our equity interests as of September 30, 2019 by:

- each stockholder or group of stockholders known by us to be the beneficial owner of more than 5% of our outstanding equity interests (our "5% and Greater Stockholders");
- each of our directors;
- our NEOs; and
- all of our directors and executive officers as a group.

Beneficial ownership is determined in accordance with the rules of the SEC, and thus represents voting or investment power with respect to our securities as of September 30, 2019. Under such rules, beneficial ownership includes any shares over which the individual has sole or shared voting power or investment power as well as any shares that the individual has the right to acquire within 60 days after September 30, 2019 through the exercise of any stock option, warrants or other rights. Unless otherwise indicated below, to our knowledge and subject to applicable community property rules, the persons and entities named in the table have sole voting and sole investment power with respect to all equity interests beneficially owned. Unless otherwise indicated, the address of each individual listed in this table is 535 Mission Street, 14th Floor, San Francisco, CA 94105.

The percentage ownership information shown in the column titled "Shares Beneficially Owned Prior to the Offering" in the table below is based on 47,800,000 shares of our common stock outstanding as of September 30, 2019, which includes 44,000,000 shares of our common stock resulting from the conversion of all outstanding shares of our convertible preferred stock into our common stock immediately prior to the completion of this offering, as if this conversion had occurred as of September 30, 2019. The percentage ownership information shown in the column titled "Shares Beneficially Owned After the Offering" in the table below is based on shares of our common stock outstanding after this offering, assuming shares of common stock being sold in this offering. Shares of our common stock that a person has the right to acquire within 60 days after September 30, 2019 are deemed outstanding for purposes of computing the percentage ownership of the person holding such rights, but are not deemed outstanding for purposes of computing the percentage ownership of any other person, except with respect to the percentage ownership of all directors and executive officers as a group.

	Shares Beneficially Owned Prior to the Offering		Shares Beneficially Owned After the Offering	
Name and Address of Beneficial Owner	Number	Percent	Number	Percent
5% and Greater Stockholders				
Entities affiliated with OrbiMed(1)	19,688,888	41.2%		%
Longitude Venture Partners III, L.P.(2)	11,916,667	24.9%		%
Entitles affiliated with RA Capital(3)	10,327,777	21.6%		%
Entities affiliated with Pontifax(4)	5,500,001	11.5%		%
Named Executive Officer and Directors				
Rohan Palekar(5)	631,865	1.3%		%
Ram Waisbourd(6)	285,149	*		%
Derek DiRocco	—	*		
Gregory Grunberg(2)	11,916,667	24.9%		
Michael Hayden(7)	594,786	1.2%		
Tomer Kariv(4)	5,500,001	11.5%		
Anat Naschitz	—	*		
All Executive Officers and Directors as a group (10 persons)	**18,928,467**	**39.6%**		**%**

* Represents beneficial ownership of less than one percent.

(1) Consists of (a) 1,900,000 shares of common stock owned by OrbiMed Israel Partners II, L.P., (b) 1,900,000 shares of common stock owned by OrbiMed Private Investments VI, L.P., (c) 7,944,444 shares of convertible preferred stock owned by OrbiMed Israel Partners II, L.P., and (d) 7,944,444 shares of convertible preferred stock owned by OrbiMed Private Investments VI, L.P. The business address of OrbiMed Israel Partners II, L.P. ("OIP II") is 89 Medinat Hayehudim St., building E, Herzliya 4614001 Israel. OrbiMed Israel GP II, L.P. ("Israel GP II") is the general partner of OIP II, and OrbiMed Advisors Israel II Limited ("Advisors Israel II") is the general partner of Israel GP II. Advisors Israel II and Israel GP II may be deemed to have shared voting and investment power over all of the shares of common and convertible preferred stock held by OIP II, and both Advisors Israel II and Israel GP II may be deemed to directly or indirectly, including by reason of their mutual affiliation, to be the beneficial owners of the shares held by OIP II. Advisors Israel II exercises this investment power through an investment committee comprised of Carl L. Gordon, Jonathan T. Silverstein, Nissim Darvish, Anat Naschitz, and Erez Chimovits, each of whom disclaims beneficial ownership of the shares held by OIP II.

(2) Consists of 11,916,667 shares of convertible preferred stock. Longitude Capital Partners III, LLC ("LCP III") is the general partner of Longitude Venture Partners III, L.P. ("LVP III") and may be deemed to have shared voting, investment and dispositive power over the shares held by LVP III. Patrick G. Enright and Juliet Tammenoms Bakker are managing members of LCP III and in their capacity as such, may be deemed to exercise shared voting and investment power over the shares held by LCP III and LVP III. Gregory Grunberg is a member of LCP III. Each of these individuals disclaims beneficial ownership of such shares except to the extent of his or her pecuniary interest therein. Gregory Grunberg shares in the control of the Company securities held directly or indirectly by LVP III/LCP III due to (a) his beneficial ownership in the Company's shares and (b) his position as a director of the Company. The mailing address of Longitude Venture Partners III, L.P. is 2740 Sand Hill Road, 2nd Floor, Menlo Park, CA 94025.

(3) Consists of (a) 7,369,105 shares of convertible preferred stock owned by RA Capital Healthcare Fund, L.P., or RA Capital Fund, (b) 1,785,061 shares of convertible preferred stock owned by a separately managed account (the "Account"), and (c) 1,173,611 shares of convertible preferred stock owned by RA Capital Nexus Fund, L.P. (the "RA Capital Nexus Fund"). Dr. Peter Kolchinsky is the managing member of RA Capital Management, LLC ("RA Capital"), the general partner and investment advisor of RA Capital Fund and the investment advisor of the Account and RA Capital Nexus Fund. Dr. Kolchinsky and RA Capital may be deemed to beneficially own the shares held by RA Capital Fund, the Account and RA Capital Nexus Fund. Dr. Kolchinsky and RA Capital disclaim beneficial ownership of all applicable shares except to the extent of their actual pecuniary interest therein. The mailing address for the entities listed above is 200 Berkeley Street, 18th Floor, Boston, MA 02116.

(4) Consists of (a) 3,322,005 shares of convertible preferred stock owned by Pontifax (Israel) V, L.P., (b) 887,328 shares of convertible preferred stock owned by Pontifax (Cayman) V, L.P., and (c) 1,290,668 shares of convertible preferred stock owned by Pontifax (China) V, L.P. (together, the "Pontifax Entities") Pontifax 5 G.P. L.P., or Pontifax 5 G.P., is the general partner of each of the Pontifax Entities, and Pontifax Management 4 G.P. (2015) Ltd., or Pontifax Management, is the general partner of Pontifax 5 G.P. Mr. Tomer Kariv, a member of our board of directors, and Mr. Ran Nussbaum, are the Managing Partners of Pontifax Management and, as a result, may be deemed to share voting and investment power with respect to the shares held by each of the Pontifax Entities. In that context, Mr. Kariv disclaims beneficial ownership of such shares, except to the extent of his pecuniary interest therein, and the inclusion of the shares in this report shall not be deemed to be an admission of beneficial ownership of the reported shares for purposes of Section 16 of the Securities Exchange Act of 1934, as amended, or otherwise. The address of each of the Pontifax Entities is c/o The Pontifax Group, 14 Shenkar Street, Herzelia, Israel.

(5) Consists of 631,865 shares of common stock underlying options that are exercisable as of September 30, 2019 or will become exercisable within 60 days after such date.

(6) Consists of 285,149 shares of common stock underlying options that are exercisable as of September 30, 2019 or will become exercisable within 60 days after such date.

(7) Consists of (a) 366,667 shares of convertible preferred stock owned by Genworks 2 Consulting Inc., over which Dr. Hayden's wife has sole voting and investment power, and (b) 228,119 shares of common stock underlying options that are exercisable as of September 30, 2019 or will become exercisable within 60 days after such date. The address of Genworks 2 Consulting Inc. is 4484 West 7th Avenue, Vancouver, BC, Canada V6R1W9.

DESCRIPTION OF CAPITAL STOCK

General

The following is a summary of the material terms of our capital stock, as well as other material terms of our Amended Certificate and Amended Bylaws, as each will be in effect prior to the closing of this offering, and certain provisions of Delaware law. This summary does not purport to be complete and is qualified in its entirety by the provisions of our Amended Certificate and Amended Bylaws, copies of which will be filed with the SEC as exhibits to the registration statement, of which this prospectus forms a part.

Upon the completion of this offering, our authorized capital stock will consist of shares of common stock, $0.001 par value per share, and shares of preferred stock, $0.001 par value per share.

As of October 11, 2019, 3,800,000 shares of our common stock and 44,000,000 shares of convertible preferred stock were outstanding and held by 10 stockholders of record. This amount does not take into account the conversion of all outstanding shares of our convertible preferred stock into common stock upon the completion of this offering.

Common Stock

Our Amended Certificate will authorize the issuance of up to shares of our common stock. All outstanding shares of our common stock are validly issued, fully paid and nonassessable, and the shares of our common stock to be issued in connection with this offering will be validly issued, fully paid and nonassessable.

The holders of our common stock will be entitled to one vote per share on all matters submitted to a vote of stockholders, and our Amended Certificate will not provide for cumulative voting in the election of directors. The holders of our common stock will receive ratably any dividends declared by our board of directors out of funds legally available therefor. In the event of our liquidation, dissolution or winding-up, the holders of our common stock will be entitled to share ratably in all assets remaining after payment of or provision for any liabilities.

Preferred Stock

As of October 11, 2019, there were 44,000,000 shares of our preferred stock outstanding, which will convert into 44,000,000 shares of our common stock upon the closing of this offering such that we will have no shares of preferred stock outstanding. Under the terms of our Amended Certificate, upon the consummation of this offering, our board of directors will have the authority, without further action by our stockholders, to issue up to shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the dividend, voting and other rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon, and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of our common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in our control and may adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock. We have no current plans to issue any shares of preferred stock.

Registration Rights

Upon the completion of this offering, the holders of shares of our common stock, including those issuable upon the conversion of convertible preferred stock will be entitled to rights with respect to the registration of these securities under the Securities Act. These rights are provided under the terms of the IRA. The IRA includes demand registration rights, short-form registration rights and piggyback registration rights. All fees, costs and expenses of underwritten registrations under this agreement will be borne by us and all selling expenses, including underwriting discounts and selling commissions, will be borne by the holders of the shares being registered.

Demand Registration Rights

Beginning 180 days after the effective date of this registration statement, the holders of shares of our common stock, including those issuable upon the conversion of convertible preferred stock upon completion of this offering, are entitled to demand registration rights. Under the terms of the IRA, we will be required, upon the written request of at least 50% of the holders of the registrable securities, including either OrbiMed Israel Partners II, L.P. or OrbiMed Private Investments VI, LP, provided that the anticipated aggregate offering price is at least $10 million, to file a registration statement on Form S-1 and use commercially reasonable efforts to effect the registration of these shares for public resale. The right to have such shares registered on Form S-1 is further subject to other specified conditions and limitations.

Piggyback Registration Rights

Pursuant to the IRA, if we register any of our common stock either for our own account or for the account of other security holders, the holders of Registrable Shares party to the IRA are entitled to include their shares in the registration, subject to certain marketing and other limitations. We may terminate or withdraw any registration initiated before the effective date of such registration in our sole discretion.

Form S-3 Registration Rights

Pursuant to the IRA, if we are eligible to file a registration statement on Form S-3, upon the written request of at least 10% of the holders of registrable securities to sell registrable securities at an aggregate price of at least $5 million, we will be required to use commercially reasonable efforts to effect a registration of such shares. The right to have such shares registered on Form S-3 is further subject to other specified conditions and limitations.

Anti-Takeover Effects of Our Amended Certificate, Amended Bylaws and Delaware Law

Our Amended Certificate and our Amended Bylaws, both to become effective upon the completion of this offering, include a number of provisions that may have the effect of delaying, deferring or preventing another party from acquiring control of us and encouraging persons considering unsolicited tender offers or other unilateral takeover proposals to negotiate with our board of directors rather than pursue non-negotiated takeover attempts.

- ***Issuance of undesignated preferred stock:*** Under our Amended Certificate, our board of directors has the authority, without further action by the stockholders, to issue up to shares of undesignated preferred stock with rights and preferences, including voting rights, designated from time to time by our board of directors. The existence of authorized but unissued shares of preferred stock enables our board of directors to make it more difficult to attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise.

- ***Classified board*****:** Our Amended Certificate establishes a classified board of directors consisting of three classes of directors, with staggered three-year terms. Only one class of directors will be

elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. This provision may have the effect of delaying a change in control of our board of directors.

- ***Election and removal of directors and board vacancies*:** Our Amended Bylaws provide that directors will be elected by a plurality vote. Our Amended Certificate and Amended Bylaws also provide that our board of directors has the right to increase or decrease the size of the board and to fill vacancies on the board. Directors may be removed only for cause by the affirmative vote of the holders of at least 66⅔% of the votes that all our stockholders would be entitled to cast in an annual election of directors. Only our board of directors is authorized to fill vacant directorships. In addition the number of directors constituting our board of directors may be set only by resolution adopted by a majority vote of the directors then in office. These provisions prevent stockholders from increasing the size of our board of directors and gaining control of our board of directors by filling the resulting vacancies with its own nominees.

- ***Requirements for advance notification of stockholder nominations and proposals*:** Our Amended Bylaws establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors that specify certain requirements as to the timing, form and content of a stockholder's notice. Business that may be conducted at an annual meeting of stockholders will be limited to those matters properly brought before the meeting. These provisions may make it more difficult for our stockholders to bring matters before our annual meeting of stockholders or to nominate directors at annual meetings of stockholders.

- ***No written consent of stockholders*:** Our Amended Certificate provides that all stockholder actions be taken by a vote of the stockholders at an annual or special meeting, and that stockholders may not take any action by written consent in lieu of a meeting. This limit may lengthen the amount of time required to take stockholder actions and would prevent the amendment of our Amended Bylaws or removal of directors by our stockholders without holding a meeting of stockholders.

- ***No stockholder ability to call special meetings*:** Our Amended Certificate and Amended Bylaws provide that only a majority of the members of our board of directors then in office may be able to call special meetings of stockholders and only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders.

- ***Amendments to certificate of incorporation and bylaws:*** Any amendment to our Amended Certificate will be required to be approved by a majority of our board of directors as well as, if required by law or the Amended Certificate, a majority of the outstanding shares entitled to vote on the amendment and a majority of the outstanding shares of each class entitled to vote thereon as a class, except that the amendment of provisions to board classification, stockholder action, certificate amendments, and liability of directors must be approved by not less than 66⅔% of the outstanding shares entitled to vote on the amendment, voting together as a single class. Any amendment to our Amended Bylaws must be approved by either a majority of our board of directors or not less than 66⅔% of the outstanding shares entitled to vote on the amendment, voting together as a single class.

These provisions are designed to enhance the likelihood of continued stability in the composition of our board of directors and its policies, to discourage certain types of transactions that may involve an actual or threatened acquisition of us and to reduce our vulnerability to an unsolicited acquisition proposal. We also designed these provisions to discourage certain tactics that may be used in proxy fights. However, these provisions could have the effect of discouraging others from making tender offers for our shares and, as a consequence, they may also reduce fluctuations in the market price of our shares that could result from actual or rumored takeover attempts.

Section 203 of the Delaware General Corporation Law

Upon completion of this offering, we will be subject to the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner.

Choice of Forum

Our Amended Certificate requires that the Court of Chancery of the State of Delaware be the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a breach of fiduciary duty owed by any director, officer or other employee to us or our stockholders; (3) any action asserting a claim against us or any director or officer or other employee arising pursuant to the Delaware General Corporation Law, our Amended Certificate or Amended Bylaws; or (4) any action asserting a claim against us or any director or officer or other employee that is governed by the internal affairs doctrine. This provision would not apply to claims brought to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Our Amended Certificate provides further that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, subject to and contingent upon a final adjudication in the State of Delaware of the enforceability of such exclusive forum provision. Although we believe these provisions benefit us by providing increased consistency in the application of Delaware law for the specified types of actions and proceedings, the provisions may have the effect of discouraging lawsuits against us or our directors or officers.

Transfer Agent and Registrar

will serve as the transfer agent and registrar for our common stock.

Listing

We intend to apply to list our common stock on The Nasdaq Global Market under the symbol "ETNB."

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for shares of our common stock. Future sales of our common stock, including shares issued upon the vesting of restricted stock units or the exercise of options or warrants, in the public market after this offering, or the perception that those sales may occur, could cause the prevailing market price for our common stock to fall or impair our ability to raise equity capital in the future. As described below, only a limited number of shares of our common stock will be available for sale in the public market for a period of several months after the completion of this offering due to the contractual and legal restrictions on resale described below. Future sales of our common stock in the public market either before (to the extent permitted) or after restrictions lapse, or the perception that those sales may occur, could adversely affect the prevailing market price of our common stock at such time and our ability to raise equity capital at a time and price we deem appropriate.

Sale of Restricted Shares

Immediately following the completion of this offering, we will have an aggregate of shares of common stock outstanding. Of the outstanding shares of our common stock, the shares sold in this offering (or shares if the underwriters exercise in full their option to purchase additional shares) will be freely tradable without restriction or further registration under the Securities Act, except that any shares held by our affiliates, as that term is defined in Rule 144 of the Securities Act, may generally be sold only in compliance with the limitations described below. All remaining shares of our common stock held by existing stockholders immediately prior to the closing of this offering will be "restricted securities" as such term is defined in Rule 144. These restricted securities were issued and sold by us, or will be issued and sold by us, in private transactions and are eligible for public sale only if registered under the Securities Act or if they qualify for an exemption from registration under the Securities Act, including the exemptions provided by Rule 144 or Rule 701, which rules are summarized below.

Lock-Up Agreements

We and all of our directors and officers, as well as the other holders of substantially all shares of our common stock outstanding immediately prior to the completion of this offering, have agreed with the underwriters that, for a period of 180 days following the date of this prospectus, subject to certain exceptions, we and they will not, directly or indirectly, offer, sell, contract to sell, pledge, grant any option to purchase, make any short sale or otherwise dispose of any of shares of our common stock, or any options or warrants to purchase any shares of our common stock, or any securities convertible into, or exchangeable for or that represent the right to receive shares of our common stock. BofA Securities, Inc., SVB Leerink LLC and RBC Capital Markets, LLC may, in their discretion, release all or any portion of the shares from these restrictions.

Rule 144

In general, under Rule 144, as currently in effect, once we have been subject to the public company reporting requirements of the Exchange Act for at least 90 days, a person (or persons whose shares are required to be aggregated) who is not deemed to have been one of our "affiliates" for purposes of Rule 144 at any time during the three months preceding a sale, and who has beneficially owned restricted securities within the meaning of Rule 144 for at least 6 months, including the holding period of any prior owner other than one of our "affiliates," is entitled to sell those shares in the public market (subject to the lock-up agreement referred to above, if applicable) without complying with the manner of sale, volume limitations or notice provisions of Rule 144, but subject to compliance with the public information requirements of Rule 144. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than affiliates, then such person is entitled to sell such shares in the public market without complying with any of the requirements of Rule 144 (subject to the lock-up agreement referred to above, if applicable). In general, under Rule 144, as currently in effect, once we have been subject to the public company

reporting requirements of the Exchange Act for at least 90 days, our affiliates, as defined in Rule 144, who have beneficially owned the shares proposed to be sold for at least 6 months are entitled to sell in the public market, upon expiration of any applicable lock-up agreements and within any three-month period, a number of those shares of our common stock that does not exceed the greater of:

- one percent of the number of shares of our common stock then outstanding, which will equal approximately shares of our common stock immediately after this offering (calculated on the basis of the assumptions described above and assuming no exercise of the underwriter's option to purchase additional shares of our common stock); or

- the average weekly trading volume of our common stock on The Nasdaq Global Market during the 4 calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Such sales under Rule 144 by our "affiliates" or persons selling shares on behalf of our "affiliates" are also subject to certain manner of sale provisions, notice requirements and to the availability of current public information about us. Notwithstanding the availability of Rule 144, the holders of substantially all of our restricted securities have entered into lock-up agreements as referenced above and their restricted securities will become eligible for sale (subject to the above limitations under Rule 144) upon the expiration of the restrictions set forth in those agreements.

Upon expiration of the 180-day lock-up period described above, shares of our common stock will be eligible for sale under Rule 144 (including shares issued pursuant to Rule 701 described below). We cannot estimate the timing or the number of shares that our existing stockholders and other equity holders may elect to sell under Rule 144 or pursuant to Form S-8 registration statements. See "Description of Capital Stock—Registration Rights."

Rule 701

In general, under Rule 701 as currently in effect, any of our employees, directors, officers, consultants or advisors who acquired common stock from us in connection with a written compensatory stock or option plan or other written agreement in compliance with Rule 701 under the Securities Act before the effective date of the registration statement of which this prospectus is a part (to the extent such common stock is not subject to a lock-up agreement) is entitled to rely on Rule 701 to resell such shares beginning 90 days after we become subject to the public company reporting requirements of the Exchange Act in reliance on Rule 144, but without compliance with the holding period requirements contained in Rule 144. Accordingly, subject to any applicable lock-up agreements, beginning 90 days after we become subject to the public company reporting requirements of the Exchange Act, under Rule 701, persons who are not our affiliates, as defined in Rule 144, may resell those shares without complying with the minimum holding period or public information requirements of Rule 144, and persons who are our affiliates may resell those shares without compliance with Rule 144's minimum holding period requirements (subject to the terms of the lock-up agreements referred to above, if applicable). In addition, after the effective date of this offering, we plan to register on a Form S-8 registration statement all shares of our common stock that we may issue under our equity compensation plans. As a result, these shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates.

Upon expiration of the 180-day lock-up period described above, shares of our common stock will be eligible for sale under Rule 144 (including shares issued pursuant to Rule 701). We cannot estimate the timing or the number of shares that our existing stockholders and other equity holders may elect to sell under Rule 144 or pursuant to registration statements. For a description of certain registration rights granted, see "Description of Capital Stock—Registration Rights."

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS

The following discussion is a summary of material U.S. federal income tax consequences to Non-U.S. Holders (as defined below) of the purchase, ownership and disposition of our common stock issued pursuant to this offering. The discussion does not purport to be a complete analysis of all potential tax consequences. The consequences of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local or non-U.S. tax laws, are not discussed. This discussion is based on the U.S. Internal Revenue Code of 1986, as amended (the "Code"), Treasury Regulations promulgated under the Code, judicial decisions and published rulings and administrative pronouncements of the U.S. Internal Revenue Service (the "IRS"), in each case in effect as of the date hereof. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a Non-U.S. Holder of our common stock. We have not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position to that discussed below regarding the tax consequences of the purchase, ownership and disposition of our common stock.

This discussion is limited to Non-U.S. Holders that purchase our common stock pursuant to this offering and hold our common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to a Non-U.S. Holder's particular circumstances, including without limitation the impact of the Medicare contribution tax on net investment income. In addition, it does not address consequences relevant to Non-U.S. Holders subject to special rules, including, without limitation:

- U.S. expatriates and former citizens or long-term residents of the United States;
- persons subject to the alternative minimum tax;
- persons holding our common stock as part of a hedge, straddle or other risk-reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, investment funds, insurance companies and other financial institutions;
- brokers, dealers or traders in securities;
- "controlled foreign corporations," "passive foreign investment companies" and corporations that accumulate earnings to avoid U.S. federal income tax;
- partnerships or other entities or arrangements classified as partnerships for U.S. federal income tax purposes (and investors therein);
- tax-exempt organizations or governmental organizations;
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- persons required to accelerate the recognition of any item of gross income with respect to our common stock as a result of such income being recognized on an applicable financial statement;
- persons that own, or have owned, actually or constructively, more than 5% of our common stock;
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation; and
- tax-qualified retirement plans.

This discussion is for informational purposes only and is not tax advice. Investors should consult their tax advisors with respect to the application of the U.S. federal income tax laws to their particular situations as well as any tax consequences of the purchase, ownership and disposition of our common stock arising under the U.S. federal estate or gift tax laws or under the laws of any state, local or non-U.S. taxing jurisdiction or under any applicable income tax treaty.

Definition of a Non-U.S. Holder

For purposes of this discussion, a "Non-U.S. Holder" is any beneficial owner of our common stock that is not a "U.S. person." A "U.S. person" is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized under the laws of the United States, any state thereof or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that: (i) is subject to the primary supervision of a U.S. court and the control of one or more "United States persons" (within the meaning of Section 7701(a)(30) of the Code); or (ii) has a valid election in effect to be treated as a U.S. person for U.S. federal income tax purposes.

Distributions

If we make distributions of cash or other property on our common stock, those distributions will generally constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If the amount of such distributions exceed our current and accumulated earnings and profits, such excess will generally constitute a tax-free return of capital and will first be applied against and reduce a Non-U.S. Holder's adjusted tax basis in its common stock, but not below zero. Any excess will be treated as capital gain and will be treated as described below under "Sale or Other Taxable Disposition."

Subject to the discussion below on effectively connected income, dividends paid to a Non-U.S. Holder of our common stock generally will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends (or such lower rate specified by an applicable income tax treaty, provided the Non-U.S. Holder furnishes the applicable withholding agent with documentation required to claim benefits under such tax treaty (generally, a valid IRS Form W-8BEN or W-8BEN-E or a suitable successor or substitute form)). This certification must be provided before the payment of dividends and must be updated periodically. A Non-U.S. Holder that does not timely furnish the required documentation, but that qualifies for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. Holders should consult their tax advisors regarding U.S. federal withholding tax on distributions, including their eligibility for benefits under any applicable income tax treaties and the availability of a refund on any excess U.S. federal tax withheld.

If dividends paid to a Non-U.S. Holder are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (or, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such dividends are attributable), the Non-U.S. Holder will generally be exempt from the U.S. federal withholding tax described above. To claim the exemption, the Non-U.S. Holder must furnish to the applicable withholding agent a valid IRS Form W-8ECI (or a suitable successor or substitute form) certifying that the dividends are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States.

However, any such effectively connected dividends will be subject to U.S. federal income tax on a net income basis at the regular graduated rates applicable to U.S. persons. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected dividends, as adjusted for certain items. Non-U.S. Holders should consult their tax advisors regarding any applicable tax treaties that may provide for different rules.

The foregoing discussion is subject to the discussion below under "Additional Withholding Tax on Payments Made to Foreign Accounts" and "Information Reporting and Backup Withholding."

Sale or Other Taxable Disposition

Subject to the discussion below regarding backup withholding and the Foreign Account Tax Compliance Act ("FATCA"), a Non-U.S. Holder generally will not be subject to U.S. federal income or withholding tax on any gain realized upon the sale or other taxable disposition of our common stock unless:

- the gain is effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (or, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such gain is attributable);
- the Non-U.S. Holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition and certain other requirements are met; or
- our common stock constitutes a U.S. real property interest ("USRPI") by reason of our status as a U.S. real property holding corporation ("USRPHC") for U.S. federal income tax purposes.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular graduated rates applicable to U.S. persons. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected gain, as adjusted for certain items.

Gain described in the second bullet point above will be subject to U.S. federal income tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty), which may be offset by U.S. source capital losses of the Non-U.S. Holder (even though the individual is not considered a resident of the United States), provided the Non-U.S. Holder has timely filed U.S. federal income tax returns with respect to such losses.

With respect to the third bullet point above, we believe we currently are not, and we do not anticipate becoming, a USRPHC. However, because the determination of whether we are a USRPHC depends on the fair market value of our USRPIs relative to the fair market value of our non-U.S. real property interests and our other business assets, we cannot assure you that we will not become a USRPHC in the future. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition by a Non-U.S. Holder of our common stock will not be subject to U.S. federal income tax if our common stock is "regularly traded" on an "established securities market" (as such terms are defined by applicable Treasury Regulations), and such Non-U.S. Holder owned, actually and constructively, 5% or less of our common stock throughout the shorter of the 5-year period ending on the date of the sale or other taxable disposition or the Non-U.S. Holder's holding period. If we are determined to be a USRPHC and the foregoing exception does not apply, the Non-U.S. Holder generally will be taxed on its net gain derived from the disposition at the graduated U.S. federal income tax rates applicable to U.S. persons and, in addition, a purchaser of our common stock may be required to withhold tax with respect to that obligation. No assurance can be provided that our common stock will be regularly traded on an established securities market for purposes of the rules described above.

Non-U.S. Holders should consult their tax advisors regarding potentially applicable income tax treaties that may provide for different rules.

Information Reporting and Backup Withholding

Payments of dividends on our common stock generally will not be subject to backup withholding provided the applicable withholding agent does not have actual knowledge or reason to know the Non-U.S. Holder is a U.S. person and the Non-U.S. Holder certifies its non-U.S. status by furnishing a valid IRS Form W-8BEN, W-8BEN-E, W-8ECI, W-8EXP, or other applicable IRS form, or otherwise establishes an exemption. Information returns are required to be filed with the IRS in connection with any dividends on our common stock paid to the Non-U.S. Holder, regardless of whether any tax was actually withheld. Copies of these information returns may also be made available under the provisions of an applicable treaty or agreement to the tax authorities of the country in which the Non-U.S. Holder resides or is established.

Information reporting and, depending on the circumstances, backup withholding generally will apply to the proceeds of the sale or other taxable disposition of our common stock within the United States or conducted through certain U.S.-related brokers, unless the applicable withholding agent receives the certification described above and does not have actual knowledge or reason to know that the Non-U.S. Holder is a U.S. person, or the holder otherwise establishes an exemption. Proceeds of a disposition of our common stock conducted through a non-U.S. office of a non-U.S. broker that does not have certain enumerated relationships with the United States generally will not be subject to backup withholding or information reporting.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a Non-U.S. Holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

Additional Withholding Tax on Payments Made to Foreign Accounts

Withholding taxes may be imposed under Sections 1471 to 1474 of the Code (such Sections commonly referred to as FATCA) on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends on, and subject to the discussion of certain proposed U.S. Treasury regulations below, the gross proceeds from the sale or other disposition of, our common stock paid to a "foreign financial institution" or a "non-financial foreign entity" (each as defined in the Code), unless: (i) the foreign financial institution undertakes certain diligence, reporting and withholding obligations; (ii) the non-financial foreign entity either certifies it does not have any "substantial U.S. owners" (as defined in the Code) or furnishes identifying information regarding each substantial U.S. owner; or (iii) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence, reporting and withholding requirements in (i) above, it must enter into an agreement with the U.S. Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain "specified U.S. persons" or "United States owned foreign entities" (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on certain payments to noncompliant foreign financial institutions and certain other account holders. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules.

The U.S. Treasury recently released proposed regulations which, if finalized in their present form, would eliminate the federal withholding tax of 30% applicable to the gross proceeds of a sale or other disposition of our common stock. In its preamble to such proposed regulations, the U.S. Treasury stated that taxpayers may generally rely on the proposed regulations until final regulations are issued. There can be no assurance that final regulations would provide an exemption from the FATCA withholding tax for gross proceeds. The FATCA withholding tax generally applies to all withholdable payments without regard to whether the beneficial owner of the payment would otherwise be entitled to an exemption from imposition of withholding tax pursuant to an applicable tax treaty with the United States or U.S. domestic law.

Prospective investors should consult their tax advisors regarding the potential application of withholding under FATCA to their investment in our common stock.

UNDERWRITING

BofA Securities, Inc., SVB Leerink LLC and RBC Capital Markets, LLC are acting as representatives of each of the underwriters named below. Subject to the terms and conditions set forth in an underwriting agreement among us and the underwriters, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the number of shares of common stock set forth opposite its name below.

Underwriter	Number of Shares
BofA Securities, Inc.	
SVB Leerink LLC	
RBC Capital Markets, LLC	
Oppenheimer & Co. Inc.	
Total	

Subject to the terms and conditions set forth in the underwriting agreement, the underwriters have agreed, severally and not jointly, to purchase all of the shares sold under the underwriting agreement if any of these shares are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the non-defaulting underwriters may be increased or the underwriting agreement may be terminated.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriters may be required to make in respect of those liabilities.

The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, including the validity of the shares, and other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officer's certificates and legal opinions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Commissions and Discounts

The representatives have advised us that the underwriters propose initially to offer the shares to the public at the public offering price set forth on the cover page of this prospectus and to dealers at that price less a concession not in excess of $ per share. After the initial offering, the public offering price, concession or any other term of the offering may be changed.

The following table shows the public offering price, underwriting discount and proceeds before expenses to us. The information assumes either no exercise or full exercise by the underwriters of their option to purchase additional shares.

	Per Share	Without Option	With Option
Public offering price	$	$	$
Underwriting discount	$	$	$
Proceeds, before expenses, to us	$	$	$

The expenses of the offering, not including the underwriting discount, are estimated at $ and are payable by us. We have also agreed to reimburse the underwriters for certain of their expenses incurred in connection with, among others, the review and clearance by the Financial Industry Regulatory Authority, Inc. in an amount of up to $.

Option to Purchase Additional Shares

We have granted an option to the underwriters, exercisable for 30 days after the date of this prospectus, to purchase up to additional shares at the public offering price, less the underwriting discount. If the underwriters exercise this option, each will be obligated, subject to conditions contained in the underwriting agreement, to purchase a number of additional shares proportionate to that underwriter's initial amount reflected in the above table.

No Sales of Similar Securities

We, our executive officers and directors and our other existing security holders have agreed not to sell or transfer any common stock or securities convertible into, exchangeable for, exercisable for, or repayable with common stock, for 180 days after the date of this prospectus without first obtaining the written consent of BofA Securities, Inc., SVB Leerink LLC and RBC Capital Markets, LLC. Specifically, we and these other persons have agreed, with certain limited exceptions, not to directly or indirectly:

- offer, pledge, sell or contract to sell any common stock,
- sell any option or contract to purchase any common stock,
- purchase any option or contract to sell any common stock,
- grant any option, right or warrant for the sale of any common stock,
- lend or otherwise dispose of or transfer any common stock,
- request or demand that we file or make a confidential submission of a registration statement related to the common stock, or
- enter into any swap or other agreement that transfers or is designed to, intended to, or which could reasonably be expected to lead to or result in the transfer, in whole or in part, the economic consequence of ownership of any common stock whether any such swap or transaction is to be settled by delivery of shares or other securities, in cash or otherwise.

This lock-up provision applies to common stock and to securities convertible into or exchangeable or exercisable for or repayable with common stock. It also applies to common stock owned now or acquired later by the person executing the agreement or for which the person executing the agreement later acquires the power of disposition.

The Nasdaq Global Market Listing

We expect the shares to be approved for listing on The Nasdaq Global Market, subject to notice of issuance, under the symbol "ETNB."

Before this offering, there has been no public market for our common stock. The initial public offering price will be determined through negotiations between us and the representatives. In addition to prevailing market conditions, the factors to be considered in determining the initial public offering price are:

- the valuation multiples of publicly traded companies that the representatives believe to be comparable to us,
- our financial information,

- the history of, and the prospects for, our company and the industry in which we compete,
- an assessment of our management, its past and present operations, and the prospects for, and timing of, our future revenues,
- the present state of our development, and
- the above factors in relation to market values and various valuation measures of other companies engaged in activities similar to ours.

An active trading market for the shares may not develop. It is also possible that after the offering the shares will not trade in the public market at or above the initial public offering price.

The underwriters do not expect to sell more than 5% of the shares in the aggregate to accounts over which they exercise discretionary authority.

Price Stabilization, Short Positions and Penalty Bids

Until the distribution of the shares is completed, SEC rules may limit underwriters and selling group members from bidding for and purchasing our common stock. However, the representatives may engage in transactions that stabilize the price of the common stock, such as bids or purchases to peg, fix or maintain that price.

In connection with the offering, the underwriters may purchase and sell our common stock in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering. “Covered” short sales are sales made in an amount not greater than the underwriters’ option to purchase additional shares described above. The underwriters may close out any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option granted to them. “Naked” short sales are sales in excess of such option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of shares of common stock made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Similar to other purchase transactions, the underwriters’ purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. The underwriters may conduct these transactions on The Nasdaq Global Market, in the over-the-counter market or otherwise.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor any of the underwriters make any representation that the representatives will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

Electronic Distribution

In connection with the offering, certain of the underwriters or securities dealers may distribute prospectuses by electronic means, such as e-mail.

Other Relationships

Some of the underwriters and their affiliates have engaged in, and may in the future engage in, investment banking and other commercial dealings in the ordinary course of business with us or our affiliates. They have received, or may in the future receive, customary fees and commissions for these transactions.

In addition, in the ordinary course of their business activities, the underwriters and their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Notice to Prospective Investors in the European Economic Area

In relation to each Member State of the European Economic Area (each a "Member State"), no shares have been offered or will be offered pursuant to the to the public in that Member State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Member State or, where appropriate, approved in another Member State and notified to the competent authority in that Member State, all in accordance with the Prospectus Regulation), except that offers of shares may be made to the public in that Member State at any time under the following exemptions under the Prospectus Regulation:

a. to any legal entity which is a qualified investor as defined under the Prospectus Regulation;

b. to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), subject to obtaining the prior consent of representatives for any such offer; or

c. in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of shares shall require us or any representative to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

Each person in a Member State who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with us and the representatives that it is a qualified investor within the meaning of the Prospectus Regulation.

In the case of any shares being offered to a financial intermediary as that term is used in Article 5(1) of the Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer to the public other than their offer or resale in a Relevant Member State to qualified investors, in circumstances in which the prior consent of the representatives has been obtained to each such proposed offer or resale.

We, the representatives and their affiliates will rely upon the truth and accuracy of the foregoing representations, acknowledgements and agreements.

For the purposes of this provision, the expression an "offer to the public" in relation to any shares in any Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129.

Notice to Prospective Investors in the United Kingdom

In addition, in the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are "qualified investors" (as defined in the Prospectus Directive) (i) who have professional experience in matters relating to investments falling within Article 19 (5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the "Order") and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as "relevant persons"). This document must not be acted on or relied on in the United Kingdom by persons who are not relevant persons. In the United Kingdom, any investment or investment activity to which this document relates is only available to, and will be engaged in with, relevant persons.

Notice to Prospective Investors in Switzerland

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange ("SIX") or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, our company or the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA (FINMA), and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes ("CISA"). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares.

Notice to Prospective Investors in the Dubai International Financial Centre

This prospectus relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority ("DFSA"). This prospectus is intended for distribution only to persons of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for the prospectus. The shares to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the shares offered should conduct their own due diligence on the shares. If you do not understand the contents of this prospectus you should consult an authorized financial advisor.

Notice to Prospective Investors in Australia

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission, in relation to the offering. This prospectus does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001 (the "Corporations Act"), and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of the shares may only be made to persons (the "Exempt Investors") who are "sophisticated investors" (within the meaning of section 708(8) of the Corporations Act), "professional investors" (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the shares without disclosure to investors under Chapter 6D of the Corporations Act.

The shares applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring shares must observe such Australian on-sale restrictions.

This prospectus contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

Notice to Prospective Investors in Hong Kong

The shares have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance; or (b) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of that Ordinance. No advertisement, invitation or document relating to the shares has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to securities which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the Securities and Futures Ordinance and any rules made under that Ordinance.

Notice to Prospective Investors in Japan

The shares have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended) and, accordingly, will not be offered or sold, directly or indirectly, in Japan, or for the benefit of any Japanese Person or to others for re-offering or resale, directly or indirectly, in Japan or to any Japanese Person, except in compliance with all applicable laws, regulations and ministerial guidelines promulgated by relevant Japanese governmental or regulatory authorities in effect at the relevant time. For the purposes of this paragraph, "Japanese Person" shall mean any person resident in Japan, including any corporation or other entity organized under the laws of Japan.

Notice to Prospective Investors in Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, the shares were not offered or sold or caused to be made the subject of an invitation for subscription or purchase and will not be offered or sold or caused to be made the subject of an invitation for subscription or purchase, and this prospectus or any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares, has not been circulated or distributed, nor will it be circulated or distributed, whether directly or indirectly, to any person in Singapore other than (i) to an institutional investor (as defined in Section 4A of the Securities and Futures Act (Chapter 289) of Singapore, as modified or amended

from time to time (the "SFA")) pursuant to Section 274 of the SFA, (ii) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

(a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or

(b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities or securities-based derivatives contracts (each term as defined in Section 2(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares pursuant to an offer made under Section 275 of the SFA except:

(a) to an institutional investor or to a relevant person, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;

(b) where no consideration is or will be given for the transfer;

(c) where the transfer is by operation of law; or

(d) as specified in Section 276(7) of the SFA.

Notice to Prospective Investors in Canada

The shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 *Prospectus Exemptions* or subsection 73.3(1) of the *Securities Act* (Ontario), and are permitted clients, as defined in National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*. Any resale of the shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 (or, in the case of securities issued or guaranteed by the government of a non-Canadian jurisdiction, section 3A.4) of National Instrument 33-105 *Underwriting Conflicts* (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

LEGAL MATTERS

The validity of the shares of our common stock offered by this prospectus will be passed upon for us by Gibson, Dunn & Crutcher LLP. Certain legal matters in connection with this offering will be passed upon for the underwriters by Cooley LLP.

EXPERTS

The consolidated financial statements included in this prospectus have been audited by Brightman Almagor Zohar & Co., a Firm in the Deloitte Global Network, an independent registered public accounting firm, as stated in their report appearing herein which report expresses an unqualified opinion on the consolidated financial statements and includes an explanatory paragraph referring to going concern. Such consolidated financial statements have been so included in reliance upon the report of such Firm given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of our common stock offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement, some items of which are contained in exhibits to the registration statement as permitted by the rules and regulations of the SEC. For further information with respect to us and our common stock, we refer you to the registration statement and its exhibits. Statements contained in this prospectus concerning the contents of any contract or any other document are not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, please see the copy of the contract or document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. The exhibits to the registration statement should be reviewed for the complete contents of these contracts and documents. A copy of the registration statement and its exhibits may be obtained from the SEC upon the payment of fees prescribed by it. The SEC maintains a website at *www.sec.gov* that contains reports, proxy and information statements and other information regarding companies that file electronically with it.

Upon completion of this offering, we will become subject to the information and periodic and current reporting requirements of the Exchange Act, and in accordance therewith, will file periodic and current reports, proxy statements and other information with the SEC. The registration statement, such periodic and current reports and other information can be obtained electronically by means of the SEC's website at *www.sec.gov.* We maintain a website at *www.89bio.com*, at which, following the completion of this offering, you may access these material free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Information contained on or accessible through our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is an inactive textual reference only.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Board of Directors of 89bio, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheet of 89bio, Inc. (the "Company") as of June 28, 2019 (inception), and the related notes (collectively referred to as the "financial statement"). In our opinion, the financial statement presents fairly, in all material respects, the financial position of the Company as of June 28, 2019, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

This financial statement is the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statement based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statement is free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statement, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statement. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statement. We believe that our audit provides a reasonable basis for our opinion.

/s/ Brightman Almagor Zohar & Co.
Certified Public Accountants
A Firm in the Deloitte Global Network

Tel Aviv, Israel
September 19, 2019

We have served as the Company's auditor since 2019.

89bio, Inc.
Balance Sheet

	June 28, 2019 (inception)
Assets	
Total assets	$ —
Liabilities and stockholders' equity	
Total liabilities	$ —
Commitments and contingencies	
Stockholders' equity:	
Common stock, $0.001 par value, 1,000 shares authorized, none issued and outstanding	$ —
Total liabilities and stockholders' equity	$ —

The accompanying notes are an integral part of this balance sheet.

89bio, Inc.
Notes to Balance Sheet

1. Organization and Background

89bio, Inc. (the "Corporation") was formed as a Delaware corporation on June 28, 2019. The Corporation was formed for the purpose of completing an initial public offering and related transactions in order to carry on the business of 89Bio Ltd. As the manager of 89Bio Ltd., the Corporation will operate and control all of the businesses and affairs of 89Bio Ltd., and its subsidiaries.

2. Summary of Significant Accounting Policies

Basis of Presentation

The balance sheet is presented in accordance with generally accepted accounting principles in the United States of America ("GAAP"). Statements of operations, stockholders' equity and cash flows have not been presented because there have been no activities in this entity.

Underwriting Commissions and Offering Costs

Underwriting commissions and offering costs to be incurred in connection with the Corporation's common share offerings will be reflected as a reduction of additional paid-in capital. Underwriting commissions and offering costs are not recorded in the Corporation's balance sheet because such costs are not the Corporation's liability until the Corporation completes a successful initial public offering.

Organizational Costs

Organizational costs are not recorded in the Corporation's balance sheet because such costs are not the Corporation's liability until the Corporation completes a successful initial public offering. Thereafter, costs incurred to organize the Corporation will be expensed as incurred.

3. Stockholders' Equity

The Corporation is authorized to issue 1,000 shares of common stock, par value $0.001 per share, none of which have been issued or are outstanding as of June 28, 2019.

4. Subsequent Events

In September 2019, the Corporation increased its authorized shares from 1,000 to 72,882,353 shares of common stock, 3,800,000 of which have been issued and are outstanding as of September 19, 2019. Additionally, the Corporation authorized 60,000,000 shares of preferred stock, 44,000,000 of which have been issued and are outstanding as of September 19, 2019.

In September 2019, an internal reorganization transaction was completed pursuant to which 89Bio, Ltd. became a wholly owned subsidiary.

Subsequent events through September 19, 2019, the date on which the balance sheet was available to be issued, were evaluated by the Corporation to determine the need, if any, for recognition or disclosure in this balance sheet. The Corporation concluded that no other subsequent events have occurred that would require recognition or disclosure to the balance sheet.

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of
89Bio Ltd.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of 89Bio Ltd. and subsidiaries (the "Company") as of December 31, 2018 and the related consolidated statements of operations and comprehensive loss, change in convertible preferred shares and shareholders' deficit and cash flows for the period from January 18, 2018 (inception) to December 31, 2018, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018, and the results of its operations and its cash flow for the period from January 18, 2018 (inception) to December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company's lack of revenues and substantial operating losses raise substantial doubt about its ability to continue as a going concern. Management's plans concerning these matters are also described in Note 1 to the financial statements. The financial statements do not include any adjustments that might result from the outcome of these uncertainties.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ Brightman Almagor Zohar & Co.
Certified Public Accountants
A Firm in the Deloitte Global Network

Tel Aviv, Israel
August 15, 2019

We have served as the Company's auditor since 2018.

89Bio Ltd.
Consolidated Balance Sheet
(In thousands, except share and per share amounts)

	December 31, 2018
Assets	
Current assets:	
Cash and cash equivalents	$ 11,234
Restricted cash	23
Other current assets	59
Total current assets	11,316
Property and equipment, net	33
Deferred tax assets	20
Total assets	$ 11,369
Liabilities and shareholders' equity	
Current liabilities:	
Accounts payable	$ 1,509
Accrued expenses	1,173
Convertible preferred share liability	1,671
Total current liabilities	4,353
Commitments and contingencies (Note 5)	
Convertible preferred shares, NIS 0.01 nominal value; 60,000,000 shares authorized as of December 31, 2018; 24,000,000 shares issued and outstanding as of December 31, 2018; aggregate liquidation preference of $24,000 as of December 31, 2018	23,073
Shareholders' deficit:	
Ordinary shares, NIS 0.01 nominal value, 10,415,900 shares authorized at December 31, 2018; 3,800,000 shares issued and outstanding as of December 31, 2018	11
Additional paid-in capital	108
Accumulated deficit	(16,176)
Total shareholders' deficit	(16,057)
Total liabilities, convertible preferred shares and shareholders' deficit	$ 11,369

The accompanying notes are an integral part of these consolidated financial statements.

89Bio Ltd.
Consolidated Statement of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)

	Period from January 18, 2018 (inception) to December 31, 2018
Operating expenses:	
Research and development	$ 13,681
General and administrative	1,481
Total operating expenses	15,162
Loss from operations	15,162
Other (income) expenses, net	986
Net loss before tax	16,148
Income tax expense	28
Net loss and comprehensive loss	$ 16,176
Net loss per share, basic and diluted	$ 5.86
Weighted-average shares used to compute net loss per share, basic and diluted	2,758,904
Pro forma net loss per share, basic and diluted (unaudited)	$ 1.22
Weighted-average shares used to compute pro forma net loss per share, basic and diluted (unaudited)	13,224,780

The accompanying notes are an integral part of these consolidated financial statements.

89Bio Ltd.
Consolidated Statement of Convertible Preferred Shares and Shareholders' Deficit (in thousands, except share amounts)

	Convertible Preferred Shares		Ordinary Shares		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Deficit
	Shares	Amounts	Shares	Amounts			
Balance as of January 18, 2018 (inception)	—	$ —	—	$ —	$ —	$ —	$ —
Issuance of ordinary shares	—	—	3,800,000	11	—	—	11
Issuance of convertible preferred shares, net of issuance costs of $235 and the recognition of the convertible preferred share liability of $692	23,900,000	22,973	—	—	—	—	—
Conversion of convertible note into preferred shares	100,000	100	—	—	—	—	—
Share-based compensation	—	—	—	—	108	—	108
Net loss and comprehensive loss	—	—	—	—	—	(16,176)	(16,176)
Balance as of December 31, 2018	24,000,000	$23,073	3,800,000	$ 11	$ 108	$ (16,176)	$ (16,057)

The accompanying notes are an integral part of these consolidated financial statements.

89Bio Ltd.
Consolidated Statement of Cash Flows (in thousands)

	Period from January 18, 2018 (inception) to December 31, 2018
Cash flows from operating activities:	
Net loss	$ (16,176)
Adjustments to reconcile net loss to net cash used in operating activities:	
Depreciation	6
Share-based compensation	108
Deferred tax assets	(20)
Revaluation of convertible preferred share liability	979
Changes in operating assets and liabilities:	
Other current assets	(48)
Accrued expenses	1,173
Accounts payable	1,509
Net cash used in operating activities	(12,469)
Cash flows from investing activities:	
Purchase of property and equipment	(39)
Net cash used in investing activities	(39)
Cash flows from financing activities:	
Proceeds from issuance of convertible preferred shares and convertible preferred share liability, net of issuance costs	23,665
Proceeds from issuance of convertible note	100
Net cash provided by financing activities	23,765
Net increase in cash and cash equivalents, and restricted cash	11,257
Cash and cash equivalents, and restricted cash at beginning of period	—
Cash and cash equivalents, and restricted cash at end of period	$ 11,257
Components of cash and cash equivalents, and restricted cash:	
Cash and cash equivalents	$ 11,234
Restricted cash	23
Total cash and cash equivalents, and restricted cash	$ 11,257
Supplemental disclosures of non-cash investing and financing information:	
Conversion of convertible note into preferred shares	$ 100

The accompanying notes are an integral part of these consolidated financial statements.

89Bio Ltd.
Notes to the Consolidated Financial Statements

1. Organization and Basis of Presentation

Description of Business

89Bio Ltd. ("89Bio" or the "Company") is a clinical-stage biopharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of liver and cardio-metabolic diseases. The Company's lead product candidate, BIO89-100, a specifically engineered glycoPEGylated analog of fibroblast growth factor 21, is currently being developed for the treatment of nonalcoholic steatohepatitis. 89Bio Ltd. was incorporated in Israel in January 2018. The Company has two wholly owned subsidiaries: 89bio Management, Inc., located in San Francisco, California and UAB 89bio Lithuania, located in Vilnius, Lithuania.

89bio, Inc., a Delaware corporation, does not currently have any operations and was incorporated in June 2019 for the purpose of an internal reorganization transaction. Prior to the consummation of the Company's initial public offering, all of the equity holders of 89Bio Ltd. will exchange 100% of the equity of 89Bio Ltd. for 100% of the equity of 89bio, Inc. Following this exchange, 89Bio Ltd. will become a wholly-owned subsidiary of 89bio, Inc. and 89bio, Inc. will indirectly own the business described herein. Upon the completion of a qualified public offering on specified terms, the Company's outstanding convertible preferred shares will automatically convert into shares of common stock (see Note 7).

Going Concern

The accompanying consolidated financial statements are prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and liquidation of liabilities in the normal course of business. To date, the Company has not generated revenues from its activities and has incurred substantial operating losses. Management expects the Company to continue to generate substantial operating losses for the foreseeable future until it completes development of its products and seeks regulatory approvals to market such products. Management will continue to fund its operations primarily through utilization of its current financial resources and through additional raises of capital.

Such conditions raise substantial doubts about the Company's ability to continue as a going concern for at least a year after the issuance date of the accompanying consolidated financial statements. Management plans to address these conditions by raising funds from its current investors as well as outside potential investors. However, there is no assurance that such funding will be available to the Company or that it will be obtained on terms favorable to the Company or will provide the Company with sufficient funds to meet its objectives. The accompanying consolidated financial statements do not include any adjustments relating to the recoverability and classification of assets, carrying amounts or the amount or classification of liabilities that may be required should the Company be unable to continue as a going concern.

2. Summary of Significant Accounting Policies

Basis of Presentation:

The consolidated financial statements have been prepared in conformity with accounting principles generally accepted in United Sates of America ("U.S. GAAP").

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

89Bio Ltd.
Notes to the Consolidated Financial Statements

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the consolidated financial statements and the reported amounts of expenses during the reporting period. Significant estimates and assumptions made in the accompanying consolidated financial statements include but are not limited to the fair value of stock options, the convertible preferred share liability and certain accruals. The Company evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors and adjusts those estimates and assumptions when facts and circumstances dictate. Actual results could differ from those estimates.

Consolidated Financial Statements in U.S. Dollars

The Company's functional currency is the U.S. dollar ("dollar" or "$") since the dollar is the currency of the primary economic environment in which the Company has operated and expects to continue to operate in the foreseeable future. Transactions and balances denominated in dollars are presented at their original amounts. Transactions and balances denominated in foreign currencies have been re-measured to dollars. All transaction gains and losses from re-measurement of monetary balance sheet items denominated in non-dollar currencies are reflected in the consolidated statement of operations and comprehensive loss as other (income) expenses, net. Net foreign currency transaction losses were not material for the period from January 18, 2018 (inception) to December 31, 2018.

Cash and Cash Equivalents and Restricted Cash

The Company considers all highly liquid investments purchased with original maturities of three months or less from the purchase date to be cash equivalents. Cash equivalents consist primarily of amounts invested in money market accounts and are stated at fair value. Restricted cash consists of a money market account that serves as collateral for a credit card agreement at one of the Company's financial institutions.

Fair Value Measurements

Financial assets and liabilities are recorded at fair value on a recurring basis in the consolidated balance sheet. The carrying values of Company's financial assets and liabilities, including cash and cash equivalents, restricted cash, other current assets, accounts payable, and accrued expenses approximate to their fair value due to the short-term maturity of these instruments. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. Assets and liabilities recorded at fair value in the consolidated financial statements are categorized based upon the level of judgment associated with the inputs used to measure their fair value. Hierarchical levels are directly related to the amount of subjectivity with the inputs to the valuation of these assets or liabilities as follows:

Level 1—Observable inputs such as unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date;

Level 2—Inputs (other than quoted prices included in Level 1) are either directly or indirectly observable inputs for similar assets or liabilities. These include quoted prices for identical or similar assets or liabilities in active markets and quoted prices for identical or similar assets of liabilities in markets that are not active;

89Bio Ltd.
Notes to the Consolidated Financial Statements

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Convertible Preferred Share Liability

The freestanding instruments related to the commitment by the Series A convertible preferred shareholders to purchase and by the Company to sell its Series A convertible preferred shares in subsequent closings, contingent upon the achievement of certain developmental milestones and approval by the board of directors, at a fixed price per share, are considered a liability (or an asset), measured at fair value as the shares underlying the rights contain liquidation preferences upon certain "deemed liquidation events" that are not solely within the Company's control and which are considered in-substance contingent redemption features (refer to Note 7 for further discussion on the redemption rights of the convertible preferred shares). The instruments are subject to revaluation at each balance sheet date until settlement, with revaluations recognized as a component of other (income) expenses, net in the consolidated statement of operations and comprehensive loss.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist primarily of cash and cash equivalents. Bank deposits are held by accredited financial institutions and these deposits may at times be in excess of insured limits. The Company limits its credit risk associated with cash and cash equivalents by placing them with financial institutions that it believes are of high quality. The Company has not experienced any losses on its deposits of cash or cash equivalents.

Property and Equipment, Net

Property and equipment are stated at cost, less accumulated depreciation. Depreciation is calculated on a straight-line basis over the estimated useful lives of the related assets, generally ranging from three to seven years. Leasehold improvements are amortized on a straight-line basis over the shorter of the assets' estimated useful life or the remaining term of the lease. Maintenance and repair costs are expensed as incurred.

Impairment of Long-Lived Assets

The Company periodically evaluates its long-lived assets, including property and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets or group of assets may not be fully recoverable. If indicators of impairment exist and the undiscounted future cash flows that the assets are expected to generate are less than the carrying value of the assets, the Company reduces the carrying amount of the assets through an impairment charge, to their estimated fair values based on a discounted cash flow approach or, when available and appropriate, to comparable market values. There were no such indicators for the period presented.

Accrued Post-Employment Benefit

Under Israeli employment laws, employees of the Company are included under Section 14 of the Severance Compensation Act, 1963 ("Section 14") for a portion of their salaries. According to Section 14, these employees are entitled to monthly payments made by the Company on their behalf with insurance companies.

Payments in accordance with Section 14 release the Company from any future severance payments with respect of those employees. The obligation to make the monthly deposits is expensed as incurred. In addition, the aforementioned deposits are not recorded as an asset in the consolidated balance sheet, and there is no liability recorded as the Company does not have a future obligation to make any additional payments.

89Bio Ltd.
Notes to the Consolidated Financial Statements

Leases

The Company leases its office facility under a non-cancelable operating lease agreement and recognizes related rent expense on a straight-line basis over the term of the lease.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for the development of the Company's lead product candidate, BIO89-100. Research and development expenses consist primarily of external costs related to acquiring and licensing patents and intellectual properties, preclinical and clinical development and related supplies, and personnel costs. Personnel costs consist of salaries, employee benefits and share-based compensation for individuals involved in research and development efforts. The Company estimates preclinical and clinical study and research expenses based on the services performed, pursuant to contracts with research institutions that conduct and manage preclinical and clinical studies and research services on its behalf. The Company records the costs of research and development activities based upon the estimated amount of services provided but not yet invoiced and includes these costs in accrued liabilities in the consolidated balance sheet. These costs are a component of the Company's research and development expenses. The Company accrues for these costs based on factors such as estimates of the work completed and in accordance with agreements established with its third-party service providers under the service agreements. The Company makes significant judgments and estimates in determining the accrued liabilities balance. As actual costs become known, the Company adjusts its accrued expenses. The Company has not experienced any material differences between accrued costs and actual costs incurred. However, the status and timing of actual services performed may vary from the Company's estimates, resulting in adjustments to expense in future periods. Changes in these estimates that result in material changes to the Company's accruals could materially affect the Company's results of operations. Payments associated with licensing agreements to acquire licenses to develop, use, manufacture and commercialize products that have not reached technological feasibility and do not have alternate commercial use are expensed as incurred. Contingent milestone payments, if any, are expensed when the milestone results are probable and estimable, which is generally upon achievement of the milestone.

Share-Based Compensation

The Company measures its share-based payment awards made to employees, directors, and non-employee service providers based on estimated fair values and recognizes compensation over the requisite service period.

The Company estimates the fair value of share-based payment awards on the date of grant using a Black-Scholes option pricing model. The value of the portion of the share-based payment award that is ultimately expected to vest is recognized as an expense over the requisite service period in the consolidated statement of operations and comprehensive loss.

The Company recognizes compensation for the value of share-based payment awards, which have graded vesting, using the straight-line method over the requisite service period of each award. The Company accounts for forfeitures as they occur.

The Black-Scholes option pricing model requires a number of assumptions, of which the most significant are share price, expected volatility, expected option term (the time from the grant date until the options are exercised or expire), risk-free rate, and expected divided rate. Expected volatility is estimated based on volatility of similar public companies in the biotechnology sector. The Company has historically not paid dividends and has no foreseeable plans to pay dividends, therefore the Company uses an expected dividend yield

89Bio Ltd.
Notes to the Consolidated Financial Statements

of 0%. The risk-free interest rate is based on the yield from U.S. Treasury zero-coupon bonds with an equivalent expected term. The expected option term is calculated for options granted to employees and directors using the "simplified" method. Under this approach, the expected term is presumed to be the midpoint between the weighted average vesting term and the contractual term of the option. The simplified method makes the assumption that the employee will exercise share options evenly over the period when the share options are vested and ending on the date when the share options expire. The expected option term for options granted to non-employees is based on the contractual term. Changes in the determination of each of the inputs can affect the fair value of the share options granted and the results of operations of the Company.

Income Taxes

Income taxes are accounted for under the asset and liability method. Under this method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the consolidated financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates applied to taxable income in the years in which those temporary differences are expected to be realized. The effect on deferred tax assets and liabilities of a change in tax rates is recognized as income or loss in the period that includes the enactment date. A valuation allowance is established when necessary to reduce deferred tax assets to the amount expected to be realized. Interest and penalties related to unrecognized tax benefits are included within the provision of income tax. To date, there have been no unrecognized tax benefits balances.

Basic and Diluted Net Loss per Share

Basic loss per share is computed by dividing the net loss by the weighted average number of ordinary shares outstanding during the period. Diluted loss per share is computed by dividing the net loss by the weighted average number of ordinary shares outstanding together with the number of additional ordinary shares that would have been outstanding if all potentially dilutive ordinary shares had been issued. Since the Company was in a loss position for the period presented, basic net loss per share is the same as diluted net loss per share since the effects of potentially dilutive securities are antidilutive.

Unaudited Pro Forma Net Loss per Share

Immediately prior to the completion of the Company's anticipated initial public offering (the "IPO"), all outstanding shares of convertible preferred shares will convert into ordinary shares. The unaudited pro forma net loss per share for the period from January 18, 2018 (inception) to December 31, 2018 was computed using the weighted-average number of shares of ordinary shares outstanding, including the pro forma effect of the conversion of all outstanding shares of convertible preferred shares into shares of ordinary shares as if such conversion had occurred at the beginning of the period, or their issuance dates if later. Pro forma net loss per share does not include the shares expected to be sold in the IPO.

Comprehensive Loss

The Company has no components of comprehensive loss other than net loss. Thus, comprehensive loss is the same as net loss for the period presented.

Segment Reporting

The Company has one operating segment. The Company's chief operating decision maker, its Chief Executive Officer, manages the Company's operations on a consolidated basis for the purposes of allocating resources and evaluating financial performance.

89Bio Ltd.
Notes to the Consolidated Financial Statements

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") 2014-09—*Revenue from contracts with customers*, to achieve a consistent application of revenue recognition, resulting in a single revenue model to be applied by reporting companies under U.S. GAAP. Under the new model, recognition of revenue occurs when a customer obtains control of the promised goods or services in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In addition, the standard requires that reporting companies disclose the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. The standard is effective for public entities for fiscal years beginning after December 15, 2017 and is effective for nonpublic entities for fiscal years beginning after December 15, 2018. The standard is required to be applied retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of initially applying it recognized at the date of initial application. The Company adopted this standard on January 1, 2019, and as the Company has not incurred revenues to date, the adoption of the standard will not have a significant impact on its consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02—*Leases*, requiring the recognition of lease assets and liabilities on the balance sheet. The standard: (a) clarifies the definition of a lease; (b) requires a dual approach to lease classification similar to current lease classifications; and (c) causes lessees to recognize leases on the balance sheet as a lease liability with a corresponding right-of-use asset for leases with a lease-term of more than twelve months. The standard is effective for public entities for fiscal years beginning after December 15, 2018 and for nonpublic entities for fiscal years beginning after December 15, 2019. The Company is currently evaluating the impact of this standard and expects the adoption will result in an insignificant increase in the assets and liabilities on its consolidated balance sheet for operating leases.

In June 2018, the FASB issued ASU No. 2018-07 *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*, which is intended to reduce the cost and complexity and to improve financial reporting for nonemployee share based payment. The standard expands the scope of Topic 718, (which currently only includes share-based payments to employees) to include share-based payments issued to nonemployees for goods or services. Consequently, the accounting for share-based payments to nonemployees and employees will be substantially aligned. The standard is effective for public entities for fiscal years beginning after December 15, 2019 and nonpublic entities for fiscal years beginning after December 15, 2020. Early adoption is permitted but no earlier than a company's adoption date of Topic 606. The Company early adopted this standard on January 1, 2019, and the impact of its adoption on the Company's consolidated financial statements is not material.

3. Fair Value Measurements

The fair value of the Company's financial liabilities measured at fair value on a recurring basis by level within the fair value hierarchy are as follows (in thousands):

	December 31, 2018			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Convertible preferred share liability	$ —	$ —	$1,671	$1,671
Total financial liabilities	$ —	$ —	$1,671	$1,671

89Bio Ltd.
Notes to the Consolidated Financial Statements

The changes in the fair value of the Company's Level 3 financial liabilities, which are measured on a recurring basis are as follows (in thousands):

	December 31, 2018
Beginning balance	$ —
Recognition of convertible preferred share liability upon issuance of convertible preferred shares	638
Revaluation of convertible preferred share liability recorded in other (income) expense, net	979
Partial settlement of convertible preferred share liability upon second closing	54
Ending balance	$ 1,671

The fair value of the Company's convertible preferred share liability is based on significant inputs not observed in the market, and thus represent a Level 3 measurement. Refer to Note 7 for further discussion on the convertible preferred share liability.

4. Consolidated Balance Sheet Components

Property and Equipment, Net

Property and equipment, net consists of the following (in thousands):

	December 31, 2018
Computer software and electronic equipment	$ 33
Furniture and office equipment	6
Total property and equipment	39
Less: accumulated depreciation	(6)
Total property and equipment, net	$ 33

Depreciation expense for property and equipment was $6,000 for the period from January 18, 2018 (inception) to December 31, 2018.

Accrued Expenses

Accrued expenses consist of the following (in thousands):

	December 31, 2018
Accrued research and development expense	$ 890
Accrued employee and related expenses	283
Total accrued expenses	$ 1,173

5. Commitments and Contingencies

Lease

In May 2018, the Company entered into an operating lease agreement for its facility in Israel. The lease term was for 12 months and was amended in April 2019 to extend the lease term to April 2020. Under the lease agreement, monthly lease payments are approximately $4,000.

89Bio Ltd.
Notes to the Consolidated Financial Statements

Future minimum lease payments under the Company's non-cancellable operating lease obligations as of December 31, 2018, are as follows (in thousands):

2019	$18
Total future minimum annual payments	$18

Rent expense was $39,000 during the period from January 18, 2018 (inception) to December 31, 2018. The Company has a security deposit balance of $23,000, which is included in other current assets in the consolidated balance sheet as of December 31, 2018.

Asset Transfer and License Agreement with Teva Pharmaceutical Industries Ltd

In April 2018, the Company concurrently entered into two Asset Transfer and License Agreements (the "Teva Agreements") with Teva Pharmaceutical Industries Ltd ("Teva") under which it acquired certain patents and intellectual property relating to two programs: (1) Teva's glycoPEGylated FGF21 program, including the compound TEV-47948 (BIO89-100), a glycoPEGylated long-acting FGF21 and (2) Teva's development program of small molecule inhibitors of Fatty Acid Synthase. Pursuant to the Teva Agreements, the Company paid Teva an initial nonrefundable upfront payment of $6.0 million and the Company could be obligated to pay Teva up to $67.5 million under each program, for a total of $135.0 million, upon the achievement of certain clinical development and commercial milestones. In addition, the Company is obligated to pay Teva tiered royalties at percentages in the low-to-mid single-digits on worldwide net sales on all products containing the Teva compounds.

The Teva Agreements can be terminated (i) by the Company without cause, after the first anniversary of the effective date, upon 120 days' written notice to Teva, (ii) by either party, if the other party materially breaches any of its obligations under the Agreements and fails to cure such breach within 60 days after receiving notice thereof, or (iii) by either party, if a bankruptcy petition is filed against the other party and is not dismissed within 60 days. In addition, Teva can also terminate the agreement related to the Company's glycoPEGylated FGF21 program in the event the Company, or any of its affiliates or sublicensees, challenges any of the Teva patents licensed to the Company, and the challenge is not withdrawn within 30 days of written notice from Teva.

The Company accounted for the acquisition of technology as an asset acquisition because it did not meet the definition of a business. The Company recorded the total consideration transferred to Teva as research and development expense in the consolidated statement of operations and comprehensive loss because the acquired technology represented in-process research and development and had no alternative future use.

6. Convertible Note

In March 2018, the Company entered into a Convertible Loan Agreement (the "Convertible Note") with a principal amount of $100,000 and a fixed interest rate of 8% per annum. The Convertible Note was automatically convertible into the Company's next equity financing, or upon an earlier event of default. In April 2018, the entire amount outstanding converted into 100,000 shares of Series A convertible preferred shares upon the closing of the Series A financing.

7. Convertible Preferred Shares

In April 2018, the Company entered into the Series A Share Purchase Agreement (the "SPA"), pursuant to which the investors committed to invest an aggregate amount of up to $60.0 million for the issuance of Series A convertible preferred shares at a price of $1.00 per share.

89Bio Ltd.
Notes to the Consolidated Financial Statements

The initial closing occurred on April 16, 2018, and the Company issued 14,900,000 Series A convertible preferred shares at a price per share of $1.00 for net cash proceeds of $14.7 million. The investors also committed to purchase 15,000,000 and 30,000,000 shares of Series A convertible preferred shares at a price of $1.00 per share in second and third closings, respectively, contingent upon the achievement by the Company of certain development milestones and approval by the board of directors.

The investors' commitment to purchase and the Company's commitment to sell Series A convertible preferred shares represent a freestanding instrument accounted for at fair value and re-measured at each reporting date. The Company estimates the fair value of this commitment using the Black Scholes option pricing model. On the date of the initial closing, the Company recorded the commitments associated with the second and third closings of the Series A convertible preferred shares at a net value of $638,000. For the period from January 18, 2018 (inception) to December 31, 2018, the Company recorded an expense of $979,000 for the revaluation of the convertible preferred share liability, within other (income) expense, net in the consolidated statement of operations and comprehensive loss.

In December 2018, the Series A convertible preferred shareholders partially accelerated the second closing and the Company issued 9,000,000 Series A convertible preferred shares at a price of $1.00 per share and received net proceeds of $9.0 million.

As of December 31, 2018, 36,000,000 Series A convertible preferred shares were subject to issuance upon completion of remaining milestones or as the preferred shareholders elected to waive such milestones.

In June 2019, the Company and the Series A convertible preferred shares investors agreed to issue the remaining 6,000,000 Series A convertible preferred shares at a price of $1.00 per share related to the second closing, and to partially accelerate 14,000,000 Series A convertible preferred shares at a price of $1.00 per share related to the third closing. The shares were issued and the aggregate net proceeds of $20.0 million were received in June and July 2019.

Convertible Preferred Shares

Convertible preferred shares consist of the following:

	December 31, 2018			
Convertible Preferred Shares	Shares Authorized	Shares Issued and Outstanding	Carrying Value	Liquidation Preference
Series A	60,000,000	24,000,000	$ 23,073,000	$ 24,000,000
Total	60,000,000	24,000,000	$ 23,073,000	$ 24,000,000

The holders of the Company's convertible preferred shares have various rights, preferences, and privileges as follows:

Dividends

The holders of each share of Series A convertible preferred share shall be entitled to receive, when and if declared by the board of directors, a noncumulative dividend at the rate of $0.08 per share per annum on each outstanding convertible preferred share. Such dividends are payable in preference to the payment of any dividends on ordinary shares declared by the board of directors. No dividends have been declared to date.

89Bio Ltd.
Notes to the Consolidated Financial Statements

Automatic Conversion Rights

Each share of Series A convertible preferred share is convertible, at the option of the holder at any time, into the number of ordinary shares as is determined by dividing the original issue price for such series of preferred share by the conversion price for such series of preferred share that is in effect at the time of conversion. The initial conversion price for the series of preferred share is the original issue price for such series of preferred share. The original issue price was $1.00 per share for the Series A convertible preferred shares. The applicable conversion price of each is subject to adjustment upon any future stock splits or combinations, recapitalizations, or upon the issuance of any new securities as a price per share lower than the applicable conversion price of the Series A convertible preferred shares in effect immediately prior to such issuance.

Each share of Series A convertible preferred share will automatically be converted into ordinary shares upon the earlier of: (i) the closing of an underwritten public offering of ordinary shares of the Company at a price per share not less than $5.00 with aggregate gross proceeds to the Company of at least $50.0 million (a “qualified public offering”); or (ii) the written consent of the holders of at least 50% of the Series A convertible preferred shares, including OrbiMed Israel Partners II, L.P., or OrbiMed Private Investments VI, L.P.

Mandatory Conversion

In the event a holder of Series A convertible preferred shares does not fund its full pro rata portion of the applicable milestone closing, then unless otherwise waived in writing by the requisite preferred, such holder’s Series A convertible preferred shares and/or ordinary shares issued upon conversion of Series A convertible preferred shares will be converted to ordinary shares, at a conversion ratio of 10 Series A convertible preferred shares to 1 ordinary share. Such holder will lose any rights as a holder of Series A convertible preferred shares, including the right to invest in any subsequent equity or debt financing, the right to received Series A convertible preferred share preference, and the right, if any, to designate a board seat.

Voting Rights

Each holder of the Series A convertible preferred share is entitled to one vote for each ordinary share into which such Series A convertible preferred share could be converted.

Liquidation Preference

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company, or deemed liquidation event (a consolidation, merger or reorganization or a sale of all or substantially all of the Company’s assets, or substantially all of the Company’s issued and outstanding share capital of the Company), the holders of the series A convertible preferred shares will be entitled to receive on a pro rata basis, prior and in preference to the holders of ordinary shares, an amount equal to the original issuance price (as adjusted for any share split, share combination, share dividend, recapitalization or like events), less the amount of any distributions received in any prior liquidation event, and all declared by unpaid dividends.

Redemption

The Company’s articles of association do not provide redemption rights to the holders of the Series A convertible preferred shares. In the event of a liquidation event, all the funds and assets of the Company available for distribution among all the shareholders shall be distributed in the following order of preference: (a) the holders of the Series A convertible preferred shares shall be entitled to receive an amount per share equal to $1.00 per each Series A convertible preferred share (less the amount of distributions actually received in any

prior liquidation event, plus all declared but unpaid dividends) and (b) the remaining assets of the Company available for distribution to shareholders shall be distributed among the holders of ordinary shares and to the holders of the Series A convertible preferred shares on an as-converted and pro rata basis.

Although the convertible preferred shares are not redeemable, in the event of certain "deemed liquidation events" that are not solely within the Company's control (including merger, acquisition, or sale of all or substantially all of the Company's assets), the holders of the convertible preferred shares would be entitled to preference amounts paid before distribution to other shareholders (as explained in the previous paragraph) and hence effectively redeeming the preference amount. The convertible preferred shares are classified outside of shareholders' deficit as a result of these in-substance contingent redemption rights.

As of December 31, 2018, the Company did not adjust the carrying values of the convertible preferred shares to the deemed liquidation values of such shares since a liquidation event was not probable of occurring.

8. Ordinary Shares

Pursuant to the Company's amended articles of association filed on May 30, 2018, the Company is authorized to issue a total of 10,415,900 ordinary shares, of which 3,800,000 ordinary shares were issued and outstanding as of December 31, 2018. The proceeds from the issuance of the Company's ordinary shares were received in April 2019.

The holders of ordinary shares are entitled to one vote per ordinary share on all matters to be voted on by the shareholders of the Company and are entitled to dividends, if and when declared by the board of directors, subject to the prior rights of the preferred shareholders. No dividends have been declared as of December 31, 2018.

Total ordinary shares reserved for issuance are summarized as follows (in thousands):

	December 31, 2018
Series A convertible preferred shares outstanding, as converted	24,000,000
Options issued and outstanding	3,677,056
Shares available for future option grants	2,938,844
Total ordinary shares reserved for issuance	30,615,900

9. Share-Based Compensation

In November 2018, the board of directors of the Company (the "Board") authorized the 2018 Equity Incentive Share Option Plan (the "2018 Plan"). The 2018 Plan provides for the grant of 6,615,900 share-based awards, including incentive stock options to employees, directors, and non-employee service providers of the Company. The aggregate number of ordinary shares reserved and available for grant under the 2018 Plan was 2,938,844 as of December 31, 2018.

The Board determines the period over which options become exercisable and options generally vest over a four-year period, with 25% of options vesting on the first anniversary of employment, and thereafter, the remaining options vesting quarterly, over the following 36-month period. The options will expire within ten years from the date of grant. The exercise price of awards granted will not be less than the estimated fair value of the shares on the date of grant.

89Bio Ltd.
Notes to the Consolidated Financial Statements

The Company recorded share-based compensation for the period indicated as follows (in thousands):

	Period from January 18, 2018 (inception) to December 31, 2018
Research and development	$ 13
General and administrative	95
Total share-based compensation	$ 108

The fair value of option awards granted was estimated at the date of grant using a Black-Scholes option-pricing model with the following assumptions:

	Period from January 18, 2018 (inception) to December 31, 2018
Expected term (years)	5.92
Expected volatility	73.16%
Risk-free interest rate	3.1%
Expected dividend	—

The following table summarizes stock option activity under the 2018 Plan:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (In Years)
Balance as of January 18, 2018 (inception)	—	$ —	
Granted	3,677,056	0.31	
Exercised	—	—	
Cancelled	—	—	
Balance outstanding as of December 31, 2018	3,677,056	$ 0.31	9.87
Exercisable as of December 31, 2018	—	$ —	—

Options granted for the period from January 18, 2018 (inception) to December 31, 2018 were subject to cliff vesting as of December 31, 2018, and accordingly, there were no vested options during the period. The weighted-average grant date fair value of options granted for the period from January 18, 2018 (inception) to December 31, 2018 was $0.20 per share. As of December 31, 2018, there was $668,000 of unrecognized share-based compensation cost related to stock options granted under the 2018 Plan, which is expected to be recognized over a weighted-average period of 3.5 years.

Included in the option activity table were 80,832 stock options granted to non-employee service providers during the period from January 18, 2018 (inception) to December 31, 2018. These options were granted in exchange for consulting services to be rendered and vest over the term specified in the grant. The Company recorded non-employee share-based compensation of $2,000 during the period from January 18, 2018 (inception) to December 31, 2018.

89Bio Ltd.
Notes to the Consolidated Financial Statements

10. Income Taxes

Tax Rates Applicable to the Income of the Company and its Subsidiaries

The Company is taxed according to Israeli tax laws. The tax rates applicable to the income of the Company and its subsidiaries are as follows:

	Period from January 18, 2018 (inception) to December 31, 2018
89Bio Ltd.	23%
89bio Management, Inc.	21%
UAB 89bio Lithuania	15%

The expense for income taxes is comprised of (in thousands):

	Period from January 18, 2018 (inception) to December 31, 2018
Current:	
Foreign	$ 48
	48
Deferred:	
Foreign	(20)
	(20)
Income tax expense	$ 28

Deferred Income Taxes

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets are as follows (in thousands):

	December 31, 2018
Net operating loss carryforward	$ 1,536
Research and development expenses	1,966
Other	20
Total deferred tax assets	3,522
Less: valuation allowance	(3,502)
Net deferred tax asset	$ 20

As of December 31, 2018, the Company has provided a valuation allowance of $3.5 million in respect of deferred tax assets resulting from tax loss carryforwards and other temporary differences. Realization of deferred tax assets is dependent upon future earnings, if any, the time and amount of which are uncertain. As the Company is still in its development stage and has not yet generated revenues, it is more likely than not that sufficient taxable income will not be available for the tax losses to be utilized in the future. Therefore, a valuation allowance was recorded to reduce the deferred tax assets to their recoverable amounts.

89Bio Ltd.
Notes to the Consolidated Financial Statements

Available Carryforward Tax Losses

As of December 31, 2018, the Company has an accumulated tax loss carryforward of approximately $6.7 million. Carryforward tax losses in Israel have no expiration date.

Loss from Continuing Operations, Before Taxes on Income

The Company recorded loss from continuing operations, before taxes on income for the period indicated as follows (in thousands):

	Period from January 18, 2018 (inception) to December 31, 2018
United States	$ 50
Lithuania	50
Israel	(16,248)
Net loss before tax	$ (16,148)

The reconciliation of income tax expense based on the statutory tax rate to the effective tax rate is as follows (in thousands):

	Period from January 18, 2018 (inception) to December 31, 2018
Income tax expense computed at statutory rates	$ (3,714)
Change in valuation allowance	3,502
Revaluation of convertible preferred share liability	226
Other	14
Income tax expense	$ 28

11. Net Loss and Unaudited Pro Forma Net Loss Per Share

The following outstanding potentially dilutive ordinary share equivalents have been excluded from the calculation of diluted net loss per share for the period presented due to their anti-dilutive effect:

	Period from January 18, 2018 (inception) to December 31, 2018
Convertible preferred shares	24,000,000
Stock options to purchase ordinary shares	3,677,056
Total	27,677,056

Unaudited Pro Forma Net Loss Per Share

Pro forma basic and diluted net loss per share has been computed to give effect to the assumed conversion of all outstanding convertible preferred shares into ordinary shares.

89Bio Ltd.
Notes to the Consolidated Financial Statements

The following table sets forth the computation of the unaudited pro forma net loss per share for the period presented (in thousands except share and per share amounts):

	Period from January 18, 2018 (inception) to December 31, 2018
Numerator:	
Net loss	$ 16,176
Denominator:	
Weighted-average number of shares used to compute net loss per share, basic and diluted	2,758,904
Pro forma adjustment to reflect assumed conversion of convertible preferred shares	10,465,876
Weighted-average number of shares used to compute pro forma loss per share, basic and diluted (unaudited)	13,224,780
Pro forma net loss per share, basic and diluted (unaudited)	$ 1.22

12. Related Party Transactions

The Company incurred $147,000 in professional services expense related to certain members of the board of directors for the period from January 18, 2018 (inception) to December 31, 2018. The related party liability balance was $23,000 as of December 31, 2018.

13. Subsequent Events

In January and July 2019, the board of directors granted 889,807 and 3,177,101 stock options, respectively, to its employees and non-employee service providers. 25% of the options will vest on the first anniversary of employment or the first anniversary of the day of grant, and the remaining options will thereafter vest quarterly over the following 36-month period.

In June 2019, the Company agreed to issue 20,000,000 Series A convertible preferred shares at $1.00 per share. The shares were issued and the aggregate net proceeds of $20.0 million were received in June and July 2019 (see Note 7).

In June 2019, the Company formed 89bio, Inc. for the purpose of an internal reorganization transaction. Prior to the consummation the Company's initial public offering, all of the equity holders of 89Bio Ltd. will exchange 100% of the equity of 89Bio Ltd. for 100% of the equity of 89bio, Inc. Following this exchange, 89Bio Ltd. will become a wholly owned subsidiary of 89bio, Inc. (as mentioned in Note 1).

In accordance with ASC 855 "*Subsequent Events*" the Company evaluated subsequent events through August 15, 2019, the date these consolidated financial statements were available to be issued. The Company concluded that no other subsequent events have occurred that would require recognition or disclosure in the consolidated financial statements.

89Bio Ltd.
Condensed Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	December 31, 2018	June 30, 2019 (unaudited)	Pro Forma June 30, 2019 (unaudited)
Assets			
Current assets:			
Cash and cash equivalents	$ 11,234	$ 21,919	
Restricted cash	23	24	
Other current assets	59	84	
Total current assets	11,316	22,027	
Property and equipment, net	33	46	
Deferred offering costs	—	204	
Deferred tax assets	20	70	
Total assets	$ 11,369	$ 22,347	
Liabilities and shareholders' (deficit) equity			
Current liabilities:			
Accounts payable	$ 1,509	$ 968	
Accrued expenses	1,173	2,656	
Convertible preferred share liability	1,671	5,913	
Total current liabilities	4,353	9,537	
Commitments and contingencies (Note 5)			
Convertible preferred shares, NIS 0.01 nominal value; 60,000,000 shares authorized as of December 31, 2018 and June 30, 2019 (unaudited); 24,000,000 and 42,826,389 shares issued and outstanding as of December 31, 2018 and June 30, 2019 (unaudited), actual; aggregate liquidation preference of $24,000 and $42,826 as of December 31, 2018 and June 30, 2019 (unaudited), actual; no shares issued and outstanding as of June 30, 2019 pro forma (unaudited)	23,073	48,168	$ —
Shareholders' (deficit) equity:			
Ordinary shares, NIS 0.01 nominal value, 10,415,900 shares authorized at December 31, 2018 and June 30, 2019 (unaudited); 3,800,000 shares issued and outstanding as of December 31, 2018 and June 30, 2019 (unaudited), actual; 46,626,389 issued and outstanding as of June 30, 2019 pro forma (unaudited)	11	11	47
Additional paid-in capital	108	219	48,351
Accumulated deficit	(16,176)	(35,588)	(35,588)
Total shareholders' (deficit) equity	(16,057)	(35,358)	$ 12,810
Total liabilities, convertible preferred shares and shareholders' (deficit) equity	$ 11,369	$ 22,347	

The accompanying notes are an integral part of these condensed consolidated financial statements.

89Bio Ltd.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)
(In thousands, except share and per share amounts)

	Period from January 18, 2018 (inception) to June 30, 2018	Six Months Ended June 30, 2019
Operating expenses:		
Research and development	$ 6,700	$ 7,474
General and administrative	268	1,357
Total operating expenses	6,968	8,831
Loss from operations	6,968	8,831
Other (income) expenses, net	405	10,552
Net loss before tax	7,373	19,383
Income tax expense	—	29
Net loss and comprehensive loss	$ 7,373	$ 19,412
Net loss per share, basic and diluted	$ 4.34	$ 5.11
Weighted-average shares used to compute net loss per share, basic and diluted	1,700,552	3,800,000
Pro forma net loss per share, basic and diluted		$ 0.68
Weighted-average shares used to compute pro forma net loss per share, basic and diluted		28,496,861

The accompanying notes are an integral part of these condensed consolidated financial statements.

89Bio Ltd.
Condensed Consolidated Statements of Convertible Preferred Shares and Shareholders' Deficit
(Unaudited)
(In thousands, except share and per share amounts)

	Convertible Preferred Shares		Ordinary Shares		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Deficit
	Shares	Amounts	Shares	Amounts			
Balance as of January 18, 2018 (inception)	—	$ —	—	$ —	$ —	$ —	$ —
Issuance of ordinary shares	—	—	3,800,000	11	—	—	11
Issuance of convertible preferred shares, net of issuance costs of $228 and the recognition of the convertible preferred share liability of $638	14,900,000	14,034	—	—	—	—	—
Conversion of convertible note into preferred shares	100,000	100	—	—	—	—	—
Net loss and comprehensive loss	—	—	—	—	—	(7,373)	(7,373)
Balance as of June 30, 2018	15,000,000	$14,134	3,800,000	$ 11	$ —	$ (7,373)	$ (7,362)

	Convertible Preferred Shares		Ordinary Shares		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Deficit
	Shares	Amounts	Shares	Amounts			
Balance as of December 31, 2018	24,000,000	$23,073	3,800,000	$ 11	$ 108	$ (16,176)	$ (16,057)
Issuance of convertible preferred shares, net of issuance costs of $0 and the partial settlement of the convertible preferred share liability of $6,269	18,826,389	25,095	—	—	—	—	—
Share-based compensation	—	—	—	—	111	—	111
Net loss and comprehensive loss	—	—	—	—	—	(19,412)	(19,412)
Balance as of June 30, 2019	42,826,389	$48,168	3,800,000	$ 11	$ 219	$ (35,588)	$ (35,358)

The accompanying notes are an integral part of these condensed consolidated financial statements.

89Bio Ltd.
Condensed Consolidated Statements of Cash Flows
(Unaudited)
(In thousands)

	Period from January 18, 2018 (inception) to June 30, 2018	Six Months Ended June 30, 2019
Cash flows from operating activities:		
Net loss	$ (7,373)	$ (19,412)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	—	7
Share-based compensation	—	111
Deferred tax assets	—	(50)
Revaluation of convertible preferred share liability	357	10,511
Changes in operating assets and liabilities:		
Other current assets	(33)	(36)
Accrued expenses	197	1,279
Accounts payable	208	(541)
Net cash used in operating activities	(6,644)	(8,131)
Cash flows from investing activities:		
Purchase of property and equipment	(31)	(20)
Net cash used in investing activities	(31)	(20)
Cash flows from financing activities:		
Proceeds from issuance of convertible preferred shares and convertible preferred share liability, net of issuance costs	14,672	18,826
Proceeds from issuance of convertible note	100	—
Proceeds from issuance of ordinary shares	—	11
Net cash provided by financing activities	14,772	18,837
Net increase in cash and cash equivalents, and restricted cash	8,097	10,686
Cash and cash equivalents, and restricted cash at beginning of period	—	11,257
Cash and cash equivalents, and restricted cash at end of period	$ 8,097	$ 21,943
Components of cash and cash equivalents, and restricted cash:		
Cash and cash equivalents	$ 8,073	$ 21,919
Restricted cash	24	24
Total cash and cash equivalents, and restricted cash	$ 8,097	$ 21,943
Supplemental disclosures of noncash investing and financing information:		
Conversion of convertible note into preferred shares	$ 100	$ —
Deferred offering costs included in accrued expenses	$ —	$ 204

The accompanying notes are an integral part of these condensed consolidated financial statements.

89Bio Ltd.
Notes to Unaudited Interim Condensed Consolidated Financial Statements

1. Organization and Basis of Presentation

Description of Business

89Bio Ltd. ("89Bio" or the "Company") is a clinical-stage biopharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of liver and cardio-metabolic diseases. The Company's lead product candidate, BIO89-100, a specifically engineered glycoPEGylated analog of fibroblast growth factor 21, is currently being developed for the treatment of nonalcoholic steatohepatitis. 89Bio Ltd. was incorporated in Israel in January 2018. The Company has two wholly owned subsidiaries: 89bio Management, Inc., located in San Francisco, California and UAB 89bio Lithuania, located in Vilnius, Lithuania.

Going Concern

The accompanying condensed consolidated financial statements are prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and liquidation of liabilities in the normal course of business. To date, the Company has not generated revenues from its activities and has incurred substantial operating losses. Management expects the Company to continue to generate substantial operating losses for the foreseeable future until it completes development of its products and seeks regulatory approvals to market such products. Management will continue to fund its operations primarily through utilization of its current financial resources and through additional raises of capital.

Such conditions raise substantial doubts about the Company's ability to continue as a going concern for at least a year after the filing date of the accompanying condensed consolidated financial statements. Management plans to address these conditions by raising funds from its current investors as well as outside potential investors. However, there is no assurance that such funding will be available to the Company or that it will be obtained on terms favorable to the Company or will provide the Company with sufficient funds to meet its objectives. The accompanying condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of assets, carrying amounts or the amount or classification of liabilities that may be required should the Company be unable to continue as a going concern.

2. Summary of Significant Accounting Policies

Unaudited Interim Condensed Consolidated Financial Statements

The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited financial statements as of December 31, 2018 and for the period from January 18, 2018 (inception) to December 31, 2018 and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to present fairly the Company's financial position as of June 30, 2019, and its results of operations and comprehensive loss, cash flows and shareholders' deficit for the period from January 18, 2018 (inception) to June 30, 2018 and the six months ended June 30, 2019. The financial data and the other financial information contained in these notes to the condensed consolidated financial statements related to the period from January 18, 2018 (inception) to June 30, 2018 and the six months ended June 30, 2019 are unaudited. The results of operations for the six months ended June 30, 2019 are not necessarily indicative of the results to be expected for the year ending December 31, 2019 or for any other future annual or interim period. These condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements.

Unaudited Pro Forma Financial Information

The Company completed an internal reorganization transaction in September 2019, pursuant to which 89Bio Ltd. became a wholly owned subsidiary of 89bio, Inc., a newly formed Delaware corporation. As part of

89Bio Ltd.
Notes to Unaudited Interim Condensed Consolidated Financial Statements

the transaction, all of the equity holders of 89Bio Ltd. exchanged 100% of the equity of 89Bio Ltd. for 100% of the equity of 89bio, Inc.

The unaudited pro forma balance sheet information as of June 30, 2019 has been prepared to give effect to the exchange of all outstanding convertible preferred shares of 89Bio Ltd. into shares of common stock of 89bio, Inc. as if the exchange had occurred on June 30, 2019. The shares of common stock issuable and the proceeds expected to be received in the Company's anticipated IPO are excluded from such pro forma financial information.

The unaudited pro forma net loss per share, basic and diluted for the six months ended June 30, 2019 was computed using the weighted-average number of shares of ordinary shares outstanding, including to give effect to the exchange of all outstanding shares of convertible preferred shares of 89Bio Ltd. into equivalent shares of common stock of 89bio, Inc. as if such exchange had occurred at the beginning of the period, or their issuance dates if later.

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the condensed consolidated financial statements and the reported amounts of expenses during the reporting period. Significant estimates and assumptions made in the accompanying condensed consolidated financial statements include but are not limited to the fair value of stock options, the convertible preferred share liability and certain accruals. The Company evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors and adjusts those estimates and assumptions when facts and circumstances dictate. Actual results could differ from those estimates.

Fair Value Measurements

Financial assets and liabilities are recorded at fair value on a recurring basis in the balance sheets. The carrying values of Company's financial assets and liabilities, including cash and cash equivalents, restricted cash, other current assets, accounts payable, and accrued expenses approximate to their fair value due to the short-term maturity of these instruments. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. Assets and liabilities recorded at fair value are categorized based upon the level of judgment associated with the inputs used to measure their fair value. Hierarchical levels are directly related to the amount of subjectivity with the inputs to the valuation of these assets or liabilities as follows:

Level 1—Observable inputs such as unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date;

Level 2—Inputs (other than quoted prices included in Level 1) are either directly or indirectly observable inputs for similar assets or liabilities. These include quoted prices for identical or similar assets or liabilities in active markets and quoted prices for identical or similar assets of liabilities in markets that are not active;

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

89Bio Ltd.
Notes to Unaudited Interim Condensed Consolidated Financial Statements

Convertible Preferred Share Liability

The freestanding instruments related to the commitment by the Series A convertible preferred shareholders to purchase and by the Company to sell its Series A convertible preferred shares in subsequent closings, contingent upon the achievement of certain developmental milestones and approval by the board of directors, at a fixed price per share, are considered a liability (or an asset), measured at fair value as the shares underlying the rights contain liquidation preferences upon certain "deemed liquidation events" that are not solely within the Company's control and which are considered in-substance contingent redemption features (refer to Note 7 for further discussion on the redemption rights of the convertible preferred shares). The instruments are subject to revaluation at each balance sheet date until settlement, with revaluations recognized as a component of other (income) expenses, net in the consolidated statements of operations and comprehensive loss.

Deferred Offering Costs

The Company has deferred offering costs consisting of legal, accounting and other fees and costs directly attributable to the Company's anticipated IPO. The deferred offering costs will be offset against the proceeds received upon the completion of the anticipated IPO. In the event the anticipated IPO is terminated, all of the deferred offering costs will be expensed. As of December 31, 2018, the Company did not record any deferred offering costs. As of June 30, 2019, the Company had $204,000 of deferred offering costs on the consolidated balance sheet.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") 2014-09—*Revenue from contracts with customers*, to achieve a consistent application of revenue recognition, resulting in a single revenue model to be applied by reporting companies under U.S. GAAP. Under the new model, recognition of revenue occurs when a customer obtains control of the promised goods or services in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In addition, the standard requires that reporting companies disclose the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. The standard is effective for public entities for fiscal years beginning after December 15, 2017 and is effective for nonpublic entities for fiscal years beginning after December 15, 2018. The standard is required to be applied retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of initially applying it recognized at the date of initial application. The Company adopted this standard on January 1, 2019, and as the Company has not incurred revenues to date, the adoption of the standard did not have a significant impact on its consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02—*Leases*, requiring the recognition of lease assets and liabilities on the balance sheet. The standard: (a) clarifies the definition of a lease; (b) requires a dual approach to lease classification similar to current lease classifications; and (c) causes lessees to recognize leases on the balance sheet as a lease liability with a corresponding right-of-use asset for leases with a lease-term of more than twelve months. The standard is effective for public entities for fiscal years beginning after December 15, 2018 and for nonpublic entities for fiscal years beginning after December 15, 2019. The Company is currently evaluating the impact of this standard and expects the adoption will result in an insignificant increase in the assets and liabilities on its consolidated balance sheet for operating leases.

In June 2018, the FASB issued ASU No. 2018-07 *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*, which is intended to reduce the cost and complexity and to improve financial reporting for nonemployee share based payment. The standard expands the

scope of Topic 718, (which currently only includes share-based payments to employees) to include share-based payments issued to nonemployees for goods or services. Consequently, the accounting for share-based payments to nonemployees and employees will be substantially aligned. The standard is effective for public entities for fiscal years beginning after December 15, 2019 and nonpublic entities for fiscal years beginning after December 15, 2020. Early adoption is permitted but no earlier than a company's adoption date of Topic 606. The Company early adopted this standard on January 1, 2019, and the impact of its adoption on the Company's consolidated financial statements is not material.

3. Fair Value Measurements

The fair value of the Company's financial liabilities measured at fair value on a recurring basis by level within the fair value hierarchy are as follows (in thousands):

	December 31, 2018			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Convertible preferred share liability	$ —	$ —	$1,671	$1,671
Total financial liabilities	$ —	$ —	$1,671	$1,671

	June 30, 2019			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Convertible preferred share liability	$ —	$ —	$5,913	$5,913
Total financial liabilities	$ —	$ —	$5,913	$5,913

The changes in the fair value of the Company's Level 3 financial liabilities, which are measured on a recurring basis are as follows (in thousands):

	December 31, 2018	June 30, 2019
Beginning balance	$ —	$ 1,671
Recognition of convertible preferred share liability upon issuance of convertible preferred shares	638	—
Revaluation of convertible preferred share liability recorded in other (income) expense, net	979	10,511
Partial settlement of convertible preferred share liability upon second closing	54	(1,860)
Partial settlement of convertible preferred share liability upon third closing	—	(4,409)
Ending balance	$ 1,671	$ 5,913

The fair value of the Company's convertible preferred share liability is based on significant inputs not observed in the market, and thus represent a Level 3 measurement. Refer to Note 7 for further discussion on the convertible preferred share liability.

89Bio Ltd.
Notes to Unaudited Interim Condensed Consolidated Financial Statements

4. Consolidated Balance Sheet Components

Accrued Expenses

Accrued expenses consist of the following (in thousands):

	December 31, 2018	June 30, 2019
Accrued research and development expense	$ 890	$2,015
Accrued employee and related expenses	283	641
Total accrued expenses	$ 1,173	$2,656

5. Commitments and Contingencies

Asset Transfer and License Agreement with Teva Pharmaceutical Industries Ltd

In April 2018, the Company concurrently entered into two Asset Transfer and License Agreements (the "Teva Agreements") with Teva Pharmaceutical Industries Ltd ("Teva") under which it acquired certain patents and intellectual property relating to two programs: (1) Teva's glycoPEGylated FGF21 program, including the compound TEV-47948 (BIO89-100), a glycoPEGylated long-acting FGF21 and (2) Teva's development program of small molecule inhibitors of Fatty Acid Synthase. Pursuant to the Teva Agreements, the Company paid Teva an initial nonrefundable upfront payment of $6.0 million and the Company could be obligated to pay Teva up to $67.5 million under each program, for a total of $135.0 million, upon the achievement of certain clinical development and commercial milestones. In addition, the Company is obligated to pay Teva tiered royalties at percentages in the low-to-mid single-digits on worldwide net sales on all products containing the Teva compounds.

The Teva Agreements can be terminated (i) by the Company without cause, after the first anniversary of the effective date, upon 120 days' written notice to Teva, (ii) by either party, if the other party materially breaches any of its obligations under the Agreements and fails to cure such breach within 60 days after receiving notice thereof, or (iii) by either party, if a bankruptcy petition is filed against the other party and is not dismissed within 60 days. In addition, Teva can also terminate the agreement related to the Company's glycoPEGylated FGF21 program in the event the Company, or any of its affiliates or sublicensees, challenges any of the Teva patents licensed to the Company, and the challenge is not withdrawn within 30 days of written notice from Teva.

The Company accounted for the acquisition of technology as an asset acquisition because it did not meet the definition of a business. The Company recorded the total consideration transferred to Teva as research and development expense in the condensed consolidated statements of operations and comprehensive loss because the acquired technology represented in-process research and development and had no alternative future use.

6. Convertible Note

In March 2018, the Company entered into a Convertible Loan Agreement (the "Convertible Note") with a principal amount of $100,000 and a fixed interest rate of 8% per annum. The Convertible Note was automatically convertible into the Company's next equity financing, or upon an earlier event of default. In April 2018, the entire amount outstanding converted into 100,000 shares of Series A convertible preferred shares upon the closing of the Series A financing.

89Bio Ltd.
Notes to Unaudited Interim Condensed Consolidated Financial Statements

7. Convertible Preferred Shares

In April 2018, the Company entered into the Series A Share Purchase Agreement (the "SPA"), pursuant to which the investors committed to invest an aggregate amount of up to $60.0 million for the issuance of Series A convertible preferred shares at a price of $1.00 per share.

The initial closing occurred on April 16, 2018, and the Company issued 14,900,000 Series A convertible preferred shares at a price per share of $1.00 for net cash proceeds of $14.7 million. The investors also committed to purchase 15,000,000 and 30,000,000 shares of Series A convertible preferred shares at a price of $1.00 per share in second and third closings, respectively, contingent upon the achievement by the Company of certain development milestones and approval by the board of directors.

The investors' commitment to purchase and the Company's commitment to sell Series A convertible preferred shares represent a freestanding instrument accounted for at fair value and re-measured at each reporting date. The Company estimates the fair value of this commitment using the Black Scholes option pricing model. On the date of the initial closing, the Company recorded the commitments associated with the second and third closings of the Series A convertible preferred shares at a net value of $638,000. For the period from January 18, 2018 (inception) to June 30, 2018 and for the six months ended June 30, 2019, the Company recorded an expense of $357,000 and $10.5 million, respectively, for the revaluation of the convertible preferred share liability, within other (income) expense, net in the condensed consolidated statements of operations and comprehensive loss.

In December 2018, the Series A convertible preferred shareholders partially accelerated the second closing and the Company issued 9,000,000 Series A convertible preferred shares at a price of $1.00 per share and received net proceeds of $9.0 million.

In June 2019, the Company and the Series A convertible preferred shares investors agreed to issue the remaining 6,000,000 Series A convertible preferred shares at a price of $1.00 per share related to the second closing, and to partially accelerate 14,000,000 Series A convertible preferred shares at a price of $1.00 per share related to the third closing. The shares were issued and the aggregate net proceeds of $20.0 million were received in June and July 2019.

Immediately subsequent to the issuance of shares as agreed by the Company and the investors in June 2019, 16,000,000 Series A convertible preferred shares were subject to issuance upon completion of remaining milestones or as the preferred shareholders elect to waive such milestones.

Convertible Preferred Shares

Convertible preferred shares consist of the following:

	December 31, 2018			
Convertible Preferred Shares	Shares Authorized	Shares Issued and Outstanding	Carrying Value	Liquidation Preference
Series A	60,000,000	24,000,000	$ 23,073,000	$ 24,000,000
Total	60,000,000	24,000,000	$ 23,073,000	$ 24,000,000

89Bio Ltd.
Notes to Unaudited Interim Condensed Consolidated Financial Statements

	June 30, 2019			
Convertible Preferred Shares	Shares Authorized	Shares Issued and Outstanding	Carrying Value	Liquidation Preference
Series A	60,000,000	42,826,389	$ 48,168,000	$ 42,826,000
Total	60,000,000	42,826,389	$ 48,168,000	$ 42,826,000

The Company's articles of association do not provide redemption rights to the holders of the Series A convertible preferred shares. In the event of a liquidation event, all the funds and assets of the Company available for distribution among all the shareholders shall be distributed in the following order of preference: (a) the holders of the Series A convertible preferred shares shall be entitled to receive an amount per share equal to $1.00 per each Series A convertible preferred share (less the amount of distributions actually received in any prior liquidation event, plus all declared but unpaid dividends) and (b) the remaining assets of the Company available for distribution to shareholders shall be distributed among the holders of ordinary shares and to the holders of the Series A convertible preferred shares on an as-converted and pro rata basis.

Although the convertible preferred shares are not redeemable, in the event of certain "deemed liquidation events" that are not solely within the Company's control (including merger, acquisition, or sale of all or substantially all of the Company's assets), the holders of the convertible preferred shares would be entitled to preference amounts paid before distribution to other shareholders and hence effectively redeeming the preference amount. The convertible preferred shares are classified outside of shareholders' deficit as a result of these in-substance contingent redemption rights.

As of December 31, 2018, and June 30, 2019, the Company did not adjust the carrying values of the convertible preferred shares to the deemed liquidation values of such shares since a liquidation event was not probable of occurring.

8. Ordinary Shares

Total ordinary shares reserved for issuance are summarized as follows (in thousands):

	December 31, 2018	June 30, 2019
Series A convertible preferred shares outstanding, as converted	24,000,000	42,826,389
Options issued and outstanding	3,677,056	4,482,991
Shares available for future option grants	2,938,844	2,132,909
Total ordinary shares reserved for issuance	30,615,900	49,442,289

9. Share-Based Compensation

As of June 30, 2019, there were 2,132,909 ordinary shares reserved and available for grant under the 2018 Plan.

89Bio Ltd.
Notes to Unaudited Interim Condensed Consolidated Financial Statements

The Company recorded share-based compensation for the periods indicated as follows (in thousands):

	Period from January 18, 2018 (inception) to June 30, 2018	Six months ended June 30, 2019
Research and development	$ —	$ 20
General and administrative	—	91
Total share-based compensation	$ —	$ 111

The fair value of option awards granted for the periods indicated was estimated at the date of grant using a Black-Scholes option-pricing model with the following assumptions:

	Period from January 18, 2018 (inception) to June 30, 2018	Six months ended June 30, 2019
Expected term (years)	—	6.11
Expected volatility	—	61.80%
Risk-free interest rate	—	2.54-2.60%
Expected dividend	—	—

The following table summarizes stock option activity under the 2018 Plan for the six months ended June 30, 2019:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (In years)	Aggregate Intrinsic Value (In thousands)
Balance outstanding as of December 31, 2018	3,677,056	$ 0.31	9.87	$ —
Granted	889,807	0.31		
Exercised	—	—		
Cancelled	(83,872)	0.31		
Balance outstanding as of June 30, 2019	4,482,991	$ 0.31	9.40	$ 852
Exercisable as of June 30, 2019	410,612	$ 0.31	9.40	$ 78

10. Net Loss and Unaudited Pro Forma Net Loss Per Share

The following outstanding potentially dilutive ordinary share equivalents have been excluded from the calculation of diluted net loss per share for the periods presented due to their anti-dilutive effect:

	Period from January 18, 2018 (inception) to June 30, 2018	Six Months Ended June 30, 2019
Convertible preferred shares	15,000,000	42,826,389
Stock options to purchase ordinary shares	—	4,482,991
Total	15,000,000	47,309,380

89Bio Ltd.
Notes to Unaudited Interim Condensed Consolidated Financial Statements

Unaudited Pro Forma Net Loss Per Share

Pro forma basic and diluted net loss per share has been computed to give effect to the completion of an internal reorganization transaction and assumes the exchange of all outstanding shares of convertible preferred shares of 89Bio Ltd. into shares of common stock of 89bio, Inc.

	Six Months Ended June 30, 2019
Numerator:	
Net loss	$ 19,412
Denominator:	
Weighted-average number of shares used to compute net loss per share, basic and diluted	3,800,000
Pro forma adjustment to reflect assumed conversion of convertible preferred shares	24,696,861
Weighted-average number of shares used to compute pro forma loss per share, basic and diluted	28,496,861
Pro forma net loss per share, basic and diluted	$ 0.68

11. Related Party Transactions

The Company incurred $128,000 and $80,000 in professional services expense related to certain members of the board of directors for the period from January 18, 2018 (inception) to June 30, 2018 and for the six months ended June 30, 2019, respectively. The related party liability balance was $23,000 and $4,000 as of December 31, 2018 and June 30, 2019, respectively.

12. Subsequent Events

In July 2019, the board of directors granted 3,177,101 stock options, to its employees and non-employee service providers. 25% of the options will vest on the first anniversary of employment or the first anniversary of the day of grant, and the remaining options will thereafter vest quarterly over the following 36-month period.

In July 2019, the Company issued 1,173,611 Series A convertible preferred shares at $1.00 per share and aggregate net proceeds of $1.2 million were also received in July 2019, related to the shares the Company agreed to issue to investors in June 2019 (see Note 7).

In September 2019, the Company completed an internal reorganization transaction pursuant to which 89Bio Ltd. became a wholly owned subsidiary of 89bio, Inc., a newly formed Delaware corporation. As part of the transaction, all of the equity holders of 89Bio Ltd. exchanged 100% of the equity of 89Bio Ltd. for 100% of the equity of 89bio, Inc.

In accordance with ASC 855 “*Subsequent Events*” the Company evaluated subsequent events through September 19, 2019, the date the unaudited interim condensed consolidated financial statements were available to be filed. The Company concluded that no other subsequent events have occurred that would require recognition or disclosure in the accompanying financial statements.

Through and including , 2019, (the 25th day after the date of this prospectus), all dealers effecting transactions in our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

Shares

Common Stock

PROSPECTUS

BofA Merrill Lynch

SVB Leerink

RBC Capital Markets

Oppenheimer & Co.

, 2019

PART II

INFORMATION NOT REQUIRED IN THE PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth the various expenses, other than underwriting discounts and commissions, payable by the registrant in connection with the sale of common stock being registered. All of the amounts shown are estimated except the Securities and Exchange Commission (the "SEC") registration fee, the Financial Industry Regulatory Authority, Inc. ("FINRA") filing fee and The Nasdaq Global Market listing fee.

	Amount To Be Paid
SEC registration fee	$ 9,086
FINRA filing fee	11,000
The Nasdaq Global Market listing fee	*
Printing and engraving expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Blue Sky, qualification fees and expenses	*
Transfer agent and registrar fees	*
Miscellaneous fees and expenses	*
Total	$ *

* To be completed by amendment.

Item 14. Indemnification of Directors and Officers.

The company is a Delaware corporation. Section 145(a) of the Delaware General Corporation Law (the "DGCL") provides that a Delaware corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative, other than an action by or in the right of the corporation, by reason of the fact that such person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with such action, suit or proceeding if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful.

Section 145(b) of the DGCL provides that a Delaware corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor by reason of the fact that such person acted in any of the capacities set forth above, against expenses (including attorneys' fees) actually and reasonably incurred by such person in connection with the defense or settlement of such action or suit if the person acted in good faith and in a manner the person reasonably believed to be in, or not opposed to, the best interests of the corporation, except that no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation, unless and only to the extent that the Court of Chancery or the court in which such action or suit was brought shall determine, upon application, that, despite the adjudication of liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the court shall deem proper.

Further subsections of DGCL Section 145 provide that:

(1) to the extent a present or former director or officer of a corporation has been successful on the merits or otherwise in the defense of any action, suit or proceeding referred to in subsections (i) and (ii) of Section 145 or in the defense of any claim, issue or matter therein, such person shall be indemnified against expenses, including attorneys' fees, actually and reasonably incurred by such person in connection therewith;

(2) the indemnification and advancement of expenses provided for pursuant to Section 145 shall not be deemed exclusive of any other rights to which those seeking indemnification or advancement of expenses may be entitled under any bylaw, agreement, vote of shareholders or disinterested directors or otherwise; and

(3) the corporation shall have the power to purchase and maintain insurance of behalf of any person who is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against any liability asserted against such person and incurred by such person in any such capacity, or arising out of such person's status as such, whether or not the corporation would have the power to indemnify such person against such liability under Section 145.

As used in this Item 14, the term "proceeding" means any threatened, pending or completed action, suit or proceeding, whether or not by or in the right of the company, and whether civil, criminal, administrative, investigative or otherwise.

Section 145 of the DGCL makes provision for the indemnification of officers and directors in terms sufficiently broad to indemnify officers and directors of the company under certain circumstances from liabilities (including reimbursement for expenses incurred) arising under the Securities Act of 1933. We expect that the Company's Second Amended and Restated Certificate of Incorporation and Second Amended and Restated Bylaws will provide, in effect, that, to the fullest extent and under the circumstances permitted by Section 145 of the DGCL, the company will indemnify any and all of its officers and directors. Before the completion of this offering, the company intends to enter into indemnification agreements with its officers and directors. The company may, in its discretion, similarly indemnify its employees and agents. We expect that the Company's Second Amended and Restated Certificate of Incorporation will also relieve the Company's directors from monetary damages to the company or its shareholders for breach of such director's fiduciary duty as a director to the fullest extent permitted by the DGCL. Under Section 102(b)(7) of the DGCL, a corporation may relieve its directors from personal liability to such corporation or its shareholders for monetary damages for any breach of their fiduciary duty as directors except (i) for a breach of the duty of loyalty, (ii) for failure to act in good faith, (iii) for intentional misconduct or knowing violation of law, (iv) for willful or negligent violations of certain provisions in the DGCL imposing certain requirements with respect to stock repurchases, redemptions and dividends or (v) for any transactions from which the director derived an improper personal benefit.

The company has purchased insurance policies that, within the limits and subject to the terms and conditions thereof, cover certain expenses and liabilities that may be incurred by directors and officers in connection with proceedings that may be brought against them as a result of an act or omission committed or suffered while acting as a director or officer of the company.

The form of Underwriting Agreement, to be entered into in connection with this offering and to be attached as Exhibit 1.1 hereto, provides for the indemnification by the underwriters of us and our officers and directors for certain liabilities, including liabilities arising under the Securities Act, and affords certain rights of contribution with respect thereto.

Item 15. Recent Sales of Unregistered Securities.

Since our inception in January 2018, we have made the following sales of unregistered securities:

Issuances of Capital Stock

In January 2018, we issued 2,250 shares of our common stock for gross aggregate consideration of $6 to two investors.

In March 2018, we issued to an investor a convertible promissory note (the "Convertible Note") in the aggregate principal amount of $100,000.

In April 2018, we issued 3,797,750 shares of our common stock for gross aggregate consideration of $10,996 to two investors.

Also in April 2018, we issued 15,000,000 shares of our Series A convertible preferred stock for gross aggregate consideration of $14,900,000 to nine investors, including the conversion of the Convertible Note.

In December 2018, we issued 9,000,000 shares of our Series A convertible preferred stock for gross aggregate consideration of $9,000,000 to nine investors.

In June and July 2019, we issued an aggregate of 20,000,000 shares of our Series A convertible preferred stock for gross aggregate consideration of $20,000,000 to ten investors.

In September 2019, pursuant to an internal reorganization, we issued 3,800,000 shares of our common stock and 44,000,000 shares of our convertible preferred stock to our existing stockholders in exchange for their shares of 89Bio, Ltd.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions, or any public offering. The offers, sales and issuances of the securities listed in this Item 15 were deemed to be exempt from registration under the Securities Act under either (1) Rule 701 promulgated under the Securities Act as offers and sales of securities pursuant to certain compensatory benefit plans and contracts relating to compensation in compliance with Rule 701 or (2) Section 4(a)(2) of the Securities Act, including Regulation D promulgated thereunder, as offers and sales made to a limited number of accredited investors and qualified institutional buyers.

Grants of Stock Options

Since January 2018, we have granted stock options to purchase an aggregate of 7,866,964 shares of our common stock at a weighted-average exercise price of $0.39 to employees, directors and non-employee service providers.

The issuances of the securities described above were deemed to be exempt from registration pursuant to Section 4(a)(2) of the Securities Act or Rule 701 promulgated under the Securities Act as transactions pursuant to compensatory benefit plans. The shares of common stock issued upon the exercise of options are deemed to be restricted securities for purposes of the Securities Act.

Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits

Exhibit Number	Description of Exhibit
1.1*	Form of Underwriting Agreement.
2.1	Contribution and Exchange Agreement, dated as of September 17, 2019, by and among 89Bio, Ltd., the registrant and its shareholders.
3.1	Certificate of Incorporation of the registrant, as currently in effect.
3.2*	Form of Second Amended and Restated Certificate of Incorporation of the registrant, to be in effect upon completion of this offering.
3.3	Bylaws of the registrant, as currently in effect.
3.4*	Form of Second Amended and Restated Bylaws of the registrant, to be in effect upon completion of this offering.
4.1*	Specimen common stock certificate of the registrant.
4.2	Investors' Rights Agreement, dated as of September 17, 2019, by and among the registrant and certain of its shareholders
5.1*	Opinion of Gibson, Dunn & Crutcher LLP.
10.1+	Form of Indemnification Agreement for directors and executive officers, to be in effect upon completion of this offering.
10.2*+	2019 Equity Incentive Plan.
10.3*+	2019 Employee Stock Purchase Plan.
10.4+	Executive Employment Offer Letter, dated June 25, 2018, by and between 89Bio Ltd. and Rohan Palekar.
10.5+	Executive Employment Agreement, dated April 23, 2018, by and between 89Bio Ltd. and Ram Waisbourd.
10.6+	Executive Employment Offer Letter, dated November 20, 2018, by and between 89Bio Ltd. and Hank Mansbach.
10.7+	Executive Employment Offer Letter, dated February 28, 2019, by and between 89Bio Ltd. and Quoc Le-Nguyen.
10.8+	Executive Employment Offer Letter, dated July 21, 2019, by and between 89Bio Ltd. and Ryan Martins.
10.9+	Director Offer Letter, dated July 1, 2018, by and between 89Bio Ltd. and Michael Hayden.
10.10*+	Non-Employee Director Compensation Policy.
10.11#	Asset Transfer and License Agreement—FGF21 by and among 89Bio Ltd., ratiopharm GmbH, Teva Branded Pharmaceutical Products R&D, Inc. and Teva Pharmaceutical Industries Ltd, dated as of April 16, 2018.
10.12#	Reagent Supply and Technology Transfer Agreement by and between 89Bio Ltd. and Teva Biotech GmbH, dated as of April 16, 2018, as amended.
10.13#	Sublicense Agreement by and between 89Bio Ltd. and ratiopharm GmbH, dated as of April 16, 2018.
10.14#	Master Services Agreement by and between 89Bio Ltd. and Biotechpharma UAB, dated as of May 7, 2018, as amended.
21.1	List of subsidiaries.
23.1	Consent of Independent Registered Public Accounting Firm.
23.2	Consent of Independent Registered Public Accounting Firm.
23.3*	Consent of Gibson, Dunn & Crutcher LLP (see Exhibit 5.1).
24.1	Power of Attorney (see signature page hereto).

* To be filed by amendment.
\+ Indicates management contract or compensatory plan.
\# Portions of the exhibit have been omitted for confidentiality purposes.

(b) No financial statement schedules are provided because the information called for is not required or is shown in the financial statements or the notes thereto.

Item 17. Undertakings.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance on Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be a part of this registration statement as of the time it was declared effective.

(2) For purposes of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of San Francisco, State of California, on October 11, 2019.

89bio, Inc.

By: /s/ Rohan Palekar
Rohan Palekar
Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Rohan Palekar, Ram Waisbourd and Ryan Martins, and each of them, the true and lawful attorneys-in-fact and agents of the undersigned, with full power of substitution and resubstitution, for and in the name, place and stead of the undersigned, to sign in any and all capacities (including, without limitation, the capacities listed below), the registration statement, any and all amendments (including post-effective amendments) to the registration statement and any and all successor registration statements of the registrant, including any filings pursuant to Rule 462(b) under the Securities Act of 1933, as amended, and to file the same, with all exhibits thereto, and all other documents in connection therewith, with the Securities and Exchange Commission, and hereby grants to such attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and anything necessary to be done to enable the registrant to comply with the provisions of the Securities Act and all the requirements of the Securities and Exchange Commission, as fully to all intents and purposes as the undersigned might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his or her substitute, or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities set forth opposite their names and on the date indicated above.

Signature	Title	Date
/s/ Rohan Palekar Rohan Palekar	Chief Executive Officer (*principal executive officer*)	October 11, 2019
/s/ Ryan Martins Ryan Martins	Chief Financial Officer (*principal financial and accounting officer*)	October 11, 2019
/s/ Derek DiRocco Derek DiRocco, Ph.D.	Director	October 11, 2019
/s/ Gregory Grunberg Gregory Grunberg, M.D.	Director	October 11, 2019
/s/ Michael Hayden Michael Hayden, M.B., Ch.B., Ph.D.	Director	October 11, 2019
/s/ Tomer Kariv Tomer Kariv	Director	October 11, 2019
/s/ Anat Naschitz Anat Naschitz	Director	October 11, 2019

Exhibit 2.1

EXECUTION VERSION

CONTRIBUTION AND EXCHANGE AGREEMENT

This Contribution and Exchange Agreement (this "***Agreement***") is made and entered into as of September 17, 2019 by and among 89bio, Inc., a Delaware corporation ("***NewCo***"), 89bio Ltd., an Israeli private limited liability company ("***OldCo***"), and (i) each holder of issued and outstanding Ordinary Shares (as defined in the Amended Articles of Association of OldCo (the "***Articles***")) (each, an "***Ordinary Shareholder***" and, collectively, the "***Ordinary Shareholders***"), (ii) each holder of issued and outstanding Preferred A Shares (as defined in the Articles) (each, a "***Preferred Shareholder***" and, collectively, the "***Preferred Shareholders***") and (iii) each holder of issued and outstanding options to purchase Ordinary Shares, (each, an "***Option Holder***" and, collectively, the "***Option Holders***" and, together with the Ordinary Shareholders and the Preferred Shareholders, the "***Equityholders***"), each as indicated on Exhibit A hereto.

RECITALS

A. The Ordinary Shareholders collectively own 100% of the issued and outstanding Ordinary Shares, each in the amounts set forth on Exhibit A hereto under the heading "OldCo Ordinary Shares" (collectively, the "***OldCo Ordinary Shares***").

B. The Preferred Shareholders collectively own 100% of the issued and outstanding Preferred A Shares, each in the amounts set forth on Exhibit A hereto under the heading "OldCo Preferred Shares" (collectively, the "***OldCo Preferred Shares***").

C. The Option Holders collectively own 100% of the issued and outstanding options and other rights to purchase Ordinary Shares, each in the amounts set forth on the signature page to this Agreement of each such Option Holder under the heading "OldCo Options" (collectively, the "***OldCo Options***" and, together with the OldCo Ordinary Shares and OldCo Preferred Shares, the "***OldCo Securities***").

D. In connection with a corporate reorganization:

a. each of the Ordinary Shareholders desire to contribute all of their OldCo Ordinary Shares to NewCo in exchange for newly issued shares of common stock of NewCo, par value $0.001 per share ("***NewCo Common Stock***"), in the amounts set forth on Exhibit A hereto under the heading "NewCo Common Shares" (collectively, the "***NewCo Common Shares***") and NewCo desires to accept such contributions and issue the NewCo Common Shares to the Ordinary Shareholders;

b. each of the Preferred Shareholders desire to contribute all of their OldCo Preferred Shares to NewCo in exchange for newly issued shares of Series A Preferred Stock of NewCo, par value $0.001 per share ("***NewCo Preferred Stock***"), in the amounts set forth on Exhibit A hereto under the heading "NewCo Preferred Shares" (collectively, the "***NewCo Preferred Shares***") and NewCo desires to accept such contributions and issue the NewCo Preferred Shares to the Preferred Shareholders; and

c. each of the Option Holders desire to exchange all of their OldCo Options for newly issued options to purchase shares of NewCo Common Stock, in the amounts set forth on the signature page to this Agreement of each such Option Holder under the heading "NewCo Options" (collectively, the "***NewCo Options***") and NewCo desires to accept and cancel the OldCo Options and issue the NewCo Options to the Option Holders, all subject to the enactment by NewCo of its 2019 Equity Incentive Plan (the "***Plan***") and an Israeli Appendix, in compliance with the Israeli Income Tax Ordinance (New Version), 5721 – 1961 (the "***Ordinance***").

Pursuant to the foregoing transactions, OldCo will became a wholly owned subsidiary of NewCo and the Equityholders will own all of the issued and outstanding equity interests of NewCo immediately following the Closing.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing recitals and for other good and valuable consideration, the receipt and adequacy of which the parties acknowledge, the parties hereby agree as follows:

1. **Contribution and Exchange of Securities**.

(a) Ordinary Shares. On the terms and subject to the conditions set forth herein, effective as of the Closing, NewCo shall issue to each Ordinary Shareholder, and each such Ordinary Shareholder shall accept from NewCo, the number of newly issued NewCo Common Shares set forth opposite each such Ordinary Shareholder's name on Exhibit A hereto under the heading "NewCo Common Shares" in consideration for the contribution and transfer, conveyance and assignment by each such Ordinary Shareholder of all of each such Ordinary Shareholder's right, title and interest in and to all of the OldCo Ordinary Shares held by such Ordinary Shareholder, free and clear of any liens or encumbrances, to NewCo, receipt of which is acknowledged by such Ordinary Shareholder and NewCo, respectively.

(b) Preferred Shares. On the terms and subject to the conditions set forth herein, effective as of the Closing, NewCo shall issue to each Preferred Shareholder, and each such Preferred Shareholder shall accept from NewCo, the number of newly issued NewCo Preferred Shares set forth opposite each such Preferred Shareholder's name on Exhibit A hereto under the heading "NewCo Preferred Shares" in consideration for the contribution and transfer, conveyance and assignment by each such Preferred Shareholder of all of each such Preferred Shareholder's right, title and interest in and to all of the OldCo Preferred Shares held by such Preferred Shareholder, free and clear of any liens or encumbrances, to NewCo, receipt of which is acknowledged by such Preferred Shareholder and NewCo, respectively.

(c) Options. On the terms and subject to the adoption of the Plan, the lapse of waiting periods under the Plan, if any, the execution by the Option Holders of award agreements reflecting the NewCo Options granted to the Option Holders and the conditions set forth herein, effective as of the Closing, NewCo shall issue to each Option Holder, and each such Option Holder shall accept from NewCo, the number of newly issued NewCo Options set forth on the signature page to this Agreement of each such Option Holder under the heading "NewCo Options" in consideration for the transfer, conveyance and assignment by each such Option Holder of all of each such Option Holder's right, title and interest in and to all of the OldCo Options held by such Option Holder, free and clear of any liens or encumbrances, to NewCo, receipt of which is acknowledged by such Option Holder and NewCo, respectively.

2. **Closing**.

(a) Subject to the satisfaction of the conditions set forth in Section 5 hereof, the delivery of the OldCo Securities to NewCo and the issuance of the NewCo Securities to the Equityholders shall be deemed to occur at such time on such date as OldCo and NewCo hereto mutually agree (which time and place are referred to in this Agreement as the "***Closing***").

(b) At the Closing, NewCo will issue and reflect in its books and records the number of: (i) NewCo Common Shares that each Ordinary Shareholder will acquire hereunder, (ii) NewCo Preferred Shares that each Preferred Shareholder will acquire hereunder, and (iii) NewCo Options which will be granted to each Option Holder as promptly as practicable following the Closing pursuant to Section 2(d) below.

(c) At the Closing, (i) the Investors' Rights Agreement, dated as of April 16, 2018, by and among OldCo and the Equityholders and (ii) the management rights letters delivered by OldCo to Longitude Venture Partners III, L.P. shall be terminated by the mutual agreement of the parties thereto.

(d) As promptly as practicable following the Closing, NewCo will deliver to the Option Holders award agreements reflecting the NewCo Options granted to the Option Holders.

3. **Representations and Warranties of Newco**. NewCo hereby represents and warrants to the Equityholders that the following statements are true and complete as of the Closing:

(a) Organization, Good Standing, Corporate Power and Qualification. NewCo has been duly incorporated and organized, and is validly existing in good standing, under the laws of the State of Delaware. NewCo has the requisite corporate power and authority to enter into and perform this Agreement. NewCo is newly formed and has not conducted any business since its formation other than in connection with the transactions contemplated hereby.

(b) Capitalization. Immediately prior to the Closing, the capitalization of NewCo consisted of (i) 72,882,353 authorized shares of NewCo Common Stock, of which no shares are issued and outstanding; and (ii) 60,000,000 authorized shares of NewCo Preferred Stock, of which no shares are issued and outstanding. The rights, privileges and preference of the NewCo Preferred Shares and the NewCo Common Shares are as stated in the Restated Certificate (as defined below).

(c) Due Authorization. All corporate action has been taken on the part of NewCo that is necessary for: (i) the authorization, execution, delivery of, and the performance of all obligations of NewCo under, this Agreement, and (ii) the authorization, issuance, reservation for issuance and delivery hereunder of the following securities (collectively, the "***NewCo Securities***"):

i. the NewCo Common Shares, NewCo Preferred Shares and NewCo Options, each as set forth on Exhibit A and on the signature page to this Agreement of each such Option Holder;

ii. the shares of NewCo Common Stock issuable upon conversion of the NewCo Preferred Shares (the "***Conversion Shares***"); and

iii. the shares of NewCo Common Stock issuable upon exercise of the NewCo Options (the "***Option Shares***").

This Agreement, when executed and delivered, will constitute the valid and legally binding obligations of NewCo, enforceable in accordance with its terms, except as may be limited by applicable law.

(d) Valid Issuance of Stock. Each of the NewCo Common Shares and the NewCo Preferred Shares, when issued as provided in this Agreement for the consideration set forth herein, will be duly authorized and validly issued, fully paid and non-assessable, will not be subject to pre-emptive rights or rights of first refusal, other than as set forth in the Restated Certificate and/or the Ancillary Investment Agreements, and will be free of restrictions on transfer other than restrictions on transfer under this Agreement, the Restated Certificate and/or the Ancillary Investment Agreements or under applicable state and federal securities laws. The Conversion Shares and the Option Shares, when issued pursuant to the terms of the Restated Certificate and the applicable option award agreement (respectively), will be duly authorized and validly issued, fully paid and non-assessable, will not be subject to pre-emptive rights or rights of first refusal, other than as set forth in the Restated Certificate and/or the Ancillary Investment Agreements, and will be free of restrictions on transfer other than restrictions on transfer under this Agreement, the Restated Certificate and/or the Ancillary Investment Agreements or under applicable state and federal securities laws.

4. **Representations, Warranties and Certain Agreements of Equityholders**. Each Equityholder (other than Option Holders where specifically noted below) hereby represents and warrants, severally and not jointly, to NewCo that the following statements are true and complete as of the Closing:

(a) Authorization. This Agreement constitutes such Equityholder's valid and legally binding obligation, enforceable in accordance with its terms except as may be limited by applicable law. Such Equityholder has full power, authority and legal capacity to enter into this Agreement.

(b) Title to OldCo Securities. Such Equityholder has good and marketable title to, and is the legal and beneficial owner of, the OldCo Securities listed opposite such Equityholder's name on Exhibit A (or with respect to each Option Holder, on the signature page to this Agreement of each such Option Holder under the heading "OldCo Options"), to be exchanged by such Equityholder under this Agreement, free and clear of any pledge, lien, security interest, encumbrance, claim or equitable interest.

(c) Restricted Securities. Such Equityholder (other than the Option Holders) understands and acknowledges that the NewCo Common Shares and/or NewCo Preferred Shares are being issued in a transaction involving a private placement of securities under Section 4(a)(2) of the Securities Act of 1933, as amended (the "***Act***") and Rule 506 of Regulation D promulgated thereunder. Accordingly, the NewCo Common Shares and/or NewCo Preferred Shares will be deemed "restricted" and any certificates or agreements evidencing the NewCo Common Shares and/or NewCo Preferred Shares may bear restrictive legends under the Act.

(d) Investment Intent. Such Equityholder (other than the Option Holders) is acquiring the NewCo Common Shares and/or NewCo Preferred Shares for its own account for investment, and not with a view to any distribution or resale thereof in violation of the Act, or any other applicable securities laws, and such Equityholder has no present plans to enter into any arrangement for any such distribution or resale.

(e) Accredited Investor. Such Equityholder (other than the Option Holders) is an "accredited investor" as such term is defined in Rule 501(a) of Regulation D promulgated under the Act.

(f) Disclosure of Information. Each Equityholder (other than the Option Holders) represents that it has been furnished with and had access to such information as such Equityholder has considered necessary or appropriate to make a determination as to the exchange of the OldCo Ordinary Shares and/or OldCo Preferred Shares into NewCo Common Shares and/or NewCo Preferred Shares together with such additional information as is necessary to verify the accuracy of the information supplied.

5. **Closing Conditions**. The obligations of NewCo and the Equityholders under this Agreement are subject to the fulfillment or waiver, at or before the Closing, of each of the following conditions:

(a) Representations and Warranties True. Each of the representations and warranties: (i) of NewCo contained in Section 3 shall be true and correct in all respects on the date of the Closing and (ii) of each Equityholder contained in Section 4 shall be true and correct in all respects on the date of the Closing.

(b) Restated Certificate. Prior to Closing, NewCo will adopt and file with the Secretary of State of the State of Delaware the Amended and Restated Certificate of Incorporation in the form of Exhibit B attached to this Agreement (the "***Restated Certificate***").

(c) Ancillary Investment Agreements. NewCo and each Equityholder (other than the Equityholder relying upon this condition to excuse such Equityholder's performance hereunder) named as a party thereto shall have executed and delivered: (i) the Investors' Rights Agreement in the form attached hereto as Exhibit C, (ii) the Right of First Refusal and Co-Sale Agreement in the form attached hereto as Exhibit D and (iii) the Voting Agreement in the form attached hereto as Exhibit E (the Investors' Rights Agreement, the Right of First Refusal and Co-Sale Agreement and the Voting Agreement, collectively the "***Ancillary Investment Agreements***").

(d) Share Transfer Documentation. Each Ordinary Shareholder and Preferred Shareholder shall have delivered to NewCo duly executed stock powers or other share transfer documentation, along with original share certificates issued by OldCo (or, alternatively, shall execute (and deliver to NewCo) an affidavit of loss with respect to such share certificate in a form reasonably approved by NewCo), in each case as may be requested by NewCo in connection with the delivery of such Ordinary Shareholder's OldCo Ordinary Shares or such Preferred Shareholder's OldCo Preferred Shares, as applicable.

(e) Stock Certificates; Stockholders' Ledger. NewCo shall (i) issue to the Ordinary Shareholders and the Preferred Shareholders validly executed stock certificates covering the NewCo Common Shares and the NewCo Preferred Shares issued in the name of the applicable Ordinary Shareholder and Preferred Shareholder; and (ii) register the allotment of the NewCo Common Shares and the NewCo Preferred Shares to the Ordinary Shareholders and Preferred Shareholders in the respective numbers indicated in Exhibit A, in the stock ledger of NewCo. In addition, OldCo shall (i) issue to NewCo validly executed share certificates covering the OldCo Ordinary Shares and the OldCo Preferred Shares transferred hereunder in the name of NewCo, and (ii) register the transfer of the OldCo Ordinary Shares and the OldCo Preferred Shares in the name of NewCo in OldCo's shareholders register.

(f) Management Rights Letters. Certain Preferred Shareholders shall have received duly executed management rights letters by NewCo, in the form attached hereto as Exhibit F.

(g) Novation Agreement. NewCo, OldCo and each Investor (as defined in the Novation Agreement) shall have executed and delivered the Novation Agreement in the form attached hereto as Exhibit G

6. **Limited Power of Attorney**. Each Equityholder appoints NewCo to be its attorney from the date of Closing until the OldCo Securities being exchanged hereunder by such Equityholder are registered in the name of NewCo on the books and records of NewCo. Under this limited power of attorney, NewCo may, in the name and on behalf of each Equityholder, do everything reasonably necessary or desirable, in NewCo's discretion, to: (a) effect the transfer or cancellation, as applicable, of the OldCo Securities being exchanged hereunder by such Equityholder; (b) exercise any rights, including any rights to appoint a proxy or representative and voting rights, attending to such Equityholder's OldCo Securities; (c) receive any dividend or other entitlement paid or credited (or to be paid or credited) in respect of such Equityholder's OldCo Securities after the Closing; and (d) do any other reasonable act or thing in connection with the transfer or cancellation, as applicable, of such Equityholder's OldCo Securities. Each Equityholder declares that all acts and things done by NewCo in exercising powers under this power of attorney will be as good and valid as if they had been done by such Equityholder and agrees to ratify and confirm whatever NewCo lawfully does in exercising power under this power of attorney.

7. **Post-Closing Obligations**. Within fourteen (14) days following the Closing, OldCo shall file the necessary reports with the Israeli Registrar of Companies with respect to the transfer of the OldCo Ordinary Shares and the OldCo Preferred Shares to NewCo.

8. **Payment and Reimbursement of Assessments**.

(a) NewCo shall promptly pay taxes, if any, in an aggregate amount up to $1,500,000 (the "***ITA Taxes Cap***"), that are imposed on Equityholders by the Israeli tax authorities as a result of the transactions contemplated by this Agreement and are not being disputed by the Equityholders ("***ITA Taxes***"); provided, that if NewCo sells shares of its capital stock in the next succeeding financing transaction following the Closing (pursuant to an initial public offering,

private placement transaction or otherwise) at a price per share that would imply an aggregate pre-money value of the total capital stock of NewCo equaling or exceeding $200,000,000, then the ITA Taxes Cap shall instead equal $2,000,000; provided further, that NewCo shall not be required to make any such payment to the extent that the amount of ITA Taxes to be paid exceeds 10% of the Company's net working capital at the time of such payment. NewCo shall make such payment to such person(s) as directed by the affected Equityholders, but shall only be required to pay ITA Taxes that are imposed on the Equityholders prior to the two (2) year anniversary of the effectiveness of NewCo's registration statement on Form S-1 filed in connection with NewCo's initial public offering.

(b) Each Equityholder shall reimburse NewCo for any and all ITA Taxes paid on its behalf (including interest thereon calculated at the then-current medium-term Applicable Federal Rate, as published by the Internal Revenue Service), with such reimbursement to be made upon the earliest of: (i) a sale or other transfer for value of any shares of NewCo held by the affected Equityholder (a "***Share Sale***"); (ii) the date of consummation of a Change of Control; and (iii) five years from the date of such reimbursement; provided, that the amount of ITA Taxes to be paid by the Equityholder to NewCo upon each Share Sale shall equal the Adjusted Proceeds with respect to any such Share Sale until any and all ITA Taxes paid on behalf of such Equityholder by NewCo have been fully reimbursed.

For purposes of clause (b) above, the following terms shall apply:

"***Adjusted Proceeds***" means the gross proceeds of any Share Sale that are attributable to the Equityholders *less* the amount of any ITA Taxes attributable to the shares sold by such Equityholders; provided, that if the amount of any ITA Taxes attributable to such shares equals or exceeds the proceeds of the Share Sale, then the Adjusted Proceeds shall be $0.

"***Change of Control***" means the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events: (i) a sale of all or substantially all of the outstanding capital stock of NewCo in which such affected Equityholder sells shares in NewCo; or (ii) a sale, lease, license or other disposition of all or substantially all of the consolidated assets of NewCo and its subsidiaries.

9. **Release**. Except as otherwise set forth herein, each Equityholder fully and irrevocably releases and forever discharges NewCo and OldCo (including their respective officers, directors, shareholders, partners, managers, advisors, employees and agents, whether current, or in the past, affiliates and subsidiaries, successors and assigns) and irrevocably waives, any and all right, claim, demand or cause of action of whatsoever kind or nature and howsoever caused, including, without limitation, any rights of first refusal, which they may have against NewCo and OldCo (including their respective officers, directors, shareholders, partners, managers, advisors, employees and agents, whether current, past or in the future, affiliates and subsidiaries, successors and assigns) arising in connection with the exchange of such OldCo Securities for NewCo's Securities hereunder.

10. **Tax Treatment**. The transactions contemplated by this Agreement are not intended to result in taxable gain under the income tax laws of both Israel and the United States in accordance with the terms of this Agreement.

11. **General Provisions**.

(a) Governing Law. Other than as explicitly set forth herein, this Agreement and all acts and transactions pursuant hereto and the rights and obligations of the parties hereto shall be governed, construed and interpreted in accordance with the laws of the State of Delaware, without giving effect to principles of conflicts of law, provided, however that agreements or arrangement referenced herein that are governed by the laws of another jurisdiction shall remain so governed.

(b) Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Facsimile signatures and electronic images of signatures shall be deemed original signatures.

(c) Notices. Any notice or communication given pursuant hereto shall be in writing and delivered in hand; mailed by registered or certified mail, postage prepaid (mailed notices shall be deemed given three business days after deposit in the United States mail); sent by overnight courier (and deemed delivered the next day or business day, as applicable); or sent by email (such notices shall be deemed given upon receipt thereof), as follows:

If to NewCo or to OldCo:	89bio, Inc., Attn: Rohan Palekar 535 Mission Street, 14th Floor San Francisco, CA 94105
With a copy to:	Gibson, Dunn & Crutcher LLP 555 Mission Street San Francisco, CA 94105 Attention: Ryan Murr
If to an Equityholder:	At the address or email address of such Equityholder as reflected on the books and records of OldCo.

(d) Amendments and Waivers. This Agreement may be altered or amended, and any provision of this Agreement may be waived, only by a writing signed, in the case of an amendment, by each party hereto or, in the case of a waiver, by the party against whom enforcement of any such waiver is sought. No waiver granted under this Agreement as to any one provision herein shall constitute a subsequent waiver of such provision or of any other provision herein, nor shall it constitute the waiver of any performance other than the actual performance specifically waived.

(e) Entire Agreement. This Agreement and the documents referred to herein constitute the entire agreement and understanding of the parties with respect to the subject matter of this Agreement, and supersede any and all prior understandings and agreements, whether oral or written, between or among the parties hereto with respect to the specific subject matter hereof.

(f) Successors and Assigns. Except as otherwise expressly provided herein, the provisions hereof shall inure to the benefit of, and be binding upon, the successors, assignees, heirs, executors and administrators of the parties hereto. No assignment of any rights or obligations pursuant to this Agreement may be made by an Equityholder.

(g) Delays or Omissions. No delay or omission to exercise any right, power or remedy, upon any breach or default under this Agreement, shall impair any such right, power or remedy of such holder nor shall it be construed to be a waiver of any such breach or default, or an acquiescence therein, or of any similar breach or default thereafter occurring.

(h) Severability. In case any provision of the Agreement shall be invalid, illegal or unenforceable, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby. The parties hereto shall be obliged to draw up an arrangement in accordance with the meaning and the object of the invalid provision.

(i) Further Assurances. The parties hereto agree to sign all other necessary documents and take all other actions as may be reasonably required or requested by any other party hereto in order to implement and consummate this Agreement and the transactions herein contemplated.

[*Signature pages follow*.]

IN WITNESS WHEREOF, the parties hereto have executed this Contribution and Exchange Agreement as of the date first written above.

NEWCO:

89BIO, INC.

By: /s/ Rohan Palekar
Name: Rohan Palekar
Title: Chief Executive Officer

OLDCO:

89BIO LTD.

By: /s/ Rohan Palekar
Name: Rohan Palekar
Title: Chief Executive Officer

[Signature Page to Contribution and Exchange Agreement]

IN WITNESS WHEREOF, the parties hereto have executed this Contribution and Exchange Agreement as of the date first written above.

ORDINARY SHAREHOLDERS:

ORBIMED ISRAEL PARTNERS II, L.P.

By: OrbiMed Israel GP II, L.P.,
its general partner

By: OrbiMed Advisors Israel II Limited,
its general partner

By: /s/ Jonathan T. Silverstein
Name: Jonathan T. Silverstein
Title: Director

ORBIMED PRIVATE INVESTMENTS VI, LP

By: OrbiMed Capital GP VI LLC
its General Partner

By: OrbiMed Advisors LLC,
its Managing Member

By: /s/ Jonathan T. Silverstein
Name: Jonathan T. Silverstein
Title: Member

IN WITNESS WHEREOF, the parties hereto have executed this Contribution and Exchange Agreement as of the date first written above.

PREFERRED SHAREHOLDERS:

ORBIMED ISRAEL PARTNERS II, L.P.

By: OrbiMed Israel GP II, L.P.,
its general partner

By: OrbiMed Advisors Israel II Limited,
its general partner

By: /s/ Jonathan T. Silverstein
Name: Jonathan T. Silverstein
Title: Director

ORBIMED PRIVATE INVESTMENTS VI, LP

By: OrbiMed Capital GP VI LLC
its General Partner

By: OrbiMed Advisors LLC,
its Managing Member

By: /s/ Jonathan T. Silverstein
Name: Jonathan T. Silverstein
Title: Member

[Signature Page to Contribution and Exchange Agreement]

IN WITNESS WHEREOF, the parties hereto have executed this Contribution and Exchange Agreement as of the date first written above.

PREFERRED SHAREHOLDERS:

LONGITUDE VENTURE PARTNERS III, L.P.

By: Longitude Capital Partners III, LLC
its General Partner

By: /s/ Gregory Grunberg
Name: Gregory Grunberg
Title: Managing Director

[Signature Page to Contribution and Exchange Agreement]

IN WITNESS WHEREOF, the parties hereto have executed this Contribution and Exchange Agreement as of the date first written above.

PREFERRED SHAREHOLDERS:

RA CAPITAL HEALTHCARE FUND, L.P.

By: /s/ Peter Kolchinsky
Name: Peter Kolchinsky
Title: Manager

[Signature Page to Contribution and Exchange Agreement]

IN WITNESS WHEREOF, the parties hereto have executed this Contribution and Exchange Agreement as of the date first written above.

PREFERRED SHAREHOLDERS:

RA CAPITAL NEXUS FUND, L.P.

By: /s/ Peter Kolchinsky
Name: Peter Kolchinsky
Title: Manager

[Signature Page to Contribution and Exchange Agreement]

IN WITNESS WHEREOF, the parties hereto have executed this Contribution and Exchange Agreement as of the date first written above.

PREFERRED SHAREHOLDERS:

BLACKWELL PARTNERS LLC – SERIES A

By: /s/ Abayomi A. Adigun
Name: Abayomi A. Adigun
Title: Investment Manager
DUMAC, Inc., Authorized Agent

By: /s/ Jannine M. Lall
Name: Jannine M. Lall
Title: Head of Finance & Controller
DUMAC, Inc., Authorized Agent

IN WITNESS WHEREOF, the parties hereto have executed this Contribution and Exchange Agreement as of the date first written above.

PREFERRED SHAREHOLDERS:

GENWORKS 2 CONSULTING INC.

By: /s/ Sandra Hayden
Name: Sandra Hayden
Title: President

[Signature Page to Contribution and Exchange Agreement]

IN WITNESS WHEREOF, the parties hereto have executed this Contribution and Exchange Agreement as of the date first written above.

PREFERRED SHAREHOLDERS:

PONTIFAX (ISRAEL) V LIMITED PARTNERSHIP

By: /s/ Tomer Kariv
Name: Tomer Kariv
Title: CEO

PONTIFAX (CAYMAN) V L.P.

By: /s/ Tomer Kariv
Name: Tomer Kariv
Title: CEO

PONTIFAX (CHINA) V L.P.

By: /s/ Tomer Kariv
Name: Tomer Kariv
Title: CEO

[Signature Page to Contribution and Exchange Agreement]

AMENDED AND RESTATED CERTIFICATE OF INCORPORATION OF 89BIO, INC.

AMENDED AND RESTATED
CERTIFICATE OF INCORPORATION
OF
89BIO, INC.

(Pursuant to Sections 241 and 245 of the
General Corporation Law of the State of Delaware)

89bio, Inc., a corporation organized and existing under and by virtue of the provisions of the General Corporation Law of the State of Delaware (the "**General Corporation Law**"),

DOES HEREBY CERTIFY:

1. That the name of this corporation is 89bio, Inc., and that this corporation was originally incorporated pursuant to the General Corporation Law on June 28, 2019.

2. That as of the date hereof, the corporation has not received payment for any of its stock.

3. That the Board of Directors duly adopted resolutions approving the amendment and restatement of the Certificate of Incorporation of this corporation in accordance with Section 241(b) of the General Corporation Law as follows:

RESOLVED, that the Certificate of Incorporation of this corporation be amended and restated in its entirety to read as follows:

FIRST: The name of this corporation is 89bio, Inc. (the "**Corporation**").

SECOND: The address of the registered office of the Corporation in the State of Delaware is 1209 Orange Street, Wilmington, New Castle County, Delaware 19801. The name of its registered agent at such address is The Corporation Trust Company.

THIRD: The nature of the business or purposes to be conducted or promoted is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law.

FOURTH: The total number of shares of all classes of stock which the Corporation shall have authority to issue is (i) 72,882,353 shares of Common Stock, $0.001 par value per share ("**Common Stock**") and (ii) 60,000,000 shares of Preferred Stock, $0.001 par value per share ("**Preferred Stock**").

The following is a statement of the designations and the powers, privileges and rights, and the qualifications, limitations or restrictions thereof in respect of each class of capital stock of the Corporation.

A. COMMON STOCK

1. General. The voting, dividend and liquidation rights of the holders of the Common Stock are subject to and qualified by the rights, powers and preferences of the holders of the Preferred Stock set forth herein.

2. Voting. The holders of the Common Stock are entitled to one vote for each share of Common Stock held at all meetings of stockholders (and written actions in lieu of meetings); provided, however, that, except as otherwise required by law, holders of Common Stock, as such, shall not be entitled to vote on any amendment to this Amended and Restated Certificate of Incorporation that relates solely to the terms of one or more outstanding series of Preferred Stock if the holders of such affected series are entitled, either separately or together with the holders of one or more other such series, to vote thereon pursuant to this Amended and Restated Certificate of Incorporation or pursuant to the General Corporation Law. There shall be no cumulative voting. The number of authorized shares of Common Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by (in addition to any vote of the holders of one or more series of Preferred Stock that may be required by the terms of this Amended and Restated Certificate of Incorporation) the affirmative vote of the holders of shares of capital stock of the Corporation representing a majority of the votes represented by all outstanding shares of capital stock of the Corporation entitled to vote, irrespective of the provisions of Section 242(b)(2) of the General Corporation Law.

B. PREFERRED STOCK

60,000,000 shares of the authorized and unissued Preferred Stock of the Corporation are hereby designated "**Series A Preferred Stock**" with the following rights, preferences, powers, privileges and restrictions, qualifications and limitations. Unless otherwise indicated, references to "sections" or "subsections" in this Part B of this Article Fourth refer to sections and subsections of Part B of this Article Fourth.

1. Dividends.

The Corporation shall not declare, pay or set aside any dividends on shares of any other class or series of capital stock of the Corporation (other than dividends on shares of Common Stock payable in shares of Common Stock) unless (in addition to the obtaining of any consents required elsewhere in this Amended and Restated Certificate of Incorporation) the holders of the Series A Preferred Stock then outstanding shall first receive, or simultaneously receive, a dividend on each outstanding share of Series A Preferred Stock in an amount at least equal to $0.08 (as adjusted for any share split, share combination, share dividend, recapitalization or like events) per annum (the "**Preferred Dividends**"). Such Preferred Dividends shall not accrue on an annual basis, but shall only be payable in each year if and as declared by the Board of Directors in such year.

In the event that a dividend declared shall be insufficient for the payment of the Preferred Dividends in full to all of the holders of Series A Preferred Stock, then the dividend amount so payable shall be distributed among the holders of Series A Preferred Stock on a pro rata *pari passu* basis in proportion to the amounts such holders would have been entitled to receive had the dividend amount been sufficient for the distribution of the Preferred Dividends in full. Following the declaration and payment in full of the Preferred Dividends, any other dividends or similar distributions shall be declared and paid to the holders of Series A Preferred Stock and Common Stock on an as converted and pro rata basis.

2. Liquidation, Dissolution or Winding Up; Certain Mergers, Consolidations and Asset Sales.

2.1 Preferential Payments to Holders of Series A Preferred Stock. In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Corporation, the holders of shares of Series A Preferred Stock then outstanding shall be entitled to be paid out of the assets of the Corporation available for distribution to its stockholders, and in the event of a Deemed Liquidation Event (as defined below), the holders of shares of Series A Preferred Stock then outstanding shall be entitled to be paid (i) out of the consideration payable to stockholders in such Deemed Liquidation Event or (ii) the consideration received by the Corporation for such Deemed Liquidation Event (net of any retained liabilities associated with the assets sold or technology licensed, as determined in good faith by the Board of Directors of the Corporation), together with any other assets of the Corporation available for distribution to its stockholders, all to the extent permitted by Delaware law governing distributions to stockholders (the "**Available Proceeds**"), as applicable, before any payment shall be made to the holders of Common Stock by reason of their ownership thereof, an amount per share equal to the Series A Original Issue Price, plus any dividends declared but unpaid thereon and less the amount of distributions actually received in any Deemed Liquidation Event for each such share of Series A Preferred Stock (the "**Series A Liquidation Amount**"). If upon any such liquidation, dissolution or winding up of the Corporation or Deemed Liquidation Event, the assets of the Corporation available for distribution to its stockholders shall be insufficient to pay the holders of shares of Series A Preferred Stock the full amount to which they shall be entitled under this Subsection 2.1, the holders of shares of Series A Preferred Stock shall share ratably in any distribution of the assets available for distribution in proportion to the respective amounts which would otherwise be payable in respect of the shares held by them upon such distribution if all amounts payable on or with respect to such shares were paid in full. The "**Series A Original Issue Price**" shall mean $1.00 per share, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series A Preferred Stock.

2.2 Distribution of Remaining Assets. In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Corporation, after the payment in full of all Series A Liquidation Amounts required to be paid to the holders of shares of Series A Preferred Stock, the remaining assets of the Corporation available for distribution to its stockholders or, in the case of a Deemed Liquidation Event, the consideration not payable to the holders of shares of Series A Preferred Stock pursuant to Section 2.1 or the remaining Available Proceeds, as the case may be, shall be distributed among the holders of the shares of Series A Preferred Stock and Common Stock, pro rata based on the number of shares held by each such holder, treating for this purpose all such securities as if they had been converted to Common Stock pursuant to the terms of this Amended and Restated Certificate of Incorporation immediately prior to such liquidation, dissolution or winding up of the Corporation.

2.3 Deemed Liquidation Events.

2.3.1 Definition. Each of the following events shall be considered a "**Deemed Liquidation Event**" unless the holders of at least 50% of the then outstanding shares of Series A Preferred Stock, including either OrbiMed Israel Partners II, L.P. ("**OrbiMed IL**") or OrbiMed Private Investments VI, LP ("**OrbiMed US**" and, together with OrbiMed IL, "**OrbiMed**") (the "**Requisite Preferred**"), elect otherwise by written notice sent to the Corporation prior to the effective date of any such event:

(a) a merger or consolidation in which

(i) the Corporation is a constituent party or

(ii) a subsidiary of the Corporation is a constituent party and the Corporation issues shares of its capital stock pursuant to such merger or consolidation,

except any such merger or consolidation involving the Corporation or a subsidiary in which the shares of capital stock of the Corporation outstanding immediately prior to such merger or consolidation continue to represent, or are converted into or exchanged for shares of capital stock that represent, immediately following such merger or consolidation, at least 50% of the voting power, of the capital stock of (1) the surviving or resulting corporation; or (2) if the surviving or resulting corporation is a wholly owned subsidiary of another corporation immediately following such merger or consolidation, the parent corporation of such surviving or resulting corporation; or

(b) (1) the sale, lease, transfer, exclusive license or other disposition, in a single transaction or series of related transactions, by the Corporation or any subsidiary of the Corporation of all or substantially all the assets of the Corporation and its subsidiaries taken as a whole (including, without limitation, the Corporation's intellectual property), or (2) the sale or disposition (whether by merger, consolidation or otherwise, and whether in a single transaction or a series of related transactions) of one or more subsidiaries of the Corporation if substantially all of the assets of the Corporation and its subsidiaries taken as a whole are held by such subsidiary or subsidiaries, except where such sale, lease, transfer, exclusive license or other disposition is to a wholly owned subsidiary of the Corporation.

2.3.2 Effecting a Deemed Liquidation Event.

(a) The Corporation shall not have the power to effect a Deemed Liquidation Event referred to in Subsection 2.3.1(a)(i) unless the agreement or plan of merger or consolidation for such transaction (the "**Merger Agreement**") provides that the consideration payable to the stockholders of the Corporation in such Deemed Liquidation Event shall be paid to the holders of capital stock of the Corporation in accordance with Subsections 2.1 and 2.2.

(b) In the event of a Deemed Liquidation Event referred to in Subsection 2.3.1(a)(ii) or 2.3.1(b), if the Corporation does not effect a dissolution of the Corporation under the General Corporation Law within ninety (90) days after such Deemed Liquidation Event, then (i) the Corporation shall send a written notice to each holder of Series A

Preferred Stock no later than the ninetieth (90th) day after the Deemed Liquidation Event advising such holders of their right (and the requirements to be met to secure such right) pursuant to the terms of the following clause; (ii) to require the redemption of such shares of Series A Preferred Stock, and (iii) if the Requisite Preferred so request in a written instrument delivered to the Corporation not later than one hundred twenty (120) days after such Deemed Liquidation Event, the Corporation shall use the consideration received by the Corporation for such Deemed Liquidation Event (net of any retained liabilities associated with the assets sold or technology licensed, as determined in good faith by the Board of Directors of the Corporation), together with any other assets of the Corporation available for distribution to its stockholders, all to the extent permitted by Delaware law governing distributions to stockholders (the "**Available Proceeds**"), on the one hundred fiftieth (150th) day after such Deemed Liquidation Event, to redeem all outstanding shares of Series A Preferred Stock at a price per share equal to the Series A Liquidation Amount (the "**Redemption Price**"). Notwithstanding the foregoing, in the event of a redemption pursuant to the preceding sentence, if the Available Proceeds are not sufficient to redeem all outstanding shares of Series A Preferred Stock, the Corporation shall redeem a pro rata portion of each holder's shares of Series A Preferred Stock to the fullest extent of such Available Proceeds, based on the respective amounts which would otherwise be payable in respect of the shares to be redeemed if the Available Proceeds were sufficient to redeem all such shares, and shall redeem the remaining shares as soon as it may lawfully do so under Delaware law governing distributions to stockholders. The Corporation shall send written notice of the redemption (the "**Redemption Notice**") to each holder of record of Series A Preferred Stock not less than forty (40) days prior to the intended redemption date (the "**Redemption Date**"). Each Redemption Notice shall state (x) the number of shares of Series A Preferred Stock held by the holder that the Corporation shall redeem on the Redemption Date specified in the Redemption Notice; (y) the Redemption Date and the Redemption Price; and (z) for holders of shares in certificated form, that the holder is to surrender to the Corporation, in the manner and at the place designated, his, her or its certificate or certificates representing the shares of Series A Preferred Stock to be redeemed. Prior to the distribution or redemption provided for in this Subsection 2.3.2(b), the Corporation shall not expend or dissipate the consideration received for such Deemed Liquidation Event, except to discharge expenses incurred in connection with such Deemed Liquidation Event or in the ordinary course of business.

2.3.3 Amount Deemed Paid or Distributed. The amount deemed paid or distributed to the holders of capital stock of the Corporation upon any such merger, consolidation, sale, transfer, exclusive license, other disposition or redemption shall be the cash or the value of the property, rights or securities to be paid or distributed to such holders pursuant to such Deemed Liquidation Event. The value of such property, rights or securities shall be determined in good faith by the Board of Directors of the Corporation, including the approval of the majority of the Preferred Directors; provided, that during such time that the Pontifax Letter Agreement is in effect such majority shall include the OrbiMed Director (the "**Requisite Preferred Directors**"). The "**OrbiMed Director**" means the member of the Board of Directors appointed, removed or replaced by OrbiMed. The "**Pontifax Letter Agreement**" means that certain letter agreement dated April 16, 2018 by and between OrbiMed and Pontifax (China) V L.P., Pontifax (Israel) V Limited Partnership, and Pontifax (Cayman) V L.P. (collectively "**Pontifax**"). The "**Preferred Directors**" means, collectively, (i) the OrbiMed Director and one (1) member of the Board of Directors (the "**OrbiMed Additional Director**") appointed, removed or replaced by OrbiMed; (ii) one (1) member of the Board of Directors (the "**Longitude Director**") appointed, removed or replaced by Longitude Venture Partners III, L.P. ("**Longitude**"); and (iii) one (1) member of the Board of Directors (the "**RA Director**") appointed, removed or replaced by RA Capital Healthcare Fund, L.P.

2.3.4 Allocation of Escrow and Contingent Consideration. In the event of a Deemed Liquidation Event pursuant to Subsection 2.3.1(a)(i), if any portion of the consideration payable to the stockholders of the Corporation is payable only upon satisfaction of contingencies (the "**Additional Consideration**"), the Merger Agreement shall provide that (a) the portion of such consideration that is not Additional Consideration (such portion, the "**Initial Consideration**") shall be allocated among the holders of capital stock of the Corporation in accordance with Subsections 2.1 and 2.2 as if the Initial Consideration were the only consideration payable in connection with such Deemed Liquidation Event; and (b) any Additional Consideration which becomes payable to the stockholders of the Corporation upon satisfaction of such contingencies shall be allocated among the holders of capital stock of the Corporation in accordance with Subsections 2.1 and 2.2 after taking into account the previous payment of the Initial Consideration as part of the same transaction. For the purposes of this Subsection 2.3.4, consideration placed into escrow or retained as a holdback to be available for satisfaction of indemnification or similar obligations in connection with such Deemed Liquidation Event shall be deemed to be Initial Consideration.

3. Voting.

3.1 General. On any matter presented to the stockholders of the Corporation for their action or consideration at any meeting of stockholders of the Corporation (or by written consent of stockholders in lieu of meeting), each holder of outstanding shares of Series A Preferred Stock shall be entitled to cast the number of votes equal to the number of whole shares of Common Stock into which the shares of Series A Preferred Stock held by such holder are convertible as of the record date for determining stockholders entitled to vote on such matter. Except as provided by law or by the other provisions of this Amended and Restated Certificate of Incorporation (including where a separate class vote is specified), holders of Series A Preferred Stock shall vote together with the holders of Common Stock as a single class and on an as-converted to Common Stock basis.

3.2 Election of Directors.

3.2.1 The holders of record of the shares of Series A Preferred Stock, exclusively and as a separate class, shall be entitled to elect six (6) directors of the Corporation (the "**Series A Directors**").

3.2.2 Any director elected as provided in the preceding sentence may be removed without cause by, and only by, the affirmative vote of the holders of the shares of the class or series of capital stock entitled to elect such director or directors, given either at a special meeting of such stockholders duly called for that purpose or pursuant to a written consent of stockholders. If the holders of shares of Series A Preferred Stock fail to elect a sufficient number of directors to fill all directorships for which they are entitled to elect directors, voting exclusively and as a separate class, pursuant to the first sentence of this Subsection 3.2, then any directorship not so filled shall remain vacant until such time as the holders of the Series A Preferred Stock elect a person to fill such directorship by vote or written consent in lieu of a

meeting; and no such directorship may be filled by stockholders of the Corporation other than by the stockholders of the Corporation that are entitled to elect a person to fill such directorship, voting exclusively and as a separate class. At any meeting held for the purpose of electing a director, the presence in person or by proxy of the holders of a majority of the outstanding shares of the class or series entitled to elect such director shall constitute a quorum for the purpose of electing such director. Except as otherwise provided in this Subsection 3.2, a vacancy in any directorship filled by the holders of any class or series shall be filled only by vote or written consent in lieu of a meeting of the holders of such class or series or by any remaining director or directors elected by the holders of such class or series pursuant to this Subsection 3.2.

3.2.3 The holders of record of the shares of Common Stock, exclusively and as a separate class, shall be entitled to elect one director of the Corporation, which shall be the then presiding chief executive officer of the Corporation.

3.2.4 The holders of record of the shares of Common Stock and of any other class or series of voting stock (including the Series A Preferred Stock), exclusively and voting together as a single class, shall be entitled to elect the balance of the total number of directors of the Corporation.

3.3 Series A Preferred Stock Protective Provisions. When shares of Series A Preferred Stock are outstanding, the Corporation shall not, either directly or indirectly by amendment, merger, consolidation or otherwise, do any of the following without (in addition to any other vote required by law or this Amended and Restated Certificate of Incorporation) the written consent or affirmative vote of the Requisite Preferred given in writing or by vote at a meeting, consenting or voting (as the case may be) separately as a class, and any such act or transaction entered into without such consent or vote shall be null and void *ab initio*, and of no force or effect.

3.3.1 liquidate, dissolve or wind-up the business and affairs of the Corporation, effect any merger or consolidation or any other Deemed Liquidation Event, or consent to any of the foregoing;

3.3.2 amend, alter or repeal any provision of this Amended and Restated Certificate of Incorporation or Bylaws of the Corporation;

3.3.3 increase or decrease the authorized number of shares of Common Stock or Preferred Stock;

3.3.4 create, or authorize the creation of, any additional class or series of capital stock unless the same ranks junior to the Series A Preferred Stock;

3.3.5 purchase or redeem (or permit any subsidiary to purchase or redeem) or pay or declare, or take any action that results in the payment or declaration of, any dividend or make any distribution on, any shares of capital stock of the Corporation (other than pursuant to share restriction agreements with founders or pursuant to equity incentive agreements with service providers giving the Corporation the right to repurchase shares upon the termination of services at the lesser of fair market value or cost);

3.3.6 results in any merger, other corporate reorganization, sale of voting control or any transaction in which all or substantially all of the assets of the Corporation are sold;

3.3.7 create, or hold capital stock in, any subsidiary that is not wholly owned (either directly or through one or more other subsidiaries) by the Corporation, or permit any subsidiary to create, or authorize the creation of, or issue or obligate itself to issue, any shares of any class or series of capital stock, or sell, transfer or otherwise dispose of any capital stock of any direct or indirect subsidiary of the Corporation, or permit any direct or indirect subsidiary to sell, lease, transfer, exclusively license or otherwise dispose (in a single transaction or series of related transactions) of all or substantially all of the assets of such subsidiary;

3.3.8 increase or decrease the authorized number of directors constituting the Board of Directors;

3.3.9 sell, assign, license, pledge, or encumber material technology or intellectual property, other than licenses granted in the ordinary course of business;

3.3.10 enter into any corporate strategic relationship involving the payment, contribution, or assignment by the Corporation or to the Corporation of assets greater than $500,000;

3.3.11 incur any aggregate indebtedness in excess of $500,000;

3.3.12 change the number of shares subject to any equity incentive plan or approve the adoption of any equity incentive plan; or

3.3.13 change the principal business of the Corporation, enter new lines of business, or exit any line of business of the Corporation.

4. Optional Conversion.

The holders of the Series A Preferred Stock shall have conversion rights as follows (the "**Conversion Rights**"):

4.1 Right to Convert.

4.1.1 Conversion Ratio. Each share of Series A Preferred Stock shall be convertible, at the option of the holder thereof, at any time and from time to time, and without the payment of additional consideration by the holder thereof, into such number of fully paid and non-assessable shares of Common Stock as is determined by dividing the Series A Original Issue Price by the Series A Conversion Price (as defined below) in effect at the time of conversion. The "**Series A Conversion Price**" shall initially be equal to $1.00. Such initial Series A Conversion Price, and the rate at which shares of Series A Preferred Stock may be converted into shares of Common Stock, shall be subject to adjustment as provided below.

4.2 Fractional Shares.

4.2.1 No fractional shares of Common Stock shall be issued upon conversion of the Series A Preferred Stock. In lieu of any fractional shares to which the holder would otherwise be entitled, the Corporation shall pay cash equal to such fraction multiplied by the fair market value of a share of Common Stock as determined in good faith by the Board of Directors of the Corporation. Whether or not fractional shares would be issuable upon such conversion shall be determined on the basis of the total number of shares of Series A Preferred Stock the holder is at the time converting into Common Stock and the aggregate number of shares of Common Stock issuable upon such conversion.

4.3 Mechanics of Conversion.

4.3.1 Notice of Conversion. In order for a holder of Series A Preferred Stock to voluntarily convert shares of Series A Preferred Stock into shares of Common Stock, such holder shall (a) provide written notice to the Corporation's transfer agent at the office of the transfer agent for the Series A Preferred Stock (or at the principal office of the Corporation if the Corporation serves as its own transfer agent) that such holder elects to convert all or any number of such holder's shares of Series A Preferred Stock and, if applicable, any event on which such conversion is contingent and (b), if such holder's shares are certificated, surrender the certificate or certificates for such shares of Series A Preferred Stock (or, if such registered holder alleges that such certificate has been lost, stolen or destroyed, a lost certificate affidavit and agreement reasonably acceptable to the Corporation to indemnify the Corporation against any claim that may be made against the Corporation on account of the alleged loss, theft or destruction of such certificate), at the office of the transfer agent for the Series A Preferred Stock (or at the principal office of the Corporation if the Corporation serves as its own transfer agent). Such notice shall state such holder's name or the names of the nominees in which such holder wishes the shares of Common Stock to be issued. If required by the Corporation, any certificates surrendered for conversion shall be endorsed or accompanied by a written instrument or instruments of transfer, in form satisfactory to the Corporation, duly executed by the registered holder or his, her or its attorney duly authorized in writing. The close of business on the date of receipt by the transfer agent (or by the Corporation if the Corporation serves as its own transfer agent) of such notice and, if applicable, certificates (or lost certificate affidavit and agreement) shall be the time of conversion (the "**Conversion Time**"), and the shares of Common Stock issuable upon conversion of the specified shares shall be deemed to be outstanding of record as of such date. The Corporation shall, as soon as practicable after the Conversion Time (i) issue and deliver to such holder of Series A Preferred Stock, or to his, her or its nominees, a notice of issuance of uncertificated shares and may, upon written request, issue and deliver a certificate for the number of full shares of Common Stock issuable upon such conversion in accordance with the provisions hereof and, may, if applicable and upon written request, issue and deliver a certificate for the number (if any) of the shares of Series A Preferred Stock represented by any surrendered certificate that were not converted into Common Stock, (ii) pay in cash such amount as provided in Subsection 4.2 in lieu of any fraction of a share of Common Stock otherwise issuable upon such conversion; and (iii) pay all declared but unpaid dividends on the shares of Series A Preferred Stock converted.

4.3.2 Reservation of Shares. The Corporation shall at all times when the Series A Preferred Stock shall be outstanding, reserve and keep available out of its authorized but unissued capital stock, for the purpose of effecting the conversion of the Series A Preferred Stock, such number of its duly authorized shares of Common Stock as shall from time

to time be sufficient to effect the conversion of all outstanding Series A Preferred Stock; and if at any time the number of authorized but unissued shares of Common Stock shall not be sufficient to effect the conversion of all then outstanding shares of the Series A Preferred Stock, the Corporation shall take such corporate action as may be necessary to increase its authorized but unissued shares of Common Stock to such number of shares as shall be sufficient for such purposes, including, without limitation, engaging in best efforts to obtain the requisite stockholder approval of any necessary amendment to this Amended and Restated Certificate of Incorporation. Before taking any action which would cause an adjustment reducing the Series A Conversion Price below the then par value of the shares of Common Stock issuable upon conversion of the Series A Preferred Stock, the Corporation will take any corporate action which may, in the opinion of its counsel, be necessary in order that the Corporation may validly and legally issue fully paid and non-assessable shares of Common Stock at such adjusted Series A Conversion Price.

4.3.3 Effect of Conversion. All shares of Series A Preferred Stock which shall have been surrendered for conversion as herein provided shall no longer be deemed to be outstanding and all rights with respect to such shares shall immediately cease and terminate at the Conversion Time, except only the right of the holders thereof to receive shares of Common Stock in exchange therefor, to receive payment in lieu of any fraction of a share otherwise issuable upon such conversion as provided in Subsection 4.2, and to receive payment of any dividends declared but unpaid thereon. Any shares of Series A Preferred Stock so converted shall be retired and cancelled and may not be reissued as shares of such series, and the Corporation may thereafter take such appropriate action (without the need for stockholder action) as may be necessary to reduce the authorized number of shares of Series A Preferred Stock accordingly.

4.3.4 No Further Adjustment. Upon any such conversion, no adjustment to the Series A Conversion Price shall be made for any declared but unpaid dividends on the Series A Preferred Stock surrendered for conversion or on the Common Stock delivered upon conversion.

4.3.5 Taxes. The Corporation shall pay any and all issue and other similar taxes that may be payable in respect of any issuance or delivery of shares of Common Stock upon conversion of shares of Series A Preferred Stock pursuant to this Section 4. The Corporation shall not, however, be required to pay any tax which may be payable in respect of any transfer involved in the issuance and delivery of shares of Common Stock in a name other than that in which the shares of Series A Preferred Stock so converted were registered, and no such issuance or delivery shall be made unless and until the person or entity requesting such issuance has paid to the Corporation the amount of any such tax or has established, to the satisfaction of the Corporation, that such tax has been paid.

4.4 Adjustments to Series A Conversion Price for Diluting Issues.

4.4.1 Special Definitions. For purposes of this Article Fourth, the following definitions shall apply:

(a) "**Option**" shall mean rights, options or warrants to subscribe for, purchase or otherwise acquire Common Stock or Convertible Securities.

(b) "**Series A Original Issue Date**" shall mean the date on which the first share of Series A Preferred Stock was issued.

(c) "**Convertible Securities**" shall mean any evidences of indebtedness, shares or other securities directly or indirectly convertible into or exchangeable for Common Stock, but excluding Options.

(d) "**Additional Shares of Common Stock**" shall mean all shares of Common Stock issued (or, pursuant to Subsection 4.4.3 below, deemed to be issued) by the Corporation after the Series A Original Issue Date, other than (1) the following shares of Common Stock and (2) shares of Common Stock deemed issued pursuant to the following Options and Convertible Securities (clauses (1) and (2), collectively, "**Exempted Securities**"):

(i) shares of Common Stock, Options or Convertible Securities issued as a dividend or distribution on Series A Preferred Stock;

(ii) shares of Common Stock or Options issued to officers, employees or directors of, or consultants to, the Corporation or any of its subsidiaries pursuant to a plan, agreement or arrangement approved by the Board of Directors of the Corporation, including the approval of the Requisite Preferred Directors;

(iii) shares of Common Stock, Options or Convertible Securities issued by reason of a dividend, stock split, split-up or other distribution on shares of Common Stock that is covered by Subsection 4.5, 4.6, 4.7 or 4.8 and approved by the Board of Directors of the Corporation, including the approval of the Requisite Preferred Directors**;**

(iv) shares of Common Stock or Options issued in connection with a Qualified Public Offering;

(v) if explicitly determined in writing by the Requisite Preferred to be "Exempted Securities" (and such determination must state the purposes for which such shares shall be "Exempted Securities");

(vi) shares of Common Stock or Convertible Securities actually issued upon the exercise of Options or shares of Common Stock actually issued upon the conversion or exchange of Convertible Securities, in each case provided such issuance is pursuant to the terms of such Option or Convertible Security;

(vii) shares of Common Stock, Options or Convertible Securities issued to banks, equipment lessors or other financial institutions, or to real property lessors, pursuant to a debt financing, equipment leasing or real property leasing transaction approved by the Board of Directors of the Corporation, including the approval of Requisite Preferred Directors; or

(viii) shares of Common Stock, Options or Convertible Securities issued as acquisition consideration pursuant to the acquisition of another corporation by the Corporation by merger, purchase of substantially all of the assets or other reorganization or to a joint venture agreement approved by the Board of Directors of the Corporation, including the approval of the Requisite Preferred Directors.

4.4.2 No Adjustment of Series A Conversion Price. No adjustment in the Series A Conversion Price shall be made as the result of the issuance or deemed issuance of Additional Shares of Common Stock if the Corporation receives written notice from the Requisite Preferred agreeing that no such adjustment shall be made as the result of the issuance or deemed issuance of such Additional Shares of Common Stock.

4.4.3 Deemed Issue of Additional Shares of Common Stock.

(a) If the Corporation at any time or from time to time after the Series A Original Issue Date shall issue any Options or Convertible Securities (excluding Options or Convertible Securities which are themselves Exempted Securities) or shall fix a record date for the determination of holders of any class of securities entitled to receive any such Options or Convertible Securities, then the maximum number of shares of Common Stock (as set forth in the instrument relating thereto, assuming the satisfaction of any conditions to exercisability, convertibility or exchangeability but without regard to any provision contained therein for a subsequent adjustment of such number) issuable upon the exercise of such Options or, in the case of Convertible Securities and Options therefor, the conversion or exchange of such Convertible Securities, shall be deemed to be Additional Shares of Common Stock issued as of the time of such issue or, in case such a record date shall have been fixed, as of the close of business on such record date.

(b) If the terms of any Option or Convertible Security, the issuance of which resulted in an adjustment to the Series A Conversion Price pursuant to the terms of Subsection 4.4.4, are revised as a result of an amendment to such terms or any other adjustment pursuant to the provisions of such Option or Convertible Security (but excluding automatic adjustments to such terms pursuant to anti-dilution or similar provisions of such Option or Convertible Security) to provide for either (1) any increase or decrease in the number of shares of Common Stock issuable upon the exercise, conversion and/or exchange of any such Option or Convertible Security or (2) any increase or decrease in the consideration payable to the Corporation upon such exercise, conversion and/or exchange, then, effective upon such increase or decrease becoming effective, the Series A Conversion Price computed upon the original issue of such Option or Convertible Security (or upon the occurrence of a record date with respect thereto) shall be readjusted to such Series A Conversion Price as would have obtained had such revised terms been in effect upon the original date of issuance of such Option or Convertible Security. Notwithstanding the foregoing, no readjustment pursuant to this clause (b) shall have the effect of increasing the Series A Conversion Price to an amount which exceeds the lower of (i) the Series A Conversion Price in effect immediately prior to the original adjustment made as a result of the issuance of such Option or Convertible Security, or (ii) the Series A Conversion Price that would have resulted from any issuances of Additional Shares of Common Stock (other than deemed issuances of Additional Shares of Common Stock as a result of the issuance of such Option or Convertible Security) between the original adjustment date and such readjustment date.

(c) If the terms of any Option or Convertible Security (excluding Options or Convertible Securities which are themselves Exempted Securities), the issuance of which did not result in an adjustment to the Series A Conversion Price pursuant to the terms of Subsection 4.4.4 (either because the consideration per share (determined pursuant to Subsection 4.4.5) of the Additional Shares of Common Stock subject thereto was equal to or greater than the Series A Conversion Price then in effect, or because such Option or Convertible Security was issued before the Series A Original Issue Date), are revised after the Series A Original Issue Date as a result of an amendment to such terms or any other adjustment pursuant to the provisions of such Option or Convertible Security (but excluding automatic adjustments to such terms pursuant to anti-dilution or similar provisions of such Option or Convertible Security) to provide for either (1) any increase in the number of shares of Common Stock issuable upon the exercise, conversion or exchange of any such Option or Convertible Security or (2) any decrease in the consideration payable to the Corporation upon such exercise, conversion or exchange, then such Option or Convertible Security, as so amended or adjusted, and the Additional Shares of Common Stock subject thereto (determined in the manner provided in Subsection 4.4.3(a)) shall be deemed to have been issued effective upon such increase or decrease becoming effective.

(d) Upon the expiration or termination of any unexercised Option or unconverted or unexchanged Convertible Security (or portion thereof) which resulted (either upon its original issuance or upon a revision of its terms) in an adjustment to the Series A Conversion Price pursuant to the terms of Subsection 4.4.4, the Series A Conversion Price shall be readjusted to such Series A Conversion Price as would have obtained had such Option or Convertible Security (or portion thereof) never been issued.

(e) If the number of shares of Common Stock issuable upon the exercise, conversion and/or exchange of any Option or Convertible Security, or the consideration payable to the Corporation upon such exercise, conversion and/or exchange, is calculable at the time such Option or Convertible Security is issued or amended but is subject to adjustment based upon subsequent events, any adjustment to the Series A Conversion Price provided for in this Subsection 4.4.3 shall be effected at the time of such issuance or amendment based on such number of shares or amount of consideration without regard to any provisions for subsequent adjustments (and any subsequent adjustments shall be treated as provided in clauses (b) and (c) of this Subsection 4.4.3). If the number of shares of Common Stock issuable upon the exercise, conversion and/or exchange of any Option or Convertible Security, or the consideration payable to the Corporation upon such exercise, conversion and/or exchange, cannot be calculated at all at the time such Option or Convertible Security is issued or amended, any adjustment to the Series A Conversion Price that would result under the terms of this Subsection 4.4.3 at the time of such issuance or amendment shall instead be effected at the time such number of shares and/or amount of consideration is first calculable (even if subject to subsequent adjustments), assuming for purposes of calculating such adjustment to the Series A Conversion Price that such issuance or amendment took place at the time such calculation can first be made.

4.4.4 Adjustment of Series A Conversion Price Upon Issuance of Additional Shares of Common Stock. In the event the Corporation shall at any time after the Series A Original Issue Date but prior to the Closing of a Qualified Public Offering issue Additional Shares of Common Stock (including Additional Shares of Common Stock deemed to be issued pursuant to Subsection 4.4.3), without consideration or for a consideration per share less than the Series A Conversion Price in effect immediately prior to such issuance or deemed issuance, then the Series A Conversion Price shall be reduced, concurrently with such issue, to a price (calculated to the nearest one-hundredth of a cent) determined in accordance with the following formula:

$$CP_2 = CP_1 * (A + B) \div (A + C).$$

For purposes of the foregoing formula, the following definitions shall apply:

(a) "CP_2" shall mean the Series A Conversion Price in effect immediately after such issuance or deemed issuance of Additional Shares of Common Stock

(b) "CP_1" shall mean the Series A Conversion Price in effect immediately prior to such issuance or deemed issuance of Additional Shares of Common Stock;

(c) "A" shall mean the number of shares of Common Stock outstanding immediately prior to such issuance or deemed issuance of Additional Shares of Common Stock (treating for this purpose as outstanding all shares of Common Stock issuable upon exercise of Options outstanding immediately prior to such issuance or deemed issuance or upon conversion or exchange of Convertible Securities (including the Series A Preferred Stock) outstanding (assuming exercise of any outstanding Options therefor) immediately prior to such issue);

(d) “B” shall mean the number of shares of Common Stock that would have been issued if such Additional Shares of Common Stock had been issued or deemed issued at a price per share equal to CP_1 (determined by dividing the aggregate consideration received by the Corporation in respect of such issue by CP_1); and

(e) “C” shall mean the number of such Additional Shares of Common Stock issued in such transaction.

No adjustment of the Series A Conversion Price pursuant to this Subsection 4.4.4 shall be made if it has the effect of increasing the Series A Conversion Price of the Series A Preferred Stock above the Series A Conversion Price in effect immediately prior to such adjustment. In addition, no adjustments of the Series A Conversion Price shall be made in an amount less than one hundredth (1/100) of one cent ($0.0001) per share; provided, that any adjustments that are not required to be made by reason of this sentence shall be carried forward and shall be either taken into account in any subsequent adjustment made prior to three (3) years from the date of the event giving rise to the adjustment being carried forward, or shall be made at the end of three (3) years from the date of the event giving rise to the adjustment being carried forward.

4.4.5 Determination of Consideration. For purposes of this Subsection 4.4, the consideration received by the Corporation for the issuance or deemed issuance of any Additional Shares of Common Stock shall be computed as follows:

(a) Cash and Property: Such consideration shall:

(i) insofar as it consists of cash, be computed at the aggregate amount of cash received by the Corporation;

(ii) insofar as it consists of property other than cash, be computed at the fair market value thereof at the time of such issue, as determined in good faith by the Board of Directors of the Corporation (including the Requisite Preferred Directors); and

(iii) in the event Additional Shares of Common Stock are issued together with other shares or securities or other assets of the Corporation for consideration which covers both, be the proportion of such consideration so received, computed as provided in clauses (i) and (ii) above, as determined in good faith by the Board of Directors of the Corporation (including the Requisite Preferred Directors).

(b) Options and Convertible Securities. The consideration per share received by the Corporation for Additional Shares of Common Stock deemed to have been issued pursuant to Subsection 4.4.3, relating to Options and Convertible Securities, shall be determined by dividing:

(i) The total amount, if any, received or receivable by the Corporation as consideration for the issue of such Options or Convertible Securities, plus the minimum aggregate amount of additional consideration (as set forth in the instruments relating thereto, without regard to any provision contained therein for a subsequent adjustment of such consideration) payable to the Corporation upon the exercise of such Options or the conversion or exchange of such Convertible Securities, or in the case of Options for Convertible Securities, the exercise of such Options for Convertible Securities and the conversion or exchange of such Convertible Securities, by

(ii) the maximum number of shares of Common Stock (as set forth in the instruments relating thereto, without regard to any provision contained therein for a subsequent adjustment of such number) issuable upon the exercise of such Options or the conversion or exchange of such Convertible Securities, or in the case of Options for Convertible Securities, the exercise of such Options for Convertible Securities and the conversion or exchange of such Convertible Securities.

4.4.6 Multiple Closing Dates. In the event the Corporation shall issue on more than one date Additional Shares of Common Stock that are a part of one transaction or a series of related transactions and that would result in an adjustment to the Series A Conversion Price pursuant to the terms of Subsection 4.4.4 then, upon the final such issuance, the Series A Conversion Price shall be readjusted to give effect to all such issuances as if they occurred on the date of the first such issuance (and without giving effect to any additional adjustments as a result of any such subsequent issuances within such period).

4.5 Adjustment for Stock Splits and Combinations. If the Corporation shall at any time or from time to time after the Series A Original Issue Date effect a subdivision of the outstanding Common Stock, the Series A Conversion Price in effect immediately before that subdivision shall be proportionately decreased so that the number of shares of Common Stock issuable on conversion of each share of such series shall be increased in proportion to such increase in the aggregate number of shares of Common Stock outstanding. If the Corporation shall at any time or from time to time after the Series A Original Issue Date combine the

outstanding shares of Common Stock, the Series A Conversion Price in effect immediately before the combination shall be proportionately increased so that the number of shares of Common Stock issuable on conversion of each share of such series shall be decreased in proportion to such decrease in the aggregate number of shares of Common Stock outstanding. Any adjustment under this subsection shall become effective at the close of business on the date the subdivision or combination becomes effective.

4.6 Adjustment for Certain Dividends and Distributions. In the event the Corporation at any time or from time to time after the Series A Original Issue Date shall make or issue, or fix a record date for the determination of holders of Common Stock entitled to receive, a dividend or other distribution payable on the Common Stock in additional shares of Common Stock, then and in each such event the Series A Conversion Price in effect immediately before such event shall be decreased as of the time of such issuance or, in the event such a record date shall have been fixed, as of the close of business on such record date, by multiplying the Series A Conversion Price then in effect by a fraction:

(1) the numerator of which shall be the total number of shares of Common Stock issued and outstanding immediately prior to the time of such issuance or the close of business on such record date, and

(2) the denominator of which shall be the total number of shares of Common Stock issued and outstanding immediately prior to the time of such issuance or the close of business on such record date plus the number of shares of Common Stock issuable in payment of such dividend or distribution.

Notwithstanding the foregoing (a) if such record date shall have been fixed and such dividend is not fully paid or if such distribution is not fully made on the date fixed therefor, the Series A Conversion Price shall be recomputed accordingly as of the close of business on such record date and thereafter the Series A Conversion Price shall be adjusted pursuant to this subsection as of the time of actual payment of such dividends or distributions; and (b) that no such adjustment shall be made if the holders of Series A Preferred Stock simultaneously receive a dividend or other distribution of shares of Common Stock in a number equal to the number of shares of Common Stock as they would have received if all outstanding shares of Series A Preferred Stock had been converted into Common Stock on the date of such event.

4.7 Adjustments for Other Dividends and Distributions. In the event the Corporation at any time or from time to time after the Series A Original Issue Date shall make or issue, or fix a record date for the determination of holders of Common Stock entitled to receive, a dividend or other distribution payable in securities of the Corporation (other than a distribution of shares of Common Stock in respect of outstanding shares of Common Stock) or in other property and the provisions of Section 1 do not apply to such dividend or distribution, then and in each such event the holders of Series A Preferred Stock shall receive, simultaneously with the distribution to the holders of Common Stock, a dividend or other distribution of such securities or other property in an amount equal to the amount of such securities or other property as they would have received if all outstanding shares of Series A Preferred Stock had been converted into Common Stock on the date of such event.

4.8 Adjustment for Merger or Reorganization, etc. Subject to the provisions of Subsection 2.3, if there shall occur any reorganization, recapitalization, reclassification, consolidation or merger involving the Corporation in which the Common Stock (but not the Series A Preferred Stock) is converted into or exchanged for securities, cash or other property (other than a transaction covered by Subsections 4.4, 4.6 or 4.7), then, following any such reorganization, recapitalization, reclassification, consolidation or merger, each share of Series A Preferred Stock shall thereafter be convertible in lieu of the Common Stock into which it was convertible prior to such event into the kind and amount of securities, cash or other property which a holder of the number of shares of Common Stock of the Corporation issuable upon conversion of one share of Series A Preferred Stock immediately prior to such reorganization, recapitalization, reclassification, consolidation or merger would have been entitled to receive pursuant to such transaction; and, in such case, appropriate adjustment (as determined in good faith by the Board of Directors of the Corporation) shall be made in the application of the provisions in this Section 4 with respect to the rights and interests thereafter of the holders of the Series A Preferred Stock, to the end that the provisions set forth in this Section 4 (including provisions with respect to changes in and other adjustments of the Series A Conversion Price) shall thereafter be applicable, as nearly as reasonably may be, in relation to any securities or other property thereafter deliverable upon the conversion of the Series A Preferred Stock.

4.9 Certificate as to Adjustments. Upon the occurrence of each adjustment or readjustment of the Series A Conversion Price pursuant to this Section 4, the Corporation at its expense shall, as promptly as reasonably practicable, compute such adjustment or readjustment in accordance with the terms hereof and furnish to each holder of Series A Preferred Stock a certificate setting forth such adjustment or readjustment (including the kind and amount of securities, cash or other property into which the Series A Preferred Stock is convertible) and showing in detail the facts upon which such adjustment or readjustment is based. The Corporation shall, as promptly as reasonably practicable after the written request at any time of any holder of Series A Preferred Stock, furnish or cause to be furnished to such holder a certificate setting forth (i) the Series A Conversion Price then in effect, and (ii) the number of shares of Common Stock and the amount, if any, of other securities, cash or property which then would be received upon the conversion of Series A Preferred Stock.

4.10 Notice of Record Date. In the event:

(a) the Corporation shall take a record of the holders of its Common Stock (or other capital stock or securities at the time issuable upon conversion of the Series A Preferred Stock) for the purpose of entitling or enabling them to receive any dividend or other distribution, or to receive any right to subscribe for or purchase any shares of capital stock of any class or any other securities, or to receive any other security; or

(b) of any capital reorganization of the Corporation, any reclassification of the Common Stock of the Corporation, or any Deemed Liquidation Event; or

(c) of the voluntary or involuntary dissolution, liquidation or winding-up of the Corporation,

then, and in each such case, the Corporation will send or cause to be sent to the holders of the Series A Preferred Stock a notice specifying, as the case may be, (i) the record date for such dividend, distribution or right, and the amount and character of such dividend, distribution or right, or (ii) the effective date on which such reorganization, reclassification, consolidation, merger, transfer, dissolution, liquidation or winding-up is proposed to take place, and the time, if any is to be fixed, as of which the holders of record of Common Stock (or such other capital stock or securities at the time issuable upon the conversion of the Series A Preferred Stock) shall be entitled to exchange their shares of Common Stock (or such other capital stock or securities) for securities or other property deliverable upon such reorganization, reclassification, consolidation, merger, transfer, dissolution, liquidation or winding-up, and the amount per share and character of such exchange applicable to the Series A Preferred Stock and the Common Stock. Such notice shall be sent at least seven (7) days prior to the record date or effective date for the event specified in such notice.

4.11 No Impairment. The Corporation will not, by amendment of its Certificate of Incorporation or through any reorganization, recapitalization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms to be observed or performed hereunder by the Corporation, but will at all times in good faith assist in the carrying out of all the provisions of this Article Fourth and in the taking of all such action as may be necessary or appropriate in order to protect the conversion rights of the holders of the Series A Preferred Stock against impairment.

5. Mandatory Conversion.

5.1 Trigger Events. Upon either (a) the closing of the sale of shares of Common Stock to the public at a price of at least $5.00 per share (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Common Stock), in a firm-commitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, resulting in at least $50,000,000 of gross proceeds to the Corporation (a "**Qualified Public Offering**") or (b) the date and time, or the occurrence of an event, specified by vote or written consent of the Requisite Preferred (the time of such closing or the date and time specified or the time of the event specified in such vote or written consent is referred to herein as the "**Mandatory Conversion Time**"), then (i) all outstanding shares of Series A Preferred Stock shall automatically be converted into shares of Common Stock, at the then effective conversion rate as calculated pursuant to Subsection 4.1.1 and (ii) such shares may not be reissued by the Corporation.

5.2 Procedural Requirements. All holders of record of shares of Series A Preferred Stock shall be sent written notice of the Mandatory Conversion Time and the place designated for mandatory conversion of all such shares of Series A Preferred Stock pursuant to this Section 5. Such notice need not be sent in advance of the occurrence of the Mandatory Conversion Time. Upon receipt of such notice, each holder of shares of Series A Preferred Stock in certificated form shall surrender his, her or its certificate or certificates for all such shares (or, if such holder alleges that such certificate has been lost, stolen or destroyed, a lost certificate affidavit and agreement reasonably acceptable to the Corporation to indemnify the Corporation against any claim that may be made against the Corporation on account of the alleged loss, theft

or destruction of such certificate) to the Corporation at the place designated in such notice. If so required by the Corporation, any certificates surrendered for conversion shall be endorsed or accompanied by written instrument or instruments of transfer, in form satisfactory to the Corporation, duly executed by the registered holder or by his, her or its attorney duly authorized in writing. All rights with respect to the Series A Preferred Stock converted pursuant to Subsection 5.1, including the rights, if any, to receive notices and vote (other than as a holder of Common Stock), will terminate at the Mandatory Conversion Time (notwithstanding the failure of the holder or holders thereof to surrender any certificates at or prior to such time), except only the rights of the holders thereof, upon surrender of any certificate or certificates of such holders (or lost certificate affidavit and agreement) therefor, to receive the items provided for in the next sentence of this Subsection 5.2. As soon as practicable after the Mandatory Conversion Time and, if applicable, the surrender of any certificate or certificates (or lost certificate affidavit and agreement) for Series A Preferred Stock, the Corporation shall (a) issue and deliver to such holder, or to his, her or its nominees, a notice of issuance of uncertificated shares and may, upon written request, issue and deliver a certificate for the number of full shares of Common Stock issuable on such conversion in accordance with the provisions hereof and (b) pay cash as provided in Subsection 4.2 in lieu of any fraction of a share of Common Stock otherwise issuable upon such conversion and for the payment of any declared but unpaid dividends on the shares of Series A Preferred Stock converted. Such converted Series A Preferred Stock shall be retired and cancelled and may not be reissued as shares of such series, and the Corporation may thereafter take such appropriate action (without the need for stockholder action) as may be necessary to reduce the authorized number of shares of Series A Preferred Stock accordingly.

5A. Special Mandatory Conversion.

5A.1. Trigger Event. In the event that any holder of shares of Series A Preferred Stock is deemed a Breaching Investor (as defined in the Series A Preferred Share Purchase Agreement, dated April 16, 2018), then, unless otherwise waived in writing by the Requisite Preferred who are not Breaching Investors, all of such Breaching Investor's Series A Preferred Stock and/or Common Stock issued upon conversion of Series A Preferred Stock (the "**Forfeited Shares**"), shall automatically, and without any further action on the part of such holder, be converted into shares of Common Stock at a conversion ratio of ten (10) Forfeited Shares to one (1) share of Common Stock (a "**Special Mandatory Conversion**"). In the event of a Special Mandatory Conversion, such Breaching Investor will lose any right it may have as a holder of shares of Series A Preferred Stock and all rights and preferences originally conferred to the Series A Preferred Stock.

5A.2. Procedural Requirements. Upon a Special Mandatory Conversion, each holder of shares of Series A Preferred Stock converted pursuant to Subsection 5A.1 shall be sent written notice of such Special Mandatory Conversion and the place designated for mandatory conversion of all such shares of Series A Preferred Stock pursuant to this Section 5A. Upon receipt of such notice, each holder of such shares of Series A Preferred Stock in certificated form shall surrender his, her or its certificate or certificates for all such shares (or, if such holder alleges that any such certificate has been lost, stolen or destroyed, a lost certificate affidavit and agreement reasonably acceptable to the Corporation to indemnify the Corporation against any claim that may be made against the Corporation on account of the alleged loss, theft or destruction of such certificate) to the Corporation at the place designated in such notice. If so required by the Corporation, any certificates surrendered for conversion shall be endorsed or

accompanied by written instrument or instruments of transfer, in form satisfactory to the Corporation, duly executed by the registered holder or by his, her or its attorney duly authorized in writing. All rights with respect to the Series A Preferred Stock converted pursuant to Subsection 5A.1, including the rights, if any, to receive notices and vote (other than as a holder of Common Stock), will terminate at the time of the Special Mandatory Conversion (notwithstanding the failure of the holder or holders thereof to surrender any certificates for such shares at or prior to such time), except only the rights of the holders thereof, upon surrender of any certificate or certificates of such holders therefor (or lost certificate affidavit and agreement), to receive the items provided for in the next sentence of this Subsection 5A.2. As soon as practicable after the Special Mandatory Conversion and, if applicable, the surrender of any certificate or certificates (or lost certificate affidavit and agreement) for Series A Preferred Stock so converted, the Corporation shall (a) issue and deliver to such holder, or to his, her or its nominees, a notice of issuance of uncertificated shares and may, upon written request, issue and deliver a certificate or certificates for the number of full shares of Common Stock issuable upon such conversion in accordance with the provisions hereof and (b) may, if applicable and upon written request, issue and deliver a new certificate for the number of shares, if any, of Series A Preferred Stock represented by such surrendered certificate and not converted pursuant to Subsection 5A.1.

5A.3. Such converted Series A Preferred Stock shall be retired and cancelled and may not be reissued as shares of such series, and the Corporation may thereafter take such appropriate action (without the need for stockholder action) as may be necessary to reduce the authorized number of shares of Series A Preferred Stock accordingly.

6. Redeemed or Otherwise Acquired Shares. Any shares of Series A Preferred Stock that are redeemed or otherwise acquired by the Corporation or any of its subsidiaries shall be automatically and immediately cancelled and retired and shall not be reissued, sold or transferred. Neither the Corporation nor any of its subsidiaries may exercise any voting or other rights granted to the holders of Series A Preferred Stock following redemption.

7. Waiver. Any of the rights, powers, preferences and other terms of the Series A Preferred Stock set forth herein may be waived on behalf of all holders of Series A Preferred Stock by the Requisite Preferred.

8. Notices. Any notice required or permitted by the provisions of this Article Fourth to be given to a holder of shares of Series A Preferred Stock shall be mailed, postage prepaid, to the post office address last shown on the records of the Corporation, or given by electronic communication in compliance with the provisions of the General Corporation Law, and shall be deemed sent upon such mailing or electronic transmission.

FIFTH: Subject to any additional vote required by this Amended and Restated Certificate of Incorporation or Bylaws, in furtherance and not in limitation of the powers conferred by statute, the Board of Directors is expressly authorized to make, repeal, alter, amend and rescind any or all of the Bylaws of the Corporation.

SIXTH: Subject to any additional vote required by this Amended and Restated Certificate of Incorporation, the number of directors of the Corporation shall be determined in the manner set forth in the Bylaws of the Corporation. Each director shall be entitled to one vote on each matter presented to the Board of Directors; provided, however, that, so long as the holders of Series A Preferred Stock are entitled to elect Series A Directors, the affirmative vote of the Requisite Preferred Directors shall be required for the authorization by the Board of Directors of any of the matters set forth in Section 5.4 of the Investors' Rights Agreement, dated as of September 17, 2019, by and among the Corporation and the other parties thereto, as such agreement may be amended from time to time.

SEVENTH: Elections of directors need not be by written ballot unless the Bylaws of the Corporation shall so provide.

EIGHTH: Meetings of stockholders may be held within or without the State of Delaware, as the Bylaws of the Corporation may provide. The books of the Corporation may be kept outside the State of Delaware at such place or places as may be designated from time to time by the Board of Directors or in the Bylaws of the Corporation.

NINTH: To the fullest extent permitted by law, a director of the Corporation shall not be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director. If the General Corporation Law or any other law of the State of Delaware is amended after approval by the stockholders of this Article Ninth to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the Corporation shall be eliminated or limited to the fullest extent permitted by the General Corporation Law as so amended.

Any repeal or modification of the foregoing provisions of this Article Ninth by the stockholders of the Corporation shall not adversely affect any right or protection of a director of the Corporation existing at the time of, or increase the liability of any director of the Corporation with respect to any acts or omissions of such director occurring prior to, such repeal or modification.

TENTH: The following indemnification provisions shall apply to the persons enumerated below.

1. Right to Indemnification of Directors and Officers. The Corporation shall indemnify and hold harmless, to the fullest extent permitted by applicable law as it presently exists or may hereafter be amended, any person (an "**Indemnified Person**") who was or is made or is threatened to be made a party or is otherwise involved in any action, suit or proceeding, whether civil, criminal, administrative or investigative (a "**Proceeding**"), by reason of the fact that such person, or a person for whom such person is the legal representative, is or was a director or officer of the Corporation or, while a director or officer of the Corporation, is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation or of a partnership, joint venture, limited liability company, trust, enterprise or nonprofit entity, including service with respect to employee benefit plans, against all liability and loss suffered and expenses (including attorneys' fees) reasonably incurred by such Indemnified Person in such Proceeding. Notwithstanding the preceding sentence, except as otherwise provided in Section 3 of this Article Tenth the Corporation shall be required to indemnify an Indemnified Person in connection with a Proceeding (or part thereof) commenced by such Indemnified Person only if the commencement of such Proceeding (or part thereof) by the Indemnified Person was authorized in advance by the Board of Directors.

2. Prepayment of Expenses of Directors and Officers. The Corporation shall pay the expenses (including attorneys' fees) incurred by an Indemnified Person in defending any Proceeding in advance of its final disposition, provided, however, that, to the extent required by law, such payment of expenses in advance of the final disposition of the Proceeding shall be made only upon receipt of an undertaking by the Indemnified Person to repay all amounts advanced if it should be ultimately determined that the Indemnified Person is not entitled to be indemnified under this Article Tenth or otherwise.

3. Claims by Directors and Officers. If a claim for indemnification or advancement of expenses under this Article Tenth is not paid in full within thirty (30) days after a written claim therefor by the Indemnified Person has been received by the Corporation, the Indemnified Person may file suit to recover the unpaid amount of such claim and, if successful in whole or in part, shall be entitled to be paid the expense of prosecuting such claim. In any such action the Corporation shall have the burden of proving that the Indemnified Person is not entitled to the requested indemnification or advancement of expenses under applicable law.

4. Indemnification of Employees and Agents. The Corporation may indemnify and advance expenses to any person who was or is made or is threatened to be made or is otherwise involved in any Proceeding by reason of the fact that such person, or a person for whom such person is the legal representative, is or was an employee or agent of the Corporation or, while an employee or agent of the Corporation, is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation or of a partnership, joint venture, limited liability company, trust, enterprise or nonprofit entity, including service with respect to employee benefit plans, against all liability and loss suffered and expenses (including attorneys' fees) reasonably incurred by such person in connection with such Proceeding. The ultimate determination of entitlement to indemnification of persons who are non-director or officer employees or agents shall be made in such manner as is determined by the Board of Directors in its sole discretion. Notwithstanding the foregoing sentence, the Corporation shall not be required to indemnify a person in connection with a Proceeding initiated by such person if the Proceeding was not authorized in advance by the Board of Directors.

5. Advancement of Expenses of Employees and Agents. The Corporation may pay the expenses (including attorneys' fees) incurred by an employee or agent in defending any Proceeding in advance of its final disposition on such terms and conditions as may be determined by the Board of Directors.

6. Non-Exclusivity of Rights. The rights conferred on any person by this Article Tenth shall not be exclusive of any other rights which such person may have or hereafter acquire under any statute, provision of this Amended and Restated Certificate of Incorporation, the Bylaws of the Corporation, or any agreement, or pursuant to any vote of stockholders or disinterested directors or otherwise.

7. Other Indemnification. The Corporation's obligation, if any, to indemnify any person who was or is serving at its request as a director, officer or employee of another Corporation, partnership, limited liability company, joint venture, trust, organization or other enterprise shall be reduced by any amount such person may collect as indemnification from such other Corporation, partnership, limited liability company, joint venture, trust, organization or other enterprise.

8. Insurance. The Board of Directors may, to the full extent permitted by applicable law as it presently exists, or may hereafter be amended from time to time, authorize an appropriate officer or officers to purchase and maintain at the Corporation's expense insurance: (a) to indemnify the Corporation for any obligation which it incurs as a result of the indemnification of directors, officers and employees under the provisions of this Article Tenth; and (b) to indemnify or insure directors, officers and employees against liability in instances in which they may not otherwise be indemnified by the Corporation under the provisions of this Article Tenth.

9. Amendment or Repeal. Any repeal or modification of the foregoing provisions of this Article Tenth shall not adversely affect any right or protection hereunder of any person in respect of any act or omission occurring prior to the time of such repeal or modification. The rights provided hereunder shall inure to the benefit of any Indemnified Person and such person's heirs, executors and administrators.

ELEVENTH: The Corporation renounces, to the fullest extent permitted by law, any interest or expectancy of the Corporation in, or in being offered an opportunity to participate in, any Excluded Opportunity. An "**Excluded Opportunity**" is any matter, transaction or interest that is presented to, or acquired, created or developed by, or which otherwise comes into the possession of (i) any director of the Corporation who is not an employee of the Corporation or any of its subsidiaries, or (ii) any holder of Series A Preferred Stock or any partner, member, director, stockholder, employee, affiliate or agent of any such holder, other than someone who is an employee of the Corporation or any of its subsidiaries (collectively, the persons referred to in clauses (i) and (ii) are "**Covered Persons**"), unless such matter, transaction or interest is presented to, or acquired, created or developed by, or otherwise comes into the possession of, a Covered Person expressly and solely in such Covered Person's capacity as a director of the Corporation while such Covered Person is performing services in such capacity. Any repeal or modification of this Article Eleventh will only be prospective and will not affect the rights under this Article Eleventh in effect at the time of the occurrence of any actions or omissions to act giving rise to liability. Notwithstanding anything to the contrary contained elsewhere in this Amended and Restated Certificate of Incorporation, the affirmative vote of the holders of at least 50% of the shares of Series A Preferred Stock then outstanding, will be required to amend or repeal, or to adopt any provisions inconsistent with this Article Eleventh.

TWELFTH: Unless the Corporation consents in writing to the selection of an alternative forum, the Court of Chancery in the State of Delaware shall be the sole and exclusive forum for any stockholder (including a beneficial owner) to bring (i) any derivative action or proceeding brought on behalf of the Corporation, (ii) any action asserting a claim of breach of fiduciary duty owed by any director, officer or other employee of the Corporation to the Corporation or the Corporation's stockholders, (iii) any action asserting a claim against the Corporation, its directors, officers or employees arising pursuant to any provision of the Delaware General Corporation Law or the Corporation's certificate of incorporation or bylaws or (iv) any action asserting a claim against the

Corporation, its directors, officers or employees governed by the internal affairs doctrine, except for, as to each of (i) through (iv) above, any claim as to which the Court of Chancery determines that there is an indispensable party not subject to the jurisdiction of the Court of Chancery (and the indispensable party does not consent to the personal jurisdiction of the Court of Chancery within ten days following such determination), which is vested in the exclusive jurisdiction of a court or forum other than the Court of Chancery, or for which the Court of Chancery does not have subject matter jurisdiction. If any provision or provisions of this Article Twelfth shall be held to be invalid, illegal or unenforceable as applied to any person or entity or circumstance for any reason whatsoever, then, to the fullest extent permitted by law, the validity, legality and enforceability of such provisions in any other circumstance and of the remaining provisions of this Article Twelfth (including, without limitation, each portion of any sentence of this Article Twelfth containing any such provision held to be invalid, illegal or unenforceable that is not itself held to be invalid, illegal or unenforceable) and the application of such provision to other persons or entities and circumstances shall not in any way be affected or impaired thereby.

THIRTEENTH: For purposes of Section 500 of the California Corporations Code (to the extent applicable), in connection with any repurchase of shares of Common Stock permitted under this Amended and Restated Certificate of Incorporation from employees, officers, directors or consultants of the Corporation in connection with a termination of employment or services pursuant to agreements or arrangements approved by the Board of Directors (in addition to any other consent required under this Amended and Restated Certificate of Incorporation), such repurchase may be made without regard to any "preferential dividends arrears amount" or "preferential rights amount" (as those terms are defined in Section 500 of the California Corporations Code). Accordingly, for purposes of making any calculation under California Corporations Code Section 500 in connection with such repurchase, the amount of any "preferential dividends arrears amount" or "preferential rights amount" (as those terms are defined therein) shall be deemed to be zero (0).

* * *

4. That the foregoing amendment and restatement was approved by the Board of Directors in accordance with Section 241(b) of the General Corporation Law.

5. That this Certificate of Incorporation, which restates and integrates and further amends the provisions of this Corporation's Certificate of Incorporation, has been duly adopted in accordance with Section 245 of the General Corporation Law.

IN WITNESS WHEREOF, this Amended and Restated Certificate of Incorporation has been executed by a duly authorized officer of this corporation on this 17th day of September, 2019.

By: /s/ Rohan A. Palekar
Chief Executive Officer

[Signature Page – Amended and Restated Certificate of Incorporation]

FIRST AMENDED AND RESTATED BYLAWS

OF

89BIO, INC.
(a Delaware corporation, the "Corporation")

These First Amended and Restated Bylaws ("Bylaws") amend and restate the previous bylaws of the Corporation in their entirety and, as of the date hereof, any previous bylaws are of no further force or effect.

ARTICLE I
CORPORATE OFFICES

Section 1.1 Registered Office. The registered office of the Corporation shall be fixed in the Certificate of Incorporation of the Corporation.

Section 1.2 Other Offices. The Corporation may also have an office or offices, and keep the books and records of the Corporation, except as otherwise required by law, at such other place or places, either within or without the State of Delaware, as the Board of Directors may from time to time determine or the business of the Corporation may require.

ARTICLE II
MEETINGS OF STOCKHOLDERS

Section 2.1 Annual Meeting. If required by law, the annual meeting of stockholders, for the election of directors and for the transaction of such other business as may properly come before the meeting, shall be held at such place, if any, either within or without the State of Delaware, on such date, and at such time as the Board of Directors shall fix. The Board of Directors may postpone, reschedule or cancel any annual meeting of stockholders previously scheduled by the Board of Directors.

Section 2.2 Special Meeting. Except as otherwise required by law, and except as otherwise provided for or fixed pursuant to the Certificate of Incorporation, a special meeting of the stockholders of the Corporation may be called at any time by the Board of Directors, the Chief Executive Officer, the Vice President or the Secretary. Except as otherwise required by law, and except as otherwise provided for or fixed pursuant to the Certificate of Incorporation, special meetings of the stockholders of the Corporation may not be called by any other person or persons. Only such business shall be conducted at a special meeting of stockholders as shall have been brought before the meeting by or at the direction of the Board of Directors. The Board of Directors may postpone, reschedule or cancel any special meeting of stockholders previously scheduled pursuant to this Section 2.2.

Section 2.3 Notice of Stockholders' Meetings. Notice of stockholders' meetings shall be given in accordance with the Delaware General Corporation Law ("DGCL").

Section 2.4 Quorum. Except as otherwise required by law, the Certificate of Incorporation or these Bylaws, at any meeting of stockholders, a majority of the voting power of the stock outstanding and entitled to vote at the meeting, present in person or represented by proxy, shall constitute a quorum for the transaction of business.

Section 2.5 Voting.

(a) Except as otherwise required by law or the Certificate of Incorporation, each holder of stock of the Corporation entitled to vote at any meeting of stockholders shall be entitled to one vote for each share of such stock held of record by such holder that has voting power upon the subject matter in question.

(b) Except as otherwise required by law, the Certificate of Incorporation, these Bylaws or any law, rule or regulation applicable to the Corporation or its securities, at each meeting of stockholders at which a quorum is present, all corporate actions to be taken by vote of the stockholders shall be authorized by the affirmative vote of at least a majority of the voting power of the stock present in person or represented by proxy and entitled to vote on the subject matter. Voting at meetings of stockholders need not be by written ballot.

Section 2.6 Action by Written Consent. Any action required or permitted to be taken at a meeting of the stockholders of the Corporation may be taken without a meeting, without prior notice and without a vote, if a consent in writing, setting forth the action so taken, is signed by all the stockholders entitled to vote on the action. Such agreement or consent may be filed with the Corporation, or such other procedure as may be required by the DGCL.

ARTICLE III
DIRECTORS

Section 3.1 Powers. Except as otherwise required by the DGCL or as provided in the Certificate of Incorporation, the business and affairs of the Corporation shall be managed by or under the direction of the Board of Directors. In addition to the powers and authorities these Bylaws expressly confer upon it, the Board of Directors may exercise all such powers of the Corporation and do all such lawful acts and things as are not by law, the Certificate of Incorporation or these Bylaws required to be exercised or done by the stockholders.

Section 3.2 Number, Term of Office and Election.

(a) The Board of Directors shall consist of seven directors or such number of directors as shall be determined from time to time solely by resolution adopted by the affirmative vote of a majority of the holders of shares of Series A Preferred Stock of the Company (the "Preferred Holders").

(b) Subject to the rights of the Preferred Holders to elect directors, directors shall be elected at each annual meeting of stockholders to serve until the next annual meeting of stockholders and his or her successor is duly elected and qualified or until his or her death, resignation or removal. At any meeting of stockholders (including any written consent in lieu of a meeting of stockholders) at which directors are to be elected, directors shall be elected by a plurality of the votes cast. Each director shall hold office until the next election of directors and until his or her successor shall have been duly elected and qualified. Directors need not be stockholders unless so required by the Certificate of Incorporation or these Bylaws, wherein other qualifications for directors may be prescribed.

Section 3.3 Vacancies and Newly Created Directorships. Subject to the rights of the Preferred Holders to elect directors and unless otherwise required by law or resolution of the Board of Directors, newly created directorships resulting from any increase in the authorized number of directors and any vacancies in the Board of Directors resulting from death, resignation, retirement, disqualification, removal from office or other cause may be filled by the affirmative vote of a majority of the remaining directors then in office and entitled to vote thereon, even though less than a quorum, or by the sole remaining director, and any director so chosen shall hold office until the next election of directors and until his or her successor shall have been duly elected and qualified. No decrease in the authorized number of directors shall shorten the term of any incumbent director.

Section 3.4 Resignations and Removal.

(a) Any director may resign at any time upon notice given in writing or by electronic transmission to the Board of Directors, the Chairman of the Board of Directors, if any, or the Secretary of the Corporation. Such resignation shall take effect upon delivery, unless the resignation specifies a later effective date or time or an effective date or time determined upon the happening of an event or events. Unless otherwise specified therein, the acceptance of such resignation shall not be necessary to make it effective.

(b) Subject to the rights of the Preferred Holders to remove directors and unless otherwise restricted by law, any director, or the entire Board of Directors, may be removed, with or without cause, by the affirmative vote of at least a majority of the voting power of the stock outstanding and entitled to vote thereon.

Section 3.5 Regular Meetings. Regular meetings of the Board of Directors shall be held at such place or places, within or without the State of Delaware, on such date or dates and at such time or times, as shall have been established by the Board of Directors and publicized among all directors. A notice of each regular meeting shall not be required.

Section 3.6 Special Meetings. Special meetings of the Board of Directors for any purpose or purposes may be called at any time by the Chairman of the Board of Directors, if any, the Chief Executive Officer or a majority of the directors then in office. The person or persons authorized to call special meetings of the Board of Directors may fix the place, within or without the State of Delaware, date and time of such meetings. Notice of each such meeting shall be given to each director, if by mail, addressed to such director at his or her residence or usual place of business, at least five days before the day on which such meeting is to be held, or shall be sent to such director by electronic transmission, or be delivered personally or by telephone, in each case at least 24 hours prior to the time set for such meeting. A notice of special meeting need not state the purpose of such meeting, and, unless indicated in the notice thereof, any and all business may be transacted at a special meeting.

Section 3.7 Participation in Meetings by Conference Telephone. Members of the Board of Directors, or of any committee thereof, may participate in a meeting of such Board of Directors or committee by means of conference telephone or other communications equipment by means of which all persons participating in the meeting can hear each other, and such participation shall constitute presence in person at such meeting.

Section 3.8 Quorum and Voting. Except as otherwise required by law, the Certificate of Incorporation or these Bylaws, a majority of the Board, including the Requisite Preferred Directors, shall constitute a quorum for the transaction of business at any meeting of the Board of Directors, and the vote of a majority of the directors present at a duly held meeting at which a quorum is present shall be the act of the Board of Directors. The chairman of the meeting or a majority of the directors present may adjourn the meeting to another time and place whether or not a quorum is present. At any adjourned meeting at which a quorum is present, any business may be transacted which might have been transacted at the meeting as originally called. As used in these Bylaws, "Requisite Preferred Directors" means the majority of the Preferred Directors, provided that during such time that the Pontifax Letter Agreement is in effect such majority shall include the OrbiMed Director. "Pontifax Letter Agreement" means that certain letter agreement by and between Pontifax and OrbiMed, dated as of April 16, 2018.

Section 3.9 Board of Directors Action by Written Consent Without a Meeting. Unless otherwise restricted by the Certificate of Incorporation or these Bylaws, any action required or permitted to be taken at any meeting of the Board of Directors, or any committee thereof, may be taken without a meeting, provided that all members of the Board of Directors or committee, as the case may be, consent in writing or by electronic transmission to such action, and the writing or writings or electronic transmission or transmissions are filed with the minutes or proceedings of the Board of Directors or committee. Such filing shall be in paper form if the minutes are maintained in paper form and shall be in electronic form if the minutes are maintained in electronic form. Any person (whether or not then a director) may provide, whether through instruction to an agent or otherwise, that a consent to action shall be effective at a future time (including a time determined upon the happening of an event), no later than 60 days after such instruction is given or such provision is made and such consent shall be deemed to have been given at such effective time so long as such person is then a director and did not revoke the consent prior to such time. Any such consent shall be revocable prior to its becoming effective.

Section 3.10 Chairman of the Board. At every meeting of the Board of Directors, the Chairman of the Board, or, if a Chairman has not been appointed or is absent, the Chief Executive Officer, or if the Chief Executive Officer has not been appointed or is absent, or, in the absence of any such person, a chairman of the meeting chosen by a majority of the directors present, shall preside over the meeting. The Chairman of the Board of Directors shall be appointed by a majority vote of the Board of Directors, in which vote the Industry Directors will not participate. The Chairman may be removed from office at any time upon written notice to the Company signed by the majority of the directors (excluding the Industry Directors), provided, however, that such removal shall not have any effect on the Chairman's position as a director.

Section 3.11 Rules and Regulations. The Board of Directors shall adopt such rules and regulations not inconsistent with the provisions of law, the Certificate of Incorporation or these Bylaws for the conduct of its meetings and management of the affairs of the Corporation as the Board of Directors shall deem proper.

Section 3.12 Fees and Compensation of Directors. Unless otherwise restricted by the Certificate of Incorporation, directors may receive such compensation, if any, for their services on the Board of Directors and its committees, and such reimbursement of expenses, as may be fixed or determined by resolution of the Board of Directors.

Section 3.13 Emergency Bylaws. In the event of any emergency, disaster or catastrophe, as referred to in Section 110 of the DGCL, or other similar emergency condition, as a result of which a quorum of the Board of Directors or a standing committee of the Board of Directors cannot readily be convened for action, then the director or directors in attendance at the meeting shall constitute a quorum. Such director or directors in attendance may further take action to appoint one or more of themselves or other directors to membership on any standing or temporary committees of the Board of Directors as they shall deem necessary and appropriate.

Section 3.14 Committees of the Board of Directors. The Board of Directors may designate one or more committees, each such committee to consist of one or more of the directors of the Corporation, which shall have and may exercise such lawfully delegable powers and duties conferred or authorized by the resolutions of designation and appointment. Each such committee, and each committee of the Board of Directors of any subsidiary of the Company, shall consist of two or more members (all of whom must be directors of the Company or of a subsidiary thereof, as applicable), including, at the option of each OrbiMed or Longitude, as applicable, at least the OrbiMed Director and Longitude Director. The Board of Directors shall have power at any time to change the members of any such committee, to fill vacancies and to discharge any such committee.

ARTICLE IV
OFFICERS

Section 4.1 Officers. The officers of the Corporation shall consist of such officers as the Board of Directors may from time to time determine, each of whom shall be elected by the Board of Directors, each to have such authority, functions or duties as set forth in these Bylaws or as determined by the Board of Directors. Each officer shall be elected by the Board of Directors and shall hold office for such term as may be prescribed by the Board of Directors and until such person's successor shall have been duly elected and qualified, or until such person's earlier death, disqualification, resignation or removal. Any number of offices may be held by the same person; provided, however, that no officer shall execute, acknowledge or verify any instrument in more than one capacity if such instrument is required by law, the Certificate of Incorporation or these Bylaws to be executed, acknowledged or verified by two or more officers. The Board of Directors may require any officer, agent or employee to give security for the faithful performance of his or her duties.

Section 4.2 Compensation. The salaries of the officers of the Corporation and the manner and time of the payment of such salaries shall be fixed and determined by the Board of Directors and may be altered by the Board of Directors from time to time as it deems appropriate, subject to the rights, if any, of such officers under any contract of employment.

Section 4.3 Removal, Resignation and Vacancies. Any officer of the Corporation may be removed, with or without cause, by the Board of Directors or by a duly authorized officer, without prejudice to the rights, if any, of such officer under any contract to which it is a party. Any officer may resign at any time upon notice given in writing or by electronic transmission to the Corporation, without prejudice to the rights, if any, of the Corporation under any contract to which such officer is a party. If any vacancy occurs in any office of the Corporation, the Board of Directors may elect a successor to fill such vacancy for the remainder of the unexpired term and until a successor shall have been duly elected and qualified.

Section 4.4 Chief Executive Officer. The Chief Executive Officer shall have general supervision and direction of the business and affairs of the Corporation, shall be responsible for corporate policy and strategy, and shall report directly to the Board of Directors. Unless otherwise provided in these Bylaws or determined by the Board of Directors, all other officers of the Corporation shall report directly to the Chief Executive Officer or as otherwise determined by the Chief Executive Officer. The Chief Executive Officer shall, if present and in the absence of the Chairman of the Board of Directors, preside at meetings of the stockholders.

Section 4.5 President. The President shall be the chief operating officer of the Corporation, with general responsibility for the management and control of the operations of the Corporation. The President shall, when requested, counsel with and advise the other officers of the Corporation and shall perform such other duties as the Board of Directors or the Chief Executive Officer may from time to time determine.

Section 4.6 Chief Financial Officer. The Chief Financial Officer shall exercise all the powers and perform the duties of the office of the chief financial officer and in general have overall supervision of the financial operations of the Corporation. The Chief Financial Officer shall, when requested, counsel with and advise the other officers of the Corporation and shall perform such other duties as the Board of Directors, the Chief Executive Officer or the President may from time to time determine.

Section 4.7 Vice Presidents. Each Vice President shall have such powers and duties as shall be prescribed by his or her superior officer, the Chief Executive Officer or the President. A Vice President shall, when requested, counsel with and advise the other officers of the Corporation and shall perform such other duties as the Board of Directors, the Chief Executive Officer, the President or another duly authorized officer may from time to time determine.

Section 4.8 Treasurer. The Treasurer shall supervise and be responsible for all the funds and securities of the Corporation, the deposit of all moneys and other valuables to the credit of the Corporation in depositories of the Corporation, borrowings and compliance with the provisions of all indentures, agreements and instruments governing such borrowings to which the Corporation is a party, the disbursement of funds of the Corporation and the investment of its funds, and in general shall perform all of the duties incident to the office of the Treasurer. The Treasurer shall, when requested, counsel with and advise the other officers of the Corporation and shall perform such other duties as the Board of Directors, the Chief Executive Officer, the President or the Chief Financial Officer may from time to time determine.

Section 4.9 Controller. The Controller shall be the chief accounting officer of the Corporation. The Controller shall, when requested, counsel with and advise the other officers of the Corporation and shall perform such other duties as the Board of Directors, the Chief Executive Officer, the President, the Chief Financial Officer or the Treasurer may from time to time determine.

Section 4.10 Secretary. The powers and duties of the Secretary are: (i) to act as Secretary at all meetings of the Board of Directors, of the committees of the Board of Directors and of the stockholders and to record the proceedings of such meetings in a book or books to be kept for that purpose; (ii) to see that all notices required to be given by the Corporation are duly given and served; (iii) to act as custodian of the seal of the Corporation, if any, and affix the seal or cause it to be affixed to all certificates of stock of the Corporation and to all documents, the execution of which on behalf of the Corporation under its seal is duly authorized in accordance with the provisions of these Bylaws; (iv) to have charge of the books, records and papers of the Corporation and see that the reports, statements and other documents required by law to be kept and filed are properly kept and filed; and (v) to perform all of the duties incident to the office of Secretary. The Secretary shall, when requested, counsel with and advise the other officers of the Corporation and shall perform such other duties as the Board of Directors, the Chief Executive Officer or the President may from time to time determine.

Section 4.11 Additional Matters. The Chief Executive Officer and the Chief Financial Officer of the Corporation shall have the authority to designate employees of the Corporation to have the title of Vice President, Assistant Vice President, Assistant Treasurer or Assistant Secretary. Any employee so designated shall have the powers and duties determined by the officer making such designation. The persons so designated shall not be deemed officers of the Corporation unless elected by the Board of Directors.

Section 4.12 Checks; Drafts; Evidences of Indebtedness. From time to time, the Board of Directors shall determine the method, and designate (or authorize officers of the Corporation to designate) the person or persons who shall have authority, to sign or endorse all checks, drafts, other orders for payment of money and notes, bonds, debentures or other evidences of indebtedness that are issued in the name of or payable by the Corporation, and only the persons so authorized shall sign or endorse such instruments.

Section 4.13 Corporate Contracts and Instruments; How Executed. Except as otherwise provided in these Bylaws, the Board of Directors may determine the method, and designate (or authorize officers of the Corporation to designate) the person or persons who shall have authority to enter into any contract or execute any instrument in the name of and on behalf of the Corporation. Such authority may be general or confined to specific instances. Unless so authorized, or within the power incident to a person’s office or other position with the Corporation, no person shall have any power or authority to bind the Corporation by any contract or engagement or to pledge its credit or to render it liable for any purpose or for any amount.

Section 4.14 Signature Authority. Unless otherwise specifically determined by the Board of Directors or otherwise provided by law or these Bylaws, contracts, evidences of indebtedness and other instruments or documents of the Corporation may be executed, signed or endorsed: (i) by the Chief Executive Officer or the President; or (ii) by the Chief Financial Officer, any Vice President, Treasurer, Secretary or Controller, in each case only with regard to such instruments or documents that pertain to or relate to such person’s duties or business functions.

Section 4.15 Action with Respect to Securities of Other Corporations or Entities. The Chief Executive Officer, Chief Financial Officer or any other officer of the Corporation authorized by the Board of Directors or the Chief Executive Officer is authorized to vote, represent, and exercise on behalf of the Corporation all rights incident to any and all shares or other equity interests of any other corporation or entity, or corporations or entities, standing in the name of the Corporation. The authority herein granted may be exercised either by such person directly or by any other person authorized to do so by proxy or power of attorney duly executed by the person having such authority.

Section 4.16 Delegation. The Board of Directors may from time to time delegate the powers or duties of any officer to any other officers or agents, notwithstanding the foregoing provisions of this Article IV.

ARTICLE V
INDEMNIFICATION AND ADVANCEMENT OF EXPENSES

Section 5.1 Right to Indemnification.

(a) Each person who was or is a party or is threatened to be made a party to, or was or is otherwise involved in, any action, suit, arbitration, alternative dispute resolution mechanism, investigation, inquiry, judicial, administrative or legislative hearing, or any other threatened, pending or completed proceeding, whether brought by or in the right of the Corporation or otherwise, including any and all appeals, whether of a civil, criminal, administrative, legislative, investigative or other nature (hereinafter a "proceeding"), by reason of the fact that he or she is or was a director or an officer of the Corporation or while a director or officer of the Corporation is or was serving at the request of the Corporation as a director, officer, employee, agent or trustee of another corporation or of a partnership, joint venture, trust or other enterprise, including service with respect to an employee benefit plan (hereinafter an "indemnitee"), or by reason of anything done or not done by him or her in any such capacity, shall be indemnified and held harmless by the Corporation to the fullest extent authorized by the DGCL, as the same exists or may hereafter be amended, against all expense, liability and loss (including attorneys' fees, judgments, fines, ERISA excise taxes, penalties and amounts paid in settlement by or on behalf of the indemnitee) actually and reasonably incurred by such indemnitee in connection therewith, all on the terms and conditions set forth in these Bylaws; provided, however, that, except as otherwise required by law or provided in Section 5.3 with respect to suits to enforce rights under this Article V, the Corporation shall indemnify any such indemnitee in connection with a proceeding, or part thereof, voluntarily initiated by such indemnitee (including claims and counterclaims, whether such counterclaims are asserted by: (i) such indemnitee; or (ii) the Corporation in a proceeding initiated by such indemnitee) only if such proceeding, or part thereof, was authorized or ratified by the Board of Directors or the Board of Directors otherwise determines that indemnification or advancement of expenses is appropriate.

(b) To receive indemnification under this Section 5.1, an indemnitee shall submit a written request to the Corporation. Such request shall include documentation or information that is necessary to determine the entitlement of the indemnitee to indemnification and that is reasonably available to the indemnitee. Upon receipt by the Corporation of such a written request, the entitlement of the indemnitee to indemnification shall be determined by the following person or persons who shall be empowered to make such determination, as selected by the Board of Directors (except with respect to clause (v) of this Section 5.1(b)): (i) the Board of Directors by a majority vote of the directors who are not parties to such proceeding, whether or not such majority constitutes a quorum; (ii) a committee of such directors designated by a majority vote of such directors, whether or not such majority constitutes a quorum; (iii) if there are no such directors, or if such directors so direct, by independent legal counsel in a written opinion to the Board of Directors, a copy of which shall be delivered to the indemnitee; or (iv) the stockholders of the Corporation. The determination of entitlement to indemnification shall be made and, unless a contrary determination is made, such indemnification shall be paid in full by the Corporation not later than 60 days after receipt by the Corporation of a written request for indemnification.

Section 5.2 Right to Advancement of Expenses.

(a) In addition to the right to indemnification conferred in Section 5.1, an indemnitee shall, to the fullest extent permitted by law, also have the right to be paid by the Corporation the expenses (including attorneys' fees) incurred in defending any proceeding in advance of its final disposition (hereinafter an "advancement of expenses"); provided, however, that an advancement of expenses shall be made only upon delivery to the Corporation of an undertaking (hereinafter an "undertaking"), by or on behalf of such indemnitee, to repay all amounts so advanced if it shall ultimately be determined by final judicial decision of a court of competent jurisdiction from which there is no further right to appeal (hereinafter a "final adjudication") that such indemnitee is not entitled to be indemnified for such expenses under this Article V or otherwise.

(b) To receive an advancement of expenses under this Section 5.2, an indemnitee shall submit a written request to the Corporation. Such request shall reasonably evidence the expenses incurred by the indemnitee and shall include or be accompanied by the undertaking required by Section 5.2(a). Each such advancement of expenses shall be made within 20 days after the receipt by the Corporation of a written request for advancement of expenses.

(c) Notwithstanding the foregoing Section 5.2(a), the Corporation shall not make or continue to make advancements of expenses to an indemnitee if a determination is reasonably made that the facts known at the time such determination is made demonstrate clearly and convincingly that the indemnitee acted in bad faith or in a manner that the indemnitee did not reasonably believe to be in or not opposed to the best interests of the Corporation, or, with respect to any criminal proceeding, that the indemnitee had reasonable cause to believe his or her conduct was unlawful. Such determination shall be made: (i) by the Board of Directors by a majority vote of directors who are not parties to such proceeding, whether or not such majority constitutes a quorum; (ii) by a committee of such directors designated by a majority vote of such directors, whether or not such majority constitutes a quorum; or (iii) if there are no such directors, or if such directors so direct, by independent legal counsel in a written opinion to the Board of Directors, a copy of which shall be delivered to the indemnitee.

Section 5.3 Right of Indemnitee to Bring Suit. In the event that a determination is made that the indemnitee is not entitled to indemnification or if payment is not timely made following a determination of entitlement to indemnification pursuant to Section 5.1(b) or if an advancement of expenses is not timely made under Section 5.2(b), the indemnitee may at any time thereafter bring suit against the Corporation in a court of competent jurisdiction in the State of Delaware seeking an adjudication of entitlement to such indemnification or advancement of expenses. If successful in whole or in part in any such suit, or in a suit brought by the Corporation to recover an advancement of expenses pursuant to the terms of an undertaking, the indemnitee shall be entitled to be paid also the expense of prosecuting or defending such suit to the fullest extent permitted by law. In any suit brought by the indemnitee to enforce a right to indemnification hereunder (but not in a suit brought by the indemnitee to enforce a right to an advancement of expenses) it shall be a defense that the indemnitee has not met any applicable standard of conduct for indemnification set forth in the DGCL. Further, in any suit brought by the Corporation to recover an advancement of expenses pursuant to the terms of an undertaking, the Corporation shall be entitled to recover such expenses upon a final adjudication that the indemnitee has not met any applicable standard of conduct for indemnification set forth in the DGCL. Neither the failure of the Corporation (including its directors who are not parties to such action, a committee of such directors, independent legal counsel or its stockholders) to have made a determination prior to the commencement of such suit that indemnification of the indemnitee is proper in the circumstances because the indemnitee has met the applicable standard of conduct set forth in the DGCL, nor an actual determination by the Corporation (including its directors who are not parties to such action, a committee of such directors, independent legal counsel or its stockholders) that the indemnitee has not met such applicable standard of conduct, shall create a presumption that the indemnitee has not met the applicable standard of conduct or, in the case of such a suit brought by the indemnitee, be a defense to such suit. In any suit brought by the indemnitee to enforce a right to indemnification or to an advancement of expenses hereunder, or brought by the Corporation to recover an advancement of expenses pursuant to the terms of an undertaking, the burden of proving that the indemnitee is not entitled to be indemnified, or to such advancement of expenses, under applicable law, this Article V or otherwise shall be on the Corporation.

Section 5.4 Non-Exclusivity of Rights. The rights to indemnification and to the advancement of expenses conferred in this Article V shall not be exclusive of any other right which any person may have or hereafter acquire under any law, agreement, vote of stockholders or disinterested directors, provisions of a certificate of incorporation or bylaws, or otherwise.

Section 5.5 Insurance. The Corporation may maintain insurance, at its expense, to protect itself and any director, officer, employee or agent of the Corporation or another corporation, partnership, joint venture, trust or other enterprise against any expense, liability or loss, whether or not the Corporation would have the power to indemnify such person against such expense, liability or loss under the DGCL.

Section 5.6 Indemnification of Employees and Agents of the Corporation. The Corporation may, to the extent and in the manner permitted by law, and to the extent authorized from time to time, grant rights to indemnification and to the advancement of expenses to any employee or agent of the Corporation.

Section 5.7 Nature of Rights. The rights conferred upon indemnitees in this Article V shall be contract rights and such rights shall continue as to an indemnitee who has ceased to be a director or officer and shall inure to the benefit of the indemnitee's heirs, executors and administrators. Any amendment, alteration or repeal of this Article V that adversely affects any right of an indemnitee or its successors shall be prospective only and shall not limit or eliminate any such right with respect to any proceeding involving any occurrence or alleged occurrence of any action or omission to act that took place prior to such amendment, alteration or repeal.

Section 5.8 Settlement of Claims. Notwithstanding anything in this Article V to the contrary, the Corporation shall not be liable to indemnify any indemnitee under this Article V for any amounts paid in settlement of any proceeding effected without the Corporation's written consent, which consent shall not be unreasonably withheld, or for any judicial award if the Corporation was not given a reasonable and timely opportunity, at its expense, to participate in the defense of such proceeding.

Section 5.9 Subrogation. In the event of payment under this Article V, the Corporation shall be subrogated to the extent of such payment to all of the rights of recovery of the indemnitee (excluding insurance obtained on the indemnitee's own behalf), and the indemnitee shall execute all papers required and shall do everything that may be necessary to secure such rights, including the execution of such documents necessary to enable the Corporation effectively to bring suit to enforce such rights.

Section 5.10 Severability. If any provision or provisions of this Article V shall be held to be invalid, illegal or unenforceable as applied to any person or entity or circumstance for any reason whatsoever, then, to the fullest extent permitted by law: (a) the validity, legality and enforceability of such provision in any other circumstance and of the remaining provisions of this Article V (including, without limitation, all portions of any paragraph of this Article V containing any such provision held to be invalid, illegal or unenforceable, that are not by themselves invalid, illegal or unenforceable) and the application of such provision to other persons or entities or circumstances shall not in any way be affected or impaired thereby; and (b) to the fullest extent possible, the provisions of this Article V (including, without limitation, all portions of any paragraph of this Article V containing any such provision held to be invalid, illegal or unenforceable, that are not themselves invalid, illegal or unenforceable) shall be construed so as to give effect to the intent of the parties that the Corporation provide protection to the indemnitee to the fullest extent set forth in this Article V.

ARTICLE VI
CAPITAL STOCK

Section 6.1 Certificates of Stock. The shares of the Corporation may be represented by certificates. Every holder of stock represented by certificates shall be entitled to have a certificate signed by or in the name of the Corporation certifying the number of shares owned by such holder in the Corporation. Any or all such signatures may be facsimiles. In case any officer, transfer agent or registrar who has signed or whose facsimile signature has been placed upon a certificate has ceased to be such officer, transfer agent or registrar before such certificate is issued, it may be issued by the Corporation with the same effect as if such person were such officer, transfer agent or registrar at the date of issue.

Section 6.2 Transfers of Stock. Transfers of shares of stock of the Corporation shall be made only on the books of the Corporation upon authorization by the registered holder thereof or by such holder's attorney thereunto authorized by a power of attorney duly executed and filed with the Secretary of the Corporation or a transfer agent for such stock, and if such shares are represented by a certificate, upon surrender of the certificate or certificates for such shares properly endorsed or accompanied by a duly executed stock transfer power and the payment of any taxes thereon; provided, however, that the Corporation shall be entitled to recognize and enforce any lawful restriction on transfer.

Section 6.3 Lost Certificates. The Corporation may issue a new share certificate or uncertificated shares in the place of any certificate theretofore issued by it, alleged to have been lost, stolen or destroyed, and the Corporation may require the owner of the lost, stolen or destroyed certificate or the owner's legal representative to give the Corporation a bond (or other adequate security) sufficient to indemnify it against any claim that may be made against it (including any expense or liability) on account of the alleged loss, theft or destruction of any such certificate or the issuance of such new certificate or uncertificated shares. The Board of Directors may adopt such other provisions and restrictions with reference to lost certificates, not inconsistent with applicable law, as it shall in its discretion deem appropriate.

Section 6.4 Registered Stockholders. The Corporation shall be entitled to recognize the exclusive right of a person registered on its books as the owner of shares to receive dividends, and to vote as such owner, and shall not be bound to recognize any equitable or other claim to or interest in such share or shares on the part of any other person, whether or not it shall have express or other notice thereof, except as otherwise required by law.

Section 6.5 Record Date for Determining Stockholders.

(a) In order that the Corporation may determine the stockholders entitled to notice of or to vote at any meeting of stockholders or entitled to receive payment of any dividend or other distribution or allotment of any rights, or entitled to exercise any rights in respect of any change, conversion or exchange of stock, or for the purpose of any other lawful action, the Board of Directors may fix, in advance, a record date, which shall not be more than 60 days or fewer than ten days before the date of such meeting, or more than 60 days prior to any other action.

Section 6.6 Regulations. To the extent permitted by applicable law, the Board of Directors may make such additional rules and regulations as it may deem expedient concerning the issue, transfer and registration of shares of stock of the Corporation.

Section 6.7 Waiver of Notice. Whenever notice is required to be given under any provision of the DGCL or the Certificate of Incorporation or these Bylaws, a written waiver, signed by the person entitled to notice, or a waiver by electronic transmission by the person entitled to notice, whether before or after the time stated therein, shall be deemed equivalent to notice. Attendance of a person at a meeting shall constitute a waiver of notice of such meeting,

except when the person attends a meeting for the express purpose of objecting at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened. Neither the business to be transacted at, nor the purpose of, any regular or special meeting of the stockholders, the Board of Directors or a committee of the Board of Directors need be specified in any written waiver of notice or any waiver by electronic transmission unless so required by the Certificate of Incorporation or these Bylaws.

ARTICLE VII
GENERAL MATTERS

Section 7.1 Fiscal Year. The fiscal year of the Corporation shall begin on the first day of January of each year and end on the last day of December of the same year, or shall extend for such other 12 consecutive months as the Board of Directors may designate.

Section 7.2 Reliance Upon Books, Reports and Records. Each director and each member of any committee designated by the Board of Directors shall, in the performance of his or her duties, be fully protected in relying in good faith upon the books of account or other records of the Corporation and upon such information, opinions, reports or statements presented to the Corporation by any of its officers or employees, or committees of the Board of Directors so designated, or by any other person as to matters which such director or committee member reasonably believes are within such other person's professional or expert competence and who has been selected with reasonable care by or on behalf of the Corporation.

Section 7.3 Subject to Law and Certificate of Incorporation. All powers, duties and responsibilities provided for in these Bylaws, whether or not explicitly so qualified, are qualified by the Certificate of Incorporation and applicable law.

ARTICLE VIII
AMENDMENTS

Section 8.1 Amendments. In furtherance and not in limitation of the powers conferred by the laws of the State of Delaware, the Board of Directors is expressly authorized to adopt, amend or repeal these Bylaws. The stockholders may make additional Bylaws and may alter and repeal any Bylaws whether adopted by them or otherwise.

The foregoing Bylaws were adopted by the Board of Directors as of September 17, 2019.

Exhibit 4.2

EXECUTION VERSION

INVESTORS' RIGHTS AGREEMENT

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INVESTORS' RIGHTS AGREEMENT

THIS INVESTORS' RIGHTS AGREEMENT (this "**Agreement**"), is made as of the 17th day of September, 2019, by and among 89bio, Inc., a Delaware corporation (the "**Company**"), each of the investors listed on Schedule A hereto, each of which is referred to in this Agreement as an "**Investor**" and any additional purchaser that becomes a party to this Agreement in accordance with Section 6.9 hereof.

RECITALS

WHEREAS, certain of the Investors previously purchased Ordinary Shares, par value NIS0.01 per share (the "**Ordinary Shares**"), of 89bio Ltd., an Israeli private limited liability company ("**89bio Ltd.**");

WHEREAS, certain of the Investors previously purchased Series A Preferred Shares, par value NIS0.01 per share (the "**Preferred A Shares**"), of 89bio Ltd.;

WHEREAS, the Company and the Investors are parties to that certain Contribution and Exchange Agreement of even date herewith (the "**Subscription Agreement**"), pursuant to which the Investors will exchange all of their respective Ordinary Shares, Preferred A Shares and/or options to purchase Ordinary Shares, as applicable, for an equal number of shares of Common Stock, Preferred Stock and/or options to purchase Common Stock; and

WHEREAS, in order to induce the Company and the Investors to enter into the Subscription Agreement, the Investors and the Company hereby agree that this Agreement shall govern the rights of the Investors to cause the Company to register shares of Common Stock issuable to the Investors, to receive certain information from the Company, and to participate in future equity offerings by the Company, and shall govern certain other matters as set forth in this Agreement.

NOW, THEREFORE, the parties hereby agree as follows:

1. Definitions. For purposes of this Agreement:

1.1 "**Affiliate**" means, with respect to any specified Person, any other Person who, directly or indirectly, controls, is controlled by, or is under common control with such Person, including without limitation any general partner, managing member, officer, director or trustee of such Person, or any venture capital fund or registered investment company now or hereafter existing that is controlled by one or more general partners, managing members or investment adviser of, or shares the same management company or investment adviser with, such Person.

1.2 "**Board of Directors**" means the board of directors of the Company.

1.3 "**Certificate of Incorporation**" means the Company's Amended and Restated Certificate of Incorporation, as amended and/or restated from time to time.

1.4 "**Common Stock**" means shares of the Company's common stock, par value $0.001 per share.

1.5 "**Competitor**" means a Person engaged, directly or indirectly (including through any partnership, limited liability company, corporation, joint venture or similar arrangement (whether now existing or formed hereafter)), in the development and/or commercialization of therapeutic interventions for liver and cardio metabolic diseases, but shall not include any financial investment firm or collective investment vehicle that, together with its Affiliates, holds less than twenty percent (20)% of the outstanding equity of any Competitor and does not, nor do any of its Affiliates, have a right to designate any members of the board of directors of any Competitor.

1.6 "**Damages**" means any loss, damage, claim or liability (joint or several) to which a party hereto may become subject under the Securities Act, the Exchange Act, or other federal or state law, insofar as such loss, damage, claim or liability (or any action in respect thereof) arises out of or is based upon: (i) any untrue statement or alleged untrue statement of a material fact contained in any registration statement of the Company, including any preliminary prospectus or final prospectus contained therein or any amendments or supplements thereto; (ii) an omission or alleged omission to state therein a material fact required to be stated therein, or necessary to make the statements therein not misleading; or (iii) any violation or alleged violation by the indemnifying party (or any of its agents or Affiliates) of the Securities Act, the Exchange Act, any state securities law, or any rule or regulation promulgated under the Securities Act, the Exchange Act, or any state securities law.

1.7 "**Derivative Securities**" means any securities or rights convertible into, or exercisable or exchangeable for (in each case, directly or indirectly)**,** Common Stock, including options and warrants.

1.8 "**Exchange Act**" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

1.9 "**Excluded Registration**" means (i) a registration relating to the sale or grant of securities to employees of the Company or a subsidiary pursuant to a stock option, stock purchase, equity incentive or similar plan; (ii) a registration relating to an SEC Rule 145 transaction; (iii) a registration on any form that does not include substantially the same information as would be required to be included in a registration statement covering the sale of the Registrable Securities; or (iv) a registration in which the only Common Stock being registered is Common Stock issuable upon conversion of debt securities that are also being registered.

1.10 "**FOIA Party**" means a Person that, in the reasonable determination of the Board of Directors, may be subject to, and thereby required to disclose non-public information furnished by or relating to the Company under, the Freedom of Information Act, 5 U.S.C. 552 ("**FOIA**"), any state public records access law, any state or other jurisdiction's laws similar in intent or effect to FOIA, or any other similar statutory or regulatory requirement.

1.11 "**Form S-1**" means such form under the Securities Act as in effect on the date hereof or any successor registration form under the Securities Act subsequently adopted by the SEC.

1.12 "**Form S-3**" means such form under the Securities Act as in effect on the date hereof or any registration form under the Securities Act subsequently adopted by the SEC that permits forward incorporation of substantial information by reference to other documents filed by the Company with the SEC.

1.13 "**GAAP**" means generally accepted accounting principles in the United States as in effect from time to time.

1.14 "**Holder**" means any holder of Registrable Securities who is a party to this Agreement, and assignee thereof in accordance with this Agreement or any Person having the right to acquire Registrable Securities.

1.15 "**Immediate Family Member**" means a child, stepchild, grandchild, parent, stepparent, grandparent, spouse, sibling, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law, including, adoptive relationships, of a natural person referred to herein.

1.16 "**Initiating Holders**" means, collectively, Holders of at least 50% of the Registrable Securities, including either Orbimed Israel Partners II, L.P. ("**OrbiMed IL**") or OrbiMed Private Investments VI, LP ("**OrbiMed US**" and together with OrbiMed IL, "**OrbiMed**").

1.17 "**IPO**" means the Company's first underwritten public offering of its Common Stock under the Securities Act.

1.18 "**Key Employee**" means any executive-level employee (including, division director and vice president-level positions) as well as any employee who, either alone or in concert with others, develops, invents, programs, or designs any Company Intellectual Property (as defined in the Purchase Agreement).

1.19 "**New Securities**" means, collectively, equity securities of the Company, whether or not currently authorized, as well as rights, options, or warrants to purchase such equity securities, or securities of any type whatsoever that are, or may become, convertible or exchangeable into or exercisable for such equity securities.

1.20 "**Person**" means any individual, corporation, partnership, trust, limited liability company, association or other entity.

1.21 "**Preferred Stock**" means shares of the Company's Series A Preferred Stock.

1.22 "**Registrable Securities**" means (i) the Common Stock issuable or issued upon conversion of the Series A Preferred Stock, excluding any Common Stock issued upon conversion of the Series A Preferred Stock pursuant to the "Special Mandatory Conversion" provisions of the Certificate of Incorporation; (ii) any Common Stock, or any Common Stock issued or issuable (directly or indirectly) upon conversion and/or exercise of any other securities of the Company, acquired by the Investors after the date hereof; and (iii) any Common Stock issued as (or issuable upon the conversion or exercise of any warrant, right, or other security that is issued as) a dividend or other distribution with respect to, or in exchange for or in replacement of, the shares referenced in clauses (i) and (ii) above; excluding in all cases, however, any Registrable Securities sold by a Person in a transaction in which the applicable rights under this Agreement are not assigned pursuant to Subsection 6.1, and excluding for purposes of Section 2 any shares for which registration rights have terminated pursuant to Subsection 2.13 of this Agreement.

1.23 "**Registrable Securities then outstanding**" means the number of shares determined by adding the number of shares of outstanding Common Stock that are Registrable Securities and the number of shares of Common Stock issuable (directly or indirectly) pursuant to then exercisable and/or convertible securities that are Registrable Securities.

1.24 "**Requisite Preferred**" means the holders of shares of Series A Preferred Stock, holding at least 50% of the then outstanding shares of Series A Preferred Stock, including either OrbiMed IL or OrbiMed US.

1.25 "**Restricted Securities**" means the securities of the Company required to be notated with the legend set forth in Subsection 2.12(b) hereof.

1.26 "**SEC**" means the Securities and Exchange Commission.

1.27 "**SEC Rule 144**" means Rule 144 promulgated by the SEC under the Securities Act.

1.28 "**SEC Rule 145**" means Rule 145 promulgated by the SEC under the Securities Act.

1.29 "**Securities Act**" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

1.30 "**Selling Expenses**" means all underwriting discounts, selling commissions, and stock transfer taxes applicable to the sale of Registrable Securities, and fees and disbursements of counsel for any Holder, except for the fees and disbursements of the Selling Holder Counsel borne and paid by the Company as provided in Subsection 2.6.

1.31 "**Series A Preferred Stock**" means shares of the Company's Series A Preferred Stock, par value $0.001 per share.

1.32 "**Strategic Investor**" means a corporation or other business entity that has a presence or a commercial interest (excluding an interest as a financial investor) in the development and/or commercialization of therapeutic interventions for liver and cardio metabolic diseases, excluding OrbiMed, Longitude Venture Partners III, L.P. ("**Longitude**"), RA Capital Healthcare Fund, L.P and Blackwell Partners LLC - Series A, Pontifax (China) V L.P., Pontifax (Israel) V Limited Partnership, and Pontifax (Cayman) V L.P. and their respective Affiliates.

2. Registration Rights. The Company covenants and agrees as follows:

2.1 Demand Registration.

(a) Form S-1 Demand. If at any time after the earlier of (i) five (5) years after September 17, 2019 or (ii) one hundred eighty (180) days after the effective date of the registration statement for the IPO, the Company receives a request from the Initiating Holders that the Company file a Form S-1 registration statement with respect to the Registrable Securities then outstanding, provided that the anticipated aggregate offering price, net of Selling Expenses, would exceed $10 million, then the Company shall (x) within twenty (20) days after the date such request is given, give notice thereof (the "**Demand Notice**") to all Holders other than the Initiating Holders; and (y) as soon as practicable file a Form S-1 registration statement under the Securities Act covering all Registrable Securities that the Initiating Holders requested to be registered and any additional Registrable Securities requested to be included in such registration by any other Holders, as specified by notice given by each such Holder to the Company within twenty (20) days of the date the Demand Notice is given, and in each case, subject to the limitations of Subsections 2.1(c) and 2.3.

(b) Form S-3 Demand. If at any time when it is eligible to use a Form S-3 registration statement, the Company receives a request from Holders of at least ten percent (10%) of the Registrable Securities then outstanding that the Company file a Form S-3 registration statement with respect to outstanding Registrable Securities of such Holders having an anticipated aggregate offering price, net of Selling Expenses, of at least $5 million, then the Company shall (i) within twenty (20) days after the date such request is given, give a Demand Notice to all Holders other than the Initiating Holders; and (ii) as soon as practicable, use its commercially reasonable efforts to file a Form S-3 registration statement under the Securities Act covering all Registrable Securities requested to be included in such registration by any other Holders, as specified by notice given by each such Holder to the Company within fifteen (15) days of the date the Demand Notice is given, and in each case, subject to the limitations of Subsections 2.1(c) and 2.3.

(c) Notwithstanding the foregoing obligations, if the Company furnishes to Holders requesting a registration pursuant to this Subsection 2.1 a certificate signed by the Company's chief executive officer or chairman of the Board of Directors stating that in the good faith judgment of the Board of Directors it would be materially detrimental to the Company and its stockholders for such registration statement to be filed and it is therefore necessary to defer the filing of such registration statement, then the Company shall have the right to defer taking action with respect to such filing, and any time periods with respect to filing or effectiveness thereof shall be tolled correspondingly, for a period of not more than ninety (90) days after the request of the Initiating Holders is given; provided, however, that the Company may not invoke this right more than once in any twelve (12) month period.

(d) The Company shall not be obligated to effect, or to take any action to effect, any registration pursuant to Subsection 2.1(a) or Subsection 2.1(b) (i) during the period that is sixty (60) days before the Company's good faith estimate of the date of filing of, and ending on a date that is (y) one hundred eighty (180) days after the effective date of the IPO or (z) ninety (90) days following the effective date of each other Company-initiated registration subject to Subsection 2.2 below, provided that the Company is actively employing in good faith commercially reasonable efforts to cause such registration statement to become effective; (ii) after the Company has effected two registrations pursuant to Subsection 2.1(a); (iii) if the Initiating Holders propose to dispose of shares of Registrable Securities that may be immediately registered on Form S-3 pursuant to a request made pursuant to Subsection 2.1(b); (iv) if within thirty (30) days of receipt of a written request from Initiating Holders, the Company gives notice to the Holders of the Company's good faith intention to file a registration statement for a public offering for a sale of the Company's shares for its own account within ninety (90) days, provided that the Company actually files such registration statement within such ninety (90) days and makes reasonable good faith efforts to cause such registration statement to become effective, and provided further that the Company shall not be entitled to invoke this clause more than once in the 365 days immediately following the receipt of such notice from the Initiating Holders; or (v) during the period starting with the date sixty (60) days prior to the Company's estimated date of filing of, and ending on the date one hundred and twenty (120) days immediately following the effective date of, any registration statement pertaining to securities of the Company (other than an Excluded Registration), provided that the Company is actively employing in good faith reasonable efforts to cause such registration statement to become effective and that the Company's estimate of the date of filing such registration statement is made in good faith. A registration shall not be counted as "effected" for purposes of this Subsection 2.1(d) until such time as the applicable registration statement has been declared effective by the SEC, unless the Initiating Holders withdraw their request for such registration, elect not to pay the registration expenses therefor, and forfeit their right to one demand registration statement pursuant to Subsection 2.6, in which case such withdrawn registration statement shall be counted as "effected" for purposes of this Subsection 2.1(d); provided, that if such withdrawal is during a period the Company has deferred taking action pursuant to Subsection 2.1(c), then the Initiating Holders may withdraw their request for registration and such registration will not be counted as "effected" for purposes of this Subsection 2.1(d).

2.2 Company Registration. If the Company proposes to register (including, for this purpose, a registration effected by the Company for stockholders other than the Holders) any of its Common Stock under the Securities Act in connection with the public offering of such securities (other than in an Excluded Registration), the Company shall, at such time, promptly give each Holder notice of such registration. Upon the request of each Holder given within twenty (20) days after such notice is given by the Company, the Company shall, subject to the provisions of Subsection 2.3, cause to be registered all of the Registrable Securities that each such Holder has requested to be included in such registration. The Company shall have the right to terminate or withdraw any registration initiated by it under this Subsection 2.2 before the effective date of such registration, whether or not any Holder has elected to include Registrable Securities in such registration. The expenses (other than Selling Expenses) of such withdrawn registration shall be borne by the Company in accordance with Subsection 2.6.

2.3 Underwriting Requirements.

(a) If, pursuant to Subsection 2.1, the Initiating Holders intend to distribute the Registrable Securities covered by their request by means of an underwriting, they shall so advise the Company as a part of their request made pursuant to Subsection 2.1, and the Company shall include such information in the Demand Notice. The underwriter(s) will be selected by the Company and shall be reasonably acceptable to the participating Holders. In such event, the right of any Holder to include such Holder's Registrable Securities in such registration shall be conditioned upon such Holder's participation in such underwriting and the inclusion of such Holder's Registrable Securities in the underwriting to the extent provided herein. All Holders proposing to distribute their securities through such underwriting shall (together with the Company as provided in Subsection 2.4(e)) enter into an underwriting agreement in customary form with the underwriter(s) selected for such underwriting. Notwithstanding any other provision of this Subsection 2.3, if the underwriter(s) advise(s) the Initiating Holders in writing that marketing factors require a limitation on the number of shares to be underwritten, then the Initiating Holders shall so advise all Holders of Registrable Securities that otherwise would be underwritten pursuant hereto, and the number of Registrable Securities that may be included in the underwriting shall be allocated among such Holders of Registrable Securities, including the Initiating Holders, in proportion (as nearly as practicable) to the number of Registrable Securities owned by each Holder or in such other proportion as shall mutually be agreed to by all such selling Holders; provided, however, that the number of Registrable Securities held by the Holders to be included in such underwriting shall not be reduced unless all other securities are first entirely excluded from the underwriting. To facilitate the allocation of shares in accordance with the above provisions, the Company or the underwriters may round the number of shares allocated to any Holder to the nearest one hundred (100) shares.

(b) In connection with any offering involving an underwriting of shares of the Company's capital stock pursuant to Subsection 2.2, the Company shall not be required to include any of the Holders' Registrable Securities in such underwriting unless the Holders accept the terms of the underwriting as agreed upon between the Company and its underwriters, and then only in such quantity as the underwriters in their sole discretion determine will not jeopardize the success of the offering by the Company. If the total number of securities, including Registrable Securities, requested by stockholders to be included in such offering exceeds the number of securities to be sold (other than by the Company) that the underwriters in their reasonable discretion determine is compatible with the success of the offering, then the Company shall be required to include in the offering only that number of such securities, including Registrable Securities, which the underwriters and the Company in their sole discretion determine will not jeopardize the success of the offering. If the underwriters determine that less than all of the Registrable Securities requested to be registered can be included in such offering, then the Registrable Securities that are included in such offering shall be allocated among the selling Holders in proportion (as nearly as practicable to) the number of Registrable Securities owned by each selling Holder or in such other proportions as shall mutually be agreed to by all such selling Holders. To facilitate the allocation of shares in accordance with the above provisions, the Company or the underwriters may round the number of shares allocated to any Holder to the nearest one hundred (100) shares. Notwithstanding the foregoing, in no event shall (i) the number of Registrable Securities included in the offering be reduced unless all other securities (other than securities to be sold by the Company) are first entirely excluded from the offering, or (ii) the

number of Registrable Securities included in the offering be reduced below thirty percent (30%) of the total number of securities included in such offering, unless such offering is the IPO, in which case the selling Holders may be excluded further if the underwriters make the determination described above and no other stockholder's securities are included in such offering. For purposes of the provision in this Subsection 2.3(b) concerning apportionment, for any selling Holder that is a partnership, limited liability company, or corporation, the partners, members, retired partners, retired members, stockholders, and Affiliates of such Holder, or the estates and Immediate Family Members of any such partners, retired partners, members, and retired members and any trusts for the benefit of any of the foregoing Persons, shall be deemed to be a single "selling Holder," and any pro rata reduction with respect to such "selling Holder" shall be based upon the aggregate number of Registrable Securities owned by all Persons included in such "selling Holder," as defined in this sentence.

(c) For purposes of Subsection 2.1, a registration shall not be counted as "effected" if, as a result of an exercise of the underwriter's cutback provisions in Subsection 2.3(a), fewer than fifty percent (50%) of the total number of Registrable Securities that Holders have requested to be included in such registration statement are actually included.

2.4 Obligations of the Company. Whenever required under this Section 2 to effect the registration of any Registrable Securities, the Company shall, as expeditiously as reasonably possible:

(a) prepare and file with the SEC a registration statement with respect to such Registrable Securities and use its commercially reasonable efforts to cause such registration statement to become effective and, upon the request of the Holders of a majority of the Registrable Securities registered thereunder, keep such registration statement effective for a period of up to one hundred eighty (180) days or, if earlier, until the distribution contemplated in the registration statement has been completed; provided, however, that (i) such one hundred eighty (180) day period shall be extended for a period of time equal to the period the Holder refrains, at the request of an underwriter of Common Stock (or other securities) of the Company, from selling any securities included in such registration, and (ii) in the case of any registration of Registrable Securities on Form S-3 that are intended to be offered on a continuous or delayed basis, subject to compliance with applicable SEC rules, such one hundred twenty (120) day period shall be extended for up to 180 days, if necessary, to keep the registration statement effective until all such Registrable Securities are sold;

(b) prepare and file with the SEC such amendments and supplements to such registration statement, and the prospectus used in connection with such registration statement, as may be necessary to comply with the Securities Act in order to enable the disposition of all securities covered by such registration statement;

(c) furnish to the selling Holders such numbers of copies of a prospectus, including a preliminary prospectus, as required by the Securities Act, and such other documents as the Holders may reasonably request in order to facilitate their disposition of their Registrable Securities;

(d) use its best efforts to register and qualify the securities covered by such registration statement under such other securities or blue-sky laws of such jurisdictions as shall be reasonably requested by the selling Holders; provided that the Company shall not be required to qualify to do business or to file a general consent to service of process in any such states or jurisdictions, unless the Company is already subject to service in such jurisdiction and except as may be required by the Securities Act;

(e) in the event of any underwritten public offering, enter into and perform its obligations under an underwriting agreement, in usual and customary form, with the underwriter(s) of such offering;

(f) use its best efforts to cause all such Registrable Securities covered by such registration statement to be listed on a national securities exchange or trading system and each securities exchange and trading system (if any) on which similar securities issued by the Company are then listed;

(g) provide a transfer agent and registrar for all Registrable Securities registered pursuant to this Agreement and provide a CUSIP number for all such Registrable Securities, in each case not later than the effective date of such registration;

(h) promptly make available for inspection by the selling Holders, any underwriter(s) participating in any disposition pursuant to such registration statement, and any attorney or accountant or other agent retained by any such underwriter or selected by the selling Holders, all financial and other records, pertinent corporate documents, and properties of the Company, and cause the Company's officers, directors, employees, and independent accountants to supply all information reasonably requested by any such seller, underwriter, attorney, accountant, or agent, in each case, as necessary or advisable to verify the accuracy of the information in such registration statement and to conduct appropriate due diligence in connection therewith all at the expense of the Holder and in a manner that does not adversely affect the progress of the registration;

(i) notify each selling Holder, promptly after the Company receives notice thereof, of the time when such registration statement has been declared effective or a supplement to any prospectus forming a part of such registration statement has been filed, and of the happening of any event as a result of which the prospectus included in such registration statement, as then in effect, includes an untrue statement of a material fact or omits to state a material fact required to be stated therein or necessary to make the statements therein not misleading in the light of the circumstances then existing;

(j) after such registration statement becomes effective, notify each selling Holder of any request by the SEC that the Company amend or supplement such registration statement or prospectus;

(k) cause senior representatives of the Company to participate in any "road show" or "road shows" reasonably requested by any underwriter of an underwritten or "best efforts" offering of Registrable Securities; and

(l) at the request of any Holder requesting registration of Registrable Securities pursuant to this Agreement, on the date that such Registrable Securities are delivered to the underwriters for sale in connection with a registration pursuant to this Agreement, if such securities are being sold through underwriters, or, if such securities are not being sold through underwriters, on the date that the registration statement with respect to such securities becomes effective, (i) an opinion, dated such date, of the counsel representing the Company for the purposes of such registration, in form and substance as is customarily given to underwriters in an underwritten public offering, addressed to the underwriters, if any, and to the Holders requesting registration of Registrable Securities and (ii) a letter dated such date, from the independent certified public accountants of the Company, in form and substance as is customarily given by independent certified public accountants to underwriters in an underwritten public offering, addressed to the underwriters, if any, and to the Holders requesting registration of Registrable Securities.

In addition, the Company shall ensure that, at all times after any registration statement covering a public offering of securities of the Company under the Securities Act shall have become effective, its insider trading policy shall provide that the Company's directors may implement a trading program under Rule 10b5-1 of the Exchange Act.

2.5 Furnish Information. It shall be a condition precedent to the obligations of the Company to take any action pursuant to this Section 2 with respect to the Registrable Securities of any selling Holder that such Holder shall furnish to the Company such information regarding itself, the Registrable Securities held by it, and the intended method of disposition of such securities as is reasonably required to effect the registration of such Holder's Registrable Securities.

2.6 Expenses of Registration. All expenses (other than Selling Expenses) incurred in connection with registrations, filings, or qualifications pursuant to Section 2, including all registration, filing, and qualification fees; printers' and accounting fees; fees and disbursements of counsel for the Company; and the reasonable fees and disbursements, not to exceed $35,000, of one counsel for the selling Holders ("**Selling Holder Counsel**"), shall be borne and paid by the Company; provided, however, that the Company shall not be required to pay for any expenses of any registration proceeding begun pursuant to Subsection 2.1 if the registration request is subsequently withdrawn at the request of the Holders of a majority of the Registrable Securities to be registered (in which case all selling Holders shall bear such expenses pro rata based upon the number of Registrable Securities that were to be included in the withdrawn registration), unless the Holders of a majority of the Registrable Securities agree to forfeit their right to one registration pursuant to Subsections 2.1(a) or 2.1(b), as the case may be; provided further that if, at the time of such withdrawal, the Holders shall have learned of a material adverse change in the condition, business, or prospects of the Company from that known to the Holders at the time of their request and have withdrawn the request with reasonable promptness after learning of such information then the Holders shall not be required to pay any of such expenses and shall not forfeit their right to one registration pursuant to Subsections 2.1(a) or 2.1(b), as the case may be. All Selling Expenses relating to Registrable Securities registered pursuant to this Section 2 shall be borne and paid by the Holders pro rata on the basis of the number of Registrable Securities registered on their behalf.

2.7 Delay of Registration. No Holder shall have any right to obtain or seek an injunction restraining or otherwise delaying any registration pursuant to this Agreement as the result of any controversy that might arise with respect to the interpretation or implementation of this Section 2.

2.8 Indemnification. If any Registrable Securities are included in a registration statement under this Section 2:

(a) To the extent permitted by law, the Company will indemnify and hold harmless each selling Holder, and the partners, members, officers, directors, and stockholders of each such Holder; legal counsel and accountants for each such Holder; any underwriter (as defined in the Securities Act) for each such Holder; and each Person, if any, who controls such Holder or underwriter within the meaning of the Securities Act or the Exchange Act, against any Damages, and the Company will pay to each such Holder, underwriter, controlling Person, or other aforementioned Person any legal or other expenses reasonably incurred thereby in connection with investigating or defending any claim or proceeding from which Damages may result, as such expenses are incurred; provided, however, that the indemnity agreement contained in this Subsection 2.8(a) shall not apply to amounts paid in settlement of any such claim or proceeding if such settlement is effected without the consent of the Company, which consent shall not be unreasonably withheld, nor shall the Company be liable for any Damages to the extent that they arise out of or are based upon actions or omissions made in reliance upon and in conformity with written information furnished by or on behalf of any such Holder, underwriter, controlling Person, or other aforementioned Person expressly for use in connection with such registration.

(b) To the extent permitted by law, each selling Holder, severally and not jointly, will indemnify and hold harmless the Company, and each of its directors, each of its officers who has signed the registration statement, each Person (if any), who controls the Company within the meaning of the Securities Act, legal counsel and accountants for the Company, any underwriter (as defined in the Securities Act), any other Holder selling securities in such registration statement, and any controlling Person of any such underwriter or other Holder, against any Damages, in each case only to the extent that such Damages arise out of or are based upon actions or omissions made in reliance upon and in conformity with written information furnished by or on behalf of such selling Holder expressly for use in connection with such registration; and each such selling Holder will pay to the Company and each other aforementioned Person any legal or other expenses reasonably incurred thereby in connection with investigating or defending any claim or proceeding from which Damages may result, as such expenses are incurred; provided, however, that the indemnity agreement contained in this Subsection 2.8(b) shall not apply to amounts paid in settlement of any such claim or proceeding if such settlement is effected without the consent of the Holder, which consent shall not be unreasonably withheld; and provided further that in no event shall the aggregate amounts payable by any Holder by way of indemnity or contribution under Subsections 2.8(b) and 2.8(d) exceed the proceeds from the offering received by such Holder (net of any Selling Expenses paid by such Holder), except in the case of fraud or willful misconduct by such Holder.

(c) Promptly after receipt by an indemnified party under this Subsection 2.8 of notice of the commencement of any action (including any governmental action) for which a party may be entitled to indemnification hereunder, such indemnified party will, if a claim in respect thereof is to be made against any indemnifying party under this Subsection 2.8, give the indemnifying party notice of the commencement thereof. The indemnifying party shall have the right to participate in such action and, to the extent the indemnifying party so desires, participate jointly with any other indemnifying party to which notice has been given, and to assume the defense thereof with counsel mutually satisfactory to the parties; provided, however, that an indemnified party (together with all other indemnified parties that may be represented without conflict by one counsel) shall have the right to retain one separate counsel, with the fees and expenses to be paid by the indemnifying party, if representation of such indemnified party by the counsel retained by the indemnifying party would be inappropriate due to actual or potential differing interests between such indemnified party and any other party represented by such counsel in such action. The failure to give notice to the indemnifying party within a reasonable time of the commencement of any such action shall relieve such indemnifying party of any liability to the indemnified party under this Subsection 2.8, to the extent that such failure materially prejudices the indemnifying party's ability to defend such action. The failure to give notice to the indemnifying party will not relieve it of any liability that it may have to any indemnified party otherwise than under this Subsection 2.8.

(d) To provide for just and equitable contribution to joint liability under the Securities Act in any case in which either: (i) any party otherwise entitled to indemnification hereunder makes a claim for indemnification pursuant to this Subsection 2.8 but it is judicially determined (by the entry of a final judgment or decree by a court of competent jurisdiction and the expiration of time to appeal or the denial of the last right of appeal) that such indemnification may not be enforced in such case, notwithstanding the fact that this Subsection 2.8 provides for indemnification in such case, or (ii) contribution under the Securities Act may be required on the part of any party hereto for which indemnification is provided under this Subsection 2.8, then, and in each such case, such parties will contribute to the aggregate losses, claims, damages, liabilities, or expenses to which they may be subject (after contribution from others) in such proportion as is appropriate to reflect the relative fault of each of the indemnifying party and the indemnified party in connection with the statements, omissions, or other actions that resulted in such loss, claim, damage, liability, or expense, as well as to reflect any other relevant equitable considerations. The relative fault of the indemnifying party and of the indemnified party shall be determined by reference to, among other things, whether the untrue or allegedly untrue statement of a material fact, or the omission or alleged omission of a material fact, relates to information supplied by the indemnifying party or by the indemnified party and the parties' relative intent, knowledge, access to information, and opportunity to correct or prevent such statement or omission; provided, however, that, in any such case (x) no Holder will be required to contribute any amount in excess of the public offering price of all such Registrable Securities offered and sold by such Holder pursuant to such registration statement, and (y) no Person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) will be entitled to contribution from any Person who was not guilty of such fraudulent misrepresentation; and provided further that in no event shall a Holder's liability pursuant to this Subsection 2.8(d), when combined with the amounts paid or payable by such Holder pursuant to Subsection 2.8(b), exceed the proceeds from the offering received by such Holder (net of any Selling Expenses paid by such Holder), except in the case of intentional misrepresentation or fraud by such Holder.

(e) Notwithstanding the foregoing, to the extent that the provisions on indemnification and contribution contained in the underwriting agreement entered into in connection with the underwritten public offering are in conflict with the foregoing provisions, the provisions in the underwriting agreement shall control.

(f) Unless otherwise superseded by an underwriting agreement entered into in connection with the underwritten public offering, the obligations of the Company and Holders under this Subsection 2.8 shall survive the completion of any offering of Registrable Securities in a registration under this Section 2, and otherwise shall survive the termination of this Agreement.

2.9 Reports Under Exchange Act. With a view to making available to the Holders the benefits of SEC Rule 144 and any other rule or regulation of the SEC that may at any time permit a Holder to sell securities of the Company to the public without registration or pursuant to a registration on Form S-3, the Company shall:

(a) make and keep available adequate current public information, as those terms are understood and defined in SEC Rule 144, at all times after the effective date of the registration statement filed by the Company for the IPO;

(b) file with the SEC in a timely manner all reports and other documents required of the Company under the Securities Act and the Exchange Act (at any time after the Company has become subject to such reporting requirements); and

(c) furnish to any Holder, so long as the Holder owns any Registrable Securities, forthwith upon request (i) to the extent accurate, a written statement by the Company that it has complied with the reporting requirements of SEC Rule 144 (at any time after ninety (90) days after the effective date of the registration statement filed by the Company for the IPO), the Securities Act, and the Exchange Act (at any time after the Company has become subject to such reporting requirements), or that it qualifies as a registrant whose securities may be resold pursuant to Form S-3 (at any time after the Company so qualifies); (ii) a copy of the most recent annual or quarterly report of the Company and such other reports and documents so filed by the Company; and (iii) such other information as may be reasonably requested in availing any Holder of any rule or regulation of the SEC that permits the selling of any such securities without registration (at any time after the Company has become subject to the reporting requirements under the Exchange Act) or pursuant to Form S-3 (at any time after the Company so qualifies to use such form).

2.10 Assignment of Registration Rights. The rights to cause the Company to register Registrable Securities pursuant to this Section 2 may be assigned (but only with all related obligations and together with the transfer of the Registrable Securities pursuant to the Certificate of Incorporation) by a Holder of Registrable Securities to a transferee or assignee of such securities provided that (i) such transfer is in accordance with the Certificate of Incorporation, (ii) the Company is, promptly following such transfer, furnished with written notice of the name and address of such transferee or assignee and the securities with respect to which such registration rights are being assigned; (iii) such transferee or assignee agrees in writing, in a form reasonably satisfactory to the Company, to be bound by and subject to the terms and conditions of this Agreement, including without limitation the provisions of Section 2.12 below; and (iv) such assignment shall be effective only if immediately following such transfer the further disposition of such securities by the transferee or assignee is restricted under the Securities Act.

2.11 Limitations on Subsequent Registration Rights. From and after the date of this Agreement, the Company shall not, without the prior written consent of the Initiating Holders, enter into any agreement with any holder or prospective holder of any securities of the Company that would (i) allow such holder or prospective holder to include such securities in any registration unless, under the terms of such agreement, such holder or prospective holder may include such securities in any such registration only to the extent that the inclusion of such securities will not reduce the number of the Registrable Securities of the Holders that are included; or (ii) allow such holder or prospective holder to initiate a demand for registration of any securities held by such holder or prospective holder.

2.12 "Market Stand-off" Agreement. Each Holder hereby agrees that it will not, without the prior written consent of the managing underwriter, during the period commencing on the date of the final prospectus relating to the registration by the Company of shares of its Common Stock or any other equity securities under the Securities Act on a registration statement on Form S-1 or Form S-3, and ending on the date specified by the Company and the managing underwriter (such period not to exceed one hundred eighty (180) days in the case of the IPO, ninety (90) days in the case of any registration other than the IPO, or such other period as may be requested by the Company or an underwriter to accommodate regulatory restrictions on (1) the publication or other distribution of research reports and (2) analyst recommendations and opinions, including, but not limited to, the restrictions contained in FINRA Rule 2711(f)(4) or NYSE Rule 472(f)(4), or any successor provisions or amendments thereto), (i) lend; offer; pledge; sell; contract to sell; sell any option or contract to purchase; purchase any option or contract to sell; grant any option, right, or warrant to purchase; or otherwise transfer or dispose of, directly or indirectly, any shares of Common Stock or any securities convertible into or exercisable or exchangeable (directly or indirectly) for Common Stock (whether such shares or any such securities are then owned by the Holder or are thereafter acquired) or (ii) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of such securities, whether any such transaction described in clause (i) or (ii) above is to be settled by delivery of Common Stock or other securities, in cash, or otherwise. The foregoing provisions of this Subsection 2.11 shall not apply to the sale of any shares to an underwriter pursuant to an underwriting agreement and shall be applicable to the Holders only if all officers and directors and all stockholders individually owning more than one percent (1%) of the Company's outstanding Common Stock (after giving effect to conversion into Common Stock of all outstanding Series A Preferred Stock) are subject to the same restrictions. The underwriters in connection with such registration are intended third-party beneficiaries of this Subsection 2.11 and shall have the right, power and authority to enforce the provisions hereof as though they were a party hereto. Each Holder further agrees to execute such agreements as may be reasonably requested by the underwriters in connection with such registration that are consistent with this Subsection 2.11 or that are necessary to give further effect thereto. Any discretionary waiver or termination of the restrictions of any or all of such agreements by the Company or the underwriters shall apply on a pro rata basis based on the number of shares of Common Stock (including Common Stock issuable upon the conversion of Series A Preferred Stock) to all Company

stockholders that are subject to such agreements, based on the number of shares subject to such agreements, including with respect to management and employees, and any lock-up agreement with underwriters shall contain a clause to this effect. In order to enforce the foregoing covenant, the Company may impose stop-transfer instructions with respect to the Registrable Securities of each Holder (and the shares or securities of every other person subject to the foregoing restriction) until the end of such period.

2.13 Restrictions on Transfer.

(a) The shares of Preferred Stock and Common Stock of the Company shall not be sold, pledged, or otherwise transferred, and the Company shall not recognize and shall issue stop-transfer instructions to its transfer agent with respect to any such sale, pledge, or transfer, except upon the conditions specified in this Agreement, which conditions are intended to ensure compliance with the provisions of the Securities Act. A transferring Holder will cause any proposed purchaser, pledgee, or transferee of the Preferred Stock and the Common Stock held by such Holder to agree to take and hold such securities subject to the provisions and upon the conditions specified in this Agreement.

(b) Each certificate, instrument, or book entry representing (i) the Preferred Stock, (ii) the Registrable Securities, and (iii) any other securities issued in respect of the securities referenced in clauses (i) and (ii), upon any stock split, stock dividend, recapitalization, merger, consolidation, or similar event, shall (unless otherwise permitted by the provisions of Subsection 2.12(c)) be notated with a legend substantially in the following form:

THE SECURITIES REPRESENTED HEREBY HAVE BEEN ACQUIRED FOR INVESTMENT AND HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933. SUCH SHARES MAY NOT BE SOLD, PLEDGED, OR TRANSFERRED IN THE ABSENCE OF SUCH REGISTRATION OR A VALID EXEMPTION FROM THE REGISTRATION AND PROSPECTUS DELIVERY REQUIREMENTS OF SAID ACT.

THE SECURITIES REPRESENTED HEREBY MAY BE TRANSFERRED ONLY IN ACCORDANCE WITH THE TERMS OF AN AGREEMENT BETWEEN THE COMPANY AND THE STOCKHOLDER, A COPY OF WHICH IS ON FILE WITH THE SECRETARY OF THE COMPANY.

The Holders consent to the Company making a notation in its records and giving instructions to any transfer agent of the Restricted Securities in order to implement the restrictions on transfer set forth in this Subsection 2.12.

(c) No transfer of Preferred Stock of the Company or Common Stock may be made unless, except in the case of Permitted Transferees (as defined below), approved by the Board of Directors. The Board of Directors shall not unreasonably withhold approval of any transfer made in compliance with the Certificate of Incorporation and this Agreement, and, with respect to transfer of Series A Preferred Stock or Common Stock issued upon conversion of Series A Preferred Stock, such approval may only be withheld if: (i) the proposed transferee does not agree to assume and be bound by all obligation of the transferor under any instrument and agreement between the transferor in its capacity as a shareholder and the Company, (ii) in the event that such a transfer is in violation of the Certificate of Incorporation or this Agreement or (iii) if the Board of Directors has determined in good faith that such transfer would be materially detrimental to the Company.

(d) The holder of such Restricted Securities, by acceptance of ownership thereof, agrees to comply in all respects with the provisions of this Section 2. Before any proposed sale, pledge, or transfer of any Restricted Securities, unless there is in effect a registration statement under the Securities Act covering the proposed transaction, the Holder thereof shall give notice to the Company of such Holder's intention to effect such sale, pledge, or transfer. Each such notice shall describe the manner and circumstances of the proposed sale, pledge, or transfer in sufficient detail and, if reasonably requested by the Company, shall be accompanied at such Holder's expense by either (i) a written opinion of legal counsel who shall, and whose legal opinion shall, be reasonably satisfactory to the Company, addressed to the Company, to the effect that the proposed transaction may be effected without registration under the Securities Act; (ii) a "no action" letter from the SEC to the effect that the proposed sale, pledge, or transfer of such Restricted Securities without registration will not result in a recommendation by the staff of the SEC that action be taken with respect thereto; or (iii) any other evidence reasonably satisfactory to counsel to the Company to the effect that the proposed sale, pledge, or transfer of the Restricted Securities may be effected without registration under the Securities Act, whereupon the Holder of such Restricted Securities shall be entitled to sell, pledge, or transfer such Restricted Securities in accordance with the terms of the notice given by the Holder to the Company. The Company will not require such a legal opinion or "no action" letter (x) in any transaction in compliance with SEC Rule 144; or (y) in any transaction in which such Holder distributes Restricted Securities to an Affiliate of such Holder for no consideration; provided that each transferee agrees in writing to be subject to the terms of this Subsection 2.12. Each certificate, instrument, or book entry representing the Restricted Securities transferred as above provided shall be notated with, except if such transfer is made pursuant to SEC Rule 144, the appropriate restrictive legend set forth in Subsection 2.12(b), except that such certificate instrument, or book entry shall not be notated with such restrictive legend if, in the opinion of counsel for such Holder and the Company, such legend is not required in order to establish compliance with any provisions of the Securities Act.

2.14 Termination of Registration Rights. The right of any Holder to request registration or inclusion of Registrable Securities in any registration pursuant to Subsections 2.1 or 2.2 shall terminate upon the earliest to occur of:

(a) the closing of a Deemed Liquidation Event, as such term is defined in the Certificate of Incorporation;

(b) such time after consummation of the IPO as Rule 144 or another similar exemption under the Securities Act is available for the sale of all of such Holder's shares without limitation during a three-month period without registration;

(c) the third anniversary of the closing of an IPO.

3. Information and Observer Rights.

3.1 Delivery of Financial Statements. The Company shall deliver to each Investor:

(a) as soon as practicable, but in any event within ninety (90) days after the end of each fiscal year of the Company (i) a balance sheet as of the end of such year, (ii) statements of income and of cash flows for such year, and (iii) a statement of stockholders' equity as of the end of such year, all such financial statements audited and certified by independent public accountants of nationally recognized standing selected by the Company and accompanied by an opinion of such accounting firm which opinion shall state that such balance sheet and income statement and statement of cash flow have been prepared in accordance with GAAP applied on a basis consistent with that of the preceding fiscal year, and present fairly and accurately the financial position of the Company as of their date, and that the audit by such accountants in connection with such financial statements has been made in accordance with GAAP; provided that, such annual financial statements may be unaudited if approved by the Board of Directors, including the Requisite Preferred Directors (as such term is defined in the Certificate of Incorporation);

(b) as soon as practicable, but in any event within thirty (30) days after the end of each of the first three (3) quarters of each fiscal year of the Company, unaudited statements of income and cash flows for such fiscal quarter, and an unaudited balance sheet as of the end of such fiscal quarter, all prepared in accordance with GAAP (except that such financial statements may (i) be subject to normal year-end audit adjustments; and (ii) not contain all notes thereto that may be required in accordance with GAAP);

(c) as soon as practicable, but in any event thirty (30) days before the end of each fiscal year, a budget and business plan for the next fiscal year (collectively, the "**Budget**"), approved by the Board of Directors in accordance with the Certificate of Incorporation, and, promptly after prepared, any other budgets or revised budgets prepared by the Company;

(d) each month, a use of cash report, balance sheet, and updated capitalization table; and

(e) such other information relating to the financial condition, business, prospects, or corporate affairs of the Company as any Investor may from time to time reasonably request; provided, however, that the Company shall not be obligated under this Subsection 3.1 to provide information (i) that the Company reasonably determines in good faith to be a trade secret or confidential information (unless covered by an enforceable confidentiality agreement, in a form acceptable to the Company); or (ii) the disclosure of which would adversely affect the attorney-client privilege between the Company and its counsel.

If, for any period, the Company has any subsidiary whose accounts are consolidated with those of the Company, then in respect of such period the financial statements delivered pursuant to the foregoing sections shall be the consolidated and consolidating financial statements of the Company and all such consolidated subsidiaries.

Notwithstanding anything else in this Subsection 3.1 to the contrary, the Company may cease providing the information set forth in this Subsection 3.1 during the period starting with the date sixty (60) days before the Company's good-faith estimate of the date of filing of a registration statement if it reasonably concludes it must do so to comply with the SEC rules applicable to such registration statement and related offering; provided that the Company's covenants under this Subsection 3.1 shall be reinstated at such time as the Company is no longer actively employing its commercially reasonable efforts to cause such registration statement to become effective.

3.2 Inspection. The Company shall permit each Investor or its authorized representatives, at such Investor's expense, to visit and inspect the Company's properties; examine its books of account and records; and discuss the Company's affairs, finances, and accounts with its officers, during normal business hours of the Company as may be reasonably requested by the Investor; provided, however, that the Company shall not be obligated pursuant to this Subsection 3.2 to provide access to any information that it reasonably and in good faith considers to be a trade secret or confidential information (unless covered by an enforceable confidentiality agreement, in form acceptable to the Company) or the disclosure of which would adversely affect the attorney-client privilege between the Company and its counsel.

3.3 Observer Rights. Each of OrbiMed IL, OrbiMed US and Longitude, for as long as each (i) owns not less than 2,000,000 the shares of Common Stock and/or Preferred Stock of the Company (as adjusted for any share split, share combination, share dividend, recapitalization or like events) and (ii) was not subject to a Special Mandatory Conversion as set forth in the Certificate of Incorporation, shall have the right to nominate one person as a non-voting observer who shall be entitled to (x) attend all meetings of the Board of Directors and (y) receive notice of, to attend and to receive copies of any documentation distributed to directors before, during or after, all meetings (including any action to be taken by written consent) of the Board of Directors at the time such notice or material is provided or delivered to members of the Board of Director; provided, however, that the Company reserves the right to withhold any information and to exclude such representative from any meeting or portion thereof if access to such information or attendance at such meeting could adversely affect the attorney-client privilege between the Company and its counsel or result in a conflict of interest. The appointment, removal or replacement of an observer may take effect at any time, by delivery of a written notice to the Company, signed by the shareholder entitled to effect such appointment, removal or replacement.

3.4 Termination of Information and Inspection Rights. The covenants set forth in Subsection 3.1, Subsection 3.2 and Subsection 3.3 shall terminate and be of no further force or effect (i) immediately before the consummation of the IPO, or (ii) when the Company first becomes subject to the periodic reporting requirements of Section 12(g) or 15(d) of the Exchange Act, whichever event occurs first.

3.5 Confidentiality. Each Investor agrees that such Investor will keep confidential and will not disclose, divulge, or use for any purpose (other than to monitor its investment in the Company) any confidential information obtained from the Company pursuant to the terms of this Agreement (including notice of the Company's intention to file a registration statement), unless such confidential information (a) is known or becomes

known to the public in general (other than as a result of a breach of this Subsection 3.5 by such Investor), (b) is or has been independently developed or conceived by such Investor without use of the Company's confidential information, or (c) is or has been made known or disclosed to such Investor by a third party without a breach of any obligation of confidentiality such third party may have to the Company; provided, however, that an Investor may disclose confidential information (i) to its attorneys, accountants, consultants, and other professionals to the extent necessary to obtain their services in connection with monitoring its investment in the Company; (ii) to any existing or prospective Affiliate, partner, member, stockholder, or wholly owned subsidiary of such Investor in the ordinary course of business; provided, that such Investor informs such Person that such information is confidential and directs such Person to maintain the confidentiality of such information.

4. Rights to Future Stock Issuances.

4.1 Right of First Offer. Subject to the terms and conditions of this Subsection 4.1 and applicable securities laws, if the Company proposes to offer or sell any New Securities, the Company shall first offer such New Securities to each Investor. An Investor shall be entitled to apportion the right of first offer hereby granted to it in such proportions as it deems appropriate, among (i) itself, (ii) its Affiliates and (iii) its beneficial interest holders, such as limited partners, members or any other Person having "beneficial ownership," as such term is defined in Rule 13d-3 promulgated under the Exchange Act, of such Investor ("**Investor Beneficial Owners**"); provided, that each such Affiliate or Investor Beneficial Owner (x) is not a Competitor or FOIA Party, unless such party's purchase of New Securities is otherwise consented to by the Board of Directors, (y) agrees to enter into this Agreement and each of the Voting Agreement and Right of First Refusal and Co-Sale Agreement of even date herewith among the Company, the Investors and the other parties named therein, as an "**Investor**" under each such agreement (provided that any Competitor or FOIA Party shall not be entitled to any rights as an Investor under Subsections 3.1, 3.2 and 4.1 hereof), and (z) agrees to purchase at least such number of New Securities as are allocable hereunder to the Investor holding the fewest number of Series A Preferred Stock and any other Derivative Securities.

(a) The Company shall give notice (the "**Offer Notice**") to each Investor, stating (i) its bona fide intention to offer such New Securities, (ii) the number of such New Securities to be offered, and (iii) the price and terms, if any, upon which it proposes to offer such New Securities.

(b) By notification to the Company within twenty one (21) days after the Offer Notice is given, each Investor may elect to purchase or otherwise acquire, at the price and on the terms specified in the Offer Notice, up to that portion of such New Securities which equals the proportion that the Common Stock then held by such Investor (including all shares of Common Stock then issuable (directly or indirectly) upon conversion and/or exercise, as applicable, of the Series A Preferred Stock and any other Derivative Securities then held by such Investor) bears to the total Common Stock of the Company held by all other Investors (assuming full conversion and/or exercise, as applicable, of all Series A Preferred Stock and any other Derivative Securities then outstanding). At the expiration of such twenty one (21) day period, the Company shall promptly notify each Investor that elects to purchase or acquire all the shares

available to it (each, a "**Fully Exercising Investor**") of any other Investor's failure to do likewise. Each Fully Exercising Investor may, by giving notice to the Company, elect to purchase or acquire, in addition to the number of shares specified above, up to that portion of the New Securities for which Investors were entitled to subscribe but that were not subscribed for by the Investors which is equal to the proportion that the Common Stock issued and held, or issuable (directly or indirectly) upon conversion and/or exercise, as applicable, of Series A Preferred Stock and any other Derivative Securities then held, by such Fully Exercising Investor bears to the Common Stock issued and held, or issuable (directly or indirectly) upon conversion and/or exercise, as applicable, of the Series A Preferred Stock and any other Derivative Securities then held, by all Fully Exercising Investors who wish to purchase such unsubscribed shares. The closing of any sale pursuant to this Subsection 4.1(b) shall occur within the later of ninety (90) days of the date that the Offer Notice is given and the date of initial sale of New Securities pursuant to Subsection 4.1(c).

(c) If all New Securities referred to in the Offer Notice are not elected to be purchased or acquired as provided in Subsection 4.1(b), the Company may, during the ninety (90) day period following the expiration of the periods provided in Subsection 4.1(b), offer and sell the remaining unsubscribed portion of such New Securities to any Person or Persons at a price not less than, and upon terms no more favorable to the offeree than, those specified in the Offer Notice. If the Company does not enter into an agreement for the sale of the New Securities within such period, or if such agreement is not consummated within thirty (30) days of the execution thereof, the right provided hereunder shall be deemed to be revived and such New Securities shall not be offered unless first reoffered to the Investors in accordance with this Subsection 4.1.

(d) The right of first offer in this Subsection 4.1 shall apply prior to the earlier of the IPO and a Deemed Liquidation Event (as defined in the Certificate of Incorporation) and shall not be applicable to (i) Exempted Securities (as defined in the Certificate of Incorporation); and (ii) shares of Common Stock issued in the IPO.

4.2 Termination. The covenants set forth in Subsection 4.1 shall terminate and be of no further force or effect (i) immediately before the consummation of the IPO, or (ii) upon the closing of a Deemed Liquidation Event, as such term is defined in the Certificate of Incorporation, whichever event occurs first.

5. Additional Covenants.

5.1 Insurance. The Company shall obtain, within ninety (90) days of the date hereof, from financially sound and reputable insurers Directors and Officers liability insurance in an amount of at least $5,000,000 and on terms and conditions satisfactory to either the Requisite Preferred Directors or the Requisite Preferred, in an amount and on terms and conditions satisfactory to the Requisite Preferred Directors or the Requisite Preferred, as the case may be, and will use commercially reasonable efforts to cause such insurance policies to be maintained until such time as the Requisite Preferred Directors or the Requisite Preferred, as the case may be, determines that such insurance should be discontinued. The policy shall not be cancelable by the Company without prior approval by the Requisite Preferred Directors or the Requisite Preferred, as the case may be.

5.2 Employee Agreements. Where permitted by law, the Company will cause (i) each Person now or hereafter employed by it or by any subsidiary (or engaged by the Company or any subsidiary as a consultant/independent contractor) with access to confidential information and/or trade secrets to enter into a nondisclosure and proprietary rights assignment agreement; and (ii) each Key Employee to enter into a noncompetition and non-solicitation agreement, substantially in the form approved by the Board of Directors. In addition, the Company shall not amend, modify, terminate, waive, or otherwise alter, in whole or in part, any of the above-referenced agreements or any restricted stock agreement between the Company and any employee, without the consent of the Board of Directors.

5.3 Employee Stock. Unless otherwise approved by the Requisite Preferred Directors, all employees, directors and consultants of the Company who purchase, receive options to purchase, or receive awards of shares of the Company's capital stock after the date hereof shall be required to execute restricted stock or option agreements, as applicable, providing for vesting of shares over a four (4) year period, with the first twenty-five percent (25%) of such shares vesting following twelve (12) months of continued employment or service, and the remaining shares vesting in equal monthly or quarterly installments over the following thirty-six (36) months, and (ii) a market stand-off provision substantially similar to that in Subsection 2.11; provided, that each recipient continues to be an employee, director or consultant of the Company on such dates, and such agreement shall not include acceleration of the vesting schedule. Without the prior approval by the Requisite Preferred Directors, the Company shall not amend, modify, terminate, waive or otherwise alter, in whole or in part, any stock purchase, stock restriction or option agreement with any existing employee or service provider if such amendment would cause it to be inconsistent with this Subsection 5.3. In addition, unless otherwise approved by the Requisite Preferred Directors, the Company shall retain (and not waive) a "right of first refusal" on employee transfers until the Company's IPO and shall have the right to repurchase unvested shares at the lower of cost and fair market value upon termination of employment of a holder of restricted stock.

5.4 Matters Requiring Investor Director Approval. So long as the holders of Series A Preferred Stock are entitled to elect directors, the Company hereby covenants and agrees with each of the Investors that it shall not, without approval of the Requisite Preferred Directors:

(a) make, or permit any subsidiary to make, any loan or advance to, or own any stock or other securities of, any subsidiary or other corporation, partnership, or other entity unless it is wholly owned by the Company;

(b) make, or permit any subsidiary to make, any loan or advance to any Person, including, without limitation, any employee or director of the Company or any subsidiary, except advances and similar expenditures in the ordinary course of business or under the terms of an employee stock or option plan approved by the Board of Directors;

(c) guarantee, directly or indirectly, or permit any subsidiary to guarantee, directly or indirectly, any indebtedness except for trade accounts of the Company or any subsidiary arising in the ordinary course of business;

(d) implement or change a cash investment policy;

(e) incur any aggregate indebtedness in excess of $150,000 that is not already included in a budget approved by the Board of Directors, other than trade credit;

(f) hire, terminate, or change the compensation of the executive officers, including approving any option plans;

(g) change the number of shares subject to any equity incentive plan or approves the adoption of any equity incentive plan; or

(h) sell, transfer, license, pledge, or encumber technology or intellectual property, other than licenses granted in the ordinary course of business.

5.5 Successor Indemnification. If the Company or any of its successors or assignees consolidates with or merges into any other Person and is not the continuing or surviving corporation or entity of such consolidation or merger, then to the extent necessary, proper provision shall be made so that the successors and assignees of the Company assume the obligations of the Company with respect to indemnification of members of the Board of Directors as in effect immediately before such transaction, whether such obligations are contained in the Company's Bylaws, the Certificate of Incorporation, or elsewhere, as the case may be.

5.6 Right to Conduct Activities. The Company hereby agrees and acknowledges that each of OrbiMed, Longitude, RA Capital Healthcare Fund, L.P and Blackwell Partners LLC - Series A, Pontifax (China) V L.P., Pontifax (Israel) V Limited Partnership, and Pontifax (Cayman) V L.P., and their respective affiliates and respective affiliated advisors and funds, are professional investment managers and/or funds and/or operating companies (collectively, the "**Investor Funds**") is a professional investment organization, and as such reviews the business plans and related proprietary information of many enterprises, some of which may compete directly or indirectly with the Company's business (as currently conducted or as currently propose to be conducted). The Company hereby agrees that, to the extent permitted under applicable law, the Investor Funds shall not be liable to the Company for any claim arising out of, or based upon, (i) the investment by the Investor Funds in any entity competitive with the Company, or (ii) actions taken by any partner, officer, employee or other representative of the Investor Funds to assist any such competitive company, whether or not such action was taken as a member of the board of directors of such competitive company or otherwise, and whether or not such action has a detrimental effect on the Company.

5.7 Termination of Covenants. The covenants set forth in this Section 5, except for Subsection 5.5, shall terminate and be of no further force or effect (i) immediately before the consummation of the IPO or (ii) upon a Deemed Liquidation Event, as such term is defined in the Certificate of Incorporation, whichever event occurs first.

5.8 FCPA. The Company represents that it shall not (and shall not permit any of its subsidiaries or affiliates or any of its or their respective directors, officers, managers, employees, independent contractors, representatives or agents to) promise, authorize or make any payment to, or otherwise contribute any item of value to, directly or indirectly, to any third party, including any Non-U.S. Official (as such term is defined in the U.S. Foreign Corrupt Practices Act of 1977, as amended (the "**FCPA**")), in each case, in violation of the FCPA, the U.K. Bribery Act,

or any other applicable anti-bribery or anti-corruption law. The Company further represents that it shall (and shall cause each of its subsidiaries and affiliates to) cease all of its or their respective activities, as well as remediate any actions taken by the Company, its subsidiaries or affiliates, or any of their respective directors, officers, managers, employees, independent contractors, representatives or agents in violation of the FCPA, the U.K. Bribery Act, or any other applicable anti-bribery or anti-corruption law. The Company further represents that, when applicable, it shall (and shall cause each of its subsidiaries and affiliates to) maintain systems of internal controls (including, but not limited to, accounting systems, purchasing systems and billing systems) to ensure compliance with the FCPA, the U.K. Bribery Act, or any other applicable anti-bribery or anti-corruption law. Upon request, the Company agrees to provide responsive information and/or certifications concerning its compliance with applicable anti-corruption laws. The Company shall promptly notify each Investor if the Company becomes aware of any Enforcement Action (as defined in the Purchase Agreement). The Company shall, and shall cause any direct or indirect subsidiary or entity controlled by it, whether now in existence or formed in the future, to comply with the FCPA. The Company shall use its best efforts to cause any direct or indirect subsidiary, whether now in existence or formed in the future, to comply in all material respects with all applicable laws.

5.9 Delivery of Tax Information. The Company will deliver to each Investor, any information or documentation as is reasonably required in connection with any U.S. tax return or filing which any such Investor or any of its Affiliates are required to make.

5.10 Strategic Stand Still. Except in connection with a Deemed Liquidation Event, the Company shall not issue, and no shareholder of the Company shall transfer, any shares or grant any right with respect to such shares (any such action, a "**Grant**"), to a Strategic Investor (including to its affiliates and/or other parties acting in concert with it; the "**Strategic Acquirers**") such that such Strategic Investor shall hold following such transfer more than 9.9% of the issued and outstanding share capital of the Company on an as converted basis, unless the holders of the Requisite Preferred have provided their prior written consent to such Grant (the "**Written Consent**"), and then, only on the terms and conditions set forth in the Written Consent. The Written Consent shall also be required for any additional Grant to a Strategic Acquirer that has already received a Written Consent with respect to a prior Grant.

6. Miscellaneous.

6.1 Successors and Assigns. The rights under this Agreement may be assigned (but only with all related obligations) by a Holder to a transferee of Registrable Securities that (i) is an Affiliate of a Holder or (ii) is a Holder's Immediate Family Member or trust for the benefit of an individual Holder or one or more of such Holder's Immediate Family Members; provided, however, in each case, that (x) the Company is, within a reasonable time after such transfer, furnished with written notice of the name and address of such transferee and the Registrable Securities with respect to which such rights are being transferred; and (y) such transferee agrees in a written instrument delivered to the Company to be bound by and subject to the terms and conditions of this Agreement, including the provisions of Subsection 2.11 (collectively, the "**Permitted Transferees**"). For the purposes of determining the number of shares of Registrable Securities held by a transferee, the holdings of a transferee (1) that is an Affiliate or stockholder of a Holder; (2) who is a

Holder's Immediate Family Member; or (3) that is a trust for the benefit of an individual Holder or such Holder's Immediate Family Member shall be aggregated together and with those of the transferring Holder; provided further that all transferees who would not qualify individually for assignment of rights shall, as a condition to the applicable transfer, establish a single attorney-in-fact for the purpose of exercising any rights, receiving notices, or taking any action under this Agreement. The terms and conditions of this Agreement inure to the benefit of and are binding upon the respective successors and permitted assignees of the parties. Nothing in this Agreement, express or implied, is intended to confer upon any party other than the parties hereto or their respective successors and permitted assignees any rights, remedies, obligations or liabilities under or by reason of this Agreement, except as expressly provided herein.

6.2 Governing Law. This Agreement shall be governed by the internal law of the State of Delaware, without regard to conflict of law principles that would result in the application of any law other than the law of the State of Delaware.

6.3 Counterparts. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, *e.g.*, www.docusign.com) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes**.**

6.4 Titles and Subtitles. The titles and subtitles used in this Agreement are for convenience only and are not to be considered in construing or interpreting this Agreement.

6.5 Notices.

(a) All notices and other communications given or made pursuant to this Agreement shall be in writing and shall be deemed effectively given upon the earlier of actual receipt or (i) personal delivery to the party to be notified; (ii) when sent, if sent by electronic mail or facsimile during the recipient's normal business hours, and if not sent during normal business hours, then on the recipient's next business day; (iii) five (5) days after having been sent by registered or certified mail, return receipt requested, postage prepaid; or (iv) one (1) business day after the business day of deposit with a nationally recognized overnight courier, freight prepaid, specifying next-day delivery, with written verification of receipt. All communications shall be sent to the respective parties at their addresses as set forth on the books of the Company, or to the principal office of the Company and to the attention of the Chief Executive Officer, in the case of the Company, or to such email address, facsimile number, or address as subsequently modified by written notice given in accordance with this Subsection 6.5. If notice is given to the Company, a copy shall also be sent to Gibson, Dunn & Crutcher LLP, 555 Mission Street, San Francisco, CA 94105, Attention: Ryan Murr.

(b) Consent to Electronic Notice. Each Investor consents to the delivery of any stockholder notice pursuant to the Delaware General Corporation Law (the "DGCL"), as amended or superseded from time to time, by electronic transmission pursuant to Section 232 of the DGCL (or any successor thereto) at the electronic mail address or the facsimile number as on the books of the Company. Each Investor agrees to promptly notify the Company of any change in such stockholder's electronic mail address, and that failure to do so shall not affect the foregoing.

6.6 Amendments and Waivers. Any term of this Agreement may be amended, modified or terminated and the observance of any term of this Agreement may be waived (either generally or in a particular instance, and either retroactively or prospectively) only with the written consent of the Company and the Initiating Holders; provided that the Company may in its sole discretion waive compliance with Subsection 2.12(c) (and the Company's failure to object promptly in writing after notification of a proposed assignment allegedly in violation of Subsection 2.12(c) shall be deemed to be a waiver); and provided further that any provision hereof may be waived by any waiving party on such party's own behalf, without the consent of any other party. Notwithstanding the foregoing, (a) this Agreement may not be amended, modified or terminated and the observance of any term hereof may not be waived with respect to any Investor without the written consent of such Investor, unless such amendment, modification, termination, or waiver applies to all Investors in the same fashion (it being agreed that a waiver of the provisions of Section 4 with respect to a particular transaction shall be deemed to apply to all Investors in the same fashion if such waiver does so by its terms, notwithstanding the fact that certain Investors may nonetheless, by agreement with the Company, purchase securities in such transaction) and (b) Subsections 3.1 and 3.2, Section 4 and any other section of this Agreement applicable to the Investors (including this clause (b) of this Subsection 6.6) may not be amended, modified, terminated or waived without the written consent of the holders of at least a majority of the Registrable Securities then outstanding and held by the Investors. Notwithstanding the foregoing, Schedule A hereto may be amended by the Company from time to time to add transferees of any Registrable Securities in compliance with the terms of this Agreement without the consent of the other parties; and Schedule A hereto may also be amended by the Company after the date of this Agreement without the consent of the other parties to add information regarding any additional Investor who becomes a party to this Agreement in accordance with Subsection 6.9. The Company shall give prompt notice of any amendment, modification or termination hereof or waiver hereunder to any party hereto that did not consent in writing to such amendment, modification, termination, or waiver. Any amendment, modification, termination, or waiver effected in accordance with this Subsection 6.6 shall be binding on all parties hereto, regardless of whether any such party has consented thereto. No waivers of or exceptions to any term, condition, or provision of this Agreement, in any one or more instances, shall be deemed to be or construed as a further or continuing waiver of any such term, condition, or provision.

6.7 Severability. In case any one or more of the provisions contained in this Agreement is for any reason held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality, or unenforceability shall not affect any other provision of this Agreement, and such invalid, illegal, or unenforceable provision shall be reformed and construed so that it will be valid, legal, and enforceable to the maximum extent permitted by law.

6.8 Aggregation of Stock. All shares of Registrable Securities held or acquired by Affiliates shall be aggregated together for the purpose of determining the availability of any rights under this Agreement and such Affiliates may apportion such rights as among themselves in any manner they deem appropriate.

6.9 Entire Agreement. This Agreement (including any Schedules and Exhibits hereto) constitutes the full and entire understanding and agreement among the parties with respect to the subject matter hereof, and any other written or oral agreement relating to the subject matter hereof existing between the parties is expressly canceled.

6.10 Dispute Resolution. The parties (a) hereby irrevocably and unconditionally submit to the jurisdiction of the state courts of Delaware and to the jurisdiction of the United States District Court for the District of Delaware for the purpose of any suit, action or other proceeding arising out of or based upon this Agreement, (b) agree not to commence any suit, action or other proceeding arising out of or based upon this Agreement except in the state courts of Delaware or the United States District Court for the District of Delaware, and (c) hereby waive, and agree not to assert, by way of motion, as a defense, or otherwise, in any such suit, action or proceeding, any claim that it is not subject personally to the jurisdiction of the above-named courts, that its property is exempt or immune from attachment or execution, that the suit, action or proceeding is brought in an inconvenient forum, that the venue of the suit, action or proceeding is improper or that this Agreement or the subject matter hereof may not be enforced in or by such court.

6.11 Delays or Omissions. No delay or omission to exercise any right, power, or remedy accruing to any party under this Agreement, upon any breach or default of any other party under this Agreement, shall impair any such right, power, or remedy of such nonbreaching or nondefaulting party, nor shall it be construed to be a waiver of or acquiescence to any such breach or default, or to any similar breach or default thereafter occurring, nor shall any waiver of any single breach or default be deemed a waiver of any other breach or default theretofore or thereafter occurring. All remedies, whether under this Agreement or by law or otherwise afforded to any party, shall be cumulative and not alternative.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, the parties have executed this Investors' Rights Agreement as of the date first written above.

89BIO, INC.

By: /s/ Rohan Palekar
Name: Rohan Palekar
Title: Chief Executive Officer

IN WITNESS WHEREOF, the parties hereto have executed this Investors' Rights Agreement as of the date first written above.

ORBIMED ISRAEL PARTNERS II, L.P.

By: OrbiMed Israel GP II, L.P.,
its general partner

By: OrbiMed Advisors Israel II Limited,
its general partner

By: /s/ Jonathan T. Silverstein
Name: Jonathan T. Silverstein
Title: Director

ORBIMED PRIVATE INVESTMENTS VI, LP

By: OrbiMed Capital GP VI LLC
its General Partner

By: OrbiMed Advisors LLC,
its Managing Member

By: /s/ Jonathan T. Silverstein
Name: Jonathan T. Silverstein
Title: Member

IN WITNESS WHEREOF, the parties hereto have executed this Investors' Rights Agreement as of the date first written above.

LONGITUDE VENTURE PARTNERS III, L.P.

By: Longitude Capital Partners III, LLC
its General Partner

By: /s/ Gregory Grunberg
Name: Gregory Grunberg
Title: Managing Director

IN WITNESS WHEREOF, the parties hereto have executed this Investors' Rights Agreement as of the date first written above.

RA CAPITAL HEALTHCARE FUND, L.P.

By: /s/ Peter Kolchinsky
Name: Peter Kolchinsky
Title: Manager

IN WITNESS WHEREOF, the parties hereto have executed this Investors' Rights Agreement as of the date first written above.

RA CAPITAL NEXUS FUND, L.P.

By: /s/ Peter Kolchinsky
Name: Peter Kolchinsky
Title: Manager

IN WITNESS WHEREOF, the parties hereto have executed this Investors' Rights Agreement as of the date first written above.

BLACKWELL PARTNERS LLC – SERIES A

By: /s/ Abayomi A. Adigun
Name: Abayomi A. Adigun
Title: Investment Manager
DUMAC, Inc., Authorized Agent

By: /s/ Jannine M. Lall
Name: Jannine M. Lall
Title: Head of Finance & Controller
DUMAC, Inc., Authorized Agent

IN WITNESS WHEREOF, the parties hereto have executed this Investors' Rights Agreement as of the date first written above.

GENWORKS 2 CONSULTING INC.

By: /s/ Sandra Hayden
Name: Sandra Hayden
Title: President

IN WITNESS WHEREOF, the parties hereto have executed this Investors' Rights Agreement as of the date first written above.

PONTIFAX (ISRAEL) V LIMITED PARTNERSHIP

By: /s/ Tomer Kariv
Name: Tomer Kariv
Title: CEO

PONTIFAX (CAYMAN) V L.P.

By: /s/ Tomer Kariv
Name: Tomer Kariv
Title: CEO

PONTIFAX (CHINA) V L.P.

By: /s/ Tomer Kariv
Name: Tomer Kariv
Title: CEO

Exhibit 10.1

INDEMNIFICATION AGREEMENT

This Indemnification Agreement (this "Agreement") is entered into as of [_____] (the "Effective Date") by and between 89bio, Inc., a Delaware corporation (the "Company"), and [_____] (the "Indemnitee").

RECITALS

WHEREAS, the Board of Directors has determined that the inability to attract and retain qualified persons as directors and officers is detrimental to the best interests of the Company's stockholders and that the Company should act to assure such persons that there shall be adequate certainty of protection through insurance and indemnification against risks of claims and actions against them arising out of their service to and activities on behalf of the Company;

WHEREAS, the Company has adopted provisions in its Certificate of Incorporation and Bylaws providing for indemnification and advancement of expenses of its directors and officers to the fullest extent authorized by the General Corporation Law of the State of Delaware (the "DGCL"), and the Company wishes to clarify and enhance the rights and obligations of the Company and the Indemnitee with respect to indemnification and advancement of expenses;

WHEREAS, in order to induce and encourage highly experienced and capable persons such as the Indemnitee to serve and continue to serve as directors and officers of the Company and in any other capacity with respect to the Company as the Company may request, and to otherwise promote the desirable end that such persons shall resist what they consider unjustified lawsuits and claims made against them in connection with the good faith performance of their duties to the Company, with the knowledge that certain costs, judgments, penalties, fines, liabilities, and expenses incurred by them in their defense of such litigation are to be borne by the Company and they shall receive appropriate protection against such risks and liabilities, the Board of Directors of the Company has determined that the following Agreement is reasonable and prudent to promote and ensure the best interests of the Company and its stockholders; and

WHEREAS, the Company desires to have the Indemnitee serve as a director or officer of the Company and in any other capacity with respect to the Company as the Company may request, as the case may be, free from undue concern for unpredictable, inappropriate, or unreasonable legal risks and personal liabilities by reason of the Indemnitee acting in good faith in the performance of the Indemnitee's duty to the Company; and the Indemnitee desires to serve the Company, provided, and on the express condition, that he or she is furnished with the protections set forth hereinafter.

AGREEMENT

NOW, THEREFORE, in consideration of the Indemnitee's continued service as a director or officer of the Company, the parties hereto agree as follows:

1. Definitions. For purposes of this Agreement:

(a) A "Change in Control" will be deemed to have occurred if, with respect to any particular 24-month period, the individuals who, at the beginning of such 24-month period, constituted the Board of Directors of the Company (the "Incumbent Board") cease for any reason to constitute at least a majority of the Board of Directors; provided, however, that any individual becoming a director subsequent to the beginning of such 24-month period whose election, or nomination for election by the stockholders of the Company, was approved by a vote of at least a majority of the directors then comprising the Incumbent Board shall be considered as though such individual were a member of the Incumbent Board, but excluding, for this purpose, any such individual whose initial assumption of office occurs as a result of an actual or threatened election contest with respect to the election or removal of directors or other actual or threatened solicitation of proxies or consents by or on behalf of a person other than the Board of Directors.

(b) "Disinterested Director" means a director of the Company who is not or was not a party to the Proceeding in respect of which indemnification is being sought by the Indemnitee.

(c) "Expenses" includes, without limitation, expenses incurred in connection with the defense or settlement of any action, suit, arbitration, alternative dispute resolution mechanism, investigation, inquiry, judicial, administrative, or legislative hearing, or any other threatened, pending, or completed proceeding, whether brought by or in the right of the Company or otherwise, including any and all appeals, whether of a civil, criminal, administrative, legislative, investigative, or other nature, attorneys' fees, witness fees and expenses, fees and expenses of accountants and other advisors, retainers and disbursements and advances thereon, the premium, security for, and other costs relating to any bond (including cost bonds, appraisal bonds, or their equivalents), and any expenses of establishing a right to indemnification or advancement under Sections 8, 10, 12, and 15 hereof, but shall not include the amount of judgments, fines, ERISA excise taxes, or penalties actually levied against the Indemnitee, or any amounts paid in settlement by or on behalf of the Indemnitee.

(d) "Independent Counsel" means a law firm or a member of a law firm that neither is presently nor in the past five years has been retained to represent (i) the Company or the Indemnitee in any matter material to either such party or (ii) any other party to the Proceeding giving rise to a request for indemnification hereunder. Notwithstanding the foregoing, the term "Independent Counsel" shall not include any person who, under the applicable standards of professional conduct then prevailing, would have a conflict of interest in representing either the Company or the Indemnitee in an action to determine the Indemnitee's right to indemnification under this Agreement.

(e) "Proceeding" means any action, suit, arbitration, alternative dispute resolution mechanism, investigation, inquiry, judicial, administrative, or legislative hearing, or any other threatened, pending, or completed proceeding, whether brought by or in the right of the Company or otherwise, including any and all appeals, whether of a civil, criminal, administrative, legislative, investigative, or other nature, to which the Indemnitee was or is a party or is threatened to be made a party or is otherwise involved in by reason of the fact that the Indemnitee is or was a director, officer, employee, agent, or trustee of the Company or while a director, officer, employee, agent, or trustee of the Company is or was serving at the request of the Company as a director, officer, employee, agent, or trustee of another corporation or of a

partnership, joint venture, trust, or other enterprise, including service with respect to an employee benefit plan, or by reason of anything done or not done by the Indemnitee in any such capacity, whether or not the Indemnitee is serving in such capacity at the time any expense, liability, or loss is incurred for which indemnification or advancement can be provided under this Agreement.

2. Service by the Indemnitee. The Indemnitee shall serve and/or continue to serve as a director or officer of the Company faithfully and to the best of the Indemnitee's ability so long as the Indemnitee is duly elected or appointed and until such time as the Indemnitee's successor is elected and qualified or the Indemnitee is removed as permitted by applicable law or tenders a resignation in writing.

3. Indemnification and Advancement of Expenses. The Company shall indemnify and hold harmless the Indemnitee, and shall pay to the Indemnitee in advance of the final disposition of any Proceeding all Expenses incurred by the Indemnitee in defending any such Proceeding, to the fullest extent authorized by the DGCL, as the same exists or may hereafter be amended, all on the terms and conditions set forth in this Agreement. Without diminishing the scope of the rights provided by this Section, the rights of the Indemnitee to indemnification and advancement of Expenses provided hereunder shall include but shall not be limited to those rights hereinafter set forth, except that no indemnification or advancement of Expenses shall be paid to the Indemnitee:

(a) to the extent expressly prohibited by applicable law or the Certificate of Incorporation and Bylaws of the Company;

(b) for and to the extent that payment is actually made to the Indemnitee under a valid and collectible insurance policy or under a valid and enforceable indemnity clause, provision of the certificate of incorporation or bylaws, or agreement of the Company or any other company or other enterprise (and the Indemnitee shall reimburse the Company for any amounts paid by the Company and subsequently so recovered by the Indemnitee);

(c) in connection with an action, suit, or proceeding, or part thereof voluntarily initiated by the Indemnitee (including claims and counterclaims, whether such counterclaims are asserted by (i) the Indemnitee, or (ii) the Company in an action, suit, or proceeding initiated by the Indemnitee), except a judicial proceeding or arbitration pursuant to Section 10 to enforce rights under this Agreement, unless the action, suit, or proceeding, or part thereof, was authorized or ratified by the Board of Directors of the Company or the Board of Directors otherwise determines that indemnification or advancement of Expenses is appropriate; or

(d) with respect to any Proceeding brought by or in the right of the Company against the Indemnitee that is authorized by the Board of Directors of the Company, except as provided in Sections 5, 6, and 7 below.

4. Action or Proceedings Other than an Action by or in the Right of the Company. Except as limited by Section 3 above, the Indemnitee shall be entitled to the indemnification rights provided in this Section if the Indemnitee was or is a party or is threatened to be made a party to, or was or is otherwise involved in, any Proceeding (other than an action by or in the right of the Company) by reason of the fact that the Indemnitee is or was a director, officer, employee, agent, or trustee of the Company or while a director, officer, employee, agent, or trustee of the Company is or was serving at the request of the Company as a director, officer, employee, agent, or trustee of another corporation or of a partnership, joint venture, trust, or other enterprise, including service with respect to an employee benefit plan, or by reason of anything done or not done by the Indemnitee in any such capacity. Pursuant to this Section, the Indemnitee shall be indemnified against all expense, liability, and loss (including judgments, fines, ERISA excise taxes, penalties, amounts paid in settlement by or on behalf of the Indemnitee, and Expenses) actually and reasonably incurred by the Indemnitee in connection with such Proceeding, if the Indemnitee acted in good faith and in a manner the Indemnitee reasonably believed to be in or not opposed to the best interests of the Company, and with respect to any criminal Proceeding, had no reasonable cause to believe his or her conduct was unlawful.

5. Indemnity in Proceedings by or in the Right of the Company. Except as limited by Section 3 above, the Indemnitee shall be entitled to the indemnification rights provided in this Section if the Indemnitee was or is a party or is threatened to be made a party to, or was or is otherwise involved in, any Proceeding brought by or in the right of the Company to procure a judgment in its favor by reason of the fact that the Indemnitee is or was a director, officer, employee, agent, or trustee of the Company or while a director, officer, employee, agent, or trustee of the Company is or was serving at the request of the Company as a director, officer, employee, agent, or trustee of another corporation or of a partnership, joint venture, trust, or other enterprise, including service with respect to an employee benefit plan, or by reason of anything done or not done by the Indemnitee in any such capacity. Pursuant to this Section, the Indemnitee shall be indemnified against all Expenses actually and reasonably incurred by the Indemnitee in connection with such Proceeding if the Indemnitee acted in good faith and in a manner the Indemnitee reasonably believed to be in or not opposed to the best interests of the Company; provided, however, that no such indemnification shall be made in respect of any claim, issue, or matter as to which the DGCL expressly prohibits such indemnification by reason of any adjudication of liability of the Indemnitee to the Company, unless and only to the extent that the Court of Chancery of the State of Delaware or the court in which such Proceeding was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, the Indemnitee is entitled to indemnification for such expense, liability, and loss as such court shall deem proper.

6. Indemnification for Costs, Charges, and Expenses of Successful Party. Notwithstanding any limitations of Sections 3(c), 3(d), 4 and 5 above, to the extent that the Indemnitee has been successful, on the merits or otherwise, in whole or in part, in defense of any Proceeding, or in defense of any claim, issue, or matter therein, including, without limitation, the dismissal of any action without prejudice, or if it is ultimately determined, by final judicial decision of a court of competent jurisdiction from which there is no further right to appeal, that the Indemnitee is otherwise entitled to be indemnified against Expenses, the Indemnitee shall be indemnified against all Expenses actually and reasonably incurred by the Indemnitee in connection therewith.

7. Partial Indemnification. If the Indemnitee is entitled under any provision of this Agreement to indemnification by the Company for some or a portion of the expense, liability, and loss (including judgments, fines, ERISA excise taxes, penalties, amounts paid in settlement by or on behalf of the Indemnitee, and Expenses) actually and reasonably incurred in connection with any Proceeding, or in connection with any judicial proceeding or arbitration pursuant to Section 10 to enforce rights under this Agreement, but not, however, for all of the total amount thereof, the Company shall nevertheless indemnify the Indemnitee for the portion of such expense, liability, and loss actually and reasonably incurred to which the Indemnitee is entitled.

8. Determination of Entitlement to Indemnification. To receive indemnification under this Agreement, the Indemnitee shall submit a written request to the Secretary of the Company. Such request shall include documentation or information that is necessary for such determination and is reasonably available to the Indemnitee. Upon receipt by the Secretary of the Company of a written request by the Indemnitee for indemnification, the entitlement of the Indemnitee to indemnification, to the extent not required pursuant to the terms of Section 6 of this Agreement, shall be determined by the following person or persons who shall be empowered to make such determination (as selected by the Board of Directors, except with respect to Section 8(e) below): (a) the Board of Directors of the Company by a majority vote of Disinterested Directors, whether or not such majority constitutes a quorum; (b) a committee of Disinterested Directors designated by a majority vote of such directors, whether or not such majority constitutes a quorum; (c) if there are no Disinterested Directors, or if the Disinterested Directors so direct, by Independent Counsel in a written opinion to the Board of Directors, a copy of which shall be delivered to the Indemnitee; (d) the stockholders of the Company; or (e) in the event that a Change in Control has occurred, by Independent Counsel in a written opinion to the Board of Directors, a copy of which shall be delivered to the Indemnitee. Such Independent Counsel shall be selected by the Board of Directors and approved by the Indemnitee, except that in the event that a Change in Control has occurred, Independent Counsel shall be selected by the Indemnitee. Upon failure of the Board of Directors so to select such Independent Counsel or upon failure of the Indemnitee so to approve (or so to select, in the event a Change in Control has occurred), such Independent Counsel shall be selected upon application to a court of competent jurisdiction. The determination of entitlement to indemnification shall be made and, unless a contrary determination is made, such indemnification shall be paid in full by the Company not later than 60 calendar days after receipt by the Secretary of the Company of a written request for indemnification. If the person making such determination shall determine that the Indemnitee is entitled to indemnification as to part (but not all) of the application for indemnification, such person shall reasonably prorate such partial indemnification among the claims, issues, or matters at issue at the time of the determination.

9. Presumptions and Effect of Certain Proceedings. The Secretary of the Company shall, promptly upon receipt of the Indemnitee's written request for indemnification, advise in writing the Board of Directors or such other person or persons empowered to make the determination as provided in Section 8 that the Indemnitee has made such request for indemnification. Upon making such request for indemnification, the Indemnitee shall be presumed to be entitled to indemnification hereunder and the Company shall have the burden of proof in making any determination contrary to such presumption. If the person or persons so empowered to make such determination shall have failed to make the requested determination with respect to indemnification within 60 calendar days after receipt by the Secretary of the

Company of such request, a requisite determination of entitlement to indemnification shall be deemed to have been made and the Indemnitee shall be absolutely entitled to such indemnification, absent actual fraud in the request for indemnification. The termination of any Proceeding described in Sections 4 or 5 by judgment, order, settlement, or conviction, or upon a plea of *nolo contendere* or its equivalent, shall not, of itself (a) create a presumption that the Indemnitee did not act in good faith and in a manner the Indemnitee reasonably believed to be in or not opposed to the best interests of the Company, and with respect to any criminal Proceeding, had reasonable cause to believe his or her conduct was unlawful or (b) otherwise adversely affect the rights of the Indemnitee to indemnification except as may be provided herein.

10. Remedies of the Indemnitee in Cases of Determination Not to Indemnify or to Advance Expenses; Right to Bring Suit. In the event that a determination is made that the Indemnitee is not entitled to indemnification hereunder or if payment is not timely made following a determination of entitlement to indemnification pursuant to Sections 8 and 9, or if an advancement of Expenses is not timely made pursuant to Section 15, the Indemnitee may at any time thereafter bring suit against the Company seeking an adjudication of entitlement to such indemnification or advancement of Expenses, and any such suit shall be brought in the Court of Chancery of the State of Delaware unless otherwise required by the law of the state in which the Indemnitee primarily resides and works. Alternatively, the Indemnitee at the Indemnitee's option may seek an award in an arbitration to be conducted by a single arbitrator in the State of Delaware pursuant to the rules of the American Arbitration Association, such award to be made within 60 calendar days following the filing of the demand for arbitration. The Company shall not oppose the Indemnitee's right to seek any such adjudication or award in arbitration. In any suit or arbitration brought by the Indemnitee to enforce a right to indemnification hereunder (but not in a suit or arbitration brought by the Indemnitee to enforce a right to an advancement of Expenses), it shall be a defense that the Indemnitee has not met any applicable standard of conduct for indemnification set forth in the DGCL, including the standard described in Section 4 or 5, as applicable. Further, in any suit brought by the Company to recover an advancement of Expenses pursuant to the terms of an undertaking, the Company shall be entitled to recover such Expenses upon a final judicial decision of a court of competent jurisdiction from which there is no further right to appeal that the Indemnitee has not met the standard of conduct described above. Neither the failure of the Company (including the Disinterested Directors, a committee of Disinterested Directors, Independent Counsel, or its stockholders) to have made a determination prior to the commencement of such suit or arbitration that indemnification of the Indemnitee is proper in the circumstances because the Indemnitee has met the standard of conduct described above, nor an actual determination by the Company (including the Disinterested Directors, a committee of Disinterested Directors, Independent Counsel, or its stockholders) that the Indemnitee has not met the standard of conduct described above shall create a presumption that the Indemnitee has not met the standard of conduct described above, or, in the case of such a suit brought by the Indemnitee, be a defense to such suit. In any suit brought by the Indemnitee to enforce a right to indemnification or to an advancement of Expenses hereunder, or brought by the Company to recover an advancement of Expenses pursuant to the terms of an undertaking, the burden of proving that the Indemnitee is not entitled to be indemnified, or to such advancement of expenses, under this Section 10 or otherwise shall be on the Company. If a determination is made or deemed to have been made pursuant to the terms of Section 8 or 9 that the Indemnitee is entitled to indemnification, the Company shall be bound by such determination and is precluded from asserting that such determination has not been made or that the procedure

by which such determination was made is not valid, binding, and enforceable. The Company further agrees to stipulate in any court or before any arbitrator pursuant to this Section 10 that the Company is bound by all the provisions of this Agreement and is precluded from making any assertions to the contrary. If the court or arbitrator shall determine that the Indemnitee is entitled to any indemnification or advancement of Expenses hereunder, the Company shall pay all Expenses actually and reasonably incurred by the Indemnitee in connection with such adjudication or award in arbitration (including, but not limited to, any appellate proceedings) to the fullest extent permitted by law, and in any suit brought by the Company to recover an advancement of Expenses pursuant to the terms of an undertaking, the Company shall pay all Expenses actually and reasonably incurred by the Indemnitee in connection with such suit to the extent the Indemnitee has been successful, on the merits or otherwise, in whole or in part, in defense of such suit, to the fullest extent permitted by law.

11. Non-Exclusivity of Rights. The rights to indemnification and to the advancement of Expenses provided by this Agreement shall not be deemed exclusive of any other right that the Indemnitee may now or hereafter acquire under any applicable law, agreement, vote of stockholders or Disinterested Directors, provisions of a charter or bylaws (including the Certificate of Incorporation or Bylaws of the Company), or otherwise.

12. Expenses to Enforce Agreement. In the event that the Indemnitee is subject to or intervenes in any action, suit, or proceeding in which the validity or enforceability of this Agreement is at issue or seeks an adjudication or award in arbitration to enforce the Indemnitee's rights under, or to recover damages for breach of, this Agreement, the Indemnitee, if the Indemnitee prevails in whole or in part in such action, suit, or proceeding, shall be entitled to recover from the Company and shall be indemnified by the Company against any Expenses actually and reasonably incurred by the Indemnitee in connection therewith.

13. Continuation of Indemnity. All agreements and obligations of the Company contained herein shall continue during the period the Indemnitee is a director, officer, employee, agent, or trustee of the Company or while a director, officer, employee, agent, or trustee is serving at the request of the Company as a director, officer, employee, agent, or trustee of another corporation or of a partnership, joint venture, trust, or other enterprise, including service with respect to an employee benefit plan, and shall continue thereafter with respect to any possible claims based on the fact that the Indemnitee was a director, officer, employee, agent, or trustee of the Company or was serving at the request of the Company as a director, officer, employee, agent, or trustee of another corporation or of a partnership, joint venture, trust, or other enterprise, including service with respect to an employee benefit plan. This Agreement shall be binding upon all successors and assigns of the Company (including any transferee of all or substantially all of its assets and any successor by merger or operation of law) and shall inure to the benefit of the Indemnitee's heirs, executors, and administrators.

14. Notification and Defense of Proceeding. Promptly after receipt by the Indemnitee of notice of any Proceeding, the Indemnitee shall, if a request for indemnification or an advancement of Expenses in respect thereof is to be made against the Company under this Agreement, notify the Company in writing of the commencement thereof; but the omission so to notify the Company shall not relieve it from any liability that it may have to the Indemnitee.

Notwithstanding any other provision of this Agreement, with respect to any such Proceeding of which the Indemnitee notifies the Company:

(a) The Company shall be entitled to participate therein at its own expense;

(b) Except as otherwise provided in this Section 14(b), to the extent that it may wish, the Company, jointly with any other indemnifying party similarly notified, shall be entitled to assume the defense thereof, with counsel satisfactory to the Indemnitee. After notice from the Company to the Indemnitee of its election so to assume the defense thereof, the Company shall not be liable to the Indemnitee under this Agreement for any expenses of counsel subsequently incurred by the Indemnitee in connection with the defense thereof except as otherwise provided below. The Indemnitee shall have the right to employ the Indemnitee's own counsel in such Proceeding, but the fees and expenses of such counsel incurred after notice from the Company of its assumption of the defense thereof shall be at the expense of the Indemnitee unless (i) the employment of counsel by the Indemnitee has been authorized by the Company, (ii) the Indemnitee shall have reasonably concluded that there may be a conflict of interest between the Company and the Indemnitee in the conduct of the defense of such Proceeding, or (iii) the Company shall not within 60 calendar days of receipt of notice from the Indemnitee in fact have employed counsel to assume the defense of the Proceeding, in each of which cases the fees and expenses of the Indemnitee's counsel shall be at the expense of the Company. The Company shall not be entitled to assume the defense of any Proceeding brought by or on behalf of the Company or as to which the Indemnitee shall have made the conclusion provided for in (ii) above; and

(c) Notwithstanding any other provision of this Agreement, the Company shall not be liable to indemnify the Indemnitee under this Agreement for any amounts paid in settlement of any Proceeding effected without the Company's written consent, or for any judicial or other award, if the Company was not given an opportunity, in accordance with this Section 14, to participate in the defense of such Proceeding. The Company shall not settle any Proceeding in any manner that would impose any penalty or limitation on or disclosure obligation with respect to the Indemnitee, or that would directly or indirectly constitute or impose any admission or acknowledgment of fault or culpability with respect to the Indemnitee, without the Indemnitee's written consent. Neither the Company nor the Indemnitee shall unreasonably withhold its consent to any proposed settlement.

15. Advancement of Expenses.

(a) All Expenses incurred by the Indemnitee in defending any Proceeding described in Section 4 or 5 shall be paid by the Company in advance of the final disposition of such Proceeding at the request of the Indemnitee. To receive an advancement of Expenses under this Agreement, the Indemnitee shall submit a written request to the Secretary of the Company. Such request shall reasonably evidence the Expenses incurred by the Indemnitee and shall include or be accompanied by an undertaking, by or on behalf of the Indemnitee, to repay all amounts so advanced if it shall ultimately be determined, by final judicial decision of a court of competent jurisdiction from which there is no further right to appeal, that the Indemnitee is not entitled to be indemnified for such Expenses by the Company as provided by this Agreement or otherwise. The Indemnitee's undertaking to repay any such amounts is not required to be

secured. Each such advancement of Expenses shall be made within 20 calendar days after the receipt by the Secretary of the Company of such written request. The Indemnitee's entitlement to Expenses under this Agreement shall include those incurred in connection with any action, suit, or proceeding by the Indemnitee seeking an adjudication or award in arbitration pursuant to Section 10 of this Agreement (including the enforcement of this provision) to the extent the court or arbitrator shall determine that the Indemnitee is entitled to an advancement of Expenses hereunder.

(b) Notwithstanding the foregoing, the Company shall not advance or continue to advance Expenses to the Indemnitee if a determination is reasonably made that the facts known at the time such determination is made demonstrate clearly and convincingly that the Indemnitee acted in bad faith or in a manner that the Indemnitee did not reasonably believe to be in or not opposed to the best interests of the Company, or, with respect to any criminal Proceeding, that the Indemnitee had reasonable cause to believe his or her conduct was unlawful. Such determination shall be made: (i) by the Board of Directors of the Company by a majority vote of Disinterested Directors, whether or not such majority constitutes a quorum; (ii) by a committee of Disinterested Directors designated by a majority vote of such directors, whether or not such majority constitutes a quorum; (iii) if there are no Disinterested Directors, or if the Disinterested Directors so direct, by Independent Counsel in a written opinion to the Board of Directors, a copy of which shall be delivered to the Indemnitee; or (iv) in the event that a Change in Control has occurred, by Independent Counsel in a written opinion to the Board of Directors, a copy of which shall be delivered to the Indemnitee.

16. Severability; Prior Indemnification Agreements. If any provision or provisions of this Agreement shall be held to be invalid, illegal, or unenforceable as applied to any person or entity or circumstance for any reason whatsoever, then, to the fullest extent permitted by law (a) the validity, legality, and enforceability of such provision in any other circumstance and of the remaining provisions of this Agreement (including, without limitation, all portions of any paragraphs of this Agreement containing any such provision held to be invalid, illegal, or unenforceable, that are not by themselves invalid, illegal, or unenforceable) and the application of such provision to other persons or entities or circumstances shall not in any way be affected or impaired thereby, and (b) to the fullest extent possible, the provisions of this Agreement (including, without limitation, all portions of any paragraph of this Agreement containing any such provision held to be invalid, illegal, or unenforceable, that are not themselves invalid, illegal, or unenforceable) shall be construed so as to give effect to the intent of the parties that the Company provide protection to the Indemnitee to the fullest extent set forth in this Agreement. This Agreement shall supersede and replace any prior indemnification agreements entered into by and between the Company and the Indemnitee and any such prior agreements shall be terminated upon execution of this Agreement.

17. Headings; References; Pronouns. The headings of the sections of this Agreement are inserted for convenience only and shall not be deemed to constitute part of this Agreement or to affect the construction thereof. References herein to section numbers are to sections of this Agreement. All pronouns and any variations thereof shall be deemed to refer to the singular or plural as appropriate.

18. Other Provisions.

(a) This Agreement and all disputes or controversies arising out of or related to this Agreement shall be governed by, and construed in accordance with, the internal laws of the State of Delaware, without regard to the laws of any other jurisdiction that might be applied because of conflicts of laws principles of the State of Delaware , unless otherwise required by the law of the state in which the Indemnitee primarily resides and works.

(b) This Agreement may be executed in two or more counterparts, all of which shall be considered one and the same instrument and shall become effective when one or more counterparts have been signed by each of the parties and delivered to the other party.

(c) This Agreement shall not be deemed an employment contract between the Company and any Indemnitee who is an officer of the Company, and, if the Indemnitee is an officer of the Company, the Indemnitee specifically acknowledges that the Indemnitee may be discharged at any time for any reason, with or without cause, and with or without severance compensation, except as may be otherwise provided in a separate written contract between the Indemnitee and the Company.

(d) In the event of payment under this Agreement, the Company shall be subrogated to the extent of such payment to all of the rights of recovery of the Indemnitee (excluding insurance obtained on the Indemnitee's own behalf), and the Indemnitee shall execute all papers required and shall do everything that may be necessary to secure such rights, including the execution of such documents necessary to enable the Company effectively to bring suit to enforce such rights.

(e) This Agreement may not be amended, modified, or supplemented in any manner, whether by course of conduct or otherwise, except by an instrument in writing specifically designated as an amendment hereto, signed on behalf of each party. No failure or delay of either party in exercising any right or remedy hereunder shall operate as a waiver thereof, and no single or partial exercise of any such right or power, or any abandonment or discontinuance of steps to enforce such right or power, or any course of conduct, shall preclude any other or further exercise thereof or the exercise of any other right or power.

[The remainder of this page is intentionally left blank.]

IN WITNESS WHEREOF, the Company and the Indemnitee have caused this Agreement to be executed as of the date first written above.

89bio, Inc.

By: _____
Name:
Title:

_____
Indemnitee

Exhibit 10.4

89bio Ltd.

June 25, 2018

Rohan Palekar

Dear Rohan:

Offer and Position

We are very pleased to extend an offer of employment to you for the position of Chief Executive Officer ("**CEO**") of 89bio Ltd. (the "**Company**"). This offer of employment is conditioned on your satisfactory completion of certain requirements, as more fully explained in this letter. Your employment is subject to the terms and conditions set forth in this letter. Your employment will be administered under a US subsidiary of the Company.

Duties

In your capacity as a CEO, you will perform duties and responsibilities that are commensurate with your position and such other duties as may be assigned to you from time to time. You will report directly to the Board of Directors of the Company (the "**Board**"). You will be elected to serve on the Board of Directors of the Company as soon as practicable following the Start Date. Your service on the Board will not entitle you to additional compensation. You agree to devote your full business time, attention and best efforts to the performance of your duties and to the furtherance of the Company's interests.

Location

Your principal place of employment shall in the San Francisco Bay area, subject to business travel as needed to properly fulfil your employment duties and responsibilities.

Start Date

Subject to satisfaction of all of the conditions described in this letter, your anticipated start date is July 16 ("**Start Date**").

Base Salary

In consideration of your services, you will be paid an initial base salary of $425,000 per year, subject to review by the Board from time to time, payable in accordance with the standard payroll practices of the Company or its US subsidiary and subject to all withholdings and deductions as required by law.

Annual Bonus

Each year, you will have an opportunity to earn a bonus of up to 45% of your base salary (the "**Target Bonus**"). Your actual bonus amount will be determined based on a combination of Company results and individual performance against the applicable performance goals established by the Board. Any annual bonus with respect to a particular calendar year will be paid within 2 1/2 months following the end of the year for which the annual bonus relates. For any partial year of employment you will receive a pro-rated annual bonus based on the number of days you are employed during the year.

You must remain continuously employed through the end of the applicable calendar year to be eligible to receive an annual bonus payment for a particular calendar year.

Expenses

The Company or its US subsidiary will reimburse you only for out of pocket business related expenses reasonably incurred in the performance of your duties, as approved by the Board in the annual budgeting process and in accordance with any expense claiming policies and guidelines promulgated by the Company or its US subsidiary from time to time.

Equity Grants

As soon as practicable following the Start Date, the Company will recommend that the Board grant you an option to purchase an aggregate of 2,021,967 Ordinary Shares of the Company (representing 5% of the issued and outstanding shares of the Company as of the close of the Series A 2nd tranche), at a per share exercise price equal to the fair market value of such shares on the date of grant. The Company will recommend to the Board that such 5% stake be trued up if and when the Company closes the third tranche of its Series A financing. The options will be governed by the Company's 2018 Equity Incentive Plan (as supplemented by the Company's 2018 United States Sub-Plan) and a stock option agreement to be entered into between the Company and you. The stock option agreement will provide, among other things, that, (i) subject to your continued employment with the Company or its subsidiary on each applicable vesting date, your options shall vest over a four-year period, 25% upon the one-year anniversary of the Start Date (or the third tranche date in respect of any true up grant), and the remaining 75% in equal quarterly installments over a period of three years thereafter, and (ii) in the event that you are terminated without Cause (as defined below) or resign for Good Reason (as defined below) within the Change in Control Protection Period (as defined below), then, subject to the Release Condition described below, any of your options then subject to vesting shall become fully vested as of the date of such termination.

Benefits and Perquisites

You will be eligible to participate in the employee benefit plans and programs generally available to the Company's senior executives in the United States, as those policies are developed and amended by the Company. You will be entitled to paid vacation in accordance with the Company's or its US subsidiary's policies in effect from time to time. The Company and its subsidiaries reserve the right to amend, modify or terminate any of its benefit plans or programs at any time and for any reason.

Withholding

All forms of compensation paid to you as an employee of the Company or its subsidiary shall be less all applicable withholdings.

At-will Employment

Your employment with the Company or its subsidiary will be for no specific period of time. Rather, **your employment will be at-will, meaning that any party may terminate the employment relationship at any time, with or without cause, and with or without notice and for any reason or no particular reason**. Although your compensation and benefits may change from time to time, the at-will nature of your employment may only be changed by an express written agreement signed by an authorized officer of the Company after approval by the Board.

Severance outside of Change in Control Protection Period

If your employment with the Company or its subsidiary is involuntarily terminated by the Company without Cause (as defined below) and not due to a breach by you of the terms and conditions of this letter (including, but not limited to, a breach of any of the representations contained herein, the enclosed Employee Proprietary Information and Invention Assignment Agreement (the "**PHA**") or the Employee Arbitration Agreement) at any time outside of the Change in Control Protection Period (as defined below), subject to your execution of a release of claims in a form provided by the Company, you will be eligible to receive severance in an amount equal to: (i) six (6) months of base salary at the rate then in effect, (ii) a pro-rata amount of the Target Bonus based on the number of months you were employed with the Company for the year in which your employment is terminated and (iii) subject to your timely election under COBRA, payment or reimbursement of a portion of your COBRA premiums for six (6) months following your termination or, if earlier, until such time as you become eligible for similar coverage through another employer, which benefits shall be paid for by the Company to the same extent that the Company paid for health insurance for your prior to termination, (such amounts described in clauses (i) through (iii) herein, collectively, the "**Severance Benefits**"). You will thereafter be responsible for the payment of COBRA premiums (including, without limitation, all administrative expenses) for any remaining COBRA period. Notwithstanding the foregoing, in the event that the Company determines, in its sole discretion, that the Company may be subject to a tax or penalty pursuant to Code Section 4980D as a result of providing some or all of the payments described in this paragraph, the Company may reduce or eliminate its obligations under this paragraph to the extent it deems necessary, with no offset or other consideration required. The Severance Benefits will be payable or provided in regular instalments in accordance with the Company's or its subsidiary's normal payroll practices over a period of six (6) months commencing on the first payroll date following the date on which the Release Condition is satisfied or in a cash lump sum, solely at the discretion of the Board. For purposes herein, the "**Release Condition**" means your execution, delivery, and non-revocation of the release within 45 days following your termination of employment and "**Cause**" means a reasonable, good faith finding by the Board that you: (i) committed, been convicted of, or entered a plea of guilty or nolo contendere or no contest with respect to, (x) any felony or (y) any misdemeanour involving dishonesty or moral turpitude; (ii) engaged in gross negligence, wilful misconduct, or any bad-faith act that is, or could reasonably be expected to be, materially injurious to the business or

reputation of the Company; (iii) committed an act of fraud, embezzlement, theft, or misappropriation against the Company or otherwise in the course of your employment with, or the performance of duties for, the Company; (iv) substantially failed to perform your duties in respect of your employment diligently and in a manner consistent with prudent business practice; (v) failed to execute and carry out any reasonable lawful directive of the Board that is related to the business of the Company; or (vi) engaged in any act or omission that is materially injurious the business, financial condition, or operations of the Company.

Severance During the Change in Control Protection Period

In the event you are terminated without Cause or resign for Good Reason (as defined below) within ninety (90) days prior to, or twelve (12) months following the consummation of a Change in Control (the "**Change in Control Protection Period**"), then, subject to the Release Condition described above, the amount of the Severance Benefits described above will be twelve (12) instead of six (6) and will be paid or provided over twelve (12) months (instead of 6-months, unless the Board determines to pay or provide such Severance Benefits in a cash lump sum in sole discretion) plus any then outstanding equity then held by you that is unvested, will vest in full. For purposes herein, "**Change in Control**" means an event (i) which constitutes a Deemed Liquidation Event as defined in the Company's Articles of Association, as may be amended from time to time, and (ii) in which the Company's Series A investors receive a multiple of invested capital of at least two (2) times their original investment, and "**Good Reason**" means your resignation based on any of the following events without your written consent, (a) a material diminution in your authority, duties or responsibilities; (b) a material diminution in reporting relationship from that determined by an acquirer at the time of such Change of Control; (c) a material diminution in your annual base salary except if the base salaries of a significant number of other executives and members of senior management of the Company also are proportionately reduced, whether or not such reduction is voluntary on your part or on the part of such other executives and senior management; (d) the Company's relocation of your primary work location outside a 40-mile radius of San Francisco that increases your one-way driving distance by more than 40 miles; (e) any other action or inaction that constitutes a material breach of the terms of an applicable employment agreement. To constitute a resignation for Good Reason: (i) you must provide written notice to the Company within thirty (30) days of the initial existence of the event constituting Good Reason, (ii) you may not terminate your employment unless the Company fails to remedy the event constituting Good Reason within fifteen (15) days after such notice has been deemed given pursuant to this offer letter, and (iii) you must terminate employment with the company no later than fifteen (15) days after the end of the 15-day cure period in which the Company fails to remedy the event constituting Good Reason.

Section 409A

This offer letter is intended to comply with Section 409A of the Internal Revenue Code ("**Section 409A**") or an exemption thereunder and shall be construed and administered in accordance with Section 409A. Notwithstanding any other provision of this offer letter, payments provided under this offer letter may only be made upon an event and in a manner that complies with Section 409A or an applicable exemption. Any payments under this offer letter that may be excluded from Section 409A either as separation pay due to an involuntary separation from service or as a short-term deferral shall be excluded from Section 409A to the maximum extent possible. For purposes

of Section 409A, each instalment payment provided under this offer letter shall be treated as a separate payment. Any payments to be made under this offer letter upon a termination of employment shall only be made upon a "separation from service" under Section 409A. Notwithstanding the foregoing, the Company makes no representations that the payments and benefits provided under this offer letter comply with Section 409A and in no event shall the Company be liable for all or any portion of any taxes, penalties, interest or other expenses that may be incurred by you on account of non-compliance with Section 409A.

Notwithstanding any other provision of this offer letter, if any payment or benefit provided to you in connection with termination of employment is determined to constitute "nonqualified deferred compensation" within the meaning of Section 409A and you are determined to be a "specified employee" as defined in Section 409A(a)(2)(b)(i), then such payment or benefit shall not be paid until the first payroll date to occur following the six-month anniversary of your termination date (the "**Specified Employee Payment Date**") or, if earlier, on the date of your death. The aggregate of any payments that would otherwise have been paid before the Specified Employee Payment Date shall be paid to you in a lump sum on the Specified Employee Payment Date and thereafter, any remaining payments shall be paid without delay in accordance with their original schedule. Whenever in this offer letter a payment or benefit is conditioned on your execution of a release of claims, such release must be executed, and all revocation periods shall have expired, within 45-days after the date of your termination of employment, failing which such payment or benefit shall be forfeited. If such payment or benefit constitutes non-exempt deferred compensation for purposes of Section 409A, and if such 45-day period begins in one calendar year and ends in the next calendar year, the payment or benefit shall not be made or commence before the second such calendar year, even if the release becomes irrevocable in the first such calendar year.

Governing Law

This offer letter shall be governed by the laws of California, without regard to conflict of law principles.

Contingent Offer

This offer is contingent upon:

(a) Verification of your right to work in the United States, as demonstrated by your completion of an I-9 form upon hire and your submission of acceptable documentation (as noted on the I-9 form) verifying your identity and work authorization within three days of your Start Date. For your convenience, a copy of the I-9 Form's List of Acceptable Documents is enclosed for your review.

(b) Your execution of the Company's enclosed (1) Employee Proprietary Information and Invention Assignment Agreement, and (2) Employee Arbitration Agreement.

Representations and Warranties

By accepting this offer, you represent that you are able to accept this job and carry out the work that it would involve without breaching any legal restrictions on your activities, such as non-competition, non-solicitation or other work-related restrictions imposed by a current or former employer. You also represent that you will inform the Company about any such restrictions and

provide the Company with as much information about them as possible, including any agreements between you and your current or former employer describing such restrictions on your activities. You further confirm that you will not remove or take any documents or proprietary data or materials of any kind, electronic or otherwise, with you from your current or former employer to the Company without written authorization from your current or former employer, nor will you use or disclose any such confidential information during the course and scope of your employment with the Company. If you have any questions about the ownership of particular documents or other information, you should discuss such questions with your former employer before removing or copying the documents or information.

By accepting this offer, you acknowledge and agree that, so long as you are employed by the Company or its subsidiary, except upon the prior written consent of the Board, you will not (i) accept any other employment, or (ii) engage, directly or indirectly, in any other business activity (whether or not pursued for pecuniary advantage) that is or may be in conflict with, or that might place you in a conflicting position to that of, the Company.

We are excited at the prospect of you joining our team. If you have any questions about the above details, please call me immediately. If you wish to accept this position, please sign below and return this letter to me. This offer is open for you to accept through 6/26, at which time it will be deemed to be withdrawn.

I look forward to hearing from you.

Yours sincerely,

Anat Naschitz

On behalf of 89bio Ltd.

Signed /s/ Anat Naschitz

Acceptance of Offer

I have read, understood and accept all the terms of the offer of employment as set forth in the foregoing letter. I have not relied on any agreements or representations, express or implied, that are not set forth expressly in the foregoing letter, and this letter supersedes all prior and contemporaneous understandings, agreements, representations and warranties, both written and oral, with respect to the subject matter of this letter.

Rohan Palekar

Signed /s/ Rohan Palekar

Date June 26, 2018

Exhibit 10.5

EMPLOYMENT AGREEMENT

This Agreement constitutes an advance notice to the Employee
under the Notice to the Employee Law (Employment Terms), 2002

THIS EMPLOYMENT AGREEMENT (this "**Agreement**" dated as of April 23, 2018, is made and entered by and between 89bio Ltd., a company organized under the laws of the state of Israel, whose registered address is 89 Medinat HaYehudim St., Herzliya, Israel (the "**Company**" and Ram Waisbourd (the "**Employee**").

WHEREAS, the Company wishes to employ the Employee, and the Employee wishes to be employed by the Company, as of May 1, 2018 (the "Commencement Date"), subject to the terms and conditions set forth herein; and

WHEREAS, the parties hereto desire to state the terms and conditions of the Employee's employment by the Company, as set forth below.

NOW, THEREFORE, in consideration of the mutual premises, covenants and other agreements contained herein, the parties hereby agree as follows:

1. **Preamble and Exhibits**

   1.1 The preamble to this agreement and its Exhibits constitute an integral part hereof.

   1.2 The titles and subtitles used in this Agreement are used for convenience only and are not to be considered in construing or interpreting this Agreement.

General

2. Position. The Employee shall serve in the position described in **Exhibit A** attached hereto. In addition, the Employee may receive different tasks, from time to time, to correlate with Company's necessities.

3. Conscientious Discharge of Duties. The Employee shall perform and discharge his duties and obligations hereunder diligently, faithfully, conscientiously and in furtherance of the Company's best interests and its good name. The Employee agrees and undertakes to inform the Company immediately and without delay after becoming aware of any affair and/or matter that may in any way raise a conflict of interest between the Employee (or any member of Employee's family) and the Company (including its affiliates) and/or the interests of the Company (including its affiliates), and to report and discuss problems that might prevent performing his tasks in an effective manner. During his employment by the Company, the Employee shall not receive any payment, compensation or benefit from any third party in connection, directly or indirectly, with the execution of the Employee's position in the Company.

4. Compliance with Company's Policies and Applicable Law. Employee will comply, the all the Company's disciplinary regulations, work-rules, policies, procedures and objectives, as in effect from time to time, and will adhere to any applicable law or provision, pertaining to his employment hereunder. In addition, the Employee will document the products of his work, and all relevant information that was generated in the course of his work, in a confidential and orderly manner that will enable access and use of such information by authorized people in the Company.

5. Scope of Employment. The scope of position of the Employee will be as set forth in **Exhibit A** hereto. The Employee shall devote his entire working time, best efforts, know-how, expertise, experience and attention to the business and affairs of the Company and to the performance of his duties to the Company, and shall not undertake or accept any other paid or unpaid employment or occupation or engage in or be associated with, directly or indirectly, any other business and/or commercial activity, except with the prior written consent of the Company's management.

6. Location. The Employee shall perform his duties hereunder at the Company's facilities in Israel, but he understands and agrees that his position may involve significant domestic and international travel which may result in extensive period time.

7. Employees Representations and Warranties. The Employee represents and warrants that the execution and delivery of this Agreement and the fulfillment of its terms: (i) will not constitute a default under or conflict with any agreement or other instrument to which he is a party or by which he is bound; and (ii) do not require the consent of any person or entity. Further, with respect to any past engagement of the Employee with third parties and with respect to any permitted engagement of the Employee with any third party during the term of his engagement with the Company (for purposes hereof, such third parties shall be referred to as "**Other Employers**") the Employee represents, warrants and undertakes that (a) his engagement with the Company is and/or will not be in breach of any of his undertakings toward Other Employers, and (b) he will not disclose to the Company, nor use, in provision of any services to the Company, any trade secrets, proprietary or confidential information belonging to any Other Employer.

8. Assignment. Neither this Agreement nor any right or interest hereunder shall be assignable or transferable by the Employee, his beneficiaries or legal representatives without the prior written consent of the Company. This Agreement shall inure to the benefit of and be enforceable by the Employee's legal personal representative.

9. The Company shall be entitled to transfer or assign its rights and/or obligations under this Agreement, in whole or in part, in its sole discretion. Without derogating from the generality of the aforesaid the Employee shall provide the services under this Agreement to the Company, and/or to companies affiliated with the Company in accordance with the Company's instructions.

Use of Company Computers and Email Monitoring

10. During his employment with the Company and in connection therewith, the Employee may be provided with a personal computer station ("**Computer**") and/or a laptop computer ("**Laptop**") and a personal e-mail account and address ("**E-mail**"), each of which shall be deemed to be solely the property of the Company.

11. Employee shall not install and/or download any software or hardware on the Computer or Laptop or on any other computers in the Company's possession (i) unless the Company has sufficient and valid license; or (ii) unless prior written consent was given by the Company.

Term of Employment

12. Term. Subject to and contingent upon the fulfillment of the Precedent Conditions as specified above this Agreement shall become effective on the Commencement Date and shall continue until it is terminated pursuant to the terms set forth herein.

13. Termination at Will. Either party may terminate the employment relationship hereunder at its/his own discretion at any time, for any reason, by giving the other party a prior written notice as set forth in **Exhibit A** (the "**Notice Period**").

14. Termination for Cause. Notwithstanding the aforesaid, in the event of Cause (as defined below) the Company shall be entitled to terminate this Agreement immediately and the employment relationship between the parties shall be deemed effectively terminated upon delivery of the Company's notice to that extent. The term "Cause" shall mean: (a) a serious breach of trust including but not limited to theft, embezzlement, self-dealing, prohibited disclosure to unauthorized persons or entities of confidential or proprietary information of or relating to the Company or its affiliates or the engaging by the Employee in any prohibited business competitive to the business of the Company or any of its affiliates or any other breach of the Employees obligations under **Exhibit B**; or (b) willful failure to perform any of the Employee's fundamental functions or duties hereunder or the directives of the Employee's superior; (c) any willful act or gross negligence of the Employee resulting in material loss to the Company or material damage to the reputation of the Company or any affiliates; or (d) any other cause justifying termination or dismissal in circumstances in which the Company can deny the Employee severance payment under applicable law.

15. Notice Period; End of Relations. During the Notice Period and unless otherwise determined by the Company in a written notice to the Employee, the employment relationship hereunder shall remain in full force and effect, the Employee shall be obligated to continue to discharge and perform all of his duties and obligations with Company, and the Employee shall cooperate with the Company and use his best efforts to assist the Company with the integration into the Company's organization of the person(s) who will assume the Employee's responsibilities. Upon termination of Employee's employment with the Company, for any reason whatsoever, the Employee shall be required to return to Company any properties, equipment, documents and any other materials of the Company (e.g., company car, cellular phone, Laptop, Computer, and/or any other equipment) which were provided (if provided) to his or which are otherwise in his possession. Employee shall have no (and hereby waives any) rights of lien with respect to any such properties, equipment, documents and materials of the Company.

16. Notwithstanding the provisions of Section 15 above to the contrary Company shall be entitled to waive Employee's employment with Company during the Notice Period or any part thereof, at any time prior to the completion of the Notice Period. In the event Company waives Employee's services with Company during the Notice Period as aforesaid, employer-employee relationship between the parties will come to an end forthwith or as of the effective date of such waiver (as applicable), and the Company shall pay the Employee a one-time amount equal to the Salary (including managers insurance, study fund, expenses, company car and all other benefits) that would have otherwise been paid to the Employee during the Notice Period or the remainder of the Notice Period in the event the termination becomes effective during the Notice Period, in lieu of such Notice Period, or part thereof.

17. Notwithstanding anything herein to the contrary, the provisions of the Proprietary Information, Assignment of Inventions and Non-Competition Agreement by and between the Company and the Employee (in the form attached hereto as **Exhibit B**) shall survive termination or expiration of this Agreement for any reason whatsoever.

Proprietary Information; Assignment of Inventions and Non-Competition

18. By executing this Agreement, the Employee confirms and agrees to the provisions of the Company's Proprietary Information Assignment of Inventions and Non-Competition Agreement attached as **Exhibit B** hereto.

Salary and Additional Compensation; Managers Insurance/Pension Fund

19. Base Salary. The Company shall pay to the Employee as compensation for the employment services an aggregate base salary in the amount set forth in **Exhibit A** (the "**Base Salary**").

20. Global Overtime Remuneration. Since Both the Company and the Employee expect that the work load at the Company may require from time to time to extensive volume of working hours the Company will pay to the Employee on a monthly basis, in addition to the Base Salary and in consideration of an services that the Employee may render at overtime hours, a global gross amount as set forth in **Exhibit A** hereto (the "**Global Overtime Remuneration**"), which reflects full compensation for the amount of overtime hours which the Employee is expected to work per month. The Global Overtime Remuneration has been determined according to Company's knowledgeable estimation of the scope of overtime hours per month which the Employee's position requires. The Base Salary together with the Global Overtime Remuneration shall constitute the "**Salary**" for purposes of this Agreement. Employee acknowledges and agrees that he shall not be allowed to provide work beyond the aforementioned scope of overtime hours, without receiving prior written consent from the Company to do so, and that he shall not be entitled to any form of salary or compensation, or any other rights or claims whatsoever, for any work performed beyond the aforementioned limited scope of hours, unless Employee has received prior written consent to perform such work beyond the aforementioned scope of overtime hours.

21. It is hereby agreed, that the Global Overtime Remuneration is and shall be a real and true supplement above and beyond the Employee's Base Salary. However, without derogating from the nature of the Global Overtime Remuneration, the Salary (i.e. Base Salary together with the Global Overtime Remuneration) shall be taken into account as a basis for the purpose of calculating the Employee's social entitlements and rights according to this Agreement including social benefits and severance payments. For the avoidance of any doubt no other payment right or benefit to which the Employee is entitled under the Agreement or by law shall be taken into account in such calculation. Except as specifically set forth herein the Salary includes any and all payments to which the Employee is entitled from the Company hereunder and under any applicable law regulation, extension order or agreement.

22. The Salary is to be paid to the Employee in accordance with the Company's normal and reasonable payroll practices no later than the 9th day of each calendar month after the month for which the Salary is paid, after deduction of applicable taxes and like payments

23. Recording of Hours. Per the requirements under applicable law, the Employee shall cooperate with the Company in maintaining a record of the number of hours of work performed, in accordance with the Company's policy and instructions.

24. Special Compensation.

    It is hereby acknowledged and agreed, that an amount equal to 10% of the Salary is paid to the Employee as special compensation for any contributions and/or inventions that have been and/or shall be created, developed and/or conceived by the Employee, including, without limitations, "service inventions" as defined in the Israeli Patent Law, 5727-1967, (the "**Patent Law**") (if and to the extent there are and/or will be any), for the assignment thereof to the Company, for any rights, benefits, royalties and other compensation, to the extent that they shall be awarded by a judicial body, including under Section 134 of the Patent Law or under the Copyright Law 5768-2007, in connection with such contributions and/or inventions, and for the Employee's waiver of any moral rights, benefits, royalties and/or other compensation in connection therewith pursuant to Sections 7 to 15 of **Exhibit B** hereto.

25. Insurance Scheme and Social Benefits. The Company and the Employee will obtain and maintain managers insurance or a pension fund according to the Employee's choice (the "**Insurance Scheme**"), as follows:

    25.1 Should the Employee elect to obtain a managers insurance policy (the "**Managers Insurance**"): *(i)* Severance—the Company will pay an amount equal to 8½% of the Salary; *(ii)* Pension and disability insurance at the rate required to insure 75% of the Employee's Salary—the Company will pay an amount equal to 6 ½% of the Salary. In any event the amount allocated to the pension component alone will not be less than 5% of the Salary. In the event that it will be necessary to increase the costs of the disability component so that the Employer's contribution will exceed the amount of 6½% of the Salary, the aggregate cost to the Company for purchasing the disability component together with the contributions towards the pension component, will not be greater than 7.5% of Salary. *(iii)* The Company will deduct from the Employee's Salary a sum equal to 6% of the Salary as Employee's contribution.

25.2 Should the Employee elect to obtain a pension fund (the "**Pension Fund**"): *(i)* Severance the Company will pay an amount equal to 8½% of the Salary; *(ii)* Pension the Company will pay an amount equal to 6½% of the Salary, and will deduct from the Employee's Salary a sum equal to 6% of the Salary as Employee's contribution.

26. Section 14. All amounts deducted and paid by the Company in accordance with Section 25 above will be transferred to the Employee upon the termination of the Employee's employment (other than in circumstances in which the Employee's entitlement to severance compensation may be denied by a final court decision and/or under applicable law) and the same shall be in lieu of the Company's statutory obligation to pay severance pay, if required, for all intents and purposes pursuant to the Severance Pay Law, 5723-1963 (the "**Severance Pay Law**"), and the Company shall be relieved from any additional or other obligation to pay the Employee severance payment. The parties acknowledge and agree that the agreement set forth in this provision is in accordance with Section 14 of the Severance Pay Law, 1963, and in accordance with the general approval of the Labor Minister dated June 9, 1998, promulgated under said Section 14, a copy of which is attached hereto as **Exhibit C**.

27. The Employee will bear any and all taxes applicable to the Employee in connection with any amounts paid by the Employee and/or Company to the Insurance Scheme under Section 25 above.

Additional Benefits

28. Vacation. The Employee shall be entitled to the number of vacation days per year as set forth in **Exhibit A**. The Company shall be entitled to direct use of the vacation days, in coordination and agreement with the Employee. Employee shall be required to utilize a minimum of ten (10) leave days annually and if Employee docs not do so, Employee shall be entitled to accrue a maximum of 30 unexploited leave days, except as per the Annual Leave Law 5711-1951.

29. Sick Leave. The Employee entitlement to sick leave shall be in accordance with applicable law, against the presentation of appropriate medical records.

30. Convalescence Pay. The Employee shall be entitled to Convalescence Pay ("**Dmei Havra'a**") if and to extent entitled pursuant to applicable extension order.

31. Additional benefits. Employee shall be entitled to additional benefits if and to the extent set forth in **Exhibit A.**

Miscellaneous

32. References to the masculine gender shall include the feminine, unless the context otherwise requires.

33. The laws of the State of Israel shall apply to this Agreement and the sole and exclusive place of jurisdiction in any matter arising out of or in connection with this Agreement shall be the Tel-Aviv Regional Labor Court.

34. The provisions of this Agreement are in lieu of the provisions of any collective bargaining agreement, and therefore, no collective bargaining agreement shall apply with respect to the relationship between the parties hereto (subject to the applicable provisions of law).

35. No failure, delay or forbearance of either party in exercising any power or right hereunder shall in any way restrict or diminish such party's rights and powers under this Agreement or operate as a waiver of any breach or nonperformance by either party of any terms or conditions hereof.

36. In the event it shall be determined under any applicable law that a certain provision set forth in this Agreement is invalid or unenforceable, such determination shall not affect the remaining provisions of this Agreement unless the business purpose of this Agreement is substantially frustrated thereby.

37. Withholdings shall be deducted at source from payments made hereunder to the Employee according to applicable law, including, but not limited to, Israeli income tax, National Security ("**Bituacb Leumi**") and Health Tax. The Employee shall bear any tax imposed in connection with the payments and benefits provided for in this Agreement.

38. The preface and Exhibits to this Agreement constitute an integral and indivisible part hereof.

39. This Agreement constitutes the entire understanding and agreement between the parties hereto, supersedes any and all prior discussions, agreements and correspondence with regard to the subject matter hereof, and may not be amended, modified or supplemented in any respect, except by a subsequent writing executed by both parties hereto.

40. The Employee acknowledges and confirms that all terms of the Employee's employment are personal and confidential, and undertake to keep such terms in confidence and refrain from disclosing such terms to any third party.

41. Sexual Harassment. Employee acknowledges that the Company complies with the Prevention of Sexual Harassment Law and Regulations, and that it has a Prevention of Sexual Harassment Charter of which Employee has been made aware. Employee undertakes to comply with such Law, Regulations and Charter, all of which may be amended from time to time.

IN WITNESS WHEREOF, the parties have duly executed this Employment Agreement on the day and year set forth above.

/s/ Anat Naschitz	/s/ Ram Waisbourd
89bio Ltd.	**Ram Waisbourd**
By: Anat Naschitz	
Title: Director	

Exhibit A

Name of Employee:	Ram Waisbourd.
Position:	COO and CBO.
Scope of Position:	Full-time.
Supervisor:	The CEO of the Company
Notice Period:	The Notice Period shall be ninety (90) days.
Base Salary:	NIS 43,200 per month.
Global Overtime Compensation:	NIS 10,800 per month.
Vacation Days per Year:	In accordance with applicable law but no less than 22 days.
Travel Expenses:	In Accordance with applicable law.
Education Fund:	The Company and Employee shall maintain an advanced study fund (Keren Hishtalmut) according to applicable law (the "**Fund**") and make it effective upon three (3) months after the Commencement Date. At this time the funds allocated to the Fund will include retroactive contributions as of the Commencement Date and shall thereafter be made on a monthly basis as set forth below. The Company shall contribute to such Fund an amount equal to 7.5% of the Salary, subject to Employee's contribution of an additional 2.5% of the Salary. Notwithstanding anything herein to the contrary, neither party shall contribute nor shall the Company deduct from each monthly Salary an amount greater than the maximum amount exempt from tax payment by applicable laws. The Employee shall be responsible for any tax imposed in connection, with the above fund and/or in connection with the above fund and/or in connection with the Company's contributions thereto. Employee hereby instructs the Company to transfer to such Fund the amount of the Employee's and the Company's contribution from each monthly Salary payment.
Options:	Subject to the approval of the Board of the Directors of the Company (the "**Board**") and the Company's share option plan to be adopted by the Company following the date hereof, the Company will grant Employee Options to purchase 608,318 Ordinary Shares of the Company, par value NIS 0.01 each (the "**Options**"), representing 2.0% of the Company's share capital on

a fully diluted basis assuming an investment amount of US$20 million in the Company, all in accordance with the grant terms as shall be determined by the Board. The Options shall be vested quarterly and exercisable over a period of four (4) years of the date of their grant.

Subject to the approval of the Board, in the event that the Employee's employment with the Company (or its successor) is terminated including by changes in terms of employment which are considered as termination under the Israeli Severance Pay law by the Company (or its successor) without cause (other than change in title or scope of work description due to organizational adjustments following the **M&A**), within a period of twelve (12) months following **M&A** of the Company all the unvested Options shall be fully vested and exercisable. Without derogating from the foregoing, upon the completion of twelve (12) months of employment with the company (or its successor) following the M&A all unvested Options shall be fully vested and exercisable.

Car-related Expenses: The Company will pay Employee an amount of NIS 4,000 per month in connection with car-related expenses. Employee shall not be required to present documentation regarding the car expenses.

Performance Bonus: The Employee shall be eligible to an "on-target" bonus in the amount of approximately 20% of the Employee's annual Salary in accordance with the Company bonus policy.

Exhibit 10.6

89bio Ltd.

November 20, 2018

Hank Mansbach, M.D.

Dear Hank:

Offer and Position

We are very pleased to extend an offer of employment to you for the position of Chief Medical Officer ("**CMO**") of 89bio Ltd. (the "**Company**"). This offer of employment is conditioned on your satisfactory completion of certain requirements, as more fully explained in this letter. Your employment is subject to the terms and conditions set forth in this letter. Your employment will be administered under a US subsidiary of the Company.

Duties

In your capacity as a CMO, you will perform duties and responsibilities that are commensurate with your position and such other duties as may be assigned to you by the CEO from time to time, provided that such duties are consistent with your position. You will report directly to Chief Executive Officer (CEO) of the company. You agree to devote your full business time, attention and best efforts to the performance of your duties and to the furtherance of the Company's interests.

Location

Your principal place of employment shall in the San Francisco Bay area, subject to business travel as needed to properly fulfil your employment duties and responsibilities.

Start Date

Subject to satisfaction of all of the conditions described in this letter, your anticipated start date is December 17, 2018.

Base Salary

In consideration of your services, you will be paid an initial base salary of $380,000 per year, subject to review for increase only by the Chief Executive Officer and Board from time to time, payable in accordance with the standard payroll practices of the Company or its US subsidiary and subject to all withholdings and deductions as required by law.

Annual Bonus

Each year, you will have an opportunity to earn a target bonus of 35% of your base salary (the "**Target Bonus**"). Your actual bonus amount will be determined based on a combination of Company results and individual performance against the applicable performance goals established by the CEO. Any annual bonus with respect to a particular calendar year will be paid within 4 months following the end of the year for which the annual bonus relates. For any partial year of employment you will receive a pro-rated annual bonus based on the number of days you are employed during the year.

You must remain continuously employed through the end of the applicable calendar year to be eligible to receive an annual bonus payment for a particular calendar year.

One-Time Payment

You will receive a one-time payment of $75,000 payable within thirty (30) days of your Start Date. If you voluntarily leave the Company before completing twelve (12) months of service from your Start Date, you will be required to repay the entire gross amount of the one-time payment. As income, this one-time payment is subject to taxation and the Company will make applicable withholdings at the time of payment.

Expenses

The Company or its US subsidiary will reimburse you only for out of pocket business related expenses reasonably incurred in the performance of your duties, as approved by the Board in the annual budgeting process and in accordance with any expense claiming policies and guidelines promulgated by the Company or its US subsidiary from time to time.

Equity Grants

As soon as practicable following the Start Date, the Company will recommend that the Board grant you an option to purchase an aggregate of 610, 536 Ordinary Shares of the Company (representing 1.50% of the issued and outstanding shares of the Company as of the close of the Series A 2nd tranche), at a per share exercise price equal to the fair market value of such shares on the date of grant. The Company will recommend to the Board that such 1.50% stake be trued up if and when the Company closes the third tranche of its Series A financing. The options will be governed by the Company's 2018 Equity Incentive Plan (as supplemented by the Company's 2018 United States Sub-Plan) and a stock option agreement to be entered into between the Company and you. The stock option agreement will provide, among other things, that, (i) subject to your continued employment with the Company or its subsidiary on each applicable vesting date, your options shall vest over a four-year period, 25% upon the one-year anniversary of the Start Date (or the third tranche date in respect of any true up grant), and the remaining 75% in equal quarterly instalments over a period of three years thereafter, and (ii) in the event that you are terminated without Cause (as defined below) or resign for Good Reason (as defined below) within the Change in Control Protection Period (as defined below), then, subject to the Release Condition described below, any of your options then subject to vesting shall become fully vested as of the date of such termination.

Benefits and Perquisites

You will be eligible to participate in the employee benefit plans and programs generally available to the Company's senior executives in the United States. You will be entitled to paid vacation in accordance with the Company's or its US subsidiary's policies in effect from time to time. The Company and its subsidiaries reserve the right to amend, modify or terminate any of its benefit plans or programs at any time and for any reason.

Withholding

All forms of compensation paid to you as an employee of the Company or its subsidiary shall be less all applicable withholdings.

At-will Employment

Your employment with the Company or its subsidiary will be for no specific period of time. Rather, **your employment will be at-will, meaning that any party may terminate the employment relationship at any time, with or without cause, and with or without notice and for any reason or no particular reason**. Although your compensation and benefits may change from time to time, the at-will nature of your employment may only be changed by an express written agreement signed by both you and the Chief Executive Officer.

Severance outside of Change in Control Protection Period

If your employment with the Company or its subsidiary is involuntarily terminated by the Company without Cause (as defined below) and not due to a breach by you of the terms and conditions of this letter (including, but not limited to, a breach of any of the representations contained herein, the enclosed Employee Proprietary Information and Invention Assignment Agreement (the "**PIIA**") or the Employee Arbitration Agreement) at any time outside of the Change in Control Protection Period (as defined below), subject to your execution of a release of claims in a form provided by the Company, you will be eligible to receive severance in an amount equal to: (i) four 4) months of base salary at the rate then in effect, (ii) a pro-rata amount of the Target Bonus based on the number of months you were employed with the Company for the year in which your employment is terminated and (iii) subject to your timely election under COBRA, payment or reimbursement of a portion of your COBRA premiums for four (4) months following your termination or, if earlier, until such time as you become eligible for similar coverage through another employer, which benefits shall be paid for by the Company to the same extent that the Company paid for health insurance for your prior to termination, (such amounts described in clauses (i) through (iii) herein, collectively, the "**Severance Benefits**"). You will thereafter be responsible for the payment of COBRA premiums (including, without limitation, all administrative expenses) for any remaining COBRA period. Notwithstanding the foregoing, in the event that the Company determines, in its sole discretion, that the Company may be subject to a tax or penalty pursuant to Code Section 4980D as a result of providing some or all of the payments described in this paragraph, the Company may reduce or eliminate its obligations under this paragraph to the extent it deems necessary, with no offset or other consideration required. The Severance Benefits will be payable or provided in regular instalments in accordance with the Company's or its subsidiary's normal payroll practices over a period of four

(4) months commencing on the first payroll date following the date on which the Release Condition is satisfied or in a cash lump sum, solely at the discretion of the Board. For purposes herein, the "**Release Condition**" means your execution, delivery, and non-revocation of the release within 45 days following your termination of employment and "**Cause**" means a reasonable, good faith finding by the Chief Executive Officer or the Board that you: (i) committed, been convicted of, or entered a plea of guilty or nolo contendere or no contest with respect to, (x) any felony or (y) any misdemeanour involving dishonesty or moral turpitude; (ii) engaged in gross negligence, wilful misconduct, or any bad-faith act that is, or could reasonably be expected to be, materially injurious to the business or reputation of the Company; (iii) committed an act of fraud, embezzlement, theft, or misappropriation against the Company or otherwise in the course of your employment with, or the performance of duties for, the Company; (iv) substantially failed to perform your duties in respect of your employment diligently and in a manner consistent with prudent business practice; (v) failed to execute and carry out any reasonable lawful directive of the Chief Executive Officer or the Board that is related to the business of the Company; or (vi) engaged in any act or omission that is materially injurious the business, financial condition, or operations of the Company.

Severance During the Change in Control Protection Period

In the event you are terminated without Cause or resign for Good Reason (as defined below) within ninety (90) days prior to, or twelve (12) months following the consummation of a Change in Control (the "**Change in Control Protection Period**"), then, subject to the Release Condition described above, the amount of the Severance Benefits described above will be six (6) instead of four (4) and will be paid or provided over six (6) months (instead of 4-months, unless the Board determines to pay or provide such Severance Benefits in a cash lump sum in sole discretion) plus any then outstanding equity then held by you that is unvested, will vest in full. For purposes herein, "**Change in Control**" means an event (i) which constitutes a Deemed Liquidation Event as defined in the Company's Articles of Association, as may be amended from time to time, and (ii) in which the Company's Series A investors receive a multiple of invested capital of at least two (2) times their original investment, and "**Good Reason**" means your resignation based on any of the following events without your written consent, (a) a material diminution in your authority, duties or responsibilities; (b) a material diminution in reporting relationship from that determined by an acquirer at the time of such Change of Control; (c) a material diminution in your annual base salary except if the base salaries of a significant number of other executives and members of senior management of the Company also are proportionately reduced, whether or not such reduction is voluntary on your part or on the part of such other executives and senior management; (d) the Company's relocation of your primary work location outside a 40-mile radius of San Francisco that increases your one-way driving distance by more than 40 miles; (e) any other action or inaction that constitutes a material breach of the terms of an applicable employment agreement. To constitute a resignation for Good Reason: (i) you must provide written notice to the Company within thirty (30) days of the initial existence of the event constituting Good Reason, (ii) you may not terminate your employment unless the Company fails to remedy the event constituting Good Reason within fifteen (15) days after such notice has been deemed given pursuant to this offer letter, and (iii) you must terminate employment with the company no later than fifteen (15) days after the end of the 15-day cure period in which the Company fails to remedy the event constituting Good Reason.

Section 409A

This offer letter is intended to comply with Section 409A of the Internal Revenue Code ("**Section 409A**") or an exemption thereunder and shall be construed and administered in accordance with Section 409A. Notwithstanding any other provision of this offer letter, payments provided under this offer letter may only be made upon an event and in a manner that complies with Section 409A or an applicable exemption. Any payments under this offer letter that may be excluded from Section 409A either as separation pay due to an involuntary separation from service or as a short-term deferral shall be excluded from Section 409A to the maximum extent possible. For purposes of Section 409A, each instalment payment provided under this offer letter shall be treated as a separate payment. Any payments to be made under this offer letter upon a termination of employment shall only be made upon a "separation from service" under Section 409A. Notwithstanding the foregoing, the Company makes no representations that the payments and benefits provided under this offer letter comply with Section 409A and in no event shall the Company be liable for all or any portion of any taxes, penalties, interest or other expenses that may be incurred by you on account of noncompliance with Section 409A.

Notwithstanding any other provision of this offer letter, if any payment or benefit provided to you in connection with termination of employment is determined to constitute "nonqualified deferred compensation" within the meaning of Section 409A and you are determined to be a "specified employee" as defined in Section 409A(a)(2)(b)(i), then such payment or benefit shall not be paid until the first payroll date to occur following the six-month anniversary of your termination date (the "**Specified Employee Payment Date**") or, if earlier, on the date of your death. The aggregate of any payments that would otherwise have been paid before the Specified Employee Payment Date shall be paid to you in a lump sum on the Specified Employee Payment Date and thereafter, any remaining payments shall be paid without delay in accordance with their original schedule. Whenever in this offer letter a payment or benefit is conditioned on your execution of a release of claims, such release must be executed, and all revocation periods shall have expired, within 45-days after the date of your termination of employment, failing which such payment or benefit shall be forfeited. If such payment or benefit constitutes non-exempt deferred compensation for purposes of Section 409A, and if such 45-day period begins in one calendar year and ends in the next calendar year, the payment or benefit shall not be made or commence before the second such calendar year, even if the release becomes irrevocable in the first such calendar year.

Governing Law

This offer letter shall be governed by the laws of California, without regard to conflict of law principle.

Contingent Offer

This offer is contingent upon:

(a) Verification of your right to work in the United States, as demonstrated by your completion of an I-9 form upon hire and your submission of acceptable documentation (as noted on the I-9 form) verifying your identity and work authorization within three days of your Start Date. For your convenience, a copy of the I-9 Form's List of Acceptable Documents is enclosed for your review.

(b) Your execution of the Company's enclosed (1) Employee Proprietary Information and Invention Assignment Agreement, and (2) Employee Arbitration Agreement.

Representations and Warranties

By accepting this offer, you represent that you are able to accept this job and carry out the work that it would involve without breaching any legal restrictions on your activities, such as non-competition, non-solicitation or other work-related restrictions imposed by a current or former employer. You also represent that you will inform the Company about any such restrictions and provide the Company with as much information about them as possible, including any agreements between you and your current or former employer describing such restrictions on your activities. You further confirm that you will not remove or take any documents or proprietary data or materials of any kind, electronic or otherwise, with you from your current or former employer to the Company without written authorization from your current or former employer, nor will you use or disclose any such confidential information during the course and scope of your employment with the Company. If you have any questions about the ownership of particular documents or other information, you should discuss such questions with your former employer before removing or copying the documents or information.

By accepting this offer, you acknowledge and agree that, so long as you are employed by the Company or its subsidiary, except upon the prior written consent of the Chief Executive Officer, you will not (i) accept any other employment, or (ii) engage, directly or indirectly, in any other business activity (whether or not pursued for pecuniary advantage) that is or may be in conflict with, or that might place you in a conflicting position to that of, the Company.

We are excited at the prospect of you joining our team. If you have any questions about the above details, please call me. If you wish to accept this position, please sign below and return this letter to me. This offer is open for you to accept through December 1, 2018, at which time it will be deemed to be withdrawn.

I look forward to hearing from you.

Yours sincerely,

Rohan Palekar

On behalf of 89bio Ltd.

Signed /s/ Rohan Palekar

Date November 26, 2018

Acceptance of Offer

I have read, understood and accept all the terms of the offer of employment as set forth in the foregoing letter. I have not relied on any agreements or representations, express or implied, that are not set forth expressly in the foregoing letter, and this letter supersedes all prior and contemporaneous understandings, agreements, representations and warranties, both written and oral, with respect to the subject matter of this letter.

Hank Mansbach, M.D.

Signed /s/ Hank Mansbach M.D.

Date November 26, 2018

Exhibit 10.7

February 28, 2019

Quoc Le-Nguyen

Dear Quoc:

Offer and Position

We are very pleased to extend an offer of employment to you for the position of Chief Technical Operations Officer ("**CTO**") of 89bio Ltd. (the "**Company**"). This offer of employment is conditioned on your satisfactory completion of certain requirements, as more fully explained in this letter. Your employment is subject to the terms and conditions set forth in this letter. Your employment will be administered under a US subsidiary of the Company.

Duties

In your capacity as a CTO, you will perform duties and responsibilities that are commensurate with your position and such other duties as may be assigned to you by the CEO from time to time, provided that such duties are consistent with your position. You will report directly to Chief Executive Officer (CEO) of the company. You agree to devote your full business time, attention and best efforts to the performance of your duties and to the furtherance of the Company's interests.

Location

Your principal place of employment shall in the San Francisco Bay area, subject to business travel as needed to properly fulfil your employment duties and responsibilities.

Start Date

Subject to satisfaction of all of the conditions described in this letter, your anticipated start date is March 18, 2019.

Base Salary

In consideration of your services, you will be paid an initial base salary of $340,000 per year, subject to review for increase only by the Chief Executive Officer and Board from time to time, payable in accordance with the standard payroll practices of the Company or its US subsidiary and subject to all withholdings and deductions as required by law.

Annual Bonus

Each year, you will have an opportunity to earn a target bonus of 30% of your base salary (the "**Target Bonus**"). Your actual bonus amount will be determined based on a combination of Company results and individual performance against the applicable performance goals established by the CEO.

Any annual bonus with respect to a particular calendar year will be paid within 4 months following the end of the year for which the annual bonus relates. For any partial year of employment you will receive a pro-rated annual bonus based on the number of days you are employed during the year.

You must remain continuously employed through the end of the applicable calendar year to be eligible to receive an annual bonus payment for a particular calendar year.

Expenses

The Company or its US subsidiary will reimburse you only for out of pocket business related expenses reasonably incurred in the performance of your duties, as approved by the Board in the annual budgeting process and in accordance with any expense claiming policies and guidelines promulgated by the Company or its US subsidiary from time to time.

Equity Grants

As soon as practicable following the Start Date, the Company will recommend that the Board grant you an option to purchase an aggregate of 404,159 Ordinary Shares of the Company (representing 1.00% of the issued and outstanding shares of the Company as of the close of the Series A 2nd tranche), at a per share exercise price equal to the fair market value of such shares on the date of grant. The Company will recommend to the Board that such 1.00% stake be trued up if and when the Company closes the third tranche of its Series A financing. The options will be governed by the Company's 2018 Equity Incentive Plan (as supplemented by the Company's 2018 United States Sub-Plan) and a stock option agreement to be entered into between the Company and you. The stock option agreement will provide, among other things, that, (i) subject to your continued employment with the Company or its subsidiary on each applicable vesting date, your options shall vest over a four-year period, 25% upon the one-year anniversary of the Start Date (or the third tranche date in respect of any true up grant), and the remaining 75% in equal quarterly instalments over a period of three years thereafter, and (ii) in the event that you are terminated without Cause (as defined below) or resign for Good Reason (as defined below) within the Change in Control Protection Period (as defined below), then, subject to the Release Condition described below, any of your options then subject to vesting shall become fully vested as of the date of such termination.

Benefits and Perquisites

You will be eligible to participate in the employee benefit plans and programs generally available to the Company's senior executives in the United States. You will be entitled to paid vacation in accordance with the Company's or its US subsidiary's policies in effect from time to time. The Company and its subsidiaries reserve the right to amend, modify or terminate any of its benefit plans or programs at any time and for any reason.

Withholding

All forms of compensation paid to you as an employee of the Company or its subsidiary shall be less all applicable withholdings.

At-will Employment

Your employment with the Company or its subsidiary will be for no specific period of time. Rather, **your employment will be at-will, meaning that any party may terminate the employment relationship at any time, with or without cause, and with or without notice and for any reason or no particular reason**. Although your compensation and benefits may change from time to time, the at-will nature of your employment may only be changed by an express written agreement signed by both you and the Chief Executive Officer.

Severance outside of Change in Control Protection Period

If your employment with the Company or its subsidiary is involuntarily terminated by the Company without Cause (as defined below) and not due to a breach by you of the terms and conditions of this letter (including, but not limited to, a breach of any of the representations contained herein, the enclosed Employee Proprietary Information and Invention Assignment Agreement (the "**PIIA**") or the Employee Arbitration Agreement) at any time outside of the Change in Control Protection Period (as defined below), subject to your execution of a release of claims in a form provided by the Company, you will be eligible to receive severance in an amount equal to: (i) three (3) months of base salary at the rate then in effect, (ii) a pro-rata amount of the Target Bonus based on the number of months you were employed with the Company for the year in which your employment is terminated and (iii) subject to your timely election under COBRA, payment or reimbursement of a portion of your COBRA premiums for three (3) months following your termination or, if earlier, until such time as you become eligible for similar coverage through another employer, which benefits shall be paid for by the Company to the same extent that the Company paid for health insurance for your prior to termination, (such amounts described in clauses (i) through (iii) herein, collectively, the "**Severance Benefits**"). You will thereafter be responsible for the payment of COBRA premiums (including, without limitation, all administrative expenses) for any remaining COBRA period. Notwithstanding the foregoing, in the event that the Company determines, in its sole discretion, that the Company may be subject to a tax or penalty pursuant to Code Section 4980D as a result of providing some or all of the payments described in this paragraph, the Company may reduce or eliminate its obligations under this paragraph to the extent it deems necessary, with no offset or other consideration required. The Severance Benefits will be payable or provided in regular instalments in accordance with the Company's or its subsidiary's normal payroll practices over a period of three (3) months commencing on the first payroll date following the date on which the Release Condition is satisfied or in a cash lump sum, solely at the discretion of the Board. For purposes herein, the "**Release Condition**" means your execution, delivery, and non-revocation of the release within 45 days following your termination of employment and "**Cause**" means a reasonable, good faith finding by the Chief Executive Officer or the Board that you: (i) committed, been convicted of, or entered a plea of guilty or nolo contendere or no contest with respect to, (x) any felony or (y) any misdemeanour involving dishonesty or moral turpitude; (ii) engaged in gross negligence, wilful misconduct, or any bad-faith act that is, or could reasonably

be expected to be, materially injurious to the business or reputation of the Company; (iii) committed an act of fraud, embezzlement, theft, or misappropriation against the Company or otherwise in the course of your employment with, or the performance of duties for, the Company; (iv) substantially failed to perform your duties in respect of your employment diligently and in a manner consistent with prudent business practice; (v) failed to execute and carry out any reasonable lawful directive of the Chief Executive Officer or the Board that is related to the business of the Company; or (vi) engaged in any act or omission that is materially injurious the business, financial condition, or operations of the Company.

Severance During the Change in Control Protection Period

In the event you are terminated without Cause or resign for Good Reason (as defined below) within ninety (90) days prior to, or twelve (12) months following the consummation of a Change in Control (the "**Change in Control Protection Period**"), then, subject to the Release Condition described above, the amount of the Severance Benefits described above will be six (6) instead of three (3) and will be paid or provided over six (6) months (instead of 3-months, unless the Board determines to pay or provide such Severance Benefits in a cash lump sum in sole discretion) plus any then outstanding equity then held by you that is unvested, will vest in full. For purposes herein, "**Change in Control**" means an event (i) which constitutes a Deemed Liquidation Event as defined in the Company's Articles of Association, as may be amended from time to time, and (ii) in which the Company's Series A investors receive a multiple of invested capital of at least two (2) times their original investment, and "**Good Reason**" means your resignation based on any of the following events without your written consent, (a) a material diminution in your authority, duties or responsibilities; (b) a material diminution in reporting relationship from that determined by an acquirer at the time of such Change of Control; (c) a material diminution in your annual base salary except if the base salaries of a significant number of other executives and members of senior management of the Company also are proportionately reduced, whether or not such reduction is voluntary on your part or on the part of such other executives and senior management; (d) the Company's relocation of your primary work location outside a 40-mile radius of San Francisco that increases your one-way driving distance by more than 40 miles; (e) any other action or inaction that constitutes a material breach of the terms of an applicable employment agreement. To constitute a resignation for Good Reason: (i) you must provide written notice to the Company within thirty (30) days of the initial existence of the event constituting Good Reason, (ii) you may not terminate your employment unless the Company fails to remedy the event constituting Good Reason within fifteen (15) days after such notice has been deemed given pursuant to this offer letter, and (iii) you must terminate employment with the company no later than fifteen (15) days after the end of the 15-day cure period in which the Company fails to remedy the event constituting Good Reason.

Section 409A

This offer letter is intended to comply with Section 409A of the Internal Revenue Code ("**Section 409A**") or an exemption thereunder and shall be construed and administered in accordance with Section 409A. Notwithstanding any other provision of this offer letter, payments provided under this offer letter may only be made upon an event and in a manner that complies with Section 409A or an applicable exemption. Any payments under this offer letter that may be excluded from Section 409A either as separation pay due to an involuntary

separation from service or as a short-term deferral shall be excluded from Section 409A to the maximum extent possible. For purposes of Section 409A, each instalment payment provided under this offer letter shall be treated as a separate payment. Any payments to be made under this offer letter upon a termination of employment shall only be made upon a "separation from service" under Section 409A. Notwithstanding the foregoing, the Company makes no representations that the payments and benefits provided under this offer letter comply with Section 409A and in no event shall the Company be liable for all or any portion of any taxes, penalties, interest or other expenses that may be incurred by you on account of noncompliance with Section 409A.

Notwithstanding any other provision of this offer letter, if any payment or benefit provided to you in connection with termination of employment is determined to constitute "nonqualified deferred compensation" within the meaning of Section 409A and you are determined to be a "specified employee" as defined in Section 409A(a)(2)(b)(i), then such payment or benefit shall not be paid until the first payroll date to occur following the six-month anniversary of your termination date (the "**Specified Employee Payment Date**") or, if earlier, on the date of your death. The aggregate of any payments that would otherwise have been paid before the Specified Employee Payment Date shall be paid to you in a lump sum on the Specified Employee Payment Date and thereafter, any remaining payments shall be paid without delay in accordance with their original schedule. Whenever in this offer letter a payment or benefit is conditioned on your execution of a release of claims, such release must be executed, and all revocation periods shall have expired, within 45-days after the date of your termination of employment, failing which such payment or benefit shall be forfeited. If such payment or benefit constitutes non-exempt deferred compensation for purposes of Section 409A, and if such 45-day period begins in one calendar year and ends in the next calendar year, the payment or benefit shall not be made or commence before the second such calendar year, even if the release becomes irrevocable in the first such calendar year.

Governing Law

This offer letter shall be governed by the laws of California, without regard to conflict of law principles.

Contingent Offer

This offer is contingent upon:

(a) Verification of your right to work in the United States, as demonstrated by your completion of an I-9 form upon hire and your submission of acceptable documentation (as noted on the I-9 form) verifying your identity and work authorization within three days of your Start Date. For your convenience, a copy of the I-9 Form's List of Acceptable Documents is enclosed for your review.

(b) Your execution of the Company's enclosed (1) Employee Proprietary Information and Invention Assignment Agreement, and (2) Employee Arbitration Agreement.

Representations and Warranties

By accepting this offer, you represent that you are able to accept this job and carry out the work that it would involve without breaching any legal restrictions on your activities, such as non-competition, non-solicitation or other work-related restrictions imposed by a current or former employer. You also represent that you will inform the Company about any such restrictions and provide the Company with as much information about them as possible, including any agreements between you and your current or former employer describing such restrictions on your activities. You further confirm that you will not remove or take any documents or proprietary data or materials of any kind, electronic or otherwise, with you from your current or former employer to the Company without written authorization from your current or former employer, nor will you use or disclose any such confidential information during the course and scope of your employment with the Company. If you have any questions about the ownership of particular documents or other information, you should discuss such questions with your former employer before removing or copying the documents or information.

By accepting this offer, you acknowledge and agree that, so long as you are employed by the Company or its subsidiary, except upon the prior written consent of the Chief Executive Officer, you will not (i) accept any other employment, or (ii) engage, directly or indirectly, in any other business activity (whether or not pursued for pecuniary advantage) that is or may be in conflict with, or that might place you in a conflicting position to that of, the Company.

We are excited at the prospect of you joining our team. If you have any questions about the above details, please call me. If you wish to accept this position, please sign below and return this letter to me. This offer is open for you to accept through March 3, 2019, at which time it will be deemed to be withdrawn.

I look forward to hearing from you.

Yours sincerely,

Rohan Palekar

On behalf of 89bio Ltd.

Signed /s/ Rohan Palekar

Date February 28, 2019

Acceptance of Offer

I have read, understood and accept all the terms of the offer of employment as set forth in the foregoing letter. I have not relied on any agreements or representations, express or implied, that are not set forth expressly in the foregoing letter, and this letter supersedes all prior and contemporaneous understandings, agreements, representations and warranties, both written and oral, with respect to the subject matter of this letter.

Quoc Le-Nguyen

Signed /s/ Quoc Le-Nguyen

Date March 1, 2019

Exhibit 10.8

July 21, 2019

Ryan Martins

Dear Ryan,

Offer and Position

We are very pleased to extend an offer of employment to you for the position of Chief Financial Officer **("CFO")** of 89bio Ltd. (the "**Company**"**)**. This offer of employment is conditioned on your satisfactory completion of certain requirements, as more fully explained in this letter. Your employment is subject to the terms and conditions set forth in this letter. Your employment will be administered under a US subsidiary of the Company.

Duties

In your capacity as a CFO, you will perform duties and responsibilities that are commensurate with your position and such other duties as may be assigned to you from time to time. You will report directly to the Chief Executive Officer, (the "**CEO**"**)**. You agree to devote your full business time, attention and best efforts to the performance of your duties and to the furtherance of the Company's interests.

Location

Your principal place of employment shall in the San Francisco Bay area, subject to business travel as needed to properly fulfil your employment duties and responsibilities.

Start Date

Subject to satisfaction of all of the conditions described in this letter, your anticipated start date is July 21, 2019 **(**"**Start Date**").

Base Salary

In consideration of your services, you will be paid an initial base salary of $330,000 per year, subject to review by the Board from time to time, payable in accordance with the standard payroll practices of the Company or its US subsidiary and subject to all withholdings and deduct ions as required by law.

Annual Bonus

Each year, you will have an opportunity to earn a bonus of up to 30% of your base salary (the "**Target Bonus**"**)**. Your actual bonus amount will be determined based on a combination of Company results and individual performance against the applicable performance goals established by the Board. Any annual bonus with respect to a particular calendar year will be paid within 2

1/2 months following the end of the year for which the annual bonus relates. For any partial year of employment, you will receive a pro-rated annual bonus based on the number of days you are employed during the year.

You must remain continuously employed through the end of the applicable calendar year to be eligible to receive an annual bonus payment for a particular calendar year.

Expenses

The Company or its US subsidiary will reimburse you only for out of pocket business related expenses reasonably incurred in the performance of your duties, as approved by the Board in the annual budgeting process and in accordance with any expense claiming policies and guidelines promulgated by the Company or its US subsidiary from time to time.

Equity Grants

As soon as practicable following the Start Date, the Company will recommend that the Board grant you an option to purchase an aggregate of 590,000 of shares Ordinary Shares of the Company (representing ~1.04% of the current fully diluted outstanding shares of the Company), at a per share exercise price equal to the fair market value of such shares on the date of grant based on the last 409A Valuation. The Company will recommend to the Board that your percentage ownership in the company be trued up through the end of its Series A financing. The options will be governed by the Company's 2018 Equity Incentive Plan (as supplemented by the Company's 2018 United States Sub-Plan) and a stock option agreement to be entered into between the Company and you. The stock option agreement will provide, among other things, that, (i) subject to your continued employment with the Company or its subsidiary on each applicable vesting date, your options shall vest over a four-year period, 25% upon the one-year anniversary of the Start Date (or the fourth tranche date in respect of any true up grant), and the remaining 75% in equal quarterly installments over a period of three years thereafter, and (ii) in the event that you are terminated without Cause (as defined below) or resign for Good Reason (as defined below) within the Change in Control Protection Period (as defined below), then, subject to the Release Condition described below, any of your options then subject to vesting shall become fully vested as of the date of such termination.

Benefits and Perquisites

You will be eligible to participate in the employee benefit plans and programs generally available to the Company's senior executives in the United States, as those policies are developed and amended by the Company. You will be entitled to paid vacation in accordance with the Company's or its US subsidiary's policies in effect from time to time. The Company and its subsidiaries reserve the right to amend, modify or terminate any of its benefit plans or programs at any time and for any reason.

Withholding

All forms of compensation paid to you as an employee of the Company or its subsidiary shall be less all applicable withholdings.

At-will Employment

Your employment with the Company or its subsidiary will be for no specific period of time. Rather, **your employment will be at-will, meaning that any party may terminate the employment relationship at any time, with or without cause, and with or without notice and for any reason or no particular reason**. Although your compensation and benefits may change from time to time, the at-will nature of your employment may only be changed by an express written agreement signed by an authorized officer of the Company after approval by the Board.

Severance During the Change in Control Protection Period

In the event you are terminated without Cause or resign for Good Reason (as defined below) within ninety (90) days prior to, or twelve (12) months following the consummation of a Change in Control (the "**Change in Control Protection Period**"), then, subject to the Release Condition described above, the amount of the Severance Benefits described above will be six (6) months paid over six (6) months, unless the Board determines to pay or provide such Severance Benefits in a cash lump sum in sole discretion) plus any then outstanding equity then held by you that is unvested, will vest in full. For purposes herein, "**Change in Control**" means an event (i) which constitutes a Deemed Liquidation Event as defined in the Company's Articles of Association, as may be amended from time to time, and (ii) in which the Company's Series A investors receive a multiple of invested capital of at least two (2) times their original investment, and "**Good Reason**" means your resignation based on any of the following events without your written consent, (a) a material diminution in your authority, duties or responsibilities; (b) a material diminution in reporting relationship from that determined by an acquirer at the time of such Change of Control; (c) a material diminution in your annual base salary except if the base salaries of a significant number of other executives and members of senior management of the Company also are proportionately reduced, whether or not such reduction is voluntary on your part or on the part of such other executives and senior management; (d) the Company's relocation of your primary work location outside a 40-mile radius of San Francisco that increases your one-way driving distance by more than 40 miles; (e) any other action or inaction that constitutes a material breach of the terms of an applicable employment agreement. To constitute a resignation for Good Reason: (i) you must provide written notice to the Company within thirty (30) days of the initial existence of the event constituting Good Reason, (ii) you may not terminate your employment unless the Company fails to remedy the event constituting Good Reason within fifteen (15) days after such notice has been deemed given pursuant to this offer letter, and (iii) you must terminate employment with the company no later than fifteen (15) days after the end of the 15-day cure period in which the Company fails to remedy the event constituting Good Reason.

Section 409A

This offer letter is intended to comply with Section 409A of the Internal Revenue Code **(**"**Section 409A**") or an exemption thereunder and shall be construed and administered in accordance with Section 409A. Notwithstanding any other provision of this offer letter, payments provided under this offer letter may only be made upon an event and in a manner that complies with Section 409A or an applicable exemption. Any payments under this offer letter that may be excluded from Section 409A either as separation pay due to an involuntary separation from service or as a short-term deferral shall be excluded from Section 409A to the maximum extent possible. For purposes

of Section 409A, each instalment payment provided under this offer letter shall be treated as a separate payment. Any payments to be made under this offer letter upon a termination of employment shall only be made upon a "separation from service" under Section 409A. Notwithstanding the foregoing, the Company makes no representations that the payments and benefits provided under this offer letter comply with Section 409A and in no event shall the Company be liable for all or any portion of any taxes, penalties, interest or other expenses that may be incurred by you on account of noncompliance with Section 409A.

Notwithstanding any other provision of this offer letter, if any payment or benefit provided to you in connection with termination of employment is determined to constitute "nonqualified deferred compensation" within the meaning of Section 409A and you are determined to be a "specified employee" as defined in Section 409A(a)(2)(b)(i), then such payment or benefit shall not be paid until the first payroll date to occur following the six-month anniversary of your termination date (the "**Specified Employee Payment Date**"**)** or, if earlier, on the date of your death. The aggregate of any payments that would otherwise have been paid before the Specified Employee Payment Date shall be paid to you in a lump sum on the Specified Employee Payment Date and thereafter, any remaining payments shall be paid without delay in accordance with their original schedule. Whenever in this offer letter a payment or benefit is conditioned on your execution of a release of claims, such release must be executed, and all revocation periods shall have expired, within 45-days after the date of your termination of employment, failing which such payment or benefit shall be forfeited. If such payment or benefit constitutes non-exempt deferred compensation for purposes of Section 409A, and if such 45-day period begins in one calendar year and ends in the next calendar year, the payment or benefit shall not be made or commence before the second such calendar year, even if the release becomes irrevocable in the first such calendar year.

Governing Law

This offer letter shall be governed by the laws of California, without regard to conflict of law principles.

Contingent Offer

This offer is contingent upon:

(a) Verification of your right to work in the United States, as demonstrated by your completion of an I-9 form upon hire and your submission of acceptable documentation (as noted on the I-9 form) verifying your identity and work authorization within three days of your Start Date. For your convenience, a copy of the I-9 Form's List of Acceptable Documents is enclosed for your review.

(b) Your execution of the Company's enclosed (1) Employee Proprietary Information and Invention Assignment Agreement, and (2) Employee Arbitration Agreement.

Representations and Warranties

By accepting this offer, you represent that you are able to accept this job and carry out the work that it would involve without breaching any legal restrictions on your activities, such as non -competition, non-solicitation or other work-related restrictions imposed by a current or former

employer. You also represent that you will inform the Company about any such restrictions and provide the Company with as much information about them as possible, including any agreements between you and your current or former employer describing such restrictions on your activities. You further confirm that you will not remove or take any documents or proprietary data or materials of any kind, electronic or otherwise, with you from your current or former employer to the Company without written authorization from your current or former employer, nor will you use or disclose any such confidential information during the course and scope of your employment with the Company. If you have any questions about the ownership of particular documents or other in formation, you should discuss such questions with your former employer before removing or copying the documents or information.

By accepting this offer, you acknowledge and agree that, so long as you are employed by the Company or its subsidiary, except upon the prior written consent of the Board, you will not (i) accept any other employment, or (ii) engage, directly or indirectly , in any other business activity (whether or not pursued for pecuniary advantage) that is or may be in conflict with, or that might place you in a conflicting position to that of, the Company.

We are excited at the prospect of you joining our team. If you have any questions about the above details, please call me immediately. If you wish to accept this position, please sign below and return this letter to me. This offer is open for you to accept through July 22, 2019, at which time it will be deemed to be withdrawn.

I look forward to hearing from you.

Yours sincerely,

/s/ Rohan Palekar

Rohan Palekar
Chief Executive Officer
On behalf of 89bio Ltd.

Acceptance of Offer

I have read, understood and accept all the terms of the offer of employment as set forth in the foregoing letter. I have not relied on any agreements or representations, express or implied, that are not set forth expressly in the foregoing letter, and this letter supersedes all prior and contemporaneous understandings, agreements, representations and warranties, both written and oral, with respect to the subject matter of this letter.

Ryan Martins

Signed: /s/ Ryan Martins

Date: July 21, 2019

Exhibit 10.9

July 1, 2018

To: Dr. Michael Hayden

Re: Industry Director Position—89bio LTD (the "Company")

Dear Michael,

In connection with your appointment as an industry expert director (the "**Industry Director**") on the Company's Board of Directors (the "**Board**"), in accordance with the provisions of Article 36(a) of the Company's Articles of Association (the "**Articles**"), we set forth the following information regarding the compensation and benefits that you will be entitled to as an Industry Director.

As compensation for your services as an Industry Director, you will receive a monthly fee of US$ 3,334 for your ongoing services as a director on the Board, until otherwise decided by the Board.

The Company will reimburse you for all reasonable out-of-pocket expenses incurred by you in connection with your services as an Industry Director. All reimbursements are in accordance with established Company policies.

Any payments made pursuant to this letter shall be subject to withholding tax by the Company according to applicable law or the tax authorities' certificate submitted by you to the Company, to the extent applicable.

Nothing in this letter shall be interpreted such that you have a right to be an Industry Director for any specific period of time; you may be removed in accordance with the Articles at any time.

This letter sets forth the compensation to which you would be entitled as an Industry Director to the Board, subject to the conditions set forth herein, and supersedes any prior representations or agreements, whether written or oral, other than the Offer Letter by and among you and the Company, dated February 2018 which shall stay in effect. This letter may not be modified or amended except by a written agreement, signed by an officer of the Company and by you.

Sincerely,

89bio LTD

By: /s/ Anat Naschitz

Title: Director

Accepted:

Dr. Michael Hayden

/s/ Dr. Michael Hayden

Exhibit 10.11

[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

CONFIDENTIAL
Execution Version

ASSET TRANSFER AND LICENSE AGREEMENT - FGF-21

THIS ASSET TRANSFER AND LICENSE AGREEMENT – FGF-21 (this "**Agreement**"), dated as of the 16th day of April, 2018 (the "**Effective Date**"), is by and between (a) 89Bio Ltd. ("**Company**") on the one hand, and (b) Ratiopharm GmbH, Teva Branded Pharmaceutical Products R&D, Inc. and Teva Pharmaceutical Industries Ltd, (collectively "**Teva**") on the other. Company, on the one hand, and Teva, on the other hand, shall each be referred to herein as a "**Party**" or, collectively, as the "**Parties**."

RECITALS:

WHEREAS, Teva and its Affiliates have been engaged in a development program relating to GlycoPEGylated FGF21 molecules, including TEV-47948, a GlycoPEGylated long acting FGF21 that targets FGFR1, FGFR2, FGFR3, and control certain patent rights and know-how with respect thereto; and

WHEREAS, Company is interested in developing and commercializing Compounds and Products (as defined below); and

WHEREAS, Company desires to purchase and take assignment of certain intellectual property rights and materials and to obtain a license with respect to other intellectual property rights from Teva, and Teva wishes to sell and assign such intellectual property rights and materials and to grant such license to Company, for Company to develop, manufacture and commercialize Compounds and Products, all on the terms set forth below.

WHEREAS, concurrently with the execution of this Agreement, the Parties will execute an additional Asset Transfer and License Agreement with respect to Teva's research and development program relating to FASN inhibitors ("**FASN Agreement**"), and a reagent supply and technology transfer agreement and a master services agreement (collectively, with the Agreement the "**Transaction Documents**").

NOW, THEREFORE, in consideration of the foregoing and of the various promises and undertakings set forth herein, the Parties agree as follows:

ARTICLE I
DEFINITIONS

Unless otherwise specifically provided herein, the following terms shall have the following meanings:

1.1 "ABF Work Order" means Work Order # 1234 version 1.02 under the Master Service Agreement between Teva and ABF for (a) [***] and (b) [***].

1.2 "**Additional Ingredient**" means any active ingredient, in addition to any Compound, which is contained in a Product. Drug delivery vehicles, adjuvants, and excipients shall not be deemed to be "active ingredients", except in the case where such delivery vehicle, adjuvant, or excipient is recognized as an active ingredient in accordance with 21 C.F.R. § 210.3(b)(7) (as amended).

1.3 "**Affiliate**" of a Person means any other Person that (directly or indirectly) controls, is controlled by or is under common control with such Party, but only for so long as such control exists. For the purposes of this Section 1.3, the word "control" (including, with correlative meaning, the terms "controlled by" or "under common control with") means (a) in the case of a corporate entity, direct or indirect ownership of voting securities entitled to cast at least fifty percent (50%) of the votes in the election of directors, (b) in the case of a non-corporate entity, direct or indirect ownership of at least fifty percent (50%), including ownership by trusts with substantially the same beneficial interest, of the equity interests with the power to direct the management and policies of such Person, provided that if local law restricts foreign ownership, control shall be established by direct or indirect ownership of the maximum ownership percentage that may, under such local law, be owned by foreign interests, or (c) the power to direct the management or policies of a Person, whether through ownership of voting securities, by contract or otherwise.

1.4 "**Agreement**" has the meaning set forth in the Preamble.

1.5 ***[****Intentionally Omitted]*

1.6 "**Assigned Assets**" means to the extent owned by Teva or an Affiliate of Teva: (i) the Assigned Patents, (ii) Teva Know-How to the extent solely and exclusively related to the FGF21 Program, including without limitation the items set forth on Schedule 2;(iii) the results generated and the deliverables to be provided under the ABF Work Order and the Pre-Clinical Studies Work Orders; and (iv) Regulatory Filings to the extent solely and exclusively related to the FGF21 Program.

1.7 "**Assigned Patents**" means those Patents owned by Teva and relating solely and exclusively to the FGF21 Program, which Patents are set forth on Schedule 3 hereto, including any patents described in clauses (b) – (d) of the definition of "Patents" relating thereto.

1.8 "Assumed Liabilities" means: (a) liabilities and obligations arising out of or relating to Company's ownership of the Assigned Assets with respect to activities taking place after the Closing Date; and (b) reimbursement of amounts due to ABF for fulfillment of the ABF Work Order. For clarity, Assumed Liabilities does not include liabilities or obligations arising out of or relating to activities undertaken prior to the Closing Date.

1.9 "**Change of Control**" means, with respect to a Party, (a) completion of a merger, reorganization, amalgamation, arrangement, share exchange, consolidation, tender or exchange offer, private purchase, business combination, recapitalization or other transaction involving a Party as a result of which the stockholders of such Party immediately preceding such transaction hold less than fifty percent (50%) of the outstanding shares, or less than fifty percent (50%) of the outstanding voting power, respectively, of the ultimate company or entity resulting from such transaction immediately after consummation thereof (including a company or entity which as a result of such transaction owns the then-outstanding securities of a Party or all or substantially all

of a Party's assets, either directly or through one or more subsidiaries), (b) the sale or disposition to a Third Party of all or substantially all the assets of a Party (determined on a consolidated basis) to which this Agreement relates, or (c) the sale or disposition to a Third Party of assets or businesses that constitute fifty percent (50%) or more of the total revenue or assets of a Party (determined on a consolidated basis).

1.10 "**Claim**" has the meaning set forth in Section 9.1.

1.11 "**Clinical Trial**" means any study in which human subjects are dosed with a drug, whether approved or investigational, including any Phase I Trial, Phase II Trial, Phase III Trial or Phase IV Trial.

1.12 "Closing Date" means the date of delivery of written proof of the wire transfer of the payments described in Section 5.1 to Teva's bank account set forth in Section 5.1.

1.13 "**Combination Product**" means a Product containing a Compound together with one or more other Additional Ingredients.

1.14 "**Commercialization**" or "**Commercialize**" means any and all activities undertaken at any time for a particular Product and that relate to obtaining pricing and reimbursement approvals, carrying out Phase IV Trials, marketing, promoting, distributing, importing or exporting for sale, offering for sale, and selling of the Product, and interacting with Regulatory Authorities regarding the foregoing.

1.15 "**Commercially Reasonable Efforts**" means, with respect to any Compound or Product, that level of effort and resources commonly dedicated in the pharmaceutical industry by a biotechnology company similarly situated to Company, to the Manufacture, Development or Commercialization, as the case may be, of a product of similar commercial potential at a similar stage in its lifecycle to such Compound or Product, in each case taking into account the following considerations (the "**CRE Considerations**"): issues of safety and efficacy, product profile, the proprietary position, the then current competitive environment and the likely timing of market entry, the regulatory environment and status of such Product, profitability, and other relevant scientific, technical and commercial factors, but without regard to any payments owed to Teva under this Agreement. Without limiting or derogating from the foregoing, Commercially Reasonable Efforts requires that, taking into account the CRE Considerations, Company: (a) promptly assign responsibility for the applicable Development and Commercialization activities to specific employees who are held accountable for progress and monitor such progress on an on-going basis, (b) set and consistently seek to achieve specific and meaningful objectives and timelines for carrying out such Development and Commercialization activities, and (c) consistently make and implement decisions and allocate resources designed to advance progress with respect to such objectives and timelines.

1.16 "**Company**" has the meaning set forth in the Preamble.

1.17 "**Company Indemnitee**" has the meaning set forth in Section 9.2.

1.18 "**Compound**" means the compound known as TEV-47948, as further described on Schedule 4, a GlycoPEGylated long acting FGF21 that targets FGFR1, FGFR2, and FGFR3 and any other GlycoPEGylated FGF21 compound claimed in the Assigned Patents.

1.19 "**Confidential Information**" has the meaning set forth in Section 7.1.

1.20 "**Controlled**" means, with respect to any patent right, Know-How, or other intellectual property right, the possession (whether by ownership or license, other than by a license or sublicense granted pursuant to this Agreement) by a Party or its Affiliates of the ability to grant to the other Party a license or access as provided herein to such item, without violating the terms of any agreement or other arrangement with any Third Party in existence as of the time such Party or its Affiliates would first be required hereunder to grant the other Party such license or access.

1.21 "**Cover**" means, with respect to a Patent, country and product, that the manufacture, use, sale, offer for sale or import of such product in such country by an unlicensed entity would infringe a Valid Claim of such Patent (assuming, for this purpose, that all patent application claims otherwise constituting a Valid Claim at such time have issued).

1.22 "**CPA Representative**" has the meaning set forth in Section 5.11.

1.23 "**CRE Considerations**" has the meaning set forth in Section 1.15.

1.24 "**Development**" or "**Develop**" means, with respect to any Compound and Product, the performance of non-clinical, preclinical and clinical development (including, without limitation, toxicology, pharmacology, test method development and stability testing, process development, formulation development, quality control development, statistical analysis), clinical trials, and regulatory activities that are required to obtain Regulatory Approval of such Product (and specifically excluding activities directed to obtaining pricing and reimbursement approvals).

1.25 "**Development Plan**" means the plan setting forth the activities and timelines relating to the Development of any Compound and Product in the Territory, as amended by Company from time to time in accordance with Section 3.1(b). The initial Development Plan is set forth on Schedule 5.

1.26 "**Disclosing Party**" has the meaning set forth in Section 7.1.

1.27 "**Distributor**" means a Third Party bona fide wholesaler or distributor (a) engaged by Company, a Sublicensee or an Affiliate of either, on an arm's-length commercially reasonable basis, only to market, distribute and sell a Product in one or more particular jurisdiction(s) (but, for clarity, not to Develop or Manufacture any Product in any way), (b) that purchases Products from Company, a Sublicensee or an Affiliate of either, and (c) that sells Product without providing any consideration to Company, the Sublicensee or an Affiliate of either, as applicable, (other than the purchase price paid by the Distributor for the Products, which for clarity may include down or advance payments).

1.28 "**Effective Date**" has the meaning set forth in the Preamble.

1.29 "**EMA**" means the European Medicines Agency or any successor agency thereto.

1.30 "**European Commission**" means the authority within the European Union that has the legal authority to grant Regulatory Approvals in the European Union based on input received from the EMA or other competent Regulatory Authorities.

1.31 "**FDA**" means the United States Food and Drug Administration or any successor agency thereto.

1.32 "**FDCA**" means the United States Federal Food, Drug and Cosmetic Act, as amended.

1.33 "FGF21 Program" means Teva's research and development program relating to GlycoPEGylated FGF21 molecules.

1.34 "**First Commercial Sale**" means, with respect to a Product in any country, the first sale of such Product to a Third Party in such country for distribution, use or consumption after Regulatory Approval has been obtained for such Product in such country. Sales for purposes of testing the Product in a Clinical Trial shall not be deemed a First Commercial Sale. For clarity, First Commercial Sale shall be determined on a Product-by-Product and country-by-country (or region-by-region) basis, as applicable. Two or more Products that contain the same Compound will be deemed the same "Product" for purposes of this definition.

1.35 "**GAAP**" means United States generally accepted accounting principles consistently applied.

1.36 "**Good Clinical Practice**" means the then current standards for Clinical Trials for pharmaceuticals (including all applicable requirements relating to protection of human subjects), as set forth in the FDCA and applicable regulations promulgated thereunder (including, for example, 21 C.F.R. Parts 50, 54, and 56), as amended from time to time, and such standards of good clinical practice (including all applicable requirements relating to protection of human subjects) as are required by other organizations and Governmental Body in any other countries, including applicable regulations or guidelines from the ICH, in which a Product is intended to be sold, to the extent such standards are not less stringent than in the United States.

1.37 "**Governmental Body**" means any: (a) nation, principality, state, commonwealth, province, territory, county, municipality, district or other jurisdiction of any nature; (b) federal, state, local, municipal, foreign or other government; (c) governmental or quasi-governmental authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, board, instrumentality, officer, official, representative, organization, unit, body or entity and any court or other tribunal); (d) multi-national or supranational organization or body; or (e) individual, entity, or body exercising, or entitled to exercise, any executive, legislative, judicial, administrative, regulatory, police, military or taxing authority or power of any nature.

1.38 "**IND**" means an Investigational New Drug Application, Clinical Study Application, Clinical Trial Exemption, or similar application or submission for approval to conduct human clinical investigations filed with or submitted to a Regulatory Authority in conformance with the requirements of such Regulatory Authority.

1.39 "**Indemnified Party**" has the meaning set forth in Section 9.3(a).

1.40 "**Indemnifying Party**" has the meaning set forth in Section 9.3(a).

1.41 "**Invoicing Entity**" has the meaning set forth in Section 1.53.

1.42 "**Know-How**" means know-how, trade secrets, chemical and biological materials, formulations, protocols, assays, formulations, methods, inventions, discoveries, information, documents, studies, results, data and regulatory approvals, data, filings and correspondence (including Drug Master Files), including biological, chemical, pharmacological, toxicological, pre-clinical, clinical and assay data, manufacturing processes and data, specifications, sourcing information, assays, and quality control and testing procedures, whether or not patented or patentable.

1.43 "**Law**" or "**Laws**" means any federal, state, provincial, local, international or multinational law, statute, standard, ordinance, code, rule, regulation, resolution or promulgation, or any order, writ, judgment, injunction, decree, stipulation, ruling, determination or award entered by or with any Governmental Body, or any license, franchise, permit or similar right granted under any of the foregoing, or any similar provision having the force or effect of law.

1.44 "**Licensed Know-How**" means Teva Know-How that is not included in the Assigned Assets, including without limitation the Teva Know-How listed in Schedule 6.

1.45 "**Licensed Patents**" means the Teva Licensed Patents and Third Party Patents.

1.46 "**Lien**" means any lien, pledge, mortgage, deed of trust, security interest, charge, claim, easement, encroachment or other similar encumbrance.

1.47 "**MAA**" means (a) a marketing authorization application filed with (i) the EMA under the centralized EMA filing procedure or (ii) a Regulatory Authority in any country of the EU if the centralized EMA filing procedure is not used, or (b) any other equivalent or related regulatory submission, in either case to gain approval to market a Product in any country in the European Union, in each case including, for clarity, amendments thereto and supplemental applications.

1.48 "**Major European Country**" means any of the United Kingdom, France, Germany, Italy or Spain.

1.49 "**Manufacture**" or "**Manufacturing**" means activities related to the manufacture, formulation and packaging of any compound or product, including any Compound and Products, including related quality control and quality assurance activities.

1.50 "Master Services Agreement" means the Master Services Agreement between the parties dated even date herewith.

1.51 "**Milestone Event**" has the meaning set forth in Section 5.2(a).

1.52 "**Milestone Payment**" has the meaning set forth in Section 5.2(a).

1.53 "**Net Sales**" means, with respect to a Product, the gross sales price invoiced to a Third Party for sales of such Product by Company or its Affiliates or Sublicensees (the "**Invoicing Entity**"), after deduction of: [***], that the Invoicing Entity allocates to sales of such Product in accordance with its standard policies and procedures consistently applied across its products, all calculated and determined in accordance with GAAP, as reflected in the Invoicing Entity's financial statements and measured in United States Dollars (unless such charges are not included in the amount invoiced and are otherwise reimbursed to Company by a Third Party).

Sales of Products by an Invoicing Entity to Company or an Affiliate or Sublicensee for resale by Company or such Affiliate or Sublicensee [***]. Net Sales will include [***], but in each case only to the extent that Company or its Affiliate or Sublicensee receives amounts therefor in excess of the fully-burdened cost thereof.

In the event that a Product is sold in any country in the form of a Combination Product, Net Sales of such Combination Product shall be adjusted by multiplying actual Net Sales of such Combination Product in such country by the fraction A/(A+B), where: A is the average invoice price in such country of a Product containing the same strength of Compound included in the Combination Product, but not containing the Additional Ingredient(s) included in such Combination Product, when sold separately in such country; and B is the average invoice price of a product containing the same strength of Additional Ingredient(s) included in the Combination Product, but not containing the Compound(s) included in such Combination Product, when sold separately in such country. If, in a specific country, any such products are not sold separately, market prices for the Compound(s) and Additional Ingredient(s) included in the Combination Product shall be determined by the Parties in good faith.

1.54 "**Novo Sublicense Agreement**" means that certain license agreement entered into between an Affiliate of Teva and Neose Technologies, Inc. on January 27, 2009.

1.55 "**Party(ies)**" has the meaning set forth in the Preamble.

1.56 "**Patents**" means (a) any issued patents and patent applications, (b) any additions, divisionals, continuations, conversion, supplemental examinations, extensions, term restorations, registrations, reinstatements, amendments, reissuances, corrections, substitutions, re-examinations, registrations, revalidations, supplementary protection certificates, renewals, and foreign counterparts of the patents and patent applications mentioned in clause (a) above, and (c) all patents issuing from any of the patents and patent applications mentioned in clause (a) or (b) above and any foreign counterparts of any such patents and patent applications, and which shall include, in any case, patents surviving post grant review and inter partes review.

1.57 "**Patent Challenge**" means any legal or administrative proceeding challenging the validity of any of the Teva Licensed Patents (or any claim thereof), including by: (a) filing a declaratory judgment action in which any of the Teva Licensed Patents is alleged to be invalid; or (b) filing or pursuing any re-examination, opposition, cancellation, nullity or other like proceedings against any of the Teva Licensed Patents. For clarity, Patent Challenge shall not include a bona fide patent infringement defense (such defense to include a declaratory judgment action) against a claim of infringement of the Teva Licensed Patents brought by Teva or any of its Affiliates.

1.58 "**Periodic Report**" has the meaning set forth in Section 5.6.

1.59 "**Person**" means any natural person, sole proprietorship, corporation, firm, business trust, trust, joint venture, association, organization, company, partnership, limited partnership or other business entity, or any government or agency or political subdivision thereof.

1.60 "**Phase III Trial**" means a clinical trial of a Product on a sufficient number of subjects that is designed to establish that a pharmaceutical product is safe and efficacious for its intended use, and to determine warnings, precautions, and adverse reactions that are associated with such Product in the dosage range to be prescribed, which trial is intended to support Regulatory Approval of such Product, as described in 21 C.F.R. 312.21(c) (as amended or any replacement thereof), or a similar clinical trial prescribed by any Regulatory Authority outside of the United States. For purposes of this Agreement, "initiation" of a Phase III Trial for any Product means the first dosing of the first human subject with such Product in such Phase III Trial.

1.61 "Pre-Clinical Study Work Orders" means the work orders entered into by Teva with third party CROs pursuant to which the reports described in Section 2 of Schedule 2 are to be prepared. The pre-clinical studies under these work orders have been completed by the relevant CROs and the relevant CROs and Teva are in the process of preparing and/or finalizing the reports in accordance with the relevant work order.

1.62 "**Product**" means any pharmaceutical product containing any Compound (alone or with Additional Ingredients), in all forms, presentations, formulations and dosage forms. For clarification, Product shall include any Combination Product.

1.63 "Reagent Supply and Technology Transfer Agreement" means the Reagent Supply and Technology Transfer Agreement between Company and Teva Biotech GmbH dated even date herewith.

1.64 "**Receiving Party**" has the meaning set forth in Section 7.1.

1.65 "**Regulatory Approval**" means, with respect to a country or region in the Territory, all approvals, licenses, registrations or authorizations from the relevant Regulatory Authority necessary for the Development, Manufacture or Commercialization of a Product in such country or region. For the avoidance of doubt, Regulatory Approval outside of the United States shall include any pricing or marketing approval needed prior to the sale of a Product in such country or region.

1.66 "**Regulatory Authority**" means (a) the FDA, (b) the EMA or the European Commission, or (c) any regulatory body or other analogous government regulatory authority or agency involved in granting approvals (including any required pricing or reimbursement approvals) for the development, manufacture or commercialization of pharmaceutical or biotechnology products (including any Product) in any other jurisdiction anywhere in the world.

1.67 "**Regulatory Filing**" means any documentation comprising or relating to or supporting any filing or application with any Regulatory Authority with respect to any compound or product (including any Compound or Product), or its use or potential use in humans, including any documents submitted to any Regulatory Authority and all supporting data, including INDs and NDAs, and all correspondence with any Regulatory Authority with respect to such compound or product (including minutes of any meetings, telephone conferences or discussions with any Regulatory Authority).

1.68 "**Royalty Term**" means, on a Product-by-Product and country-by-country basis, the period commencing on the First Commercial Sale of such Product in such country and continuing until the latest to occur of: (a) the date of expiration of the last Valid Claim included in any of the Transferred Patents claiming the composition, formulation, manufacture or use of such Product in such country; (b) the end of any regulatory or data exclusivity for the Product granted by a Regulatory Authority or Governmental Body applicable to such country; or (c) ten (10) years from the date of First Commercial Sale of such Product in such country. For purposes of Sections 1.68(b) and 1.68(c), two or more Products that contain the same Compound will be deemed the same "Product" and the Royalty Term shall expire upon on a country-by-country basis on the expiration of the Royalty Term of the first such Product in the relevant country.

1.69 "**Sublicense**" means any grant by Company to its Affiliate or a Third Party of any of the rights acquired by Company under Section 2.1 of this Agreement, including the right to Develop, Manufacture, or Commercialize any Compound or Product, in accordance with Section 2.5.

1.70 "**Sublicensee**" means any Affiliate of Company or Third Party to whom Company shall grant a Sublicense or option to obtain such Sublicense in accordance with Section 2.5. Sublicensee shall include any other Third Party to whom such Sublicense or option shall be transferred or assigned, by operation of law or otherwise. For clarity, Sublicensee excludes Distributor.

1.71 "**Tax**" or "**Taxes**" means any federal, state, local or foreign income, gross receipts, license, payroll, employment, excise, severance, stamp, occupation, premium, windfall profits, environmental, customs duties, capital stock, franchise, profits, withholding, social security, unemployment, disability, real property, personal property, sales, use, transfer, registration, value added, alternative or add-on minimum, estimated, or other tax of any kind whatsoever, including any interest, penalty, or addition thereto, whether disputed or not.

1.72 "**Term**" has the meaning set forth in Section 10.1.

1.73 "**Territory**" means worldwide.

1.74 "**Teva**" has the meaning set forth in the Preamble.

1.75 "**Teva Indemnitee**" has the meaning set forth in Section 9.1.

1.76 "**Teva Know-How**" means any and all Know-How that (i) is Controlled by Teva or any of its Affiliates as of the Effective Date or is developed by Teva or any of its Affiliates after the Effective Date and delivered to Company in accordance with Section 15 of the Reagent Supply and Technology Transfer Agreement and (ii) is necessary or reasonably useful to Develop, Manufacture, or Commercialize any Compound or Product.

1.77 "**Teva Licensed Patents**" means those Patents owned by Teva or its Affiliates on the Effective Date or at any time during the term of this Agreement that are not Assigned Patents, and are necessary or useful for the Development or Commercialization of the Compounds or the Products, that are relevant to development programs other than the FGF21 Program, including without limitation Patents Covering methods of glycoPEGylation and resulting compounds.

1.78 "**Teva Licensed Technology**" means the Teva Licensed Patents and Licensed Know-How.

1.79 "**Third Party**" means any Person other than Teva, Company or their respective Affiliates.

1.80 "**Third Party Patents**" means those Patents sublicensed to Company under the Novo Sublicense Agreement entered into contemporaneously with this Agreement.

1.81 "**Teva Transferred Patents**" means the Assigned Patents and Teva Licensed Patents.

1.82 "Transferee" means any Third Party to whom Company or its Affiliate sells and assigns the Assigned Assets.

1.83 "**Transferred Patents**" means the Teva Transferred Patents together with the Third Party Patents.

1.84 "**United States**" or "**US**" means the United States of America and its territories and possessions.

1.85 "**Valid Claim**" means a claim of any pending patent application or any issued, unexpired United States or granted foreign patent that has not been dedicated to the public, disclaimed, abandoned or held invalid or unenforceable by a court or other body of competent jurisdiction from which no further appeal can be taken, and that has not been explicitly disclaimed, or admitted in writing to be invalid or unenforceable or of a scope not Covering a particular product or service through reissue, disclaimer or otherwise, provided that if a particular claim has not issued within five (5) years of its earliest priority date, it shall not be considered a Valid Claim for purposes of this Agreement unless and until such claim is included in an issued or granted Patent, notwithstanding the foregoing definition.

ARTICLE II
TRANSFER OF ASSETS, LICENSES AND OTHER RIGHTS

2.1 Transfer of Assets. On the Closing Date and upon the terms and subject to the conditions of this Agreement, including receipt of the payments set forth in Sections 5.1, Teva shall, and shall cause its Affiliates to, (and, as of the Closing Date, Teva and its Affiliate hereby) sell, assign, transfer, convey and deliver to Company, and Company shall purchase, acquire and accept, all right, title and interest of Teva or its Affiliates, as applicable, in, to and under the Assigned Assets, free and clear of all Liens. In order to effectuate the assignment, transfer and conveyance of the Assigned Assets, the Parties shall, and Teva shall cause its Affiliates, as applicable, to, duly execute and deliver patent assignments substantially in the forms attached hereto as **Schedule 7** ("Patent Assignments"), and any other document that may be needed in order to effectively transfer, convey and assign to Company all of Teva's and Teva's Affiliates' rights, title and interest in and to the Assigned Assets, including without limitation assignment of the IND with respect to Compounds and any other regulatory documents related thereto. Subject to the terms and conditions set forth herein, Company shall assume and agree to pay, perform and discharge when due any and all Assumed Liabilities.

2.2 Grant of Licenses to Company. Subject to the terms and conditions of this Agreement and the reserved rights described in Section 2.4, Teva hereby grants to Company, and Company hereby accepts, a perpetual (subject to termination in accordance with the terms of this Agreement), non-exclusive (but exclusive with respect to Compounds), worldwide, royalty-bearing (as provided in Section 5.3 below), non-transferable (except in accordance with Section 11.2) license (with the right to grant Sublicenses as provided for in Section 2.5 only) under the Teva Licensed Technology to research, have researched, Develop, have Developed, use, have used, Commercialize and have Commercialized, Manufacture and have Manufactured the Compounds and Products in the Territory.

2.3 License to Teva. Company hereby grants to Teva and Teva's Affiliates, and Teva hereby accepts, a non-exclusive, worldwide, royalty-free, non-transferable license, under the Assigned Patents to make and have made the Compound and Products, solely for supply to Company under the terms of the supply agreement to be executed between the Parties. In addition, to the extent that Company or its Sublicensees or Transferees makes any improvements to the reagents known as [***], [***] or [***] (as described in the Reagent Supply and Technology Transfer Agreement) or the manufacturing process relating to any of such reagents, Company shall, and shall cause its Sublicensees and Transferees to grant, and hereby grants Teva a non-exclusive worldwide, royalty-free, non-transferable license, to such improvements, solely to research, have researched, Develop, have Developed, use, have used such reagents for the sole purpose of Commercializing and having Commercialized, Manufacturing and having Manufactured Teva's product with an INN of lipegfilgrastim, known as Lonquex.

2.4 Reservation of Rights.

Except as expressly set forth in this Agreement, no licenses or other rights are granted or created hereunder to use any Patent, Know-How or other intellectual property rights owned, Controlled or otherwise in-licensed by a Party or any of its Affiliates, and all licenses and other rights are or shall be granted only as expressly provided in this Agreement, and no other licenses or other rights is or shall be created or granted hereunder by implication, estoppel or otherwise. The licenses granted in Section 2.2 above shall not grant or create (by implication, estoppel or

otherwise) any license or right under any Teva Licensed Patents or Teva Know-How to Develop, Manufacture or Commercialize any molecule that is not a Compound or Product. For clarity and without limiting the foregoing, nothing shall be deemed to confer any ownership interest, license or other rights upon Teva as to any invention, Patent, Know-How, technology, intellectual property (whether patentable or not), data or other materials developed, made, discovered, invented, conceived and/or created by or on behalf of Company, its Affliliates, Sublicensees or Transferees based on or using the Assigned Assets or in exercising its licenses under this Agreement or otherwise.

2.5 Grant of Sublicenses by Company.

(a) Company shall be entitled to grant Sublicenses through multiple tiers of the rights granted by Teva hereunder:

(i) to any Affiliate of Company (including the rights to allow such Affiliates to grant further Sublicenses in accordance with this Section 2.5), provided such Sublicense only remains in effect for as long as such Sublicensee remains an Affiliate of Company;

(ii) to Third Parties that are clinical research organizations, contract manufacturers, contract laboratory organizations, and other similar organizations that support the Development, Manufacture and Commercialization of any Compounds and Products on a fee-for-service basis as Sublicensees hereunder, provided that such Sublicenses include obligations of confidentiality and non-use of the Teva Licensed Technology and Teva Confidential Information substantially in accordance with the terms of this Agreement;

(iii) to other Third Parties as a Sublicensee hereunder (including the rights to allow such Third Parties to grant further Sublicenses in accordance with this Section 2.5)

(b) All Sublicenses granted by Company (or any option to a Sublicense) must (i) be in writing (other than in the case of Sublicenses to Affiliates of Company), (ii) be subject and subordinate to, and consistent with, the terms and conditions of this Agreement and (iii) require the applicable Sublicensee to comply with all applicable terms of this Agreement (except for the payment obligations, for which Company shall remain responsible). Company shall provide a copy of each agreement containing a Sublicense granted under Section 2.5(a)(iii), redacted of any confidential terms (including without limitation, the identity of the proposed Sublicensee) that are not material to the rights of Teva hereunder, to Teva at least [***] prior to execution. Teva shall keep any such copies of Sublicense agreements in its confidential files, shall not disclose such agreements or the contents thereof to any third party (except auditors or legal advisors of Teva for the purpose set forth below), and shall use them solely for the purpose of monitoring Company's compliance with its obligations hereunder and enforcing Teva's rights under this Agreement. If Company so requests, Teva will limit disclosure of such agreements to members of Teva's legal staff, provided however that Teva's legal staff may disclose to its alliance management individuals the information necessary for Teva to appropriately track payment and reporting obligations to Teva. No Sublicense shall diminish, reduce or eliminate any obligation of Company under this Agreement, and Company shall remain responsible for its obligations under this Agreement. Company shall include Teva as a third party beneficiary with respect to any Teva Confidential Information (as defined below) disclosed to the Sublicensee, if any, and with respect to indemnification obligations relating to Products.

(c) Any Sublicense shall be dependent on the existence of the licenses and rights granted hereunder. Notwithstanding the foregoing, upon termination of this Agreement by Teva pursuant to Section 10.3, or 10.4, and provided that Sublicensee is not in breach of the Sublicense at the time of termination of this Agreement, Teva shall work diligently and in good faith to expeditiously enter into an agreement with each Sublicensee to the extent of the scope of the applicable Sublicense, as the Sublicensee's direct licensor, provided that such Sublicensee delivers to Teva within [***] after termination of this Agreement a license agreement, proposed for execution by such Sublicensee and Teva, that is consistent with the terms and conditions set forth in this Agreement, as reasonably modified to be no greater in scope than the scope of the Sublicense granted to such Sublicensee with respect to territory, duration/term of sublicense grant, Products, fields of use, etc. (e.g., if the Sublicensee's Sublicense, as in effect immediately prior to such termination, included rights and obligations only with respect to a particular Product, Compound, country, indication and/or other matter, the proposed license agreement shall only include rights and obligations with respect to such particular Product, Compound, country, indication and/or other matter) (each such license agreement, a "**New License Agreement**"); provided further that (A) Teva shall have no liability to such Sublicensee for any actual or alleged breach by Company of the Sublicense agreement under which such Sublicensee was granted the initial Sublicense and (B) Teva shall not have any obligations to such Sublicensee in excess of those obligations corresponding to, and consistent with, those of Teva set forth in this Agreement with respect to the applicable rights of such Sublicensee to the Teva Licensed Technology. Notwithstanding the foregoing, the license rights of each Sublicensee that is entitled to request a direct license from Teva under the conditions set forth above shall be deemed to continue during the ninety-day period in which such Sublicensee may request a direct license from Teva, and during a reasonable time thereafter while the direct license is being finalized, pursuant to this Section 2.5(c). Each Sublicensee shall be deemed a third-party beneficiary for purposes of this Section 2.5(c). Notwithstanding anything herein to the contrary, this provision shall not apply to a Sublicense with an Affiliate of Company.

(d) Without limiting the foregoing, Company shall ensure that each Sublicense shall include terms that bind the Sublicensee to observe the applicable terms of this Agreement, the material breach of which terms shall be a material breach resulting, if not cured in accordance with the terms of the Sublicense (which shall be consistent with Section 10.3), in the right of Company to terminate the Sublicense. In case of any act or omission by any Sublicensee that would have constituted a material breach of this Agreement by Company entitling Teva to terminate this Agreement had it been an act or omission of Company hereunder, Company will notify Teva of such act or omission promptly after Company is informed or becomes aware of such act or omission thereof. Company and Teva will discuss possible courses of action, including, if necessary, terminating such Sublicense agreement in accordance with the terms thereof if the breach is not cured within a reasonable period. Company shall take all such actions reasonably requested by Teva to enforce the terms of the Sublicense Agreement upon the Sublicensee. For clarity, if Company complies with the terms of this paragraph, Teva will not have the right to terminate this Agreement on account of such breach by such Sublicensee.

2.6 Technology Transfer of Teva Know-How. Teva shall deliver to Company all documents and materials specified in Schedule 2 in accordance with the timeframes and manner of delivery established in Schedule 2. During the [***] period following the Effective Date, to the extent required, Company's representatives will be granted reasonable access, at Teva's election, to Teva's personnel by teleconference or in-person at Teva's facilities, in coordination with Teva, in order to gain a reasonable level of first-hand knowledge of the Teva Know-How under guidance of the relevant research and development personnel up to the total hours of technical assistance set forth in the table attached hereto as Schedule 8, according to the terms specified therein. For the avoidance of doubt, the services described in the Reagent Supply and Technology Transfer Agreement, the services described in the Master Services Agreement and any bioanalysis support and assay transfer related services shall not be covered by this Section 2.6 and shall be covered by the separate services agreement, to be negotiated between the Parties.

2.7 Pre-Clinical Study Work Orders; ABF Work Order; Notebooks, Novo US Patent.

2.7.1 ***Pre-Clinical Study Work Orders***. With respect to the Pre-Clinical Study Work Orders, Teva shall (a) supervise and ensure completion of the reports and any other deliverable due under such work orders, (b) make any outstanding payments due under such work orders and (c) provide the Company with such reports and other deliverables. Teva will provide such reports and deliverables to Company on or prior to the dates set forth in Section 2 of Schedule 2, provided that the deliverables to be provided by the relevant vendor are delivered to Teva according to the timeframes specified in the relevant work plan or otherwise agreed among Teva, Company and the third party vendor. In the event of any delay in the deliverables to be provided by any such vendor, the date for the delivery of the relevant reports and deliverables by Teva shall be pushed back by the term of such delay. For clarity, Teva will not be entitled to reimbursement of such payments.

2.7.2 ***ABF Work Order***. With respect to the ABF Work Order, Teva shall supervise performance of, and use reasonable efforts to ensure performance of, such work order by ABF on behalf of Company until delivery of the clinical material at ABF's storage facility in the United States, as described in the Work Order. Company shall reimburse Teva for amounts paid by Teva with respect to the ABF Work Order prior to the Closing Date in accordance with Section 5.1(c). All other amounts to be paid under the ABF Work Order after the Closing Date will be paid by Company directly to ABF.

2.7.3 ***Assignment of US Patent***. The parties acknowledge that [***] and [***] ("**US Patents**") are part of a patent family that is included in the Assigned Patents. The US Patents were licensed to Teva by Neose, but not assigned to Teva to date, and such license agreement was subsequently assigned by Neose to Novo Nordisk. Pursuant to a patent management agreement between Teva and Novo Nordisk, Teva has the right to require Novo Nordisk to assign the US Patents to Teva upon request. Teva has sent Novo a request to perform such assignment and Novo has acknowledged receipt of such request and its intention to work with Teva to execute such assignment. Teva shall use its best efforts to obtain such assignment from Novo Nordisk as soon as possible after the Effective Date. Upon formal assignment of the US Patent to Teva, Teva shall assign the US Patent to Company in accordance with the second sentence of Section 2.1 and the US Patent shall become part of the Assigned Patents. Until such assignment occurs, the US Patent shall be deemed licensed to Company under the Novo Sublicense Agreement.

2.7.4 ***Notebooks***. Within [***] following the Closing, Teva will make available the notebooks and binders listed in Appendix 2 to Schedule 2 attached hereto, to a third party chosen by Company, so that such third party may scan and/or copy the notebooks and binders. The notebooks and binders will be copied in their original language. Upon completion of the copying and scanning, Teva will send the scanned copies to Company via electronic means. In addition, upon [***] prior notice from Company, at any time during the [***] following Closing, Teva shall make the originals and the hard copies of the notebooks and binders available to a notary public designated by Company, at Teva's facility, to review the copies and confirm that they are true copies of the originals. Teva will send such notarized copies to Company. All such costs and expenses relating to producing copies of the notebooks and binders, shipping copies of such notebooks to Company, and notarizing such copies shall be the responsibility of Company. Teva shall maintain the originals of the notebooks and binders in its archives indefinitely and, at Company's request shall make them available to regulatory agencies within [***] of a written request from Company. If Teva, at any time, wishes to cease maintaining any of the original notebooks or binders, it shall notify Company and shall deliver such originals to Company.

2.8 Supply and Technology Transfer. Teva understands that Company's research and development activities with respect to assets purchased under this Agreement are dependent on, and the Company is relying on, Teva's performance of its obligations under Sections 2.6 and 2.7, and on Teva Biotech GmbH's performance of its obligations under the Reagent Supply and Technology Transfer Agreement. Teva undertakes to ensure that Teva Biotech GmbH performs its obligations under the Reagent Supply and Technology Transfer Agreement. In order to facilitate communication between the parties regarding fulfillment of such activities and the performance of Teva's obligations, Teva shall appoint an alliance manager (the "**Alliance Manager**") as the main point of contact for the Company for day-to-day activities, including as the initial contact with respect to any concerns regarding the fulfillment Teva's obligations under Sections 2.6 and 2.7. Teva shall keep an Alliance Manager until completion of all of Teva Biotech GmbH's obligations under the Reagent Supply and Technology Transfer Agreement.

2.9 Company's Recording and Similar Responsibilities. It shall be Company's responsibility (i) to record the patent assignments following execution thereof and (ii) to bear the fees and other costs in connection therewith.

ARTICLE III
DEVELOPMENT, MANUFACTURE AND COMMERCIALIZATION

3.1 Development.

(a) Company, alone and/or through its Affiliates and/or Sublicensees, shall use Commercially Reasonable Efforts to Develop a Product for approval in the United States, and each of the Major European Countries. The Parties acknowledge that Company, alone and/or through its Affiliates and/or Sublicensees, may Develop Products that are a Combination Product. Without limiting the generality of the foregoing, Company, alone and/or through its Affiliates and/or Sublicensees, shall use Commercially Reasonable Efforts to execute and perform, or cause to be

performed, the Development Plan, in accordance with the timelines set forth therein, and Company shall conduct its Development activities in good scientific manner and in compliance with applicable Law, including Laws regarding environmental, safety and industrial hygiene, and, to the extent applicable, Good Laboratory Practice, Good Clinical Practice, current standards for pharmacovigilance practice, and all applicable requirements relating to the protection of human subjects. Company, alone and/or through its Affiliates and/or Sublicensees, shall have the right to engage Third Party subcontractors (including Distributors) to conduct any of its Development, Manufacturing and Commercialization obligations under this Agreement; provided that (a) Company shall be liable hereunder for all actions or inactions of any of such Person, and (b) each such Person shall execute a non-disclosure/nonuse agreement no less restrictive than the terms and conditions contained in Article VII if Teva Confidential Information is to be disclosed.

(b) Company shall use Commercially Reasonable Efforts to conduct all Development activities relating to the Products in accordance with the Development Plan. Company shall have the right to amend the Development Plan from time to time; provided that no such Development Plan amendment may reduce or otherwise lessen the general diligence (except that the timelines for achieving development and commercialization milestones may be amended) and other obligations of Company pursuant to this Agreement. The terms of and activities set forth in the Development Plan shall at all times be designed to be in compliance with all applicable Laws and to be conducted in accordance with professional and ethical standards customary in the pharmaceutical industry.

(c) As between the Parties, Company shall be responsible, at its, its Affiliates' and/or Third Parties' sole cost and expense, for all Development activities under this Agreement and the Development Plan.

3.2 Commercialization.

(a) Company (alone and/or through its Affiliates and/or Sublicensees) shall use Commercially Reasonable Efforts to Commercialize a Product in the Territory in those countries for which Regulatory Approval and pricing and reimbursement approval have been obtained.

(b) As between the Parties, Company shall be responsible, at its, its Affiliates' and/or Third Parties' sole cost and expense, for all Commercialization activities under this Agreement and shall keep Teva reasonably informed as to the progress of such activities under Section 3.3.

3.3 Development, Regulatory and Commercialization Reports. Every [***] months during the Term, Company shall issue to Teva a report on the Development, regulatory and commercialization activities Company has performed or caused to be performed for the Compounds and Products since the last such report, including a summary of the work performed in relation to the goals of the Development Plan and a summary of progress against each Development and regulatory-related Milestone Event and an estimate of the timing of the achievement of the all Development and regulatory-related Milestone Events (which estimate will not be construed as a guarantee of such timing), and shall provide such other information as may be reasonably requested by Teva with respect to such Development and regulatory activities. In addition to the foregoing, upon Teva's reasonable request no more frequently than once every

[***], Company shall participate in a telephone or video conference to discuss any of the foregoing as is reasonably necessary to convey an understanding of the status of the applicable Development or regulatory activity. In addition to the foregoing, Company shall provide prompt written notice to Teva if, in any year, the Company has elected to suspend for a period equal to or greater than three (3) consecutive months, or to no longer proceed with, all Development, Manufacturing and Commercialization activities relating to Compounds.

3.4 Trademarks. As between Teva and Company, Company shall have the sole authority to select trademarks for Products and shall own all such trademarks, and shall be responsible for the registration, filing, maintenance and enforcement thereof.

3.5 Other Government Laws. Company shall comply with, and ensure that its Affiliates comply and Sublicensees undertake to comply with, all applicable government statutes and regulations that relate to Compounds or Products. These include but are not limited to FDA statutes and regulations, the Export Administration Act of 1979, as amended, codified in 50 App. U.S.C. 2041 et seq. and the regulations promulgated thereunder or other applicable export statutes or regulations.

ARTICLE IV
REGULATORY MATTERS

4.1 Regulatory Responsibilities. Company (alone and/or through its Affiliates and/or Sublicensees) shall use Commercially Reasonable Efforts to seek and obtain Regulatory Approval for a Product in the United States, and each of the Major European Countries in accordance with the Development Plan.

4.2 Ownership of Regulatory Approvals. As between Company and Teva, Company (or its applicable Affiliate) shall own and maintain all Regulatory Filings made after the Effective Date for Products and all Regulatory Approvals for Products. All such filings shall be in the name of Company or its Affiliate or Sublicensee, except where otherwise required by local law.

4.3 Regulatory Cooperation. The report described in Section 3.3 shall summarize material submissions made by Company with, and material correspondence received by Company from, a Regulatory Authority pertaining to any Regulatory Filing or Regulatory Approval for Products. In the [***] after the Effective Date, to the extent reasonably requested by Company, Teva shall use reasonable efforts, at Company's expense, to provide Company with any information relating to the Licensed Know-How that is in Teva's possession, is not in the possession of Company and is needed for Regulatory Filing or Regulatory Approval for Products. For clarity, except as stated in the previous sentence, Teva shall have no obligation, responsibility or liability relating to any Regulatory Filing or Regulatory Approval for any Compound or Product, and Teva shall have no obligation, responsibility or liability to maintain, comment on, respond to or file any Regulatory Filings or Regulatory Approvals for any Compound or Product.

4.4 Regulatory Audits. To the extent that Teva's participation is requested by Company, the Parties shall cooperate in good faith with respect to Regulatory Authority inspections of any site or facility where Clinical Trials or Manufacturing of Products are conducted pursuant to this Agreement, whether such site or facility is Company's or its Affiliate's or a permitted subcontractor's.

4.5 Pricing and Reimbursement Standards. Company (alone and/or through its Affiliates and/or Sublicensees) shall be responsible for and have the exclusive right to seek and attempt to obtain pricing and reimbursement approvals for the Products in the Territory.

ARTICLE V
FINANCIAL PROVISIONS

5.1 Upfront and CRO Payments.

(a) **Upfront Payment**. Within [***] of the Effective Date, Company shall pay to Teva a total of Six Million US Dollars (US$6,000,000) as an aggregate one-time upfront payment for the rights granted under this Agreement and under the FASN Agreement. Such payment shall be non-refundable and non-creditable and not subject to set-off. For clarity, such amount shall serve as the upfront payment for both this Agreement and the FASN Agreement.

(b) **CRO Payment**. Within [***] of the Effective Date, Company shall pay to Teva, [***].

(c) **ABF Work Order Payment**. Within [***] of the Effective Date, Company shall pay to Teva, an amount equal to Teva's payments made to ABF as of the Effective Date under the ABF Work Order.

(d) **Timing of Payments**. Company shall pay to Teva the payments set forth in this Section 5.1 within [***] of the Effective Date. Any failure to provide such payments within such [***] shall be a material breach of this Agreement permitting Teva to terminate this Agreement with immediate effect.

(e) **Wire Transfer Instructions**. The payments described in this Section 5.1 shall be made by wire transfer to the following account:

[***]
Branch no. [***]
Account No: [***]
Swift: [***]
Beneficiary: [***]

5.2 Milestone Payments.

(a) **Product-based Milestones**. As consideration for Teva's grant of the rights and licenses to Company hereunder and the assignment of the Assigned Assets, Company shall pay to Teva the following one-time, product-based milestone payments (the "**Milestone Payments**") upon the first achievement of each of the milestone events set forth in the table below (the "**Milestone Events**") by a Product. Each Milestone Payment will be payable one time only, regardless of the number of Products and/or indications to achieve the corresponding Milestone

Event. Company shall pay the relevant Milestone Payment within [***] of such achievement (or in the case of the [***] milestones, of the end of the calendar quarter in which the [***] milestone was obtained) by Company or its Affiliates or Sublicensees, or any Transferee. For the avoidance of doubt, each of the Milestone Payments shall become payable upon the first occurrence of the associated Milestone Event, irrespective of the order in which the Milestone Events occur relative to each other. If a development Milestone Event (i.e., [***]) for a Product is skipped, then the skipped Milestone Event(s) for such Product will be deemed to have been met upon the achievement of the subsequent milestone for such Product. Such payments shall be non-refundable and non-creditable and not subject to set-off.

Milestone Events	Milestone Payment
[***]	$[***]
[***]	$[***]
[***]	$[***]
[***]	$[***]
[***]	$[***]

5.3 Royalties.

(a) As further consideration for Teva's grant of the rights and licenses to Company hereunder and the assignment of the Assigned Assets, Company shall pay to Teva a royalty at the graduated royalty rates specified in the table below with respect to the aggregate annual worldwide Net Sales of all Products by Company and its Affiliates, Sublicensees or any Transferee of the Assigned Assets, in the Territory in a calendar year (subject to the reductions and set-offs set forth below):

Aggregate Annual Worldwide Net Sales of All Products in a calendar year (US Dollars)	Royalty Rate
For that portion of aggregate annual Net Sales of all Products up to and including $[***].	[***]%
For that portion of aggregate annual Net Sales of all Products exceeding $[***] but less than and including $[***].	[***]%
For that portion of aggregate annual Net Sales of all Products exceeding $[***].	[***]%

The applicable royalty rate shall be calculated as provided in this Section 5.3(a) by reference to the aggregate annual worldwide Net Sales of all Products in a calendar year. By way of example, in a given calendar year, if the aggregate annual worldwide Net Sales of all Products for which royalties are due under this Section 5.3(a) were US$[***], the following royalty payment would be payable under this Section 5.3(a): [***].

(b) Royalties shall be payable from the First Commercial Sale of a Product, on a country-by-country basis, until the expiration of the Royalty Term for such Product and country.

(c) Only one royalty shall be due with respect to the sale of the same unit of Product regardless of how many Valid Claims included in any of the Transferred Patents Cover the manufacture, use, sale, offer for sale or importation of such Product.

(d) On a Product-by-Product and country-by-country basis, upon expiration of the Royalty Term for a Product in a country, the licenses granted to Company under Section 2 with respect to such Product in such country shall continue in effect but become fully paid-up, royalty-free, irrevocable and perpetual.

5.4 Reductions

(a) *Expiration of Transferred Patents*. Subject to Section 5.4(c), if royalties are payable under Section 5.3 on Net Sales of a particular Product (i) in a particular country after the expiration of all Valid Claims included in the Transferred Patents (including any applicable patent term extension) Covering such Product in such country or (ii) in a particular country in which there is no Valid Claim included in the Transferred Patents (including any applicable patent term extension) covering such Product, then the royalties payable on Net Sales of such Product shall be calculated as set forth in Section 5.3, provided that the portion of the royalties payable on Net Sales of such Product in the particular country shall be reduced by [***] after the date of expiration of the last-to-expire Valid Claim of the Transferred Patents Covering such Product in the country of sale.

(b) *Third Party Royalties.* If Company identifies any Patent owned or controlled by a Third Party in a particular jurisdiction that, absent a license or agreement with such Third Party, would be infringed (or in the case of pending application, the would be infringed if the claims therein were to issue) by manufacturing, using or selling a Product (except, in the case of Combination Products, intellectual property rights that are specific to Additional Ingredient(s) included in such Combination Product) ("**Blocking IP**"), then Company shall notify Teva. In the event that the Company acquires a license from such Third Party with respect to such Blocking IP, then Company will be entitled to offset [***] of any amounts paid under such license agreement with respect to such Product against amounts due under Section 5.3 (after the deductions described in Section 5.4(a)), provided however that Company shall not be entitled to deduct any such amounts until the relevant patent included in the Blocking IP has granted. Upon the granting of such patent included in the Blocking IP, Company shall be entitled to deduct from the royalties payable [***] of the amounts previously paid by Company to the Third Party licensee, all in accordance with this Section 5.4(b) and subject to Section 5.4(c).

(c) *Maximum Deduction*. In no event shall (a) the reduction under Section 5.4(b) reduce royalties otherwise due to Teva by more than [***] in any calendar [***] in any particular country and (b) the cumulative reductions under Sections 5.4(a) and 5.4(b) reduce the royalties otherwise due to Teva by more than [***] in any calendar [***] in any particular country.

(d) *No Obligation to Pay Third Party Royalties*. In no event shall Teva be required to contribute to Company's payments to Third Parties from which it has received (sub)licenses to intellectual property that claims or covers any Compound or Product. In no event shall Company be required to contribute to Teva's payments to Third Parties from which it has received (sub)licenses to intellectual property that claims or covers any Compound or Product.

(e) *No Other Deductions*. There shall be no deductions or other reductions to any royalties or other amounts payable to Teva hereunder, except to the extent provided by Sections 5.4(a), and 5.4(b).

5.5 Notice. Company shall give Teva written notice of any First Commercial Sale of a Product, or Milestone Event achieved under Section 5.2(a) within [***] of the occurrence of each such event.

5.6 Periodic Reports. Within [***] after the end of each calendar quarter commencing upon the First Commercial Sale of a Product, Company shall furnish Teva with a quarterly report ("**Periodic Report**") detailing, at a minimum, the following information for the applicable calendar quarter, each listed by Product and by country of sale: (i) the total number of units of Product sold by Company, its Affiliates, Sublicensees or Transferee for which royalties are owed to Teva hereunder, including a breakdown of the number and type of Products sold (example dosage strength, formulation and count as applicable), (ii) gross amounts received for all such sales, (iii) deductions by type taken from Net Sales as specified in Section 1.53, (iv) Net Sales, (v) royalties and milestone payments owed to Teva, listed by category, (vi) the currency in which the sales were made, including the computations for any applicable currency conversions pursuant to Section 5.8, and (vii) a summary of progress against each Net Sales Milestone Event. Once the first Commercial Sale has occurred, Periodic Reports shall be provided to Teva whether or not royalties, milestone payments or Sublicense fees are payable for a particular calendar quarter. In addition to the Periodic Report, and commencing upon the First Commercial Sale of a Product, Company shall furnish to Teva an annual forecast for the projected sales of Products in the foregoing calendar year, provided that (a) if sales are being made under a Sublicense agreement, Company shall only be required to provide such estimates if it has received the relevant estimates from the Sublicensee and is authorized under the relevant Sublicense agreement to share such estimates with Teva and (b) if substantially all of the shares of Company or substantially all of the assets to which this Agreement relates are sold in a bona fide transaction, the obligation to provide such forecasts shall terminate. Company agrees to suggest language requiring the Sublicensee to provide such information and allow such disclosure in its negotiations with Sublicensees; provided however, that Teva understands that the relevant Sublicensee may not agree to the inclusion of such language. In addition to the foregoing, upon Teva's reasonable request, Company shall provide to Teva such other information as may be reasonably requested by Teva, and shall otherwise cooperate with Teva as reasonably necessary, to enable Teva to verify Company's compliance with the payment and related obligations under this Agreement, including verification of the calculation of amounts due to Teva under this Agreement and of all financial information provided or required to be provided in the reports; provided that with respect to information related to sales by Sublicensees, Company shall only be obligated to provide Teva the information that it obtains from its Sublicensees, provided that Company shall use reasonable efforts to require its Sublicensee to provide all of the information requested by Teva pursuant to this sentence.

5.7 Payments. On the date prescribed for the submission of each Periodic Report, Company shall pay the royalties due to Teva for the reported period. All payments under this Agreement shall be computed and paid in United States Dollars. All Payments shall be made by wire transfer to such bank accounts as Teva may designate by written notice.

5.8 Currency Exchange. With respect to Net Sales invoiced in United States Dollars, the Net Sales and the amounts due to Teva hereunder shall be expressed in United States Dollars. With respect to Net Sales invoiced in a currency other than United States Dollars, the Net Sales shall be expressed in the domestic currency of the entity making the sale, together with the United States Dollars equivalent, calculated based on the average conversion rate existing in the United States (as reported in the Wall Street Journal) for the calendar quarter for which remittance is made for Royalties. For purposes of calculating the Net Sales thresholds set forth in Section 5.3, the aggregate Net Sales with respect to each calendar quarter within a calendar year shall be calculated based on the currency exchange rates for the calendar quarter in which such Net Sales occurred, in a manner consistent with the exchange rate procedures set forth in the immediately preceding sentence.

5.9 Taxes. Each Party is responsible for its own taxes, duties, levies, imposts, assessments, deductions, fees, withholdings or similar charges imposed on or measured by net income or overall gross income, gross receipts, capital, ability or right to do business, property, and franchise or similar taxes pursuant to applicable laws. All amounts to be paid to Teva pursuant to this Agreement are exclusive of Value Added Tax. Company shall add value added tax, as required by Law, to all such amounts. If applicable Laws require that taxes be withheld from any amounts due to Teva under this Agreement, Company shall (a) deduct these taxes from the remittable amount, (b) pay the taxes to the proper taxing authority, and (c) promptly deliver to Teva a statement including the amount of tax withheld, and such other information as may be necessary for tax credit purposes. Company shall cooperate with Teva in claiming exemptions from such deductions or a reduced withholding tax rate as allowable under any agreement or treaty from time to time in effect. If Company receives a refund of any such withheld taxes, in whole or in part, and whether in the form of cash, credit or other similar offset, Company shall refund such amount to Teva within a reasonable period of time, provided that nothing in this Agreement shall require Company to take any particular steps to obtain such refund. Payment of Value Added Tax – or of any analogous foreign tax, charge or levy (if charged), applicable to the sale of Products shall be added to each payment in accordance with the statutory rate in force at such time. Teva shall not be liable for any penalties or interest due to the failure of Company to remit any withholding or deductions to the proper tax authorities.

5.10 Records. Company shall keep, and shall require its Affiliates and Sublicensees to keep, full and correct books of account in accordance with GAAP enabling the royalties, Sublicense fees and Milestone Payments, and all corresponding deductions, to be calculated accurately. Company shall, and shall require and cause its Affiliates and Sublicensees to, retain such books of account with respect to a given report provided under Section 5.6, for three (3) years after the end of the calendar year to which such report relates, which reports shall be kept at each of their principal place of business and shall be open for inspection and audit in accordance with Section 5.11 below.

5.11 Audit. Teva shall be entitled to appoint, at its sole expense, a certified public accountant or other professional as appropriate and reasonably acceptable to Company (the "**CPA Representatives**") to inspect, not more than once a calendar year, during normal business hours Company's and its Affiliates' books and records contemplated by Section 5.10 above, including all books of account, records and other relevant documentation to the extent relevant or necessary for the sole purpose of verifying compliance with the payment and related obligations under this Agreement, the calculation of amounts due to Teva under this Agreement and of all financial information required to be provided in the Periodic Reports, provided that Teva shall coordinate such inspection with Company or its Affiliate (as the case may be) reasonably in advance. In addition, Teva may require that Company, through the CPA Representatives, inspect, at Teva's expense, during normal business hours the books and records contemplated by Section 5.10 above, including all applicable books of account, records and other relevant documentation of any Sublicensees, not more than once a calendar year, to the extent relevant or necessary for the sole purpose of verifying the compliance with the payment obligations under this Agreement, the calculation of amounts due to Teva under this Agreement and of all financial information provided in the Periodic Reports, and Company shall use its commercially reasonable efforts to cause such inspection to be performed. The Parties shall reconcile any underpayment or overpayment within thirty (30) days after the CPA Representatives deliver the results of the audit to Teva and Company. The results of such inspection, if any, shall be binding on both Parties. Any underpayment shall be subject to interest in accordance with the terms of Section 5.13, below. Any overpayments shall be fully creditable against amounts payable in subsequent payment periods during the Term, or if such overpayments are identified following the Term, then such overpayments shall be refunded within [***] of receipt of the corresponding audit results. In the event that any inspection of Company aforesaid reveals any underpayment by Company to Teva in respect of any calendar year of the Agreement in an amount exceeding five percent (5%) of the correct amount due by Company to Teva in respect of such calendar year, then Company shall pay the reasonable out-of-pocket cost of such inspection. Any underpayments or overpayments under this Section 5.11 shall be subject to the currency exchange provisions set forth in Section 5.8 as applied to the calendar quarter during which the payment obligations giving rise to such underpayment or overpayment were incurred by Company.

5.12 Blocked Payments. In the event that, by reason of applicable Law in any country, it becomes impossible or illegal for Company to transfer, or have transferred on its behalf, payments owed Teva hereunder, Company shall promptly notify Teva of the conditions preventing such transfer and such payments shall be deposited in local currency in the relevant country to the credit of Teva in a recognized banking institution designated by Teva or, if none is designated by Teva within a period of [***], in a recognized banking institution selected by Company, as the case may be, and identified in a written notice given to Teva.

5.13 Interest Due. Any sum of money due to Teva which is not duly paid on time shall bear interest from the due date of payment until the actual date of payment at the rate of [***], computed for the actual number of days the payment was past due.

5.14 Mutual Convenience. The royalty and other payment obligations set forth hereunder have been agreed to by the Parties for the purpose of reflecting and advancing their mutual convenience, including the ease of calculating and paying royalties and other amounts to Teva. Company hereby stipulates to the fairness and reasonableness of such royalty and other payments obligations and covenants not to allege or assert, nor to allow any of its Affiliates or Sublicensees to allege or assert, nor further to cause or support any other Third Parties to allege or assert, that any such royalty or other payments obligations are unenforceable or illegal in any way.

ARTICLE VI
INTELLECTUAL PROPERTY

6.1 Intellectual Property.

(a) The Parties acknowledge that the ownership rights set out in this Section 6.1 are subject to the terms and conditions of this Agreement (including the license grants and restrictions on licensing that are set forth in Article II).

(b) Teva shall own all right, title and interest in and to the Teva Licensed Technology. Company shall own all right, title and interest in and to the Assigned Assets. Ownership of any Third Party Patents shall be as set forth in the applicable Third Party License Agreement.

(c) Company agrees that it will use reasonable efforts to prosecute and maintain the patents included in the patent family [***] in the following countries: [***]. Notwithstanding the foregoing, the Company shall have no such obligation with respect to a country listed above if Company reaches the conclusion, in its reasonable judgment after consultation with patent counsel, that (i) it is unlikely that a patent will be granted on the relevant Assigned Patents in such country or (ii) if any such patent is granted, it is unlikely to be enforceable in a manner that provides a competitive advantage to Company in such country. In the event that Company decides that it will not file, prosecute or maintain any patents included in the Assigned Patents, Company shall provide Teva with prior written notification thereof. Teva shall have the right, but not the obligation to, assume control of and responsibility for the filing, prosecution or maintenance of such Assigned Patent in such country at Teva's expense.

ARTICLE VII
CONFIDENTIALITY

7.1 Definitions. Company and Teva each recognizes that during the Term, a Party (the "**Disclosing Party**") may disclose or provide Confidential Information (as defined herein) to the other Party (the "**Receiving Party**"). The disclosure and use of Confidential Information shall be governed by the provisions of this Article VII. Neither Company nor Teva shall use the other's Confidential Information except as expressly permitted in this Agreement, which includes the exercise of rights or performance of obligations under this Agreement. For purposes of this Agreement, "**Confidential Information**" means all confidential or proprietary information (including information relating to the business, operations and products of a Party or any of its Affiliates), including Third Party information, disclosed or provided by the Disclosing Party to the Receiving Party or its Affiliates or Sublicensees, regardless of whether any of the foregoing are marked "confidential" or "proprietary" or communicated to the other by the disclosing Party or its Affiliates in oral, written, graphic, or electronic form. Notwithstanding the foregoing, all non-public information within the Assigned Assets will be deemed Confidential Information of the Company (and not of Teva) and Company shall be deemed the Disclosing Party and Teva will be deemed the Receiving Party with respect to such information.

7.2 Obligation. Each Receiving Party agrees that it may use the Disclosing Party's Confidential Information solely for the purpose performing its obligations and/or exercising its rights under this Agreement. Each Receiving Party further agrees that it may disclose the Disclosing Party's Confidential Information to its own (or its respective Affiliate's, or with respect to Company, also its Sublicensees' and contractors') shareholders, officers, employees, consultants, representatives, agents only if and to the extent necessary to carry out the Receiving Party's responsibilities under this Agreement or in accordance with the exercise of Receiving Party's rights under this Agreement, and such disclosure shall be limited to the maximum extent possible consistent with such responsibilities and rights, and only if such recipient is under written obligations of confidentiality and non-use at least as stringent as those herein. Except as set forth in the foregoing sentence, the Receiving Party shall not disclose Confidential Information of the Disclosing Party to any Third Party without the Disclosing Party's prior written consent. In all events, however, any and all disclosure to a Third Party (or to any such Affiliate or Sublicensee) shall be pursuant to the terms of a non-disclosure/nonuse agreement no less restrictive than this Article VII. The Party which disclosed Confidential Information of the other to any Third Party (or to any such Affiliate or Sublicensee) shall be responsible and liable for any disclosure or use by such Third Party, Affiliate or Sublicensee (or its disclosees) which would have violated this Agreement if committed by the Party itself. Each Receiving Party shall take such action to preserve the confidentiality of the Disclosing Party's Confidential Information as it would customarily take to preserve the confidentiality of its own Confidential Information (but in no event less than a reasonable standard of care). Upon expiration or termination of this Agreement, each Receiving Party, upon the Disclosing Party's request, shall return or destroy (at Disclosing Party's discretion) all the Confidential Information disclosed to the Receiving Party pursuant to this Agreement, including all copies and extracts of documents, within sixty (60) days after the request, except for one archival copy (and such electronic copies that exist as part of the Receiving Party's computer systems, network storage systems and electronic backup systems) of such materials solely to be able to monitor its obligations that survive under this Agreement.

7.3 Exceptions. The non-use and non-disclosure obligations set forth in this Article VII shall not apply to any Confidential Information, or portion thereof, that the Receiving Party can demonstrate by competent evidence:

(a) at the time of disclosure is in the public domain;

(b) after disclosure, becomes part of the public domain, by publication or otherwise, through no fault of the Receiving Party or its disclosees (including any Affiliates or Sublicensees);

(c) is made available to the Receiving Party by an independent Third Party without an obligation of confidentiality with respect to such information; or

(d) is independently developed by the Receiving Party without access, use or reference to the Disclosing Party's information.

In addition, the Receiving Party may disclose information that is required to be disclosed by Law, by a valid order of a court or by order or regulation of a governmental agency, including but not limited to, regulations of the SEC or in the course of arbitration or litigation; provided, however, that in all cases the Receiving Party shall give the other party prompt notice of the pending disclosure, to the extent permitted and practicable, and make a reasonable effort to assist the Disclosing Party, at the Disclosing Party's expense, in obtaining, a protective order or confidential-treatment order preventing or limiting (to the greatest possible extent and for the longest possible period) the disclosure and/or requiring that the Confidential Information so disclosed be used only for the purposes for which the law or regulation required, or for which the order was issued. The foregoing notwithstanding, with respect to any such disclosure required by applicable Law or the requirements of any stock exchange to which a Party is subject, the Party required to make such disclosure shall (a) provide the other Party with notice and a copy of such proposed disclosure as far in advance of such filing or other disclosure as is reasonably practicable under the circumstances, and (b) provide the other Party a reasonable opportunity to request confidential treatment or review and comment on such communications. Notwithstanding anything to the contrary herein, if a Party is seeking to make a disclosure required by applicable Law as set forth in Section 7.5 or this Section 7.3, and the other Party provides comments, the Party seeking to make such disclosure or its counsel, as the case may be, shall in good faith (i) consider incorporating such comments and (ii) use reasonable efforts to incorporate such comments, limit disclosure or obtain confidential treatment to the extent reasonably requested by the other Party, to the extent that such Party reasonably determines such request to be consistent with applicable Law.

Notwithstanding the foregoing, (i) the Receiving Party may disclose the Disclosing Party's Confidential Information to actual or potential investors, acquirors, licensees, sublicensees, contractors and other financial or commercial partners solely for the purpose of evaluating or carrying out an actual or potential investment, acquisition, service (on behalf of Receiving Party) or collaboration; provided that in each such case such disclosure is on the condition that such recipients are bound by confidentiality and non-use obligations substantially consistent with those contained in the Agreement; provided, however, that the term of confidentiality and non-use for such recipients shall be no less than [***] years, and (ii) Company may disclose Teva's Confidential Information to the extent such disclosure is reasonably necessary, and subject to any available confidentiality protection, (A) to the patent offices in any country in which Patents are sought for purposes of prosecuting any applications for Patents or defending any Patents in opposition or other actions; or (B) to Regulatory Authorities to pursue Development, Manufacture and Commercialization of Products.

7.4 Terms of this Agreement. The Parties agree that the terms of this Agreement shall be treated as Confidential Information of both Parties, and may only be disclosed to actual or potential investors, acquirors, licensees, or sublicensees, solely for the purpose of evaluating or carrying out an actual or potential investment, acquisition, or collaboration, and subject to confidentiality protections at least as strict as those contained herein. In addition, each Party may disclose this Agreement or its terms to the extent required to be disclosed by Law, by a valid order of a court or by order or regulation of a governmental agency, including but not limited to, regulations of the SEC or in the course of arbitration or litigation; provided, however, that the Party required to make such disclosure shall (a) provide the other Party with notice and a copy of

such proposed disclosure as far in advance of such filing or other disclosure as is reasonably practicable under the circumstances, and (b) provide the other Party a reasonable opportunity to request confidential treatment or review and comment on such communications. Notwithstanding anything to the contrary herein, if a Party is seeking to make a disclosure required by applicable Law as set forth in this Section 7.4, and the other Party provides comments, the Party seeking to make such disclosure or its counsel, as the case may be, shall in good faith (i) consider incorporating such comments and (ii) use reasonable efforts to incorporate such comments, limit disclosure or obtain confidential treatment to the extent reasonably requested by the other Party, to the extent that such Party reasonably determines such request to be consistent with applicable Law.

7.5 Publicity; Publications. Neither Party, nor its Affiliates shall originate any publicity, news release, public announcement or publication, written or oral, relating to this Agreement, the transactions contemplated hereby or the terms hereof, or the existence of any arrangement between the Parties, without the prior written consent of the other Party (not to be unreasonably withheld, conditioned or delayed), whether or not named in such publicity, news release, other public announcement or publication, except that such consent shall not be required for disclosures to the extent described in the penultimate paragraph of Section 7.3, previously approved for disclosure under this Section 7.5 or otherwise made public not in breach of this Article VII. Notwithstanding the foregoing, Company shall have the right to publish and present publicly the results of its activities under this Agreement, and shall provide Teva with a copy (to the attention of "Alliance Management" pursuant to Section 11.7) of each abstract, presentation, manuscript and similar materials intended to be published or presented by Company in any medium or forum (including information to be presented verbally) that may disclose Teva Confidential Information at least five (5) days prior to Company publishing (or submitting for publication) or presenting such materials.

7.6 Survival. The provisions of this Article VII shall survive expiry or termination of this Agreement for a period of [***] thereafter.

ARTICLE VIII
REPRESENTATIONS, WARRANTIES AND COVENANTS

8.1 Representations and Warranties. (a) Company represents and warrants to Teva, and (b) Teva represents to Company, in each case as of the Effective Date that:

(a) Such Party is a corporation duly organized and validly existing under the Laws of the jurisdiction of its incorporation;

(b) Such Party has all right, power and authority to enter into this Agreement, and to perform its obligations under this Agreement;

(c) Such Party has taken all action necessary to authorize the execution and delivery of this Agreement and the performance of its obligations under this Agreement;

(d) This Agreement is a legal and valid obligation of such Party, binding upon such Party and enforceable against such Party in accordance with the terms of this Agreement;

(e) The execution, delivery and performance of this Agreement by such Party does not conflict with, breach or create in any Third Party the right to accelerate, terminate or modify any agreement or instrument to which such Party is a party or by which such Party is bound;

(f) All consents, approvals and authorizations from all governmental authorities or other Third Parties required to be obtained by such Party in connection with the execution and delivery of this Agreement have been obtained; and the execution, delivery and performance of this Agreement by such Party does not violate any Law of any Governmental Body having authority over such Party;

(g) No person or entity has or shall have, as a result of the execution and delivery of or as a result of the transactions contemplated by this Agreement, any right, interest or valid claim against or upon such Party for any commission, fee or other compensation as a finder or broker because of any act by such Party or its Affiliates, agents or Sublicensees; and

(h) No agreement between it and any Third Party is in conflict with the rights granted to the other Party pursuant to this Agreement.

8.2 Additional Representations and Warranties of Teva. Teva represents, warrants and covenants to Company as of the Effective Date that:

(a) No consent by any Third Party or Governmental Body is required with respect to the execution and delivery of this Agreement by Teva or the consummation by Teva of the transactions contemplated hereby;

(b) Except as described in Section 2.7.3, Teva or its Affiliates exclusively own all right, title and interest in and to the Assigned Assets free and clear of all Liens.

(c) Teva has the full right to grant the licenses granted under this Agreement with respect to the Teva Licensed Patents and Teva Licensed Know-How without breaching any third party rights.

(d) Intellectual Property

(i) The Assigned Patents are all of the Patents owned by Teva or its Affiliates that relate solely and exclusively to the FGF21 Program.

(ii) To the best of Teva's knowledge, the Assigned Assets and the use and practice of the Assigned Assets for the Development and Commercialization of Compounds and Products, and the use of and the practice of the inventions claimed in the Teva Licensed Patents and the Teva Know-How, do not violate or infringe the intellectual property rights of any Third Party. To the best of Teva's knowledge, no Third Party has the right to assert any claim regarding the use of, or challenging or questioning Teva's right or title in, any Assigned Asset. To the best of Teva's knowledge, no Third Party is making an unauthorized use or disclosure of any Assigned Asset.

(iii) Teva has taken security measures to protect the secrecy, confidentiality and value of all of the Assigned Assets, which measures are reasonable and customary in the industry in which Teva operates.

(iv) No government, university, college, other educational institution research center, or nonprofit institution (each an "**Institution**" and collectively the "**Institutions**") provided facilities or funding for the development of any intellectual property included in the Assigned Assets.

(v) With respect to all Assigned Patents, all necessary filing, examination, registration, maintenance, renewal and other fees and taxes have been timely paid, and all necessary documents and certificates have been timely filed with all relevant registration offices for the purposes of maintaining such intellectual property, in each case in accordance with applicable law, except in each case as would not be expected to have a material adverse effect on the Assigned Patents.

(vi) With respect to all Assigned Patents, in each case (A) such Assigned Patents have been prosecuted in good faith, and (B) Teva and its patent counsel have complied with their duty of candor and disclosure to all registration offices with respect to such Assigned Patents and have made no intentional misrepresentations in connection with the prosecution or maintenance of such Assigned Patents.

(e) Litigation. There are no actions, suits, claims, charges, hearings, arbitrations, audits, proceedings (public or private) or investigations (collectively, "**Proceedings**") that have been brought or initiated by or against any governmental authority, customer, distributer or any other third party, or are pending or threatened in writing (whether settled or unsettled) regarding any of the Assigned Assets, the Product or the Compound, or (b) that seek or would reasonably be expected to prevent, enjoin, alter or delay the transactions contemplated by this Agreement.

(f) Tax. There is no unpaid Tax which constitutes a Lien upon any of the Assigned Assets or any Teva Licensed Patents.

(g) Patent Claims. No action, claim, proceeding or inquiry or investigation is pending or, to the knowledge of Teva, threatened by any Third Party with respect to any Compound or Product or the patentability or validity of any claims of any of the Assigned Patents or the Teva Licensed Patents;

(h) Notice of Infringement. Teva has not received any written notice or threat from any Third Party asserting or alleging that any research, manufacture or development of Compounds or Products by Teva prior to the Effective Date infringed or misappropriated the intellectual property rights of such Third Party.

8.3 Disclaimer. Notwithstanding the representations and warranties set forth in this Article VIII, Company acknowledges and accepts the risks inherent in attempting to Develop and Commercialize any pharmaceutical product. There is no implied representation that the Compounds or Products can be successfully Developed or Commercialized.

8.4 EXCEPT AS EXPRESSLY SET FORTH HEREIN, NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, WITH RESPECT TO ANY TEVA PATENT OR TEVA KNOW-HOW, ANY COMPOUND, ANY PRODUCTS OR ANY INVENTORY, INCLUDING ANY WARRANTIES OF VALIDITY OR ENFORCEABILITY OF ANY PATENTS, TITLE, QUALITY, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, PERFORMANCE OR NONINFRINGEMENT OF ANY THIRD PARTY PATENTS OR OTHER INTELLECTUAL PROPERTY RIGHTS.

ARTICLE IX
INDEMNIFICATION; LIMITATION OF LIABILITY; INSURANCE

9.1 Indemnification

(a) **Indemnification by Company**. Company shall indemnify, defend and hold Teva and its Affiliates and each of their respective employees, officers, directors and agents (each a "**Teva Indemnitee**") harmless from and against any and all actions, judgments, settlements, liabilities, damages, penalties, fines, losses, costs and expenses (including reasonable attorneys' fees and expenses) to the extent arising out of any Third Party claim, demand, action or other proceeding (each, a "**Claim**") to the extent arising out of or resulting from (i) the Development, Manufacture, Commercialization (including testing, handling, storage, transportation, sale or use or other disposition) of any Compound or Product by or on behalf of Company or its Affiliates or Sublicensees; (ii) Company's or its Affiliates' and Sublicensees' use or practice of the Teva Licensed Technology, Third Party Licensed Patents, Assigned Patents; (iii) breach by Company of any of its representations, warranties, covenants or obligations set forth in this Agreement, (iv) a Company Indemnitee's or any of Company's Sublicensees' gross negligence, recklessness or willful misconduct; or (e) use of the Assigned Assets by or on behalf of Company, its Affiliates, Sublicensees and/or Transferees, provided, however, that Company's obligations pursuant to this Section 9.1 shall not apply to the extent such Claims arise out of or result from Teva's breach of this Agreement or the negligence, recklessness or willful misconduct of any Teva Indemnitee.

(b) **Indemnification by Teva**. Teva shall indemnify, defend and hold Company and its Affiliates and each of their respective agents, employees, officers and directors (each a "**Company Indemnitee**") harmless from and against any and all Claims to the extent arising out of or resulting from (a) the Development or Manufacture (including testing, handling, storage, transportation, use or other disposition) of any Compound or Product by or on behalf of Teva or its Affiliates or licensees prior to the Effective Date; (b) breach by Teva of any of its representations, warranties, covenants or obligations set forth in this Agreement, or (c) a Teva Indemnitee's gross negligence, recklessness or willful misconduct; provided, however, that Teva's obligations pursuant to this Section 9.2 shall not apply to the extent such Claims arise out of or result from Company's breach of this Agreement or the negligence, recklessness or willful misconduct of any Company Indemnitee.

9.2 Procedure.

(a) The Party or other Person intending to claim indemnification under this Article IX (an "**Indemnified Party**") shall promptly notify the other Party (the "**Indemnifying Party**") of any Claim in respect of which the Indemnified Party intends to claim such indemnification (provided, that no delay or deficiency on the part of the Indemnified Party in so notifying the Indemnifying Party shall relieve the Indemnifying Party of any liability or obligation under this Agreement except to the extent the Indemnifying Party has suffered actual prejudice directly caused by the delay or other deficiency), and the Indemnifying Party shall assume the defense thereof (with counsel selected by the Indemnifying Party and reasonably satisfactory to the Indemnified Party) whether or not such Claim is rightfully brought; provided, however, that an Indemnified Party shall have the right to retain its own counsel and to participate in the defense thereof, with the fees and expenses to be paid by the Indemnified Party unless the Indemnifying Party does not assume the defense or unless a representation of both the Indemnified Party and the Indemnifying Party by the same counsel would be inappropriate due to the actual or potential differing interests between them, in which case the reasonable fees and expenses of counsel retained by the Indemnified Party shall be paid by the Indemnifying Party. For clarity, in no event shall the Indemnifying Party be required to pay for more than one separate counsel no matter the number or circumstances of all Indemnified Parties.

(b) If the Indemnifying Party shall fail to timely assume the defense of and reasonably defend such Claim, the Indemnified Party shall have the right to retain or assume control of such defense and the Indemnifying Party shall pay (as incurred and on demand) the fees and expenses of counsel retained by the Indemnified Party.

(c) The Indemnifying Party shall not be liable for the indemnification of any Claim settled (or resolved by consent to the entry of judgment) without the written consent of the Indemnifying Party. Also, if the Indemnifying Party shall control the defense of any such Claim, the Indemnifying Party shall have the right to settle such Claim; provided, that the Indemnifying Party shall obtain the prior written consent (which shall not be unreasonably withheld or delayed) of the Indemnified Party before entering into any settlement of (or resolving by consent to the entry of judgment upon) such Claim unless (i) there is no finding or admission of any violation of law or any violation of the rights of any person by an Indemnified Party, no requirement that the Indemnified Party admit negligence, fault or culpability, and no adverse effect on any other claims that may be made by or against the Indemnified Party and (ii) the sole relief provided is monetary damages that are paid in full by the Indemnifying Party and such settlement does not require the Indemnified Party to take (or refrain from taking) any action.

(d) The Indemnified Party, and its employees and agents, shall cooperate fully with the Indemnifying Party and its legal representatives in the investigations of any Claim.

(e) Regardless of who controls the defense, each Party hereto shall reasonably cooperate in the defense as may be requested.

(f) Teva shall not be liable under this Article 9 for any Claims and losses arising therefrom, to the extent based upon or arising out of any inaccuracy in or breach of any of the representations or warranties of Teva contained in Sections 8.2(d)(ii), 8(d)(iv), 8(e) or 8(h) of this Agreement if either [***] or [***] had actual knowledge of such inaccuracy or breach prior to the Effective Date.

9.3 Expenses. As the Parties intend complete indemnification, all costs and expenses of enforcing any provision of this Article IX shall also be reimbursed by the Indemnifying Party.

9.4 Limitation of Liability. IN NO EVENT SHALL EITHER PARTY OR ITS AFFILIATES BE LIABLE TO THE OTHER PARTY FOR ANY PUNITIVE, EXEMPLARY OR CONSEQUENTIAL DAMAGES ARISING OUT OF A BREACH OF THIS AGREEMENT, PROVIDED THAT, NOTWITHSTANDING ANYTHING TO THE CONTRARY, THE FOREGOING SHALL NOT BE CONSTRUED TO LIMIT THE INDEMNITY OBLIGATIONS SET FORTH IN SECTIONS 9.1 AND 9.2 OR EITHER PARTY'S LIABILITY FOR A BREACH OF Article VII. THE TOTAL AGGREGATE LIABILITY OF EITHER PARTY UNDER THIS AGREEMENT, THE TRANSACTIONS DOCUMENTS, AND ANCILLARY DOCUMENTS RELATED THERETO WILL BE THE TOTAL SUMS OF MONEY PAID UNDER THE TRANSACTIONS DOCUMENTS, OTHER THAN IN CASE OF FRAUD, INTENTIONAL MISREPRESENTATION OR WILLFUL MISCONDUCT BY THE BREACHING PARTY, IN WHICH CASE THE BREACHING PARTY SHALL BE LIABLE TO ANY AMOUNT.

9.5 Insurance. During the Term and for at least [***] thereafter, Company shall carry and maintain insurance of the types and in amounts which are reasonable and customary in the pharmaceutical industry for companies of comparable size for comparable activities. Such insurance shall insure against all liability, including but not limited to (when applicable to Company's activities), bodily injury or property damage arising out of the manufacture, sale, distribution, marketing, Development or Commercialization of any Compounds or Products. Such insurance shall include commercial general liability insurance (when applicable to Company's activities), including product liability insurance, which coverage shall have limits of liability which are commercially reasonable for the pharmaceutical industry. The coverage limits set forth herein will not create any limitation on Company's liability to Teva under this Agreement.

ARTICLE X
TERM AND TERMINATION

10.1 Term. The term of this Agreement shall commence on the Effective Date and, unless earlier terminated as provided in this Article X, shall continue in full force and effect, on a country-by-country and Product-by-Product basis, until the Royalty Term in such country with respect to such Product expires, at which time this Agreement shall expire with respect to such Product in such country, subject to the perpetual license under Section 5.3(d) and other rights and obligations surviving such expiration. The "**Term**" means the period from the Effective Date until the earlier of termination of this Agreement as provided in this Article X or expiration of this Agreement upon the expiration of the last-to-expire Royalty Term. The Parties confirm that subject to the foregoing sentence, this Agreement shall not be terminated or invalidated by any future determination that any or all of the Teva Licensed Patents have expired or been invalidated.

10.2 Termination Without Cause. Company may terminate this Agreement without cause upon [***] prior written notice to Teva, provided that Company may only exercise its right to terminate under this Section 10.2, and provide such notice, after the first anniversary of the Effective Date. Any notice of termination sent prior to [***] shall be deemed to be delivered upon the first anniversary of the Effective Date.

10.3 Termination upon Material Breach. If a Party materially breaches any of its material obligations under this Agreement, the Party not in breach may give to the breaching Party a written notice specifying the nature of the breach, requiring it to cure such breach, and, if desired, stating its intention to terminate this Agreement if such breach is not cured. If such breach is not capable of being cured, or is capable of being cured but nonetheless has not within [***] after the receipt of such notice been cured, then the Party not in breach shall (in addition to and not in lieu of all other available rights and remedies) be entitled to at its option either (i) terminate this Agreement immediately by written notice to the other Party, or (ii) continue this Agreement in full force and effect and seek any legal or equitable remedies that the non-breaching Party may have; provided that if such material breach is curable but is incapable of being cured within such [***], then the non-breaching Party's right of termination shall be suspended only if, and for so long as, the other Party has provided to the non-breaching Party and is diligently implementing a written plan that is reasonably calculated to effect a cure of such material breach in as prompt a manner as reasonably practicable, but no longer than an additional [***]. Notwithstanding the foregoing provisions, in the event of a good-faith dispute as to whether any alleged breach is in fact a material breach, termination under this Section 10.3 in respect of such alleged breach shall not take effect unless and until such dispute is finally resolved (by the final unappealable decision of a court or otherwise) in favor of the Party alleging the breach and the breaching Party fails to cure such breach within [***] after the date of such final decision. In case of a breach of an obligation to pay money, which obligation to pay is not disputed in good faith, the cure period shall be [***]instead of [***]. Notwithstanding anything to the contrary contained herein, a failure by Company to make the payments specified in Section 5.1 within [***] of the Effective Date shall be a material breach permitting termination by Teva with immediate effect.

10.4 Termination for Bankruptcy. Teva may terminate this Agreement immediately upon written notice to Company in the event that Company has a petition in bankruptcy filed against it that is not dismissed within sixty (60) days of such filing, files a petition in bankruptcy, or makes an assignment for the benefit of creditors. Company may terminate this Agreement immediately upon written notice to Teva in the event that Teva has a petition in bankruptcy filed against it that is not dismissed within sixty (60) days of such filing, files a petition in bankruptcy, or makes an assignment for the benefit of creditors. Notwithstanding the foregoing, in the event a receiver or trustee (or the like) is appointed to a party or a party has entered into a settlement with its creditors and such party is otherwise meeting its obligations pursuant to this Agreement, the other party shall not be entitled to terminate this Agreement as contemplated under Section 10.4 during such period.

10.5 Termination for Patent Challenge

(a) In the event that Company or any of its Affiliates or Sublicensees, directly or indirectly commences a Patent Challenge with respect to any of the Teva Licensed Patents and does not withdraw such Patent Challenge within [***] of Teva's written notice, Teva may terminate the license with respect to the Teva Licensed Patents that are subject to such Patent Challenge; provided, that with respect to any such Patent Challenge by any non-Affiliate Sublicensee, Teva will not have the right to terminate this Agreement under this Section 10.5(a) if Company (i) causes such Patent Challenge to be terminated or dismissed or (ii) terminates such Sublicensee's Sublicense to the Teva Licensed Patents being challenged by the Sublicensee, in each case within [***] of Teva's notice to Company under this Section 10.5(a). In the event Company or any of its Affiliates intends to bring a Patent Challenge in any forum, not less than [***] prior to commencing such action, Company will provide to Teva a complete written disclosure of each basis known to Company and its Affiliates for such Patent Challenge.

10.6 Effect of Termination.

(a) **No release**. Upon expiration or termination of this Agreement for any reason, nothing in this Agreement may be construed to release either party from any liability or obligation that accrued or matured prior to the effective date of the expiration or termination, nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity, with respect to any breach of this Agreement nor prejudice either Party's right to obtain performance of any obligation.

(b) **Survival**.

(i) Article 7, Article 9 and Sections 11.2, 11.3, 11.6 and 11.7, as well as any rights, obligations and duties which by their nature extend beyond the expiration or termination of this Agreement, shall survive termination or expiration of this Agreement.

(ii) In addition, unless the Agreement is terminated in accordance with Section 5.1(d) or in accordance with Section 10.2 (in which case the Assigned Assets will be assigned back to Teva), the following provisions will survive termination or expiration of this Agreement: Section 2.1, the first sentence of Section 2.6, Section 2.7, Article V (other than Section 5.1) and Article VI.

(c) **Consequences of Termination Without Cause or Termination by Teva**. The following provisions shall apply in the event of termination by Company pursuant to Section 10.2 or by Teva pursuant to Sections 10.3, 10.4 or 10.5:

(i) *Wind-down.* Except as may otherwise be agreed in writing by the Parties, Company will be responsible at its own expense for an orderly wind-down, in accordance with accepted pharmaceutical industry norms and ethical practices, of any then on-going clinical trials hereunder for which it has responsibility.

(ii) *Licenses.* All licenses and other rights granted by Teva to Company under the Teva Licensed Technology pursuant to Section 2.2 will terminate and such licenses will revert to Teva, and Company and its Affiliates and Sublicensees will have no further rights to use any Teva Licensed Technology (except as necessary for Company to conduct any activities expressly set forth in Section 10.6(c)(i)). Each Party will promptly return to the other Party (or as directed by such other Party destroy and certify to such other Party in writing as to such destruction) all of such other Party's Confidential Information and any materials and Teva Licensed Technology provided by or on behalf of such other Party hereunder that are in such Party's (or its Affiliates' or in the case of Company's Sublicensees') possession or control, save that such Party will have the right to retain (A) one (1) copy of intangible Confidential Information of such other Party for legal purposes, and (B) any of the foregoing to which such Party retains any license or other right hereunder.

(iii) *Sublicenses.* Any sublicenses shall survive termination of this Agreement solely if and to the extent provided in Section 2.5(c) and otherwise they shall terminate contemporaneously with this Agreement.

(d) **Additional Consequences of Termination without Cause**. In addition, in the event of termination by Company pursuant to Section 10.2, Company shall assign all of the Assigned Assets back to Teva.

10.7 Bankruptcy Code. All rights and licenses granted under or pursuant to this Agreement by a Party are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that each Party as licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code or any other provisions of applicable law outside the United States that provide similar protection for "intellectual property." The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against a Party under the U.S. Bankruptcy Code or analogous provisions of applicable law outside the United States, the other Party shall be entitled to a complete duplicate of (or complete access to, as appropriate) any Teva Licensed Technology, Third Party Licensed Patents and all embodiments of such Teva Licensed Technology and Third Party Licensed Patents, which, if not already in such Party's possession, shall be promptly delivered to it (a) upon any such commencement of a bankruptcy proceeding upon the other Party's written request therefor, unless such Party elects to continue to perform all of its obligations under this Agreement or (b) if not delivered under (a) above, following the rejection of this Agreement by or on behalf of such Party upon written request therefor by the other Party. Nothing in this Section shall limit or derogate from any Party's rights pursuant to Section 11.12 below (*Equitable Relief*). Any agreements supplemental hereto shall be deemed to be "agreements supplementary to" this Agreement for purposes of Section 365(n) of the Bankruptcy Code.

ARTICLE XI
MISCELLANEOUS PROVISIONS

11.1 Relationship of the Parties. Nothing in this Agreement is intended or shall be deemed to constitute a partnership, agency, joint venture or employer-employee relationship between the Parties. No Party shall have any right or authority to commit or legally bind any other Party in any way whatsoever including, without limitation, the making of any agreement, representation or warranty and each Party agrees to not purport to do so.

11.2 Assignment.

(a) Any assignment not in accordance with this Section 11.2 shall be void.

(b) Company may not delegate, transfer or assign its rights or obligations under this Agreement, in whole or in part, by operation of law or otherwise, to any Third Party without the prior written consent of Teva, which consent shall not be unreasonably withheld, conditioned or delayed; *provided that*, notwithstanding the foregoing, Company may, without such consent, assign its rights or licenses and/or delegate its obligations in whole or in part under this Agreement to an Affiliate or in connection with a Change of Control. As a condition to any permitted assignment hereunder, the assignee must expressly assume, in a writing delivered to Teva and signed by a duly authorized officer of the assignee, all of Company's obligations under this Agreement arising at or after the assignment.

(c) Any permitted assignee will assume all assigned obligations of its assignor under this Agreement. Subject to the foregoing, this Agreement shall be binding on the Parties and their successors and permitted assigns.

11.3 Further Actions. Each Party agrees to execute, acknowledge and deliver such further instruments and to do all such other acts as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

11.4 Force Majeure. No Party shall be liable to any other Party or be deemed to have breached or defaulted under this Agreement for failure or delay in the performance of any of its obligations under this Agreement (other than obligations for the payment of money) for the time and to the extent such failure or delay is caused by or results from acts of God, earthquake, riot, civil commotion, terrorism, war, strikes or other labor disputes, fire, flood, failure or delay of transportation, omissions or delays in acting by a governmental authority, acts of a government or an agency thereof or judicial orders or decrees or restrictions or any other like reason which is beyond the control of the respective Party. The Party affected by force majeure shall provide the other Party with full particulars thereof as soon as it becomes aware of the same (including its best estimate of the likely extent and duration of the interference with its activities), and shall use commercially reasonable efforts to overcome the difficulties created thereby and to resume performance of its obligations hereunder as soon as practicable, and the time for performance shall be extended for a number of days equal to the duration of the force majeure.

11.5 Entire Agreement of the Parties; Amendments. This Agreement, the Transaction Documents, and the Schedules hereto and thereto constitute and contain the entire understanding and agreement of the Parties respecting the subject matter hereof and cancel and supersede any and all prior or contemporaneous negotiations, correspondence, understandings and agreements between the Parties, whether oral or written, regarding such subject matter (provided, that any and all previous nondisclosure/nonuse obligations are not superseded and remain in full force and effect in addition to the nondisclosure/nonuse provisions hereof). Each Party acknowledges that it has not relied, in deciding whether to enter into this Agreement on this Agreement's expressly stated terms and conditions, on any representations, warranties, agreements, commitments or promises which are not expressly set forth within this Agreement. No modification or amendment of any provision of this Agreement shall be valid or effective unless made in a writing referencing this Agreement and signed by a duly authorized representative of each Party.

11.6 Governing Law. All disputes, claims or controversies arising out of this Agreement, or the negotiation, validity or performance of this Agreement, or the transactions contemplated hereby shall be governed by and construed in accordance with the laws of Israel without regard to its rules of conflict of laws. Each of the parties hereto hereby irrevocably and unconditionally consents to submit to the sole and exclusive jurisdiction of the courts of Tel Aviv, Israel for any litigation among the parties hereto arising out of or relating to this Agreement, or the negotiation, validity or performance of this Agreement, waives any objection to the laying of venue of any such litigation in such courts.

11.7 Notices and Deliveries. Any notice, request, approval or consent required or permitted to be given under this Agreement shall be in writing and shall be deemed to have been sufficiently given if and only if delivered in person, or by express or overnight courier service to the Party to which it is directed at its physical address shown below or such other physical address as such Party shall have last given by such written notice to the other Party. Notices will be deemed given upon receipt.

If to Company, addressed to:

89 Bio Ltd. c/o Orbimed Israel Partners
89 Midanat Hayehudim
Herzliya 46766
Israel
Attention: CEO

If to Teva, addressed to:

Teva Pharmaceutical Products R&D, Inc.
41 Moores Road, Frazer, PA 19355
Attention: Head of Alliance Management

With a copy to:

Teva Pharmaceuticals
425 Privet Road, Horsham, PA 19044
Attention: General Counsel

11.8 Waiver. No waiver of any provision of this Agreement shall be valid or effective unless made in a writing referencing this Agreement and signed by a duly authorized representative of the waiving Party. A waiver by a Party of any of the terms and conditions of this Agreement in any instance shall not be deemed or construed to be a waiver of such term or condition for the future, or of any other term or condition hereof.

11.9 Rights and Remedies are Cumulative. Except to the extent expressly set forth herein, all rights, remedies, undertakings, obligations and agreements contained in or available upon violation of this Agreement shall be cumulative and none of them shall be in limitation of any other remedy or right authorized in law or in equity, or any undertaking, obligation or agreement of the applicable Party.

11.10 Severability. This Agreement is severable. When possible, each provision of this Agreement shall be interpreted in such manner as to be effective and valid under applicable Law, but if any provision of this Agreement is held to be to any extent prohibited by or invalid under applicable Law, such provision shall be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this Agreement (or of such provision). The Parties shall make a good faith effort to replace the invalid or unenforceable provision with a valid one which in its economic effect is most consistent with the invalid or unenforceable provision.

11.11 Third Party Beneficiaries. Except for the rights of Indemnified Parties pursuant to Article IX hereof, the terms and provisions of this Agreement are intended solely for the benefit of each Party hereto and their respective successors or permitted assigns and it is not the intention of the Parties to confer third-party beneficiary rights upon any other Person.

11.12 Equitable Relief. Each Party recognizes that the covenants and agreements herein and their continued performance as set forth in this Agreement are necessary and critical to protect the legitimate interests of the other Party, that the other Party would not have entered into this Agreement in the absence of such covenants and agreements and the assurance of continued performance as set forth in this Agreement, and that a Party's breach or threatened breach of such covenants and agreements may cause the opposed Party irreparable harm and significant injury, the amount of which shall be extremely difficult to estimate and ascertain, thus potentially making any remedy at law or in damages inadequate. Therefore, each Party agrees that an opposed Party shall be entitled to seek specific performance, an order restraining any breach or threatened breach of Article VII and all other provisions of this Agreement, and any other equitable relief (including but not limited to temporary, preliminary and/or permanent injunctive relief). This right shall be in addition to and not exclusive of any other remedy available to such other Party at law or in equity.

11.13 Interpretation. The language used in this Agreement is the language chosen by the Parties to express their mutual intent, and no provision of this Agreement shall be interpreted for or against a Party because that Party or its attorney drafted the provision.

11.14 Performance by Affiliates. Each Party may discharge any obligations and exercise any right hereunder through any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

11.15 Construction. The words "include," "includes" and "including" shall be deemed to be followed by the phrase "without limitation." All references herein to Articles, Sections and Schedules shall be deemed references to Articles and Sections of, and Schedules to, this Agreement unless the context shall otherwise require. The definitions of the terms herein will apply equally to the singular and plural forms of the terms defined. Whenever the context may require, any pronoun will include the corresponding masculine, feminine and neuter forms. The Parties each acknowledge that they have had the advice of counsel with respect to this Agreement, that this Agreement has been jointly drafted, and that no rule of strict construction will be applied in the interpretation hereof. Unless the context requires otherwise, (a) any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein), (b) any reference to any Laws herein will be construed as referring to

such Laws as from time to time enacted, repealed or amended, (c) any reference herein to any person will be construed to include the person's permitted successors and assigns, (d) the words "herein", "hereof" and "hereunder", and words of similar import, will be construed to refer to this Agreement in its entirety and not to any particular provision hereof, and (e) all references herein to Articles, Sections, or Schedules, unless otherwise specifically provided, will be construed to refer to Articles, Sections, and Schedules of this Agreement.

11.16 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original, and all of which together shall be deemed to be one and the same instrument. A facsimile or a portable document format (.pdf) copy of this Agreement, including the signature pages, shall be deemed an original.

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[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

IN WITNESS WHEREOF, the Parties have caused this Asset Transfer and License Agreement to be executed and delivered by their respective duly authorized representatives as of the day and year first above written.

89Bio Ltd.

By: /s/ Anat Naschitz
Name: Anat Naschitz
Title: Director

[SIGNATURE PAGE OF ASSET TRANSFER AND LICENSE AGREEMENT — FGF-21]

IN WITNESS WHEREOF, the Parties have caused this Asset Transfer and License Agreement to be executed and delivered by their respective duly authorized representatives as of the day and year first above written.

Teva Pharmaceutical Industries LTD

By: /s/ Doran Herman
Name: Dr. Doron Herman
Title: Head of Tax

By: /s/ Dror Bashan
Name: Dror Bashan
Title: SVP Corporate Business Development

ratiopharm GmbH

By: /s/ Miran Denac
Name: Miran Denac
Title: Managing Director Operations

By: /s/ Andreas Burkhardt
Name: /s/ Andreas Burkhardt
Title: Managing Director Genetics

Teva Branded Pharmaceutical Products R&D, Inc.

By: /s/ Rivka Kreitman
Name: Rivka Kreitman, PhD
Title: SVP, Head of Global Specialty Regulatory Affairs

By: /s/ Stephen P. Trusko
Name: Stephen P. Trusko
Title: Director, Business Development

[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

REAGENT SUPPLY AND TECHNOLOGY TRANSFER AGREEMENT

between

89 Bio Ltd.

a company incorporated in accordance with the laws of Israel
("BUYER")

and

Teva Biotech GmbH

a company incorporated in accordance with the laws of Germany
("SUPPLIER")

WHEREAS, SUPPLIER and BUYER agreed to enter into a supply agreement ("Agreement") to serve as the general framework for, and to govern the supply of [***], [***] and [***] by SUPPLIER to BUYER or its Affiliates; and

WHEREAS, SUPPLIER has the know-how, expertise, capability, experience and the infrastructure necessary to supply the [***], [***], [***] and [***] (the "Products", as such term is defined below) subject to and in accordance with the terms hereof;

THEREFORE, THE PARTIES AGREE AS FOLLOWS:

1. INTERPRETATION AND DEFINITIONS

1.1. The preamble to this Agreement forms an integral part hereof.

1.2. Clause headings in this Agreement are intended solely for convenience of reference and shall be given no effect in the interpretation of this Agreement.

1.3. All appendices to this Agreement, if any, whether attached at the time of signature hereof or by signature at any time thereafter, shall be construed as an integral part of this Agreement.

1.4. In this Agreement, the following expressions shall bear the meanings assigned to them below and cognate expressions shall bear corresponding meanings.

1.4.1. "**Affiliate**" shall mean a company that, directly or indirectly, through one or more intermediates, controls, is controlled by, or is under common control with the company specified. For such purpose the term "control" means the holding of fifty or more than fifty percent (50%) or, if less than fifty percent (50%), the maximum percentage as allowed by applicable law, of the common voting stock or ordinary shares in, or the right to appoint more than fifty percent (50%) of the directors of, or the right to share more than fifty percent (50%) of the profits of, the said corporation, company, partnership, joint venture or entity.

1.4.2. "**cGMP**" shall mean Current Good Manufacturing Practice;

1.4.3. "**Classified Information**" is information such as know-how and trade secrets that is (i) not necessary for Tech Transfer described in Section 15 to an experienced CMO (i.e. is not needed to enable an experienced CMO to manufacture products meeting the same specifications and quality as the Products), and (ii) necessary only for the purpose described in Section 2.4 and 3.10, and (iii) regarded as highly confidential of e.g. third party manufacturers, and notified as such by SUPPLIER to BUYER.

1.4.4. "**Effective Date**" shall be April 16, 2018.

1.4.5. "**Manufacture**" or "**Manufacturing**" shall mean the manufacturing, testing, labeling, packaging and release of the Product and the Batches in accordance with the Quality System Requirements and the Specifications.

1.4.6. "**Product**" shall mean any of the following: [***] or [***] or [***] or [***] further details of which are set out in the description and Specification (as defined in Annex 1 through Annex 4 attached hereto).

1.4.7. "**Products**" shall mean more than one Product.

1.4.8. "**Quality Agreement**" shall mean the quality agreement between the Parties in respect of the Products and the supply thereof, realized in a separate agreement as soon as practicable after the Effective Date.

1.4.9. "**Quality System Requirements**" shall mean current Good Manufacturing Practices; the then-current good manufacturing practices and standards for the manufacture, testing, filling and/or preparation for delivery of drug substance pursuant to (a) the U.S. Federal Food, Drug and Cosmetics Act as amended (21 USC 301 et seq.), (b) relevant U.S. regulations found in Title 21 of the U.S. Code of Federal Regulations (including but not limited to Parts 11, 210, 211, and (c) the EC Guide to Good Manufacturing Practice for Medicinal Drug Products, including respective guidance documents and any comparable laws, rules or regulations of any of the above jurisdictions, as each may be amended from time to time. cGMP also includes adherence to any applicable product license requirements, to the current requirements of the United States

Pharmacopoeia/National Formulary, the current requirements of the European Pharmacopoeia and the relevant current International Conference on Harmonization (ICH) guidance documents, including without limitation the ICH Guidance Q7 Good Manufacturing Practices Guidance for Active Pharmaceutical Ingredients and including the Japanese Pharmaceutical Affairs Law (PAL) in the cGMP, all as applicable.

1.4.10. "**Regulatory Authorities**" shall mean any and all governmental bodies and organizations with jurisdiction over the processing, manufacturing, testing, labeling, packaging, delivery, importation, distribution, use or sale of the Product.

1.4.11. "**Shelf Life**" shall mean the recommendation of time during which the Product can be stored under specified conditions with defined quality remaining. The time starts with the manufacturing date and ends with expiry date. The Shelf Life of the Products is defined in Annexes 1 - 4.

1.4.12. "**Specifications**" shall mean the specifications for a Product (including without limitation, the technical and release specifications) set out in the Quality Agreement, which will be consistent with the specifications set forth in the Certificate of Analysis for the most recent batches of Products produced (referred to as "acceptance criterion", "specifications" or "acceptance limits" depending on the relevant certificate).

1.5. Each of SUPPLIER and BUYER shall be called individually as a "**Party**" and collectively as "**Parties**".

2. SUPPLY OF PRODUCTS

2.1. With effect from the Effective Date, and subject to the terms herein, SUPPLIER undertakes to manufacture, sell and supply to the BUYER all of BUYER's orders to SUPPLIER for the Products (provided that such demand is made in accordance with the ordering mechanism and volume limitations set forth in Section 3 and Annexes 1—4 of this Agreement), and BUYER hereby undertakes to purchase the Products supplied to BUYER by SUPPLIER on the terms and conditions set out in this Agreement.

2.2. Promptly following the execution of this Agreement, the Parties will enter into a separate Quality Agreement. In the event of contradiction in any issue other than quality issues, the terms and conditions of this Agreement will prevail upon those of the Quality Agreement. Any term or definition appearing in the Quality Agreement will be interpreted in accordance to this Agreement unless specifically defined in the Quality Agreement.

2.3. The Products will be Manufactured or supplied by the SUPPLIER in accordance with the Specifications and in accordance with the Quality System Requirements, the terms hereof and the requirements of applicable Regulatory Authorities, and quantities thereof will be supplied by SUPPLIER to BUYER as agreed between the Parties, and as illustrated in Annexes 1 - 4 hereto, free and clear of any and all encumbrances, liens, or other third party rights.

2.4. SUPPLIER shall Manufacture / supply the Products solely for further processing by or on behalf of BUYER and/or its licensees to support production of material for research and development purposes (including without limitation clinical trials).

2.5. For any Product supplied following the Effective Date, SUPPLIER shall guarantee a Shelf Life for each of the Products as defined in detail in Annexes 1 - 4. For any Product supplied following the Effective Date, SUPPLIER shall supply the Products with a Shelf life remaining at the date of delivery, which allows BUYER to further process the Products, but in any case not less than twelve months of Shelf Life. In the event that the Product has less than twelve months of Shelf life at the date of delivery for any reason, BUYER may send the Product back to the SUPPLIER and the cost of such Product described above shall be borne by SUPPLIER. In such cases BUYER may, at its sole discretion, (a) decide to accept, keep and use Batches with less than the guaranteed remaining Shelf life at the date of delivery or (b) request a replacement Product, in which case SUPPLIER shall as soon as practicably feasible deliver a replacement Product with a Shelf life meeting the guaranteed remaining Shelf life. BUYER will inform the SUPPLIER of the decision not later than thirty (30) days from delivery in writing.

2.6. SUPPLIER shall only make available for delivery quantities of Product to BUYER once SUPPLIER’s quality control department has found the Product suitable to be delivered, based on its own testing results with regard to the Products Manufactured by SUPPLIER, or based on testing results received from the third party manufacturer of the Products (if SUPPLIER bases its quality control decisions with respect to the use of the same Product for production of its products on such results), all in accordance with the Specifications, the Quality Agreement, the Quality System Requirements and in accordance with the relevant regulatory demands, all at BUYER’s requested delivery dates (as specified in accordance with the provisions of Section 3 below).

2.7. SUPPLIER shall inform BUYER in advance and in writing of any specific precautionary and protective measures which SUPPLIER is aware that are required for the safe handling of the Products to the best knowledge of the SUPPLIER.

2.8. SUPPLIER will not subcontract certain part(s) of the Manufacturing (for the Products manufactured by the SUPPLIER) and will not change the subcontractor for certain part(s) of the Manufacturing (for the Products manufactured by third party manufacturers defined in Annexes 1 - 4) to a third party or to another third party respectively without BUYER prior written approval in accordance to the terms and conditions of the Quality Agreement. BUYER shall not withhold such approval unreasonably.

3. ORDERS, QUANTITIES, LEAD TIME AND DELIVERIES

3.1. BUYER shall provide the SUPPLIER with a monthly updated, rolling, nonbinding forecast ("Forecast"), specifying BUYER's requirements of each of the Products separately covering the following twelve (12) months. The forecasted quantities of each of the Products per month shall be within the quantity ranges defined in the Annexes 1 - 4.

3.2. Promptly after the Effective Date with respect to the First Order (as defined below) or one hundred and eighty (180) days prior to the delivery date at the latest with respect to all further orders for Products, BUYER shall place firm orders ("Purchase Order") specifying the required quantity of the Products at the Supply Prices in Annexes 1 - 4 and delivery conditions effective at the order date. For clarity, the order described in Annex 6 ("First Order") will be delivered in accordance with dates listed in Annex 6.

3.3. Each Purchase Order shall detail the total order quantity of Product(s) to be delivered, and shall specify BUYER's requested date of delivery (taking into consideration a one hundred and eighty (180) days lead time with respect to orders other than the First Order).

3.4. Within seven (7) business days following the receipt of each Purchase Order, SUPPLIER shall acknowledge receipt of such Purchase Order. No order shall be binding upon SUPPLIER until acceptance by written acknowledgment was sent by SUPPLIER to BUYER; provided that SUPPLIER is obliged to confirm BUYER's Purchase Order within such seven (7) business days period in the event that such Purchase Order complies with the terms of this Agreement. Failure to respond within such seven (7) business days period shall be deemed acceptance of BUYER's Purchase Order, provided such Purchase Order complies with the terms of this Agreement.

3.5. SUPPLIER shall be required to supply to BUYER all quantities of Product requested in any Purchase Order in accordance with the terms thereof and on the delivery date requested in respect thereof; provided that the quantities ordered under such Purchase Order do not exceed the maximum order quantity per Product defined in Annexes 1 - 4.

3.6. A delay in delivery, attributed to the SUPPLIER, of any Purchase Order of Product or deviation in quantity of Product supplied, shall entitle BUYER to terminate the applicable Purchase Order without any requirement to compensate SUPPLIER in respect of same, provided that a delay of up to ten (10) days in the delivery of any Purchase Order of Product or discrepancy of ± ten (10)% between the quantity as stated on the invoice and the actual quantity delivered, shall not constitute a breach by SUPPLIER hereunder and shall not entitle BUYER to terminate the Purchase Order as set forth above (provided that BUYER shall only be required to pay for the quantities of Product that BUYER actually receives).

3.7. In case of the implementation of a Change defined in Section 6 which might delay an original delivery date of a Purchase Order, the Parties will agree on a revised delivery date of such Purchase Order, unless such delay is due to SUPPLIER's fault.

3.8. The ordered Products shall be delivered to EXW SUPPLIER facility, Ulm, Germany, (Incoterms 2010) in accordance with the delivery configuration (as defined in Annexes 1 - 4). Risk of loss of or damage to the Products shall pass to BUYER according the rule of Incoterms 2010.

3.9. At the time of the delivery, the Product shall conform to the Specifications. SUPPLIER undertakes to provide with every delivery of the Products each a Certificate of Analysis in accordance with the Quality Agreement. Such Certificate of Analysis shall be issued by the SUPPLIER for the Products CMP-SA-PEG and ST6GALNAC1, and by the third party manufacturers for MBP-GALNAC T2 and UDP-GalNAc. In addition, SUPPLIER undertakes to provide BUYER, together with the delivery of the Products, the applicable invoice, and packing list.

3.10. Furthermore, upon BUYER's request to answer authorities' requests BUYER has received, SUPPLIER undertakes to provide BUYER for the Products being delivered any needed support with data to address such inquiries, complaints and requests, if such data and/or specific details are available with the SUPPLIER and do not include SUPPLIER's Classified Information. All documentation/data from SUPPLIER submitted to answer regulatory requests is considered as confidential information. Upon BUYER's request, SUPPLIER will provide Classified Information requested by, or needed for, a Regulatory Authority directly to the applicable Regulatory Authority. Supply of documents and information is further defined in Section 15.

3.11. SUPPLIER understands that this Agreement is being executed in connection with that certain Asset Transfer and License Agreement among BUYER and Teva Pharmaceutical Industries Ltd., Ratiopharm GmbH and Teva Branded Pharmaceutical Products R&D, Inc. dated as of the date hereof ("Asset Transfer and License Agreement") and that BUYER's research and development activities with respect to assets purchased under such Agreement are dependent on, and BUYER is relying on, SUPPLIER's timely delivery of the Products ordered by BUYER under this Agreement.

3.12. In the event that SUPPLIER anticipates to be unable to deliver the Product to BUYER in accordance with the confirmed order dates due to a reason beyond the reasonable control of SUPPLIER, SUPPLIER shall inform BUYER thereof and the Parties shall establish each time by mutual consultation the necessary arrangements for minimizing the possible loss and damage which BUYER may suffer from such delay in delivery.

3.13. In case SUPPLIER faces a shortage in supply or manufacture of the Product, so that the amounts available are not sufficient to cover BUYER's orders as well as SUPPLIER's requirements, SUPPLIER will proceed to a partition between its own requirements and BUYER's orders on a pro rata basis.

4. PRICE AND PAYMENT

4.1. The prices for the Products will be as set forth in Annexes 1 - 4 hereof.

4.2. All prices and deliveries provided for herein are on EXW SUPPLIER's facility, Ulm, Germany, (as per Incoterms 2010) basis.

4.3. Any payment according to this Agreement shall be paid against invoices [***] days after the delivery date for the Products. Each payment due to SUPPLIER hereunder shall be paid by wire transfer of immediately available funds to an account designated by SUPPLIER in writing at least ten (10) days in advance of the payment date.

4.4. SUPPLIER will issue an invoice to BUYER in respect of the Products on the day of delivery of the applicable ordered and released Product to BUYER.

5. MANUFACTURING, STABILITY TESTING AND SUPPLY

5.1. The Product shall be manufactured by the companies and in the manufacturing sites as follows:

- [***]
- [***]
- [***]
- [***]

It shall be SUPPLIER's [***] decision for each confirmed order, which [***] Product to supply to BUYER, provided in each case that the supplied Product meets the Specifications set forth in the Quality Agreement.

5.2. The Products [***] and [***] to be supplied by SUPPLIER under this Agreement may be submitted to a change of the manufacturing process for the purpose of optimization.

With regard to [***], SUPPLIER is currently [***]. Supplies of [***] until [***] shall be processed using [***] unless confirmed otherwise by BUYER in writing.

With regard to [***], SUPPLIER is currently [***]. It shall be SUPPLIER's [***] decision for each confirmed order, according to which [***] to be supplied will be manufactured, provided that the supplied Product meets the Specifications set forth in the Quality Agreement.

5.3. With regard to [***] and [***] there are no changes in the manufacturing process planned by SUPPLIER.

5.4. Independent of any changes in the manufacturing process, as described above, SUPPLIER shall supply the Products in accordance with the Quality System Requirements, this Agreement, the Quality Agreement and the Specifications, as amended from time to time in accordance with the provision of the Quality Agreement.

6. CHANGE CONTROL

6.1. SUPPLIER shall be solely responsible for any and all costs with respect to any change or modification that SUPPLIER intends to carry out in respect of the Product or the Manufacture thereof, including a change to the Specifications ("Change").

6.2. SUPPLIER shall be free to unilaterally proceed to any change in the manufacturing of the Products, provided that the Products supplied after such change comply with the Specifications and the quality criteria as defined under Section 5.4.

6.3. With regard to any changes in the manufacturing which will lead to the Products supplied no longer complying with the original Specifications, but to which the SUPPLIER and/or its manufacturing subcontractors are mandatorily submitted to, as they are required to bring SUPPLIER's Facility and or it's subcontractor's Facility and any general systems, operations and procedures relating to its performance of Manufacturing into compliance with cGMP, applicable laws or with the requirements of applicable Regulatory Authorities generally, SUPPLIER is obliged to inform BUYER before implementation. The implementation is nevertheless not subject to BUYER's approval.

In advance of implementing a Change which will lead to the Products supplied no longer complying with the original Specifications, SUPPLIER shall, upon BUYER's request, produce sufficient stock of Product (according to the original Specifications) to enable continued manufacturing of BUYER finished medicinal product while evaluation of the potential impact of the Changes on BUYER's manufacturing process is being performed. BUYER will place the required Purchase Orders in accordance to Section 3. BUYER acknowledges that the implemented Change may affect the shelf life of the Product, and in such cases the guaranteed shelf life according to Section 2.5, shall be adjusted as agreed by the Parties.

6.4. With regard to [***] SUPPLIER may not be capable to produce such stock of Product, in view of the fact, that the [***] Product out the original manufacturing process is manufactured by SUPPLIER's subcontractor, and this supply agreement with the subcontractor will terminate within the term of this Agreement. Such termination may even lead to SUPPLIER not be capable to confirm all orders for [***] out of the original manufacturing process, depending from the quantities required.

7. SUPPLIER WARRANTIES AND UNDERTAKINGS

7.1. SUPPLIER represents, warrants and covenants to BUYER that:

7.1.1. it will perform all its obligations under this Agreement in accordance with this Agreement and all applicable laws and regulations, including but not limited to those pertaining to employee safety and health and environmental protection. SUPPLIER and/or its manufacturing subcontractors shall obtain and maintain, at its expense, all necessary permits, licenses and other documentation required now or hereafter in order to perform the Manufacturing, including, without limitation, facility licenses, registrations, authorizations and approvals which are necessary to perform the Manufacturing in accordance with the Quality System Requirements, and to comply with all applicable laws and regulations relating to SUPPLIER's and/or its subcontractors' activities.

7.1.2. SUPPLIER and/or its manufacturing subcontractors have the requisite experience, knowledge and expertise, they have qualified personnel and the legal right to perform the Manufacturing hereunder in lawful and workmanlike manner, in accordance with the Quality System Requirements (including without limitation, in the event that any such Quality System Requirements change during the term of this Agreement), the Quality Agreement and this Agreement.

7.1.3. the Products that are delivered hereunder shall (i) conform to the Specifications, (ii) be compliant with the Quality System Requirements, (iii) conform to the Quality Agreement, (iv) be in accordance to the terms and conditions to this Agreement, (v) shall be free from defects in workmanship and materials, and (vi) be free and clear of any and all encumbrances, liens, or other third party claims.

7.1.4. all Products supplied by SUPPLIER to BUYER pursuant to this Agreement shall be Manufactured at the manufacturing sites defined in Annexes 1 - 4 and Section 5.1 and in compliance with the Quality System Requirements, the Quality Agreement and this Agreement. SUPPLIER may use third parties according to provisions in the Quality Agreement.

7.1.5. SUPPLIER and/or its manufacturing subcontractors is not under any obligation to any third party that would interfere with its performing the Manufacturing or which would be inconsistent with any of its representations or obligations during the term of this Agreement.

7.1.6. it has rights and is entitled to supply the Products to BUYER. SUPPLIER confirms that to SUPPLIER's best knowledge, nothing in its activities according and in connection with the obligations under this Agreement, including the manufacturing, selling, and supply of the Products, infringes or will infringe any third party intellectual property rights.

7.2. EXCEPT AS EXPRESSLY SET FORTH UNDER IN THIS AGREEMENT, THE SUPPLIER HEREBY EXPRESSLY DISCLAIMS ANY AND ALL REPRESENTATIONS AND WARRANTIES OF ANY KIND OR NATURE, WHETHER EXPRESS OR IMPLIED, RELATING TO PRODUCTS AND SERVICES, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, VALIDITY, PATENTABILITY OR ENFORCEABILITY.

7.3. BUYER represents, warrants and covenants to SUPPLIER that it will perform all its obligations under this Agreement in accordance with this Agreement and all applicable laws and regulations, including but not limited to those pertaining to employee safety and health and environmental protection.

7.4. Neither Party shall be entitled to claim from or recover from, the other Party, any special, incidental, consequential or punitive damages in connection with this Agreement.

8. ACCEPTANCE; CONFORMITY DISPUTES; RECORDS; AUDITS

8.1. Without derogating in any way from SUPPLIER's warranty regarding the conformance of the Products to the Specifications and their Manufacture in accordance with the Quality System Requirements, BUYER shall, upon receipt of each shipment of the Products, only proceed to a visual examination of intactness and identity and quantity of the Products. In the event that BUYER detects by its visual examination, that Products delivered by SUPPLIER to BUYER is not conforming with the Specifications, or not conforming in its Manufacture with the Quality System Requirements, or is not complying with the Shelf life requirements, or not conforming with the confirmed order, then BUYER shall so inform SUPPLIER within thirty (30) days of BUYER's receipt of the Products, without which BUYER is deemed to accept the Products with regard to conforming with the Specifications and Shelf life requirements, and subject to Section 8.3 below:

8.1.1. SUPPLIER's obligation, in case said above non-conformity is attributed to SUPPLIER, shall be to dispatch to BUYER a replacement Product that does meet the Specifications and does conform in its Manufacture with the Quality System Requirements and does comply with the Shelf life requirements at no additional cost to BUYER, in a reasonable delay, but latest within the lead time according to Section 3.2. At BUYER's sole discretion SUPPLIER will alternatively reimburse BUYER for all payments made in connection with the Products at issue and all related costs.

8.1.2. BUYER shall, if so requested by SUPPLIER, return to SUPPLIER at SUPPLIER's expense, any ordered Product which the Parties agree that is non-conforming, or otherwise dispose of such ordered Product, at SUPPLIER's expense, in accordance with instructions provided by SUPPLIER. If SUPPLIER does not provide any such instructions, within thirty (30) days following BUYER's notification of non-conformity, BUYER may dispose of such ordered Product as BUYER may deem reasonably appropriate, provided that any such disposal complies with environmentally acceptable standards and applicable laws, and SUPPLIER shall bear the costs of such disposal.

8.1.3. Notwithstanding the foregoing, SUPPLIER warrants the Products shall conform to the Specifications during its Shelf life, provided that BUYER has transported and stored the Products under the recommended transport and storage conditions. Any non-conformation of the Product to the Specifications during its Shelf life that was not or could not be detected by BUYER within its visual examination and identity testing upon receipt, shall be notified by BUYER to SUPPLIER or by SUPPLIER to BUYER promptly after discovery thereof, and Section 8.1.1. and 8.1.2. shall apply mutatis mutandis and SUPPLIER shall provide BUYER in case of nonconforming Product with an investigation report.

8.2. In the event of a dispute between BUYER and SUPPLIER regarding the rejection by BUYER of any delivered Product in respect of any deviation from the Specifications or from the Quality System Requirements or from the Shelf life requirements, the Parties' quality assurance representatives shall jointly investigate such delivered Product in good faith. If the Parties are still unable to resolve such dispute, an independent, mutually agreed third party shall be retained to test representative samples of the allegedly non-conforming Product, and the details of BUYER's contentions as to nonconformance, which third party laboratory shall examine such samples in a method specified by the Parties as part of a mutually agreed testing procedure. The Parties shall endeavor to procure that within thirty (30) days, the said laboratory issues its finding as to whether the delivered Product conform to the Specifications and/or the Quality System Requirements and/or the Shelf life requirements. The results of the said laboratory shall be final and binding on the Parties, and the costs associated with such submission and determination shall be borne by the Party against which the laboratory decides, as shall the costs of the Manufacture of a replacement if such is needed.

8.3. BUYER's obligation to effect payment for any Purchase Order alleged by BUYER not to be in compliance with the Specifications and/or the Quality System Requirements and/or the Shelf life requirements shall be held in abeyance pending resolution of the matter.

8.4. During the period of five (5) years unless a longer period may be required by applicable law, rule or regulation, SUPPLIER will retain originals of the documentation related to the Manufacturing and the Products as required by applicable law, rule or regulation and Quality System Requirements (as applicable).

8.5. SUPPLIER shall allow representatives of any regulatory authority or other governmental agency with jurisdiction over the Manufacture of the Products to audit SUPPLIER's Facilities utilized in the Manufacture, testing, packaging, storage, and delivery of the Products. SUPPLIER shall further support BUYER to achieve the right to audit the relevant facilities of SUPPLIER's manufacturing subcontractors or any of its subcontractor's facilities in which any part of the Manufacturing is conducted.

9. CONFIDENTIAL INFORMATION

9.1. The Parties acknowledge that there may be disclosure of each other's Confidential Information to the other Party and/or its Affiliates. ("Confidential Information" means, subject to Section 9.3, any and all non-public information of whatever nature that is supplied by one Party to the other Party, whether disclosed directly or indirectly, 1) in writing (irrespective of the way of the writing, e.g., hardcopy fax, electronic writing, drawings, etc.) and designated or marked as secret, confidential, or proprietary by the disclosing Party, 2) orally and confirmed in writing as confidential within thirty (30) days from the date of disclosure or 3) by observation by the receiving Party. Confidential Information of SUPPLIER shall include, without limitation, all non-public information relating to the Product. Confidential Information of BUYER shall include, without limitation, all nonpublic information relating to the finished medicinal product;

9.2. In consideration of the disclosing Party making available its Confidential Information to the recipient Party and/or its Affiliates, the recipient Party undertakes that it shall, and shall procure that each of its permitted recipients shall:

9.2.1. treat and safeguard as private and confidential all the Confidential Information of the disclosing Party;

9.2.2. use the Confidential Information of the disclosing Party only for those purposes reasonably required or anticipated under this Agreement and/or the Asset Transfer and License Agreement and without prejudice to the generality of the foregoing, not use any Confidential Information of the disclosing Party to obtain any commercial advantage over the disclosing Party;

9.2.3. ensure the proper and secure storage of all Confidential Information of disclosing Party, applying standards of care reasonably expected to maintain the confidentiality thereof and no less stringent than standards applied to protection of recipient Party's own confidential information;

9.2.4. not at any time without the disclosing Party's prior written consent disclose or reveal, whether directly or indirectly any of the disclosing Party's Confidential Information to any person whatsoever save its permitted recipients, and then on a limited need to know basis, who shall be informed by it of the confidential nature of the Confidential Information and of the confidentiality terms of this Agreement and for whom it hereby accepts full responsibility in the event that any such person shall breach the duty of confidence imposed upon them; and

9.2.5. not at any time have any discussion, correspondence or contact with any third party, other than permitted recipients, concerning the disclosing Party's Confidential Information without the prior written consent of the disclosing Party.

"permitted recipient" shall mean, with respect to each Party, any of such Party's actual or potential employees, consultants, contractors, licensees and acquirers.

9.3. Notwithstanding the above, "Confidential Information" shall not include and the obligations in this Agreement regarding Confidential Information do not apply to the extent that the recipient Party can prove by written evidence that the respective information:

9.3.1. is, at the time of its disclosure by the disclosing Party, wholly available to the public and could be obtained without reference to the Confidential Information by any person with no more than reasonable diligence;

9.3.2. becomes generally available to the public after such disclosure otherwise than by reason of a breach of any of the undertakings in this Agreement or any breaches of confidence by the recipient Party or its permitted recipients;

9.3.3. is, at the time of such disclosure, lawfully already within its possession, as evidenced by written records;

9.3.4. is independently developed by the recipient party without reference to the Confidential Information of the disclosing Party, as evidenced by records; or

9.3.5. is received by recipient Party from a third party who disclosed such information to recipient Party without breaching an obligation of confidentiality to disclosing Party.

9.4. Other than the limited and restricted rights of use set out in this Section 9 nothing in this Agreement intends to or has the effect of granting any right, title, license or interest to the recipient Party in respect of the disclosing Party's Confidential Information except as otherwise expressly provided herein.

9.5. If the recipient Party or any of its permitted recipients becomes compelled to disclose any Confidential Information in the circumstances where the recipient Party is required to disclose by law or by any stock exchange or other regulatory authorities having jurisdiction, a breach or threatened breach of this Section 9 occurs or becomes apparent, or the recipient Party becomes aware of any misuse of the Confidential Information, the recipient Party shall inform the disclosing Party in writing of such obligation or fact as soon as possible after it is informed or the recipient Party becomes aware of it and, if any and possible, before any Confidential Information is disclosed, so that (if the disclosing Party in its absolute discretion shall see fit) a protective order or other appropriate remedy may be sought. The recipient Party agrees to assist and co-operate (and shall procure that each of its permitted recipients shall, as appropriate, assist and co-operate) in any action which the disclosing Party may decide to take. The recipient Party shall notify the disclosing Party prior to each disclosure of Confidential Information if it is under any obligation which would or might compel it to disclose any Confidential Information and subsequent to such disclosure it shall not voluntarily assume any such obligation.

9.6. Upon termination of this Agreement or at the request of the disclosing Party, each Party shall promptly return to the other, at the other's request, any and all Confidential Information of the other (including copies of documents, computer records and records on all other media) then in its possession or under its control except where such Confidential Information is covered under surviving license rights between the Parties and/or their Affiliates (including under the Asset Transfer and License Agreement) and except of one single copy for archival purposes, kept in secure nature, to fulfill legal requirements regarding documentation of business processes.

9.7. The provisions of this Section 9 shall survive termination or expiry of this Agreement and shall continue in effect for [***] years after such termination or expiry; provided, however, that each Party thereafter will continue to use commercially reasonable endeavors to maintain the confidentiality of the other Party's Confidential Information.

10. LIABILITY AND INDEMNIFICATION

10.1. The SUPPLIER shall indemnify and hold harmless BUYER and its Affiliates and each of its directors, officers and employees (the "BUYER Parties") against any and all third party Claims (as defined below) and associated Losses (as defined below) that the BUYER Parties may suffer or incur in consequence of the following:

10.1.1. any material failure by the SUPPLIER to perform any obligations under this Agreement and any unremedied breach by SUPPLIER of the representations, warranties or covenants given pursuant to Section 7.1;

10.1.2. any infringement or alleged infringement or breach of any third party rights by the SUPPLIER, including without limitation any intellectual property rights, patents, trademarks, copyrights, know-how or confidential information, by the manufacturing of the Products, and/or use of the SUPPLIER's intellectual property rights and/or the SUPPLIER's Confidential Information in the performance of SUPPLIER's activities in connection with this Agreement;

provided, however, that the SUPPLIER shall have no obligation to indemnify BUYER Parties if, and solely to the extent that, any such Claims and associated Losses are caused by BUYER Parties' own negligence or willful misconduct in the performance of its rights or obligations hereunder or by BUYER Parties' breach of a representation, warranty or covenant herein or failure by BUYER Parties to perform an express obligation under this Agreement.

10.2. BUYER shall indemnify and hold harmless the SUPPLIER and its Affiliates and each of its directors, officers, employees and shareholders ("SUPPLIER Parties") against any and all third party Claims and associated Losses suffered or incurred in consequence of the following:

10.2.1. any material failure by BUYER to perform any obligations under this Agreement and any unremedied breach by BUYER of the representations, warranties or covenants given pursuant to Section 7.3;

10.2.2. any infringement or alleged infringement or breach of any third party rights by BUYER, including without limitation any intellectual property rights, patents, trademarks, copyright, know-how or confidential information, by use of the BUYER intellectual property rights and/or BUYER Confidential Information in the performance of BUYER's activities in connection with this Agreement;

10.2.3. any product liability claims relating to BUYER's finished products and materials including any derivatives of the foregoing, conjugated form or formulation of the same to the extent such claim is based on the use of the finished products following the BUYER's release; or

10.2.4. the negligence of BUYER in relation to the use, processing, storage or sale of the Product or any derivative, conjugated form or formulation thereof;

provided, however, that BUYER shall have no obligation to indemnify the SUPPLIER Parties if, and solely to the extent, that any such Claims and associated Losses are caused by SUPPLIER Parties' own negligence or willful misconduct in the performance of its rights and obligations under this Agreement or by SUPPLIER Parties' breach of a representation, warranty or covenant herein or failure by SUPPLIER Parties to perform an express obligation under this Agreement.

10.3. In this Section 10 the below definitions are to be applied:

10.3.1. "Claims" means any and all charges, complaints, actions, suits, proceedings, hearings, investigations, claims and demands imposed upon a Party;

10.3.2. "Losses" means any and all damages awards, deficiencies, settlement amounts, defaults, assessments, fines, dues, penalties, costs, fees, liabilities, obligations and expenses payable or awarded to a third party with respect to a Claim, together with all reasonable documented out-of-pocket costs and expenses incurred by a Party in defending against or complying with any Claims of a third party in accordance with the terms of this Agreement;

10.4. Indemnification Procedure

The Party (the "Indemnitee") that intends to claim indemnification under this Section 101 shall:

10.4.1. promptly, and in any event within twenty (20) business days of it receiving notice of the Claim, notify the other Party (the "Indemnitor") in writing in general terms of any Claim which gives rise to or has the potential to give rise to the Indemnitee seeking to rely on and claim the benefit of the indemnification together with notification of the Indemnitee's intention to rely on such indemnity, provided however, that failure to give such notice shall not relieve the Indemnitor of its indemnification obligations except and only to the extent such failure actually and materially prejudices the ability of the Indemnitor to defend against such Claims;

10.4.2. not prejudice any defense to any Claim;

10.4.3. subject to its other rights and obligations and compliance with the procedures set out in this Section 10, permit the Indemnitor to have overall control of the conduct of the negotiations and the proceedings including any counterclaim as well as retain and direct any legal counsel;

10.4.4. cooperate as reasonably requested by the Indemnitor, at the Indemnitor's expense, in the conduct of such Claim (and any counterclaim); and

10.4.5. have the right (at its own expense) to participate in all proceedings and negotiations whether named or not as a party in the Claim or proceedings.

10.5. The Indemnitor shall not settle or consent to an adverse judgment in any such Claim that adversely affects the rights or interests of any Indemnitee or imposes additional obligations (financial or otherwise) on such Indemnitee, without the prior express written consent of such Indemnitee (such consent not to be unreasonably withheld).

10.6. If Indemnitee shall be obliged to provide testimony or records regarding the Claim in any legal or administrative proceeding not covered by the indemnity set forth above, Indemnitor shall reimburse Indemnitee for its reasonable out-of-pocket costs plus a reasonable hourly fee for its employees or representatives at Indemnitee's standard commercial rates.

11. INSURANCE

During the Term and for [***] thereafter, BUYER shall carry and maintain insurance of the types and in amounts which are reasonable and customary in the pharmaceutical industry for companies of comparable size and for comparable activities. Such insurance shall insure against all liability, including but not limited to (when applicable to BUYER's activities), bodily injury or property damage arising out of the manufacture, sale, distribution, marketing, Development or Commercialization of any Compounds or Products. Such insurance shall include commercial general liability insurance, including (when applicable to BUYER's activities), product liability insurance, which coverage shall have limits of liability which are commercially reasonable for the pharmaceutical industry. The coverage limits set forth herein will not create any limitation on BUYER's liability to Teva under this Agreement.

12. TERM

12.1. This Agreement shall be effective form the Effective Date until 31.12.2019 ("Term"). Thereafter, this Agreement shall terminate automatically without the requirement for any Party to give notice, unless extended by the mutual written agreement of the Parties.

12.2. During the term of this Agreement, this Agreement may not be prematurely terminated by the Parties except for the cases set forth in Section 13.

13. BREACH AND TERMINATION

13.1. Either Party ("Non-Defaulting Party") may terminate this Agreement before expiry of the Term with immediate effect upon written notice to the other Party ("Defaulting Party") if:

13.1.1. the Defaulting Party fails to deliver the Product and remedy within [***], or pay any undisputed sum payable under this Agreement [***] after a written demand issued after the original due date;

13.1.2. the Defaulting Party makes or has made a material misrepresentation or commits a material breach of its obligations under this Agreement and, if the breach is capable of remedy, fails to remedy it during the period of [***] starting on the date of receipt of notice from the Non-Defaulting Party generally identifying the breach and requiring it to be remedied;

13.1.3. there has been a filing of a bankruptcy or insolvency petition by or against a Defaulting Party, or entry by the Defaulting Party into an arrangement with its creditors, or application for or consent to the appointment of a receiver or trustee by the Defaulting Party, or the making of an assignment by the Defaulting Party for the benefit of creditors, or the Defaulting Party suffering or permitting the entry of an order adjudicating it as a bankrupt or insolvent which is not removed, dismissed or cured within sixty (60) days, or any shareholders' meeting convened for the dissolution of the Defaulting Party.

13.2. Unless agreed otherwise between the Parties, upon the termination of this Agreement, BUYER will purchase the Product in respect of which orders have been placed and accepted by SUPPLIER prior to expiration or termination of this Agreement, but not yet supplied on the date of termination.

13.3. In the event that a condition of Force Majeure as defined in Article 16, prevents a Party from performing any of its material obligations for more than [***], the other Party may terminate this Agreement by giving written notice to the Party which has been prevented from performing with immediate effect.

13.4. In the case SUPPLIER is not able to deliver Products within the Specification within [***] after SUPPLIER detected and informed BUYER immediately and/or BUYER detected that the manufactured / delivered Products are out of the Specification, BUYER is entitled to terminate this Agreement by written notice with immediate effect.

13.5. In the event of termination or expiration of this Agreement for any reason whatsoever, neither Party shall be entitled as a result of such termination to any consequential damages or other similar payment whatsoever from the other, whether in respect of goodwill, loss of profit or otherwise.

14. GOVERNING LAW AND DISPUTE RESOLUTION

This Agreement shall be governed and interpreted according to the laws of Israel without regard to provisions to conflicts of law. The UN Convention for the International Sale of Goods shall be excluded. Any dispute arising from this Agreement shall be resolved through the courts of Tel Aviv, Israel, and by no other court or jurisdiction.

15. TRANSFER OF THE MANUFACTURING PROCESS

15.1. At any time during the term of this Agreement, the BUYER has the right, at its sole discretion, to request a technology transfer from SUPPLIER or SUPPLIER's Affiliate(s). Such technology transfer shall be limited to the Products [***], [***] and [***]. There will be no technology transfer for [***] under this Agreement.

15.1.1. With regard to [***], SUPPLIER will transfer a Package of Documents of the original manufacturing process, such Package to be supplied [***] after Closing. Further, SUPPLIER will transfer a Package of Documents of the optimized manufacturing process, such Package to be supplied [***] after Closing. With regard to [***], SUPPLIER will transfer a Package of Documents of the original manufacturing process, such Package to be supplied [***] after Closing. Package of Documents for [***] shall comprise in addition to the standard documents, documentation relating to possible improvements of [***] Process demonstrated in small scale.

15.1.2. For [***], as used by [***] will be transferred. A transfer of [***] of [***] as used by [***] shall be limited to transfer of a Package of Documents, as available within SUPPLIER. SUPPLIER will transfer a Package of Documents of [***] within the limits defined above, such Package to be supplied [***] after Closing. SUPPLIER will transfer a Package of Documents of [***], such Package to be supplied [***] after Closing.

15.2. "Package of Documents" under this Section 15 shall mean all documents as listed in Annex 1 to 4 in their original language.

15.3. Further, Supplier shall supply the physical materials listed in Annex 5 ("Materials") to BUYER [***] after Closing.

15.4. In addition to the Package of Documents and Materials, BUYER has the right to request and SUPPLIER shall supply, limited by its technical and personnel capacities, additional available documents and materials as well as consultancy (in written, per telephone, and/or on-site).

15.5. Any such supply of additional documents and materials, as well as any such consultancy may be granted until latest [***] after termination of this Agreement.

15.6. The supply of the Package of Documents and the Materials in accordance with Section 15.2 and 15.3 will be [***] to BUYER.

15.7. The supply of additional documents as well as consultancy will be remunerated based on [***]. The supply of additional materials will be remunerated on a [***] basis.

15.8. SUPPLIER does not take any liability for the successful transfer of the Manufacturing Process of the Products. Nothing in this Section 15.8 shall be deemed to limit SUPPLIER's obligations under Section 15.

16. FORCE MAJEURE

Neither Party shall be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement or the Services to the extent, and for so long as, such failure or delay is caused by or results from causes beyond the reasonable control of such Party including but not limited to fires, earthquakes, floods, embargoes, wars, acts of war (whether war is declared or not), terrorist acts, insurrections, riots, civil commotion, strikes, lockouts or other labor disturbances, acts of God or other acts, omissions or delays in acting by any administrative authority or other party.

17. GENERAL PROVISIONS

17.1. Assignment: Neither Party hereto may assign its rights and/or obligations hereunder in whole or in part, without the prior written consent of the other Party hereto, provided that each Party shall be entitled, at any time, to assign this Agreement to an Affiliate of such Party or to any purchaser of all or substantially all of its assets to which the subject matter of this Agreement relates, or to any successor corporation resulting from any merger or consolidation of such party with or into such corporation; provided, in each case, that the assignee agrees in writing to be bound by the terms of this Agreement, and the assigning Party shall remain liable for performance of all obligations of the assignee.

17.2. Power and representation: Each Party has full power and authority to execute, deliver and perform this Agreement and to incur the obligations provided herein under their respective laws. The entering into of this Agreement has been duly authorized by all proper and necessary action or otherwise, of each of the Parties. No consent or approval of shareholders or of any other person, other than directors, officers, or employees of each Party (which approvals have been obtained) is required as a condition to the validity, implementation or enforceability of this Agreement.

17.3. UN Convention: To the extent that it may otherwise be applicable, the Parties hereby expressly agree to exclude from the operation of this Agreement, the United Nations Convention on Contracts for the International Sale of Goods, concluded at Vienna, on 11 April 1980, as amended and as may be amended further from time to time.

17.4. Entire Agreement: This Agreement constitutes the entire understanding between the Parties with regard to the subject matter hereof other than the Asset Transfer and License Agreement, the Quality Agreement, and except for such agreements supersedes all other prior written and oral understandings and agreements with respect to the subject matter hereof. This Agreement may be amended only by a written instrument signed by the Parties.

17.5. Conflict with other documents: In the event of any conflict between the terms and conditions of this Agreement and the terms and conditions set forth in any standard or other Purchase Order documentation or any document evidencing acceptance thereof or setting out terms of delivery and/or payment, the terms and conditions of this Agreement shall prevail unless such other document records expressly state that it prevails over this Agreement and is signed by duly authorized representatives of both Parties.

18. NOTICES

Any payment's notice, or other written communication required or permitted to be made or given hereunder may be made or given by either Party by facsimile; by first-class mail, postage prepaid; or by courier to the mailing address or facsimile numbers set as below:

If to SUPPLIER:

Teva Biotech GmbH
Dornierstrasse 10
D-89079 Ulm
Germany
Attention: Geschäftsführung

If to BUYER:

89 Bio Ltd.
c/o Orbimed Israel Partners
89 Midanat Hayehudim
Herzliya 46766
Israel
Attention: CEO

or to such other addresses or facsimile numbers as a Party shall designate by notice, similarly given, to the other Party. Notices or written communications shall be deemed to have been sufficiently made or given: (i) if mailed, seven days after being dispatched by mail, postage prepaid; (ii) if by air courier, three days after delivery to the air courier company; or (iii) if by facsimile with confirmed transmission, within one day of transmission.

19. SIGNATURES

This Agreement may be executed in counterparts, each of which shall be deemed an original, and all of which together shall be deemed to be one and the same instrument. A facsimile or a portable document format (.pdf) copy of this Agreement, including the signature pages, shall be deemed an original.

[signatures on following pages]

[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

IN WITNESS WHEREOF, each of the Parties has executed this Agreement and the Appendices hereto as of the Effective Date.

89Bio Ltd.	**Teva Biotech GmbH**
signature: /s/ Anat Naschitz	signature: /s/ Hermann Allgaier
name: Anat Naschitz	name: Dr. Hermann Allgaier
designation: Director	designation: Managing Director of Teva Biotech GmbH
Date: March 29, 2018	Date: May 4, 2018

[SIGNATURE PAGE OF REAGENT SUPPLY AND TECHNOLOGY TRANSFER AGREEMENT]

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First Amendment
to Reagent Supply and Technology Transfer Agreement

This Agreement ("First Amendment Agreement"), effective as of the 25 day of June, 2018, (the "Amendment Date"), is entered into by and among: Teva Biotech GmbH, a company formed under the laws of Germany ("Supplier"); 89Bio Ltd., a company formed under the laws of Israel ("Buyer"); and UAB Rigridas, a company formed under the laws of the Republic of Lithuania, with an address at Jogailos str. 9, Vilnius, the Republic of Lithuania ("Buyer Subsidiary").

WHEREAS, Supplier and Buyer are party to that certain Reagent Supply and Technology Transfer Agreement dated April 5, 2018 (the "Original Agreement"); and

WHEREAS, the Original Agreement contemplates, among other things, that Buyer will order, receive and pay for certain Products (as defined in the Original Agreement) and that Supplier will supply Buyer with, and invoice Buyer for, such Products; and

WHEREAS, the Parties wish to enable Buyer to have Buyer Subsidiary receive and pay for Products under the Original Agreement on Buyer's behalf and to have Supplier supply Products to Buyer Subsidiary and invoice Buyer Subsidiary for such Products; and

WHEREAS, in order to enable such actions by Buyer Subsidiary, the parties wish to add Buyer Subsidiary as a party to the Original Agreement;

WHEREAS, the parties wish to amend the Agreement, with effect as of the date of the execution of the Original Agreement (the "Effective Date"), in accordance with the terms and conditions of this First Amendment Agreement.

NOW THEREFORE, the parties agree as follows:

20. The parties agree to amend the Original Agreement as set forth below, with effect as of the Effective Date.

21. The parties hereby agree to add Buyer Subsidiary as a party to the Original Agreement.

22. The parties hereby agree that each Purchase Order provided by Buyer pursuant to Section 3 of the Original Agreement will clearly state whether Buyer or Buyer Subsidiary will be the entity receiving and paying for the Products covered by such Purchase Order. If a Purchase Order states that Buyer Subsidiary will be the entity receiving and paying for the Products covered by such Purchase Order, the following shall apply:

22.1. References in the Original Agreement to Supplier's obligations to deliver the Products covered by such Purchase Order to Buyer shall be changed to an obligation to deliver such Products to Buyer Subsidiary;

22.2. Buyer Subsidiary shall be responsible for collecting and inspecting the Products covered by such Purchase Order and references to Buyer's obligations relating to the collection or inspection of Purchase Orders will be changed to Buyer Subsidiary with respect to such Purchase Order; provided that any action or inaction of Buyer Subsidiary shall be attributed to Buyer, as if it was Buyer's own action or inaction.

22.3. Supplier will invoice Buyer Subsidiary for such Purchase Order; and

22.4. Buyer Subsidiary shall be responsible paying the amounts due for such Purchase Order; provided that Buyer shall remain liable towards Supplier for any failure by Buyer Subsidiary to pay any such invoices when due.

23. The parties hereby agree that the Forecast provided to Supplier pursuant to Section 3.1 of the Original Agreement will be provided by the Buyer. The Buyer shall ensure that the Forecast includes all Purchase Orders placed by the Buyer or the Buyer Subsidiary.

24. All other terms and conditions of the Original Agreement shall remain unchanged and in full force and effect.

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IN WITNESS WHEREOF, each of the Parties has executed this First Amendment Agreement and the Appendices hereto as of the Effective Date.

89 Bio Ltd.

signature: /s/ Anat Naschitz
name: Anat Naschitz
designation: Director

Date: June 25, 2018

Teva Biotech GmbH

signature: /s/ Hermann Allgaier
name: Dr. Hermann Allgaier
designation: Managing Director of Teva Biotech GmBH

signature: /s/ Eric Kurzhals
name: Eric Kurzhals
designation: Director PMI

Date: June 26, 2018

UAB Rigridas

signature: /s/ Ram Waisbourd
name: Ram Waisbourd
designation: CEO

Date: June 25, 2018

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Second Amendment
to Reagent Supply and Technology Transfer Agreement

This Agreement ("Second Amendment Agreement"), effective as of the 26 day of July, 2018, (the "Amendment Date"), is entered into by and among: Teva Biotech GmbH, a company formed under the laws of Germany ("Supplier"); 89Bio Ltd., a company formed under the laws of Israel ("Buyer"); and UAB 89bio Lithuania (foremerly UAB Rigridas), a company formed under the laws of the Republic of Lithuania, with an address at Jogailos str. 9, Vilnius, the Republic of Lithuania ("Buyer Subsidiary"). This Agreement replaces the Second Amendment Agreement formerly signed by the Buyer and Buyer Subsidiary on the 31 day of July, 2018 and signed by the Supplier on 26 day of July, 2018.

WHEREAS, Supplier and Buyer are party to that certain Reagent Supply and Technology Transfer Agreement dated April 5, 2018 (the "Original Agreement") and the Buyer Subsidiary has become Party to the Original Agreement as per the First Amendment Agreement dated June 25, 2018; and

WHEREAS, the Original Agreement contemplates, among other things, BUYER shall provide the SUPPLIER with a monthly updated, rolling, non-binding forecast ("Forecast"), specifying BUYER's requirements of each of the Products separately covering the following twelve (12) months. The forecasted quantities of each of the Products per month shall be within the quantity ranges defined in the Annexes 1—4 of the Reagent Supply and Technology Transfer Agreement (the "Original Agreement").

WHEREAS, promptly after the Effective Date with respect to the First Order (as defined below) or one hundred and eighty (180) days prior to the delivery date at the latest with respect to all further orders for Products, BUYER shall place firm orders ("Purchase Order") specifying the required quantity of the Products at the Supply Prices in Annexes 1—4 and delivery conditions effective at the order date.

WHEREAS, each Purchase Order shall detail the total order quantity of Product(s) to be delivered, and shall specify BUYER's requested date of delivery (taking into consideration a one hundred and eighty (180) days lead time with respect to orders other than the First Order).

WHEREAS, 89Bio wishes to have the right to cancel the August Order 2018 agreed in Annex 6—First Order of the Reagent Supply and Technology Transfer Agreement (the "Original Agreement")

WHEREAS, 89Bio wishes to place a new Purchase Order for delivery in January 2019

NOW THEREFORE, the Parties agree as follows:

1. The First Order, as described in Annex 6 to the Original Agreement, as far as referring to the delivery agreed for August 2018, is herewith cancelled.
2. Buyer and/or Buyer Subsidiary will place an order, which will cover the same materials as the cancelled part of the First Order. This order shall be placed keeping the standard lead-time of one hundred and eighty (180) days prior to the delivery date.

3. The Parties are today already aware that, depending upon a milestone result in 89Bio's project, Buyer and/or Buyer Subsidiary shall have the right to cancel this Purchase Order described under Clause 2 of this Second Amendment by providing written notification to Supplier no later than November 16, 2018.

4. If Buyer and/or Buyer Subsidiary cancels this Purchase Order, Buyer and/or Buyer Subsidiary shall pay Supplier a cancellation fee of 50% of the order value.. In case of a partial cancellation (reduction of the quantities), the cancellation fee will be calculated accordingly. Numeric example for partial cancellation fee only:

   Quantity of reagent ST6 in Purchase Order 1550 grams ST6 Partial cancellation by 89Bio before Nov 16th, 2018 550 grams ST6 Resulting partial cancellation fee without VAT 54450 Euro (275g)

   Supplier will invoice Buyer or Buyer Subsidiary for such cancellation fee, and Buyer or Buyer Subsidiary will pay cancellation fee within 30 days of receipt of invoice.

5. All other terms and conditions of the Original Agreement shall remain unchanged and in full force and effect.

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IN WITNESS WHEREOF, each of the Parties has executed this Second Amendment Agreement as of the Effective Date.

89 Bio Ltd.

signature: /s/ Ram Waisbourd
name: Ram Waisbourd
designation: COO

Date: August 1, 2018

Teva Biotech GmbH

signature: /s/ Hermann Allgaier
name: Dr. Hermann Allgaier
designation: Managing Director of Teva Biotech GmBH

signature: /s/ Eric Kurzhals
name: Eric Kurzhals
designation: Director PMI

Date: August 1, 2018

UAB 89bio Lithuania

signature: /s/ Ram Waisbourd
name: Ram Waisbourd
designation: CEO

Date: August 1, 2018

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Third Amendment
to Reagent Supply and Technology Transfer Agreement

This Agreement ("Third Amendment Agreement"), effective as of the 30 day of January, 2019, (the "Amendment Date"), is entered into by and among: Teva Biotech GmbH, a company formed under the laws of Germany ("Supplier"); 89Bio Ltd., a company formed under the laws of Israel ("Buyer"); and UAB 89Bio Lithuania, a company formed under the laws of the Republic of Lithuania ("Buyer Subsidiary").

WHEREAS, Supplier and Buyer are party to that certain Reagent Supply and Technology Transfer Agreement dated April 5, 2018 (the "Original Agreement"); and

WHEREAS, the Buyer Subsidiary has become Party to the Original Agreement as per the First Amendment Agreement dated June 25, 2018 (the "First Amendment Agreement"; and

WHEREAS, the parties entered into a Second Amendment Agreement dated August 1, 2018 (the "Second Amendment Agreement"); and

WHEREAS, SUPPLIER and BUYER agreed that the Original Agreement shall be effective from the Effective Date until 31.12.2019 ("Original Term"); and

WHEREAS, SUPPLIER and BUYER agreed in the Original Agreement that in the context of process transfer any supply of additional documents and materials, as well as any such consultancy may be granted until latest [***] after termination of the Original Agreement; and

WHEREAS, SUPPLIER and BUYER agreed in the Original Agreement that the supply prices and the maximum order quantities for the Products will be as set forth in Annexes 1—4 of the Original Agreement; and

WHEREAS, SUPPLIER and BUYER agreed in the Original Agreement that the supplies of [***] until [***] shall be processed using [***] unless confirmed otherwise by BUYER in writing; and

WHEREAS, SUPPLIER and BUYER agreed in the Original Agreement that it shall be SUPPLIER's [***] decision for each confirmed order, according to which [***] to be supplied will be manufactured, provided that the supplied Product meets the Specifications set forth in the Quality Agreement; and

WHEREAS, the parties now wish to extend the Term ("Original Term") of the Reagent Supply and Technology Transfer Agreement (the "Original Agreement") until 31.12.2022 ("Extended Term"), and to agree to further amendments, whereas those further amendments shall become effective from 01.01.2020 only;

The Original Agreement, as amended by the First Amendment Agreement, the Second Amendment Agreement and this Third Amendment Agreement, shall be referred to as this "Agreement".

NOW THEREFORE, the Parties agree as follows:

The Term ("Original Term") agreed in Clause 12 of the Original Agreement shall be extended until 31.12.2022 (The period between 01.01.2020 and 31.12.2022 shall be referred to as the "Extended Term"). Thereafter, this Agreement shall terminate automatically without the requirement for any Party to give notice, unless extended by the mutual written agreement of the Parties.

In the context of transfer of the manufacturing process any supply of additional documents and materials from the SUPPLIER to BUYER, as well as any such consultancy, as stipulated in Clause 15.5, may be granted until latest twenty-four (24) months after termination of this Agreement, but in any case no longer than until the end of the Extended Term (31.12.2022).

The prices set forth in Annexes 1-4 of the Original Agreement shall remain the same during the Original Term. During the Extended Term, the prices shall be as set forth in Annex 1 to this Third Amendment Agreement.

The maximum order quantities set forth in Annexes 1-4 of the Original Agreement shall be for the Extended Term as follows:

The order quantities for [***]:

Maximum annual quantity:

Quantity per calendar year	Year
[***]	[***]

Maximum order quantity:

Quantity per Order	Year
[***]	[***]

The order quantities for [***]:

Maximum annual quantity:

Quantity per calendar year	Year
[***]	[***]

Maximum order quantity:

Quantity per Order	Year
[***]	[***]

[***]

The order quantities for [***]:

Maximum annual quantity:

Quantity per calendar year	Year
[***]	[***]

Maximum order quantity:

Quantity per Order	Year
[***]	[***]

[***]

The order quantities for [***]:

Maximum annual quantity:

Quantity per calendar year	Year
[***]	[***]

Maximum order quantity:

Quantity per Order	Year
[***]	[***]

With regard to [***], SUPPLIER is currently [***]. It shall be SUPPLIER's [***] decision for each confirmed order, according to which [***] to be supplied will be manufactured, provided that the supplied Product meets the Specifications set forth in the Quality Agreement.

With regard to [***], SUPPLIER has [***]. It shall be SUPPLIER's [***] decision for each confirmed order, according to which [***] be supplied will be manufactured, provided that the supplied Product meets the Specifications set forth in the Quality Agreement.

No later than [***] prior to the delivery of [***], Supplier will send Buyer a CoA of the batch from which the material will be supplied. If the activity of the batch is [***], Buyer will have the right to send, within [***], a new purchase order for additional quantities of the material to compensate for the [***] These additional quantities will be provided together with the rest of the order of the material at the same price per gram.

No later than thirty [***] prior to the delivery of [***], Supplier will send buyer a CoA of the batch from which the material will be supplied. If the activity of the batch is [***], Buyer will have the right to send, within [***], a new purchase order for additional quantities of the material to compensate for the [***]. These additional quantities will be provided together with the rest of the order of the material at the same price per gram.

For the avoidance of doubt, this right to order and to receive further quantities of material shall be valid only within the limits of the quantities stipulated under Clause 4 of this Third Amendment Agreement.

The amendments stipulated under 2.—7 of this Third Amendment Agreement shall become effective from 01.01.2020 only.

All other terms and conditions of the Agreement shall remain unchanged and in full force and effect.

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IN WITNESS WHEREOF, each of the Parties has executed this Third Amendment Agreement as of the Effective Date.

89 Bio Ltd.

signature: /s/ Rohan Palekar
name: Rohan Palekar
designation: CEO

signature: /s/ Anat Naschitz
name: Anat Naschitz
designation: Director

Date: February 1, 2019

Teva Biotech GmbH

signature: /s/ Hermann Allgaier
name: Dr. Hermann Allgaier
designation: Managing Director of Teva Biotech GmBH

signature: /s/ Eric Kurzhals
name: Eric Kurzhals
designation: Director PMI

Date: January 30, 2019

UAB 89bio Lithuania

signature: /s/ Ram Waisbourd
name: Ram Waisbourd
designation: Director

Date: January 31, 2019

Exhibit 10.13

[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

CONFIDENTIAL
Execution Version

SUBLICENSE AGREEMENT

This Sublicense Agreement (the "**Agreement**") is made and entered into as of April 16th, 2018, by and between 89Bio, Ltd. a company organized under the laws of Israel ("**Company**"), and ratiopharm GmbH company a company organized under the laws of Germany ("**Teva**"). This Sublicense Agreement shall become effective upon the closing of the Asset Purchase Agreement, as defined below, (the "**Effective Date**").

RECITALS:

WHEREAS, Teva, certain Affiliates of Teva and Company are parties to an Asset Transfer and License Agreement that was executed contemporaneously herewith (the "**Asset Purchase Agreement**") whereby Teva assigned certain assets and licensed certain assets with respect to Teva's FGF-21 program;

WHEREAS, BioGenerix AG ("**BGX**") (a company that was subsequently merged into of) Teva entered into a License Agreement with Neose Technologies dated January 27, 2009, a copy of which is attached hereto as Exhibit A, (the "**Neose License Agreement**") relating to a license under certain Novo Assets as such term is defined therein, and Neose subsequently assigned the Neose License Agreement to Novo Nordisk; and

WHEREAS, Teva desires to sublicense its rights to the Licensed Technology (as such term is defined below) under the Neose License Agreement to 89Bio, in accordance with the terms hereof.

NOW, THEREFORE, the Parties hereto agree as follows:

ARTICLE 1
DEFINITIONS AND INTERPRETATION

1.1 Unless specifically set forth to the contrary herein, the following terms, whether used in the singular or plural, shall have the respective meanings set forth below:

"**Affiliate**" means, with respect to any Person, any other Person directly or indirectly Controlling or Controlled by, or under direct or indirect common Control with, such first Person.

"**Agreement**" has the meaning set forth in the preamble.

"**BGX**" has the meaning set forth in the preamble.

"**BGX Assets**" means those assets sold to BGX by Neose pursuant to the BGX Asset Purchase Agreement.

"**BGX Asset Purchase Agreement**" means the asset purchase agreement entered into between BGX and Neose on September 17, 2008.

"**BGX Field of Use**" means the discovery, research, development, commercialization or other Exploitation of any compound or product in any field, use, product, method or application, other than the Novo Field of Use and the Retained Neose Field of Use.

"**Company Indemnitee**" has the meaning set forth in Section 4.2.

"**Compound**" means the compound known as TEV-47948, as further described on Schedule 4 of the Asset Purchase Agreement, a GlycoPEGylated long acting FGF21 that targets FGFR1, FGFR2, and FGFR3 and any other GlycoPEGylated FGF21 compound claimed in the Assigned Patents (as such term is defined in the Asset Purchase Agreement).

"**Control**" including its various tenses and derivatives (such as "**Controlled**" and "**Controlling**") means (a) for purposes of the definition of Affiliate, a Person that (i) owns or controls, directly or indirectly, or has the ability to direct or cause the direction or control of, more than 50% of the voting equity of the other Person, or (ii) has the ability to direct, cause the direction of, or control the actions of such other Person, whether through direct or indirect ownership of voting equity, by contract or otherwise and (b) when used with respect to any item of intellectual property, possession of the right, whether directly or indirectly, and whether by ownership, license or otherwise, to assign or grant a license, sublicense or other right to or under such intellectual property.

"**Effective Date**" has the meaning set forth in the preamble.

"**Exploit"** or "**Exploitation**" means to make, have made, import, have imported, use, have used, sell, have sold, offer for sale, or have offered for sale, or otherwise dispose of, including all discovery, research, development, registration, modification, enhancement, improvement, manufacture, storage, formulation, optimization, importation, exportation, transportation, distribution, promotion and marketing activities related thereto anywhere in the world.

"**Field of Use**" means the BGX Field of Use or Novo Field of Use, as applicable.

"**Indemnifying Party**" has the meaning set forth in Section 4.3.

"**Indemnitee**" has the meaning set forth in Section 4.3.

"**Licensed Know-How**" means technical information and know-how (including any and all formulae, procedures, processes, methods, designs, know-how, show-how, trade secrets, discoveries, inventions on which no patent application has been filed (whether or not patentable), software and source code, programs, prototypes, designs, techniques, methods, ideas, concepts, data, engineering and manufacturing information, chemical, pharmacological, toxicological, clinical, and assay information, the specifications of ingredients, manufacturing processes, sourcing information, quality control and testing procedures, electronic control circuits, specifications, diagrams, drawings, schematics, blueprints and parts lists and other proprietary information, rights and works of authorship, whether or not reduced to writing), copyrights,

confidential information, trade secrets, and similar proprietary rights in inventions, discoveries, analytic models, improvements, processes, techniques, devices, methods, patterns, formulations and specifications, copies and tangible embodiments of any of the foregoing (in whatever form or media) and other tangible and intangible proprietary information or material in each case that (i) is reasonably necessary for Company to Exploit Licensed Products in the BGX Field of Use, (ii) is known to and Controlled by Neose or its Affiliates as of the time just prior to closing of the BGX Asset Purchase Agreement and (iii) the ownership of which was not otherwise transferred to Teva pursuant to the BGX Asset Purchase Agreement.

"**Licensed Patents**" means (a) the patents and patent applications listed on Schedule A to the Neose License Agreement, (b) all divisionals, continuations, continuations-in-part thereof or any other patent application claiming priority to any patent or patent application listed on Schedule A to the Neose License Agreement, and (c) all patents issuing on any of the foregoing, and any foreign counterparts thereof, together with all registrations, reissues, reexaminations, renewals, supplemental protection certificates, or extensions of any of the foregoing, and any foreign counterparts thereof; notwithstanding the foregoing, Licensed Patents do not include any patent application or patent the ownership of which is assigned to BGX under the BGX Asset Purchase Agreement or the Patent Cooperation Agreement.

"**Licensed Products**" means any pharmaceutical product containing any Compound (alone or with Additional Ingredients), in all forms, presentations, formulations and dosage forms.

"**Licensed Technology**" means Licensed Patents and Licensed Know-How.

"**Losses**" has the meaning set forth in Section 4.1.

"**Neose**" has the meaning set forth in the preamble.

"**Novo**" has the meaning set forth in the recitals.

"**Novo Asset Purchase Agreement**" has the meaning set forth in the recitals.

"**Novo Field of Use**" means the discovery, research, development, commercialization or other Exploitation of any compound or product developed utilizing any Licensed Patent or other intellectual property or Third Party License transferred by Neose to Novo under the Novo Asset Purchase Agreement for the use in the prevention or treatment of acquired or hereditary hemorrhagic disorders as defined in WHO, ICD-10, Chapter III, D65 through D69, but does not include any compound or product comprising, derived from, or containing G-CSF or any erythropoietin. For clarification: WHO ICD-10 lists certain hemorrhagic conditions being the result of other non-hemorrhagic diseases. While the prevention or treatment of such hemorrhagic conditions is included in the Novo Field of Use, the treatment of the underlying non-hemorrhagic disease is not.

"**Party**" means, individually, Teva or Company, and "**Parties**" means, collectively, Teva and Company.

"**Patent Cooperation Agreement**" means that Patent Cooperation Agreement entered into between BGX and Neose dated January 27, 2008.

"**Person**" means a human being, labor organization, partnership, firm, enterprise, association, joint venture, corporation, limited liability company, cooperative, legal representative, foundation, society, political party, estate, trust, trustee, trustee in bankruptcy, receiver or any other organization or entity whatsoever, including any governmental organization.

"**Sale**" has the meaning set forth in Section 6.9.

"**Retained Neose Field of Use**" means the Exploitation of non-GlycoPEGylated glycolipids or oligosaccharides, in each case not attached to a peptide or protein.

"**Term**" has the meaning set forth in Section 5.1.

"**Terminating Party**" has the meaning set forth in Section 2.

"**Teva"** has the meaning set forth in the preamble.

"**Teva Indemnitee**" has the meaning set forth in Section 4.1.

"**Third Party**" means a Person other than Teva, Company, or their respective Affiliates.

"**Third Party Claim**" has the meaning set forth in Section 4.1.

1.2 Interpretation.

(a) Descriptive headings are for convenience only and shall not control or affect the meaning or construction of any provision of this Agreement.

(b) Except as otherwise expressly provided in this Agreement or as the context otherwise requires, the following rules of interpretation apply to this Agreement: (i) the singular includes the plural and the plural includes the singular; (ii) "or" and "any" are not exclusive and the words "include" and "including," the phrase "such as", and variations thereof, shall not be deemed to be terms of limitation, but rather shall be deemed to be followed by the words "without limitation;" (iii) a reference to any agreement includes permitted supplements and amendments; (iv) a reference to an applicable law includes any amendment or modification to such applicable law; (v) a reference to a Person includes its successors, heirs and permitted assigns; (vi) a reference to one gender shall include any other gender; (vii) a reference in this Agreement to an Article, Section, Exhibit or Schedule is to the referenced Article, Section, Exhibit or Schedule of this Agreement; (viii) "hereunder," "hereof," and words of similar import shall be deemed references to this Agreement as a whole and not to any particular Article, Section or other provision, and (ix) "commercially reasonable efforts" of a Party to this Agreement shall be construed as the efforts that a prudent Person in such Party's industry, desirous of achieving a result, would use in similar circumstances to achieve that result as expeditiously as possible.

(c) The Parties acknowledge that they have been represented by counsel during the negotiation, drafting, preparation and execution of this Agreement and, therefore, waive the application of any applicable law or rule of construction.

ARTICLE 2
SUBLICENSE

2.1 Sublicense. Subject to the terms and conditions of this Agreement, Teva hereby grants to Company and its Affiliates an exclusive (even as to Teva and its Affiliates, and as to all Third Parties), irrevocable (except as provided in Section 5.4), perpetual, worldwide, fully paid up, royalty free sublicense, under the Licensed Technology to Exploit Licensed Products in the BGX Field of Use.

2.2 Conditions Relating to Neose License Agreement. Company agrees that it shall comply with the terms of the Neose License Agreement. This Sublicense Agreement shall immediately and automatically terminate upon termination of the Neose License Agreement. Teva undertakes not to terminate the Neose License Agreement and not give its licensor under the Neose License Agreement cause to terminate the Neose License Agreement.

2.3 Fully Paid Licenses. The licenses granted to Company and its Affiliates under Section 2.1 are fully paid by the payments and other consideration given under the Asset Purchase Agreement. Company and its Affiliates, shall owe Teva no other payments or consideration for such licenses.

2.4 Prosecution, Maintenance and Enforcement. Company acknowledges and agrees that this Agreement does not confer upon Company any rights or obligations with respect to the prosecution, maintenance and enforcement of the Licensed Patents.

ARTICLE 3
REPRESENTATIONS AND WARRANTIES / PARTIES' COVENANTS

3.1 Teva has the full right to grant the licenses granted under this Agreement with respect to the Licensed Technology without breaching any Third Party rights.

3.2 No Implied Warranty. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS AND/OR WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, VALIDITY AND SCOPE OF THE LICENSED PATENTS, PATENT CLAIMS, ISSUED OR PENDING, AND THE ABSENCE OF LATENT OF OTHER DEFECTS, WHETHER OR NOT DISCOVERABLE, OR THAT THE USE OF THE LICENSED PRODUCTS WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK OR OTHER RIGHTS OF THIRD PARTIES. IN NO EVENT SHALL EITHER PARTY BE LIABLE FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES OF ANY KIND, INCLUDING ECONOMIC DAMAGE OR INJURY TO PROPERTY AND LOST PROFITS, REGARDLESS OF WHETHER SUCH PARTY HAS BEEN ADVISED, SHALL HAVE OTHER REASON TO KNOW, OR IN FACT SHALL KNOW OF THE POSSIBILITY OF SUCH DAMAGE.

ARTICLE 4
INDEMNIFICATION

4.1 Indemnification by Company. Company hereby agrees to save, defend and hold Teva, its Affiliates, and their respective directors, officers, agents and employees (the "**Teva Indemnitees**") harmless from and against any and all losses, damages, liabilities, costs and expenses (including reasonable attorneys' fees and expenses) (collectively, **"Losses**") arising in connection with any and all charges, complaints, actions, suits, proceedings, hearings, investigations, claims, demands, judgments, orders, decrees, stipulations or injunctions by a Third Party (each a "**Third Party Claim**") resulting or otherwise arising from (a) any product, process, material, information or service that is developed, made, provided, sold or used by Company, its Affiliates pursuant to any right or license granted under this Agreement, including any injury, damage or health complication suffered as a result of the Exploitation of the Licensed Product, (b) any breach by Company of its covenants or obligations pursuant to this Agreement or (c) the negligence or willful misconduct by Company or its Affiliates or their respective officers, directors and employees in performing any obligations under this Agreement; in each case except to the extent that such Losses arise from: (i) Teva's breach of its covenants or obligations under this Agreement, or (ii) the negligence or willful misconduct of a Teva Indemnitee.

4.2 Indemnification by Teva. Teva hereby agrees to save, defend and hold Company, its Affiliates, and their respective directors, officers, agents and employees (the "**Company Indemnitees**") harmless from Losses arising in connection with Third Party Claims resulting or otherwise arising from (a) any breach by Teva of any of its covenants or obligations pursuant to this Agreement or (b) the negligence or willful misconduct by Teva or its Affiliates or their respective officers, directors and employees in performing any obligations under this Agreement; in each case except to the extent that such Losses arise from: (i) Company's breach of its covenants or obligations under this Agreement, or (ii) the negligence or willful misconduct of a Company Indemnitee.

4.3 Indemnification Procedure. If a Teva Indemnitee or a Company Indemnitee (as appropriate, the "**Indemnitee**") wishes to seek indemnification hereunder, such Indemnitee shall inform the Party under an obligation to indemnify (the "**Indemnifying Party**") of the Third Party Claim giving rise to the obligation to indemnify as soon as reasonably practicable after receiving notice of such Third Party Claim. The Indemnifying Party shall have the right to assume and control the defense or settlement of any such Third Party Claim for which it is obligated to indemnify the Indemnitee under this Agreement. The Indemnitee shall cooperate with Indemnifying Party (and its insurer) as the Indemnifying Party may reasonably request, and at Indemnifying Party's sole cost and expense. The Indemnitee shall have the right to participate in such defense, subject to the Indemnifying Party's control, using its own counsel at its own expense. The Indemnifying Party shall have no obligation to indemnify any Indemnitee in connection with any settlement made without the Indemnifying Party's written consent.

ARTICLE 5
TERM AND TERMINATION

5.1 Term. The term ("**Term**") of this Agreement shall commence on the Effective Date and shall continue unless terminated as provided herein.

5.2 Termination for Breach.

(a) Teva may terminate this Agreement only if (i) Company breaches Section 2.2 or Section 4.1; and (ii) Company fails to cure such breach within [***] written notice by Teva; and (iii) such breach causes or is likely to cause a material adverse impact on Teva's or Novo's patent rights or business relating to the Novo Field of Use; and (iv) termination of this Agreement is the only appropriate remedy for such breach. In addition to the foregoing, in the event of a termination of the Neose License Agreement, this Agreement shall automatically terminate.

(b) In the event that (i) Teva elects to terminate this Agreement pursuant to clause (a) of this Section 5.2 and Company disputes whether the criteria set forth in clause (a) have been satisfied and (ii) Company wishes to pursue such matter, Company shall, upon prior written notice to Teva, submit the dispute to arbitration, as set forth in Section 6.13, to determine whether the criteria for such termination set forth in clause (a) have been satisfied. Upon such written notice by Company to Teva, this Agreement will remain in full force and effect until such arbitration is complete and the arbitrator has determined that the criteria for termination set forth in clause (a) of this Section 5.2 have been satisfied.

(c) Notwithstanding anything to the contrary contained herein, in the event that the Asset Purchase Agreement is terminated, this Sublicense Agreement, and the licenses contained herein, shall automatically terminate.

5.3 Termination for Other Causes. Either Party (the "**Terminating Party**") shall have the right to terminate this Agreement immediately upon written notice, (i) if the other Party shall file a petition in bankruptcy, or if an involuntary petition in bankruptcy shall be filed against the other Party and such petition shall not be dismissed within sixty (60) days, or if a receiver or guardian has been appointed for the other Party, or (ii) upon the dissolution, termination of existence or insolvency of the other Party.

5.4 Additional Termination Right of Company. Company shall also have the right to terminate this Agreement, including the licenses granted in Article 2, for any reason and without cause upon [***] prior written notice to Teva.

ARTICLE 6
MISCELLANEOUS

6.1 Governing Law. Construction and interpretation of this Agreement shall be governed by the laws of the State of New York, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive applicable law of another jurisdiction. The United Nations Convention for the International Sale of Goods shall not apply to the construction or interpretation of this Agreement.

6.2 Jurisdiction; Venue; Service of Process. The Parties hereby irrevocably and unconditionally consent to the exclusive jurisdiction of the courts of the State of New York and the United States District Court for the Southern District of New York for any action (other than appeals therefrom) arising out of or relating to this Agreement or otherwise in connection with the transactions contemplated hereby, and agree not to commence any action, (other than appeals therefrom) related thereto except in such courts. The Parties further hereby irrevocably and unconditionally waive any objection to the laying of venue of any action (other than appeals therefrom) arising out of or relating to this Agreement or otherwise in connection with the transactions contemplated hereby in the courts of the State of New York or the United States District Court for the Southern District of New York, and hereby further irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such action brought in any such court has been brought in an inconvenient forum. Each Party further agrees that service of any process, summons, notice or document by registered mail to its address set forth below shall be effective service of process for any action brought against it under this Agreement in any such court. Notwithstanding the provisions of this Section 6.2, the Parties will submit to arbitration as set forth in this Agreement.

6.3 Notices. All notices, requests, demands and other communications that are required or may be given pursuant to the terms of this Agreement shall be in written form, and shall be deemed delivered (a) on the date of delivery when delivered by hand on a business day, (b) on the business day designated for delivery if sent by reputable overnight courier maintaining records of receipt and (c) on the date of transmission when sent by facsimile, electronic mail or other electronic transmission during normal business hours on a business day, with confirmation of transmission by the transmitting equipment. All such communications shall be addressed to the Parties at the address set forth as follows, or at such other address as a Party may designate upon ten (10) days' prior written notice to the other Party.

If to Teva:

Teva Pharmaceuticals
425 Privet Road
Horsham PA 19044
Attn: General Counsel

If to Company:

89 Bio Ltd. c/o Orbimed Israel Partners
89 Midanat Hayehudim
Herzliya 46766
Israel
Attention: CEO

6.4 Benefits of Agreement. All of the terms and provisions of this Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns. Except for the provisions of Article 4, this Agreement is for the sole benefit of the Parties and its Affiliates hereto and not for the benefit of any Third Party.

6.5 Amendments and Waivers. No modification, amendment or waiver of any provision of, or consent or approval required by, this Agreement, nor any consent to or approval of any departure herefrom, shall be effective unless it is in writing and signed by the Party against whom enforcement of any such modification, amendment, waiver, consent or approval is sought. Such modification, amendment, waiver, consent or approval shall be effective only in the specific instance and for the purpose for which given. Neither the failure of either Party to enforce, nor the delay of either Party in enforcing, any condition or part of this Agreement at any time shall be construed as a waiver of that condition or part or forfeit any rights to future enforcement thereof. No action taken pursuant to this Agreement, including any investigation by or on behalf of either Party hereto, shall be deemed to constitute a waiver by the Party taking action of compliance by the other Party with any representation, warranty, covenant, agreement or obligation contained herein.

6.6 Cumulative Rights. Except as expressly provided herein, the various rights under this Agreement shall be construed as cumulative, and no one of them is exclusive of any other or exclusive of any rights allowed by applicable law.

6.7 Expenses. Except as otherwise specified herein, each Party shall bear any costs and expenses with respect to the transactions contemplated herein incurred by it.

6.8 WAIVER OF JURY TRIAL. EACH PARTY IRREVOCABLY AND UNCONDITIONALLY WAIVES ANY RIGHT TO TRIAL BY JURY WITH RESPECT TO ANY ACTION RELATING TO OR ARISING OUT OF THIS AGREEMENT, THE RELATED DOCUMENTS, OR THE TRANSACTIONS CONTEMPLATED HEREIN OR THEREIN.

6.9 Assignment. Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other, except that either Party may make such assignment without consent to a successor of all or substantially all of the business to which this Agreement relates, whether in a merger, sale of stock, sale of assets or other transaction (the "**Sale**"). Any permitted assignment shall be binding on the successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the terms of this Section 6.9 shall be null, void and of no legal effect.

6.10 Enforceability; Severability. (a) If any covenant or provision hereof is determined to be void or unenforceable in whole or in part, it shall not be deemed to affect or impair the validity of any other covenant or provision hereof if the rights and obligations of a Party hereto will not be materially and adversely affected, each of which is hereby declared to be separate and distinct, (b) if any provision of this Agreement is so broad as to be unenforceable, such provision shall be interpreted to be only so broad as is enforceable, and (c) if any provision of this Agreement is declared invalid or unenforceable for any reason other than overbreadth, the Parties hereto agree to modify the offending provision so as to maintain the essential benefits of the bargain (including the rights and obligations hereunder) between the Parties to the maximum extent possible, consistent with applicable law and public policy.

6.11 Entire Agreement. This Agreement, together with the Schedules expressly contemplated hereby and attached hereto, the Asset Purchase and the other agreements, certificates and documents referenced in these agreements, contain the entire agreement among the Parties with respect to the transactions contemplated by this Agreement and supersede all prior agreements or understandings among the Parties with respect to the subject matter hereof.

6.12 Counterparts. This Agreement may be executed in any number of counterparts, and each such counterpart hereof shall be deemed to be an original instrument, but all such counterparts together shall constitute but one agreement. Delivery of an executed counterpart of a signature page of this Agreement by facsimile or other electronic transmission shall be effective as delivery of a manually executed original counterpart of this Agreement.

6.13 Arbitration.

(a) BGX shall, as contemplated in Section 5.2(b), submit disputes relating to Section 5.2(b) to arbitration under the rules and guidelines of the International Chamber of Commerce (ICC). The arbitration shall be conducted in English and shall take place in Geneva, Switzerland. Arbitration shall be limited to and only binding on the Parties with respect to the matters specified in Section 5.2(b) of this Agreement. To the extent permitted by applicable law, the arbitration shall be final and binding on all Parties, will be enforceable in any court of competent jurisdiction, and will not be appealable by either Party to any court.

(b) Subject to compliance with the dispute resolution procedures set forth in this Section 6.13, each Party will have the right to pursue all rights and remedies in connection with this Agreement. Notwithstanding the dispute resolution procedures of this Section 6.13, each Party shall also have the right at any time to bring a lawsuit in a court of competent jurisdiction to seek specific performance of this Agreement through the injunctive power of the court to mitigate damages that might otherwise result from acts or failures to act by the other Party.

[*Signature Page Attached*]

[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

IN WITNESS WHEREOF, the Parties hereto have each caused this Agreement to be executed by their respective authorized officers as of the Effective Date.

89Bio Ltd.

By: /s/ Anat Naschitz
Name: Anat Naschitz
Title: Director

[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

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Ratiopharm GmbH

By: /s/ Miran Denac
Name: Miran Denac
Title: Managing Director Operations

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Ratiopharm GmbH

By: /s/ Andreas Burkhardt
Name: Andreas Burkhardt
Title: Managing Director Genetics

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MASTER SERVICES AGREEMENT

between

89bio Ltd.
with its registered office at
89 Medinat HaYehudim St., Herzliya, Israel ("**CLIENT**")

and

Biotechpharma UAB
with its registered office at
4 Mokslininku street, Vilnius, Lithuania LT-08412
("**BTPH**")

Effective as of May 7th, 2018
("**Effective Date**")

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Table of Content

WHEREAS, CLIENT is involved in the development of pharmaceutical products;

WHEREAS, BTPH has certain expertise and experience relating to providing research, process-development and manufacturing services in the field of biotechnology;

WHEREAS, CLIENT and BTPH have agreed to enter into this Agreement under which BTPH would provide certain services to CLIENT and its Affiliates (as defined below) on the terms and conditions contained in this Agreement; and

WHEREAS, BTPH and Teva Biopharmaceuticals USA, Inc. ("**Teva**") were parties to a certain Master Services Agreement, dated as of the 28th of May 2014, as amended by Amendment No. 1 dated the 20th of April 2016 ("**Teva Agreement**"), under which BTPH provided services to Teva with respect to products covered by this Agreement for which Teva sold to CLIENT.

NOW, THEREFORE, the Parties agree as follows:

1. DEFINITIONS

1.1 "**Affiliate**" means a company or business entity being controlled by, controlling or being under common control with a Party. For purposes of this definition, "control" shall mean the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of an entity (other than a natural person), whether through the majority ownership of voting capital stock, by contract or otherwise.

1.2 "**Agreement**" means this Master Service Agreement.

1.3 "**Batch**" means the quantity of Product derived from a single run of the process.

1.4 "**Batch Record**" means the filled-in record of the history of a Batch and the production thereof as required under GMP in accordance with the Master Batch Record.

1.5 "**BTPH Facility**" means BTPH's facilities at Mokslininku str. 4, 4A, 4C LT-08412 Vilnius and/or S. Zukausko str. 19, LT-08234, Vilnius Lithuania.

1.6 "**Business Day**" means any calendar day on which banking institutions in Lithuania and Israel are open for business.

1.7 "**Cancellation**" shall have the meaning as defined in Section 12.1.

1.8 "**Commercially Reasonable Efforts**" mean the skill, care, efforts and resources required to undertake the Services comparable to those that parties experienced in the field typically dedicate or would reasonably be expected to dedicate under comparable circumstances to those biopharmaceutical product(s) of similar manufacturing complexity manufactured for itself or for any third party. Notwithstanding the foregoing, to the extent that a Party is hindered from performing its obligations hereunder by the other Party's failure to perform its obligations hereunder, such Party is excused from the performance of its obligations to the extent the Party's performance is affected adversely.

1.9 "**Confidential Information**" means any information and/or materials disclosed by Teva to BTPH under the Teva Agreement, or a Party or an Affiliate of such Party to the other Party or its Affiliate(s), which information includes, but is not limited to: Product, RCB, MCB, WCB, the Existing Process, the Manufacturing Process and methods employed in the manufacture of Product; Batch Records, Specifications; information related to the facilities at BTPH; information related to BTPH's Manufacturing Process and/or technologies or to any products produced at the BTPH Facility; any prices and costs of BTPH; regulatory filings for the Product; CLIENT's and BTPH's business, regulatory plans and strategies, patent disclosures, patent applications, structures, models, techniques, formulas, processes, compositions, compounds, antigens, antibodies, hybridomas, apparatus, designs, sketches, photographs, plans, drawings, specifications, samples, reports, customer lists, price lists, studies, findings, inventions and other data and information disclosed or exchanged under this Agreement.

1.10 "**CLIENT Deliverables**" shall have the meaning as defined in Section 3.1.

1.11 "**CLIENT Specifications**" shall mean the Specifications of the CLIENT as set out in the Scope of Work or agreed between the Parties for the Products from time to time.

1.12 "**Delivery Date**" means the date by which CLIENT requests delivery of Product as set out in a Scope of Work.

1.13 "**Drug (Medicinal) Product**" means the dosage form in the final immediate packaging intended for marketing. Drug Product shall meet the CLIENT Specifications as specified in relevant Scope of Work in Appendix I.

1.14 "**Drug Substance**" means Drug Substance intended to be used in a manufacture of a drug (medicinal) product and that, when used in the production of a drug, becomes an active ingredient of drug product. Drug Substance shall meet the CLIENT Specifications as specified in relevant Scope of Work in Appendix I.

1.15 "**Engineering Batch**" is a batch performed in a GMP environment with Master Batch records but without quality oversight. The produced material is only for non-clinical usage.

1.16 "**Existing Process**" means the current BTPH manufacturing process and analytical methods for in-process control and release tests for Drug Substance as applied for manufacture of Drug Substance as of the Effective Date and described in the technology transfer documents provided by CLIENT or otherwise disclosed on behalf of CLIENT to BTPH at the time CLIENT assists BTPH personally with the technology transfer at the BTPH facility.

1.17 "**GMP**" means (current) Good Manufacturing Practices as prescribed by the guidelines laid down by the European Medicines Agency and the U.S. Food and Drug Administration (FDA) that control authorization and licensing for manufacture and sale of drug product or a medical device, active pharmaceutical products and microbiological cultures in Europe and the U.S.

1.18 "**GMP Batch**" means a Batch manufactured according to GMP.

1.19 "**Health Authorities**" mean all regulatory authorities having jurisdiction over the development, manufacture, use and/or sale of the Product in the Territory, namely the European Medicines Agency ("**EMA**") and the U.S. Food and Drug Administration ("**FDA**").

1.20 "**Information**" shall have the meaning as defined in Section 14.1.

1.21 "**Intellectual Property Rights**" means all Patent Rights, trade secrets, trademarks, service marks, registered designs, applications for any of the foregoing, trade and business names, unregistered trademarks and service marks, copyrights, rights in designs, inventions, know-how, rights under licenses, and RCBs, MCBs, WCBs as well as cell strains, and rights of the same or similar effect or nature, in any part of the world.

1.22 "**Manufacturer's Release**" means BTPH's release of a GMP Batch of Product in accordance with the Quality Agreement.

1.23 "**Manufacturing Process**" means the manufacturing process for Drug Substance or Drug Product or Placebo, as applicable, based on the Existing Process.

1.24 "**Master Batch Record**" means the master production instructions for manufacture of a Batch.

1.25 "**Materials**" mean raw materials, filters, membranes, consumables and resins applied in the manufacture of Product. Materials may be provided to BTPH by CLIENT as part of the Deliverables or may be procured or manufactured by BTPH.

1.26 "**MCB**" means master cell bank.

1.27 "**Non-Conforming Batch**" means a GMP Batch that does not conform to the Product Specifications after its manufacturing or for which there has been a deviation of conformity with GMP.

1.28 "**Optimized Process**" means improvements that BTPH introduced to the Existing Process.

1.29 "**Party**" and "**Parties**" means CLIENT or BTPH, or both, as applicable, including its Affiliates.

1.30 "**Patent Rights**" mean issued patents and patent applications, whether such Patent Rights exist now or in the future anywhere in the world, including, but not limited to, any issued patent, including inventor's certificates, utility model, substitutions, confirmations, reissues, re-examination, renewal or any like governmental grant for protection of inventions; and any pending application for any of the foregoing, including any continuation, divisional, substitution, additions, continuations-in-part, provisional and converted provisional applications, as well as extensions and supplementary protection certificates based thereon.

1.31 "**Placebo**" means the control product for clinical trials without an active ingredient.

1.32 "**Process Inherent Issue**" shall mean characteristics of the Existing Process which negatively affect the Manufacturing Process and which would not be reasonably expected to occur and which are not the result of either Party's negligent or willful act or omission.

1.33 "**Product**" shall mean the Drug Substance and / or the Drug Product and /or Placebo, as applicable.

1.34 "**Project Team**" shall have the meaning as defined in Section 7.2.1.

1.35 "**Quality Agreement**" means the agreement that will be entered into by the Parties before commencing GMP manufacturing, to be signed no later than thirty (30) calendar days before start of GMP manufacturing, which sets forth the Parties' rights and obligations with regard to quality management, documentation to be provided to CLIENT in support of Product release, including the language of such documentation, regulatory items such as audits and inspections, etc.

1.36 "**RCB**" means research cell bank.

1.37 "**Scope of Work**" or "**SOW**" shall have the meaning as defined in Section 2.1.

1.38 "**SOPs**" mean written standard operating procedures established, or to be established, by BTPH and employed in the production, quality control, quality assurance, warehousing, labelling and packaging, among other things.

1.39 "**Services**" shall have the meaning as defined in Section 2.1.

1.40 "**Specifications**" means tests, references to analytical procedures, appropriate acceptance criteria that are numerical limits, ranges or other criteria for which the Materials (as applicable), Product and its intermediates, or Manufacturing Process, must conform to in order for the Product, be acceptable for its intended use and approved in writing by CLIENT.

1.41 "**Steering Committee**" shall have the meaning as defined in Section 7.1.1.

1.42 "**Technology Transfer**" means the transfer of all required technology documentation and materials (including the transfer of the Existing Process from CLIENT or Teva to BTPH) in order to implement the Manufacturing Process at the BTPH Facility.

1.43 "**Territory**" means the countries belonging to the current European Economic Area and the United States.

1.44 "**WCB**" means working cell bank.

2. SERVICES

2.1 During the term of this Agreement, BTPH shall provide to CLIENT certain services as agreed between the Parties from time to time and set out in a Scope of Work ("**SOW**") (the "**Services**"). Each SOW shall be executed by the Parties and incorporated by reference as an attachment to this Agreement. Nothing contained in a SOW shall be construed to amend or modify any provision of this Agreement. CLIENT shall pay BTPH for such Services as provided in this Agreement and each SOW. BTPH shall perform such Services upon the terms and conditions set forth herein and in each SOW.

2.2 Each SOW shall set forth the Services to be performed, including any deliverables, a timeline for performance of Services, and the fee for each of the Services. BTPH agrees that it will use it best efforts, skills, and abilities to perform the Services and to diligently and competently perform its obligations under this Agreement.

2.3 In providing the Services, BTPH shall at all times comply with the requirements set out in the Quality Agreement, signed by both Parties and attached hereto as Appendix 2 of this Agreement. In the event of any conflict between this Agreement and the Quality Agreement, the Quality Agreement shall control with respect to matters relating to quality, and this Agreement shall control with respect to all other matters.

2.4 BTPH shall in regular intervals, no less than weekly, during the term of the execution of a SOW and as reasonably requested by CLIENT, keep CLIENT advised as to BTPH's progress in performing the Services.

2.5 BTPH shall carry out the Services in accordance with the SOW and will comply with all requirements of applicable federal, state and local laws, rules and regulations as far as they pertain to the Services, including but not limited to cGMP regulations.

2.6 CLIENT will use its best efforts to support BTPH in the performance of the Services, such support to include the requirement to approve documents or the provision of all information, documentation, data and material available to CLIENT which may be necessary or useful for the performance of the Services. CLIENT must ensure that all approvals and documentation necessary to perform the Services are made available to BTPH on a timely basis which shall not exceed [***] or another time as specifically agreed upon between the project teams of both Parties and set forth in approved meeting minutes, and must ensure that BTPH is informed of all events and circumstances that may be relevant for the performance of the Services. In particular, CLIENT shall inform BTPH of any issues arising from discussions with any regulatory authorities which should be considered when performing the Services. In the event that any delay of the project results from CLIENT's failure to provide necessary consent, information and/ or materials within the specified or mutually agreed time, CLIENT shall be solely responsible for such delay, provided that BTPH has alerted CLIENT to such potential delay.

2.7 CLIENT will use Commercially Reasonable Efforts to support BTPH in performing the Services. It is common understanding of both Parties that the timeline as outlined in the SOW has to be confirmed by the Parties when all the documents needed for tech transfer and/ or cell strains sent by CLIENT and all raw materials, process aids and process consumables have arrived at BTPH's Facility.

2.8 CLIENT shall have the right to reject any Work Product (as defined in Section 13.1) or Services provided hereunder that does not meet Drug Substance or Drug Product specifications, and/or quality standards (GMP), and/or the applicable SOW. CLIENT shall provide BTPH with written notification of the deficiency or non-conformance and, within [***] of receipt of such written notification, BTPH shall, at CLIENT's sole discretion, (i) promptly correct the deficiency or non-conformance [***] or (ii) refund CLIENT for all fees and expenses paid to BTPH for such Services or Work Product. CLIENT's acceptance or failure to reject any Work Product or Services provided hereunder shall not act to waive any of CLIENT's rights under any of the warranties provided herein or CLIENT's ability to enforce any other provisions of this Agreement. BTPH shall make all attempts to implement a preventive process so that the deficiency does not reoccur and documents the corrective and preventative action. This Section shall survive any termination or expiration of this Agreement.

2.9 BTPH acknowledges that CLIENT operates in a highly regulated industry. As such, BTPH agrees, at CLIENT's reasonable and timely request, to perform drug and/or alcohol testing of an employee, agent or other representative of BTPH ("**BTPH Representative**") should CLIENT have reasonable suspicion that a BTPH Representative (a) is under the influence of one (1) or more intoxicants while performing Services or (b) has diverted pharmaceuticals and/or any product or compound used in the manufacture or testing of pharmaceuticals while performing the Services. BTPH further agrees that all such drug and/or alcohol testing will be at BTPH's sole expense if it turns out that a BTPH representative was indeed under the influence of intoxicants, otherwise CLIENT has to bear all respective costs. For the purpose of this Section 2.9, "reasonable suspicion" is defined as the CLIENT's belief, based on reasonable evidence, that a BTPH Representative committed, caused, or is a party to the unauthorized diversion of pharmaceuticals and/or any product or compound used in the manufacture or testing of pharmaceuticals. CLIENT reserves the right to request BTPH to withdraw immediately a BTPH Representative from the SOW-execution that is found to be in violation of this Section and an alternate BTPH Representative, with the required level of experience, will be appointed by BTPH. CLIENT will not be responsible for any associated costs or expenses for the alternate BTPH Representative for one (1) week of knowledge transition effort.

3. CLIENT DELIVERABLES

3.1 Subject to the provisions of this Agreement, either Teva has or CLIENT shall provide BTPH with all necessary materials of CLIENT (e.g. supplies of cell banks, samples, reference standards, etc.), and respective documentation (which shall be including but not limited to documents describing the Existing Process and standard operating procedures of analytical release and in-process-control methods) reasonably required and necessary for the performance of the Services (hereinafter the "**CLIENT Deliverables**").

3.2 Should CLIENT not be able to deliver parts of the CLIENT Deliverables to BTPH, the Parties shall negotiate in good faith about alternative sources for such CLIENT Deliverables. If possible, such CLIENT Deliverables may be purchased or manufactured by BTPH at CLIENT's costs as set forth in an SOW. Such CLIENT Deliverables will be treated as Materials.

3.3 CLIENT shall also supply BTPH with any material safety data sheets relating to such CLIENT Deliverables and shall provide to BTPH any available information known to CLIENT relating to handling, safety and environmental precautions with respect to any Deliverables (if applicable). Furthermore, CLIENT shall inform BTPH within a reasonable period of time of any circumstances it becomes aware of which may have a material influence on the manufacture or safety of Product.

3.4 Assistance and Support by CLIENT

3.4.1 Notwithstanding BTPH's responsibilities to ensure compliance with its legal and regulatory requirements hereunder, CLIENT shall inform, instruct and assist BTPH with regard to all legal and regulatory requirements known or becoming known to CLIENT including, but not limited to applicable laws, regulations, ordinances, regulatory guidelines and guidance necessary and conducive for the manufacture of Product destined for the Territory.

3.4.2 BTPH has agreed to meet the timelines set forth in each SOW.

3.4.3 In the event there are unexpected delays at any point during the conduct of the Services, as evidenced by milestones not being completed, and if CLIENT is not accountable for such delays, BTPH agrees to take whatever action may be necessary to ensure the recovery from any unexpected delay and the completion of Services, under the original Specifications, without modification of said Specifications, and according to the original timelines. Costs associated with any necessary remedial actions will be borne by BTPH.

3.4.4 BTPH understands and acknowledges that time is of the essence under this Agreement and CLIENT will suffer substantial monetary loss and other damages by any unreasonable delay in the completion of Services. However, the aforementioned shall only be valid for the manufacturing of Product according to a manufacturing process which is already established at BTPH. For the purpose of clarity, any process development activities and/ or applying a different manufacturing process which was not yet executed by BTPH before at least two times in the form of an Engineering Batch at final production scale shall be excluded from the regulation above, since the nature of such activities is research and development which carries inherent uncertainty and timelines cannot be fully guaranteed, even if BTPH will use best efforts to achieve these.

4. RELEASE, STORAGE AND DELIVERY OF PRODUCT

4.1 Release

4.1.1 BTPH is responsible for the Manufacturer's Release as set forth in the Quality Agreement.

4.2 Packaging, Storage and Delivery of Product

4.2.1 BTPH shall package and label Product in accordance with the approved batch production record, applicable SOPs and following cGMP.

4.2.2 BTPH will store the Product following Manufacturer's Release is compliance with GMP and BTPH's applicable SOP. Storage for [***] is free-of-charge, thereafter BTPH can further store the Product for a storage fee as outlined in a SOW.

4.2.3 BTPH shall support, cooperate with and assist CLIENT by preparing the Product, including the respective documents, for delivery. All samples (such as but not limited to retain samples, for analytical use, standards, stability, samples sent for external testing) delivered by BTPH to approved subcontractors of BTPH or CLIENT shall be agreed between the Parties.

4.2.4 All delivery of Product to CLIENT or a location designated by CLIENT shall be made according to Incoterm 2010 [***]. Where applicable, BTPH will provide assistance in obtaining any export license, security clearance or other official authorization necessary for the export of Product.

4.3 Ownership and Insurance

4.3.1 BTPH shall retain title (but not the Intellectual Property therein) to any tangible work-in progress (including intermediates, Product) and to any Batch of Product as of production which has not yet been delivered to or paid for in full by CLIENT. Title to a Batch or the parts thereof actually delivered to CLIENT shall pass to CLIENT upon payment in full to BTPH for respectively such Batch or such parts thereof.

4.3.2 BTPH shall hold appropriate insurance for the work-in-progress and Batches that are on site at the BTPH Facility.

5. CHANGES OF PRODUCT SPECIFICATIONS AND PROCESS-CHANGES

5.1 Except as otherwise expressly set forth to the contrary in the Quality Agreement, if CLIENT is required, or desires, to change the Product Specifications or the Manufacturing Process, then BTPH shall use Reasonable Commercial Efforts to accommodate such request, subject to the following:

5.1.1 CLIENT shall promptly advise BTPH in writing of any such change(s), and provide information necessary for BTPH to evaluate the effect of such change(s). BTPH shall promptly advise CLIENT as to scheduling changes, if any, which may result from such change(s). The notification and approval procedure shall be in accordance with standard operating procedures (i.e., change control procedures) agreed by the Parties from time to time, as described in the Quality Agreement. The Parties shall hold a meeting in a timely manner to discuss such changes as appropriate.

5.1.2 Prior to implementation of any change(s), BTPH shall provide CLIENT with a quote of the price of the services and equipment that will he provided and/ or purchased by BTPH in order to implement any such change(s) to the Product Specifications or the Manufacturing Process, including, but not limited to, the price of BTPH's validation and analytical services. If such changes will be implemented, then CLIENT shall pay the price of the services and/ or equipment.

5.1.3 BTPH shall make changes in accordance with timelines agreed to by the Parties, except that BTPH shall have no obligation to make any such change where doing so could, in BTPH's reasonable judgment, (i) violate any applicable law or regulations, or (ii) are in contradiction to filings for other BTPH products, or (iii) are incompatible with BTPH's established operations for biopharmaceuticals, provided that BTPH shall make any changes which CLIENT is required to make due to requests of Health Authorities in line with Section 5.3. BTPH shall cooperate with CLIENT in good faith to implement all agreed upon changes to the Product Specifications or Manufacturing Process in accordance with the timelines agreed to by the Parties.

5.1.4 CLIENT acknowledges that the Parties must agree in advance as of which point in time and to which services and or manufacture of Batches changes to the Product Specifications or Manufacturing Process apply.

5.1.5 If any changes to the Product Specifications or Manufacturing Process render obsolete or unusable any Materials, BTPH shall either destroy or deliver at CLIENT's costs to CLIENT, at CLIENT's sole option, those obsolete or unusable Materials. CLIENT shall reimburse BTPH for the costs of such Materials destroyed or provided to CLIENT if not yet paid for by CLIENT.

5.2 Procedure for Product Specifications or Manufacturing Process changes by BTPH.

5.2.1 BTPH shall not change the Product Specifications or the Manufacturing Process except with CLIENT's prior written consent.

5.2.2 Any BTPH-requested changes approved by CLIENT shall be in accordance with the Quality Agreement and SOPs agreed in writing by CLIENT and BTPH.

5.3 Health Authority Requested Changes.

5.3.1 BTPH Facility related. If a Health Authority requests or requires that a change be made in the BTPH Facility or the related utilities, automated systems or multi-product equipment used to manufacture the Product, or if changes to the BTPH Facility or the related utilities, automated systems or equipment used to manufacture the Product are required in order to comply with applicable laws or regulations (including, without limitation, GMP), then BTPH shall make such changes in accordance with the Quality Agreement and applicable SOPs. BTPH is responsible for all of its costs incurred in connection with making those change(s).

5.3.2 Manufacturing Process and /or Product related. If a Health Authority requests or requires that a change be made to the Manufacturing Process or to the Product Specifications, or if changes to the Manufacturing Process or Product Specifications are required in order to comply with applicable laws or regulations (including, without limitation, GMP), then BTPH shall make such changes in accordance with the Quality Agreement and SOPs (i.e., change control procedures) agreed in writing by CLIENT and BTPH. The Parties shall bear the price of all services of BTPH and costs of equipment and Materials incurred in connection with making those changes in equal shares, except that the CLIENT is responsible for those costs incurred for changes to the equipment exclusively dedicated to manufacture of Product which shall be borne by CLIENT.

6. BATCH REPLACEMENT AND RISK ALLOCATION

6.1 Replacement

6.1.1 If the Parties agree that any GMP Product is a Non-Conforming Batch, BTPH shall replace, with no additional charge, this Batch within a commercially reasonable period of time.

6.2 Risk Allocation during the SOW Period

6.2.1 BTPH shall perform the number of transfer runs as agreed in order to verify robustness and reproducibility of the Existing Process or Optimized Process prior to implementation into BTPH's GMP facilities, and to train the staff at BTPH Facility.

6.2.2 In the event of the occurrence of Process Inherent Issues during the term of the SOW, the Parties shall use Commercially Reasonable Efforts to resolve such Process Inherent Issues as soon as reasonably possible.

6.2.3 Should such Process Inherent Issues require repeating the performance of an Engineering Batch, BTPH shall use Reasonable Commercial Efforts to make a slot available for such a repeat batch within a reasonable period of time in order to avoid or limit delays in the timeline set forth in the SOW. In the event that an Engineering Batch needs to be repeated for reasons other than operator errors or equipment failure, the Engineering Batch shall be repeated at [***] costs.

6.2.4 During the Technology Transfer period and the establishment of the Manufacturing Process (including fill & finish) at BTPH's Facility, except for an operational failure of BTPH (which shall for the purpose of clarity be defined as a technical break-down of equipment, negligence, mistakes and/or misconduct of a BTPH operator), [***] shall be responsible for and shall bear the technical risk and potential delays in respect of the robustness, reproducibility and scalability of the Manufacturing Process, and the analytical methods transferred, if any, to BTPH.

7. STEERING COMMITTEE AND PROJECT MANAGEMENT

7.1 Steering Committee

7.1.1 Establishment; Membership; Meetings. The Parties shall establish a joint executive steering committee (the "**Steering Committee**" or "**SC**"), consisting of 3 members appointed by each of BTPH and CLIENT. Additional people may attend the SC meeting as required based on the agenda, and their participation shall not be unreasonably withheld by either Party. CLIENT and BTPH each shall appoint as representatives individuals having seniority and decision-making power, at least one of whom must have scientific or technical expertise. Either Party may replace any or all of its representatives at any time upon prior written notice to the other Party. The Steering Committee will meet at least once a year, or more frequently, as agreed by the SC. Minutes of SC meetings shall be taken in alternate turns and sent to each SC member for review and approval within [***] after such meeting. Review by the respective other Party and approval through sign-off of the minutes by a representative of the SC of each Party shall be made within [***] after receipt of the minutes.

7.1.2 Responsibilities. The Steering Committee is responsible (i) for strategic oversight of the Services and the manufacture of Product; (ii) to settle disputes or disagreements not resolved by the PT (as defined below) unless otherwise indicated in this Agreement; (iii) to discuss major issues regarding the performance of the Existing Process or Manufacturing Process which cannot timely be resolved despite efforts of both Parties, and (iv) for approving by written documentation any major changes to the Services, the SOW, or budget.

7.2 Project Management

7.2.1 Establishment; Membership; Meetings. The Parties shall establish a joint project team (the "**Project Team**" or "**PT**"), consisting of the required representatives of either Party. Either Party may replace any or all of its representatives at any time upon written notice to the other Party. The PT will meet via teleconference and/or videoconference at least every two weeks, or more frequently if needed, as mutually agreed by the PT. Face to face meetings shall be mutually agreed by the PT. The PT must provide agreed upon agendas prior to meetings, meeting minutes and timelines. The PT shall ensure timely review, and where appropriate approve, documents to meet the agreed timelines to satisfy the objectives of this Agreement.

7.2.2 Appointment of Project Coordinator or Project Manager. Each Party shall appoint a project manager to act as the primary contact for such Party in connection with matters related to the performance of the Services and/or manufacture of the Product and to assume principal day-to-day operational responsibility for coordination of that Party's responsibilities under this Agreement (each a "**Project Manager**"). Both Project Managers shall serve as a member of the PT. A Party may replace its Project Manager at any time and from time to time for any reason by providing advance written notice of the change to the other Party.

7.2.3 Responsibilities. The PT is responsible for management of the ongoing activities related to the Services and the manufacture of Product, for oversight regarding performance of the Services, overseeing the transfer of the Existing Process, making decisions and disseminating information regarding implementation of the Manufacturing Process and manufacture of the Product, and monitoring and reviewing BTPH's performance of the Services and CLIENT's fulfilment of its obligations.

7.3 Person in Plant

7.3.1 CLIENT may send designated observers, which number shall be limited to [***] due to practical reasons, to monitor some or all GMP operations relating to the manufacture and testing of Product, subject to agreement with BTPH. The observers will not conduct an audit, but will monitor operations and be available for technical discussions with the BTPH staff.

7.3.2 Apart from the observation of GMP operations of an ongoing manufacturing of the Product, CLIENT has the right to audit BTPH each calendar year, following procedures as referred to in the Quality Agreement.

8. REPRESENTATIONS AND WARRANTIES

8.1 Each Party hereby represents and warrants to the other Party that: (a) the person(s) executing this Agreement is/are authorized to execute this Agreement, and (b) this Agreement is legal and valid and the obligations binding upon such Party are enforceable by their terms.

8.2 BTPH represents and warrants that:

8.2.1 As of the Effective Date, BTPH is duly organized and in good standing under the laws of Lithuania and any authorizations and rights necessary for making and performing under this Agreement has been given.

8.2.2 As of the Effective Date, the making and performance of this Agreement does not conflict with BTPH's governing documents or any contractual obligation to another third party.

8.2.3 To BTPH's knowledge as of the Effective Date, (i) BTPH is free to supply the BTPH Confidential Information to CLIENT and BTPH has the necessary authorizations to provide the Services and manufacture of CLIENT's Product; and (ii) BTPH has not infringed on any third party Intellectual Property Rights with regard to any BTPH's technology intended to be used to manufacture CLIENT's Product, or incorporated into CLIENT's Product, provided that any and all CLIENT Information and CLIENT Deliverables provided to BTPH by CLIENT do not infringe such third party Intellectual Property Rights.

8.2.4 BTPH shall comply with regulatory requirements and shall obtain and maintain all regulatory approvals that are required for BTPH to manufacture and fill and finish the Drug Substance at BTPH facility.

8.2.5 All GMP-Products supplied by BTPH under this Agreement shall conform at the Manufacturer's Release to Product Specifications, be manufactured in accordance with GMP, be free from defects in processing, materials and workmanship, and not be subject to any liens, security interests or any other encumbrances.

8.2.6 Manufacture of Product will he conducted with the approved master production records and relevant established SOPs of BTPH. However, such manufacturing may be fulfilled including the occurrence of deviations allowed under GMP to the extent as a cause is attributed and assigned to those deviations and appropriate corrective actions can be implemented for such deviation. The warranty shall not limit BTPH's representations and warranties as set out in Section 8.2.5 above.

8.2.7 BTPH hereby certifies that no person employed or retained by BTPH to perform Services has been debarred under Section 306(a) or Section 306(b) of the United States Federal Food, Drug and Cosmetic Act and that no debarred person will in the future be employed or retained by BTPH in connection with the Services. If at any time after execution of this Agreement or any SOW, BTPH becomes debarred or becomes aware that any person employed or retained by BTPH in connection with the Services has been, or is in the process of being debarred or is on any of the three FDA restricted lists (Disqualified/Totally Restricted List for Clinical Investigators, Restricted List for Clinical Investigators, Adequate Assurances List for Clinical Investigators), BTPH hereby certifies that it will notify CLIENT at once.

8.2.8 BTPH represents and warrants that BTPH does not, and will not during the term of this Agreement, have any relationships with third parties that would (i) present a conflict of interest with rendering the Services, or (ii) prevent BTPH from carrying out the terms of this Agreement.

8.2.9 Except as expressly provided for in Sections 8.1 and 8.2, BTPH makes no further warranties of the merchantability or fitness of the Product for any purpose, or any warranties of any other nature, express or implied. BTPH shall not be liable for damages resulting from the lack of features or other qualities which BTPH does not represent and warrant in this Section 8.2.

8.3 CLIENT represents and warrants that:

8.3.1 It is duly organized and in good standing under the laws of the jurisdiction of its formation, and any authorizations necessary for making and performing this Agreement have been given.

8.3.2 That the signing and performance of this Agreement does not conflict with CLIENT's governing documents or any contractual obligation to another third party.

8.3.3 To CLIENT's knowledge as of the Effective Date, (i) CLIENT is free to supply the CLIENT Confidential Information to BTPH; and (ii) CLIENT has not received written notice alleging infringement of third party Intellectual Property Rights with regard to any CLIENT's technology intended to be used to manufacture CLIENT's Product, or to be incorporated into CLIENT's Product, provided that any and all information and CLIENT Deliverables provided to BTPH by CLIENT do not infringe such third party Intellectual Property Rights.

9. INSURANCE

9.1 Without derogating from BTPH's liability at law and/or under this Agreement, during the term of this Agreement, and with regards to "claims made" policies for an additional period, to the extent legal liability attaches to BTPH or CLIENT, BTPH shall, at its own cost and expense, maintain at a minimum the following insurance policies (collectively "**Policies**"):

(a) Worker's Compensation insurance at least in accordance with the statutory requirements of the state or country in which the Services under this Agreement are to be performed and in addition Employer's Liability; and

(b) Comprehensive General Liability insurance, including coverage for product liability, Bodily Injury, Property Damage, and Personal Injury, with minimum Limits of [***] and [***].

(c) Any and all risks insurance policy/policies shall cover any and all CLIENT property in the ownership, care, custody or control of BTPH against any physical loss or damage, including but not limited to, fire, water damage, natural hazard, storm, tempest, rain and spoilage at full reinstatement value. BTPH has the right to procure and maintain business interruption insurance covering BTPH and CLIENT's loss of income due to damage to its property insured by BTPH for a minimum of 12 months from the date of loss indemnity period.

BTPH's Policies shall all include: (i) [***] notice of cancellation or reduction in coverage to be submitted to the CLIENT's CEO, (ii) a waiver of subrogation clauses towards the CLIENT and/or its parent company, subsidiary company, shareholders, managers, directors, officers and employees (collectively the "**Additional Party**"), however such a waiver shall not be made available towards a person committing a malicious act, and (iii) all of the policies include the CLIENT and the Additional Parties as an additional insured subject to a cross liability clause (excluding workers compensation and employers liability insurance policies). Notwithstanding and in addition to the foregoing, BTPH shall maintain insurance coverage, have indemnity obligations and be responsible for its actions as may be required under applicable laws, rules or regulations. BTPH shall provide CLIENT with a certificate evidencing its policies and coverage upon request of the CLIENT.

BTPH shall provide the CLIENT with prompt written notice in the event that BTPH becomes aware of any claim or potential claim for indemnification that may be asserted against CLIENT.

Required insurance shall he placed with carriers having a minimum [***] rating of [***]. Upon execution of this Agreement, BTPH shall forward an insurance certificate to CLIENT evidencing said insurance coverage prior to performing the Services for CLIENT. The certificate of insurance shall reflect the insurance carrier to use its best efforts to provide CLIENT with at least [***] prior notice of cancellation of such insurance. BTPH shall provide written notice within [***] of becoming aware of any cancellation, material change or non-renewal in the required insurance. The amount of insurance coverage shall not limit in any way BTPH's obligations to indemnify CLIENT hereunder. If any insurance policy is written on a claims basis, BTPH shall ensure continuity of cover for claims which may present themselves following expiry of the insurance policies. Failure to maintain required insurance may he deemed a material breach of this Agreement.

10. PAYMENTS

10.1 Payments shall be made as set out in the relevant SOW. The amount specified in each SOW is the maximum amount due from CLIENT for Services performed pursuant to that SOW. Such compensation may be modified only upon the prior written agreement of the Parties. Should the scope of Services as set forth in a SOW be expanded, resulting in any change in compensation, both Parties shall agree in a signed modified SOW prior to services commencing. Each invoice shall set forth in detail: (a) the specific SOW; (b) reference to the stage of the SOW if there are several stages in the SOW (c) if applicable (i.e. SOW has not a lump-sum but based on FTE-hours) the number of hours expended for each Service; (d) if applicable, a detailed itemization of any expenses incurred which were approved in advance by CLIENT. Moreover, each BTPH invoice must be accompanied by such supporting data as CLIENT may reasonably require. BTPH must submit copies of third party provider (including approved subcontractors and independent contractors) invoices (if any) with the BTPH invoice that it submits to CLIENT. Third party provider charges, if applicable, will be invoiced to [***] at [***] cost plus a mark-up of [***]. Payment by CLIENT to BTPH shall be made within [***] after CLIENT'S receipt of an undisputed invoice for Services as described in the SOW. [***] will be cross charged to the CLIENT at the actual invoiced price paid by BTPH plus a [***] fee of [***]; except that no [***] fee shall apply to [***]. BTPH shall use commercially reasonable efforts to procure raw materials and consumables from reputable suppliers at the lowest available pricing, and, prior to procurement, BTPH will provide CLIENT with estimates of anticipated quantity and expenditure on raw materials intended for use during provision of Services. Raw materials, process aids and consumables purchases as well as potential outsourcing costs related to the Services with written approval and confirmation of the CLIENT shall be paid for in full by the CLIENT within [***] from the date of invoice, it being understood that BTPH shall he entitled to invoice the CLIENT for such purchase at the time it orders such materials and the intent of the Parties is for the CLIENT to pay BTPH for such materials on or before the time BTPH must pay the vendors.

Fees will be paid by a bank transfer to BTPH's bank account as indicated in section 10.4. In the event that BTPH does not receive the full payment for any undisputed amount on its due date, it shall have the right to charge interest at rate of [***] per annum on the outstanding amount of the invoice until such payment is received in full.

CLIENT's failure to comply with payment terms defined above shall be deemed a material breach of this Agreement by CLIENT.

The prices stated in the SOW are exclusive of (a) taxes, duties and other fees imposed by any government authority (other than taxes on BTPH's income); (b) external analysis costs; (c) raw materials and (d) shipping and handling. CLIENT must pay these amounts in addition to the Price. CLIENT must also reimburse BTPH for all travel costs and out of pocket expenses requested by or required by CLIENT that are approved in advance, in writing by CLIENT.

10.2 Any disputed amounts shall be communicated to BTPH within ten (10) calendar days after receipt of an invoice. The Parties shall work together to resolve any disputed amount. In the event that the Parties cannot resolve a disputed amount within thirty (30) calendar days since the 1st communication on such an issue, then the matter shall be escalated in accordance with Section 18.7.2.

10.3 All BTPH invoices should be sent to:

Address: 89 Medinat HaYehudim St., Herzliya, Israel
Contact person: [***]
Contact info: [***]
VAT: [***]

10.4 All payments should be made to BTPH bank account by bank transfer using bank details provided below:

Beneficiary: [***]
Bank account #: [***]
SWIFT: [***]
Bank name and address: [***]

11. TERM AND TERMINATION

11.1 This Agreement shall be effective as of Effective Date and shall continue in effect for the duration of BTPH providing the Services, unless earlier terminated in accordance herewith.

11.2 CLIENT may terminate this Agreement upon [***] prior written notice to BTPH.

11.3 CLIENT has the right to terminate this Agreement, with written notice, upon the occurrence of any of the following events:

a) BTPH's breach of any material provision under this Agreement if not remedied within [***] written notice of such breach;

b) bankruptcy or insolvency of BTPH;

c) commission of fraud upon CLIENT by BTPH;

d) an event of Force Majeure affecting BTPH as hereinafter defined occurs and continues for ninety (90) calendar days or more.

11.4 BTPH has a right to terminate this Agreement, with written notice, upon the occurrence of any of the following events:

a) CLIENT's breach of any material provision under this Agreement if not remedied within [***] written notice of such breach;

b) CLIENT's failure to pay any undisputed sum payable under this Agreement [***] after a written demand issued after the original due date;

c) bankruptcy or insolvency of the CLIENT;

d) commission of fraud upon BTPH by the CLIENT; or

e) an event of Force Majeure affecting the CLIENT as hereinafter defined occurs and continues for ninety (90) calendar days or more.

For the purpose of this Agreement, "**Force Majeure**" shall be deemed to be any cause affecting the performance of this Agreement arising from or attributable to acts, events, omissions or accidents beyond the reasonable control of the Party to perform and without its fault, including, without limitation:

a) strikes, lock-outs or other industrial action;

b) civil commotion, riot, invasion, terrorist attack, war, threat of or preparation for war;

c) fire, explosion, storm, flood, earthquake, subsidence, epidemic or other natural physical disaster; or

d) political interference with the normal operations of any Party.

11.5 On the effective date of termination, BTPH shall immediately cease all work requested hereunder and CLIENT's obligation to compensate BTPH for further work shall end. However, CLIENT shall not be relieved of its obligation to compensate BTPH for fees earned and expenses incurred prior to the date of termination, which have not yet been paid. CLIENT should fully reimburse BTPH for the cost of raw materials and consumables purchased by BTPH for provision of Services and remaining in stock at the date of termination if such materials have not yet been paid for by the CLIENT. Such reimbursement should be made within [***] after the termination date of the Agreement. CLIENT will take possession of such remaining materials and consumables upon the full payment. Within [***] after receipt of the written CLIENT's instruction, but not before the reimbursement has been made by CLIENT to BTPH, such remaining unused materials will be made available for CLIENT pick-up at BTPH facility.

11.6 Upon expiry or termination of this Agreement by either Party, or at the request of CLIENT, BTPH shall use, at the request of CLIENT, Commercially Reasonable Efforts to assist CLIENT in transferring the Manufacturing Process to CLIENT or a third party designated by CLIENT. Such transfer will include: (1) all documents regarding the manufacturing process, analytical methods, Specifications, and stability protocols to CLIENT or its

designee as further; (2) all relevant materials (master cell banks, reagents, etc.) to CLIENT or its designee; and (3) availability of its personnel for consulting. The transfer will be agreed upon by the Parties in a SOW. BTPH and CLIENT will use best efforts to enter into an SOW within [***] and the cost of the SOW will be commercially reasonable. BTPH shall be compensated for such efforts and will submit a SOW detailing the technology transfer program to CLIENT if requested so by CLIENT. Expenses of travel at standard class and accommodation at business hotel, if travel of BTPH personnel is required with prior written consent of CLIENT, shall be paid by CLIENT. In the event of termination of this Agreement by CLIENT pursuant to Section 11.3 above, BTPH is obligated to support the transfer of documentation and materials of the process to CLIENT or a third party designated by CLIENT at no additional cost.

11.7 Upon termination or expiration of this Agreement, BTPH will return to CLIENT (or a third party designated by CLIENT) or destroy the CLIENT Deliverables and any documents supplied by CLIENT, as well as all copies of and extracts from such documents provided, as instructed by CLIENT; however, BTPH may retain one (1) copy for the sole purpose of verifying compliance with BTPH's obligations under this Agreement. The documents which BTPH are allowed to maintain shall include documents as required by law and/ or GMP-regulations.

11.8 Upon the completion of the Services or the expiration or earlier termination of this Agreement, BTPH shall promptly return to CLIENT all Information in any physical media in its possession, and unless prohibited by applicable regulatory requirements, erase or destroy, and document the destruction of, all additional copies and recordings thereof, including, but not limited to, any and all summaries, abstracts, drawings, notes or other records or data (or copies thereof) prepared by BTPH based upon such Information.

12. CANCELLATION FEES

BTPH has allocated resources to the project which may be difficult or impractical to reallocate to other projects in the event of any cancellation of any Batch productions by BTPH ("**Cancellation**"). In case of a Cancellation, CLIENT shall pay a cancellation fee in accordance with the following schedule:

CLIENT must pay BTPH the Cancellation Fees stated below if any Batch scheduled for manufacture is delayed or cancelled as a result of:

(a) [***]

(b) [***]

(c) [***]

In case of [***] CLIENT will pay [***] of agreed Price of the cancelled Services and reimburse BTPH for all [***] which BTPH has purchased for the performance of the respective Services if not yet paid by CLIENT.

CLIENT must pay the following amounts to BTPH for each Cancelled Batch that is not cancelled as a result of [***] ("**Cancellation Fees**"):

Timing of Notice of Cancellation	Cancellation Fees
Notice served **[***]**.	[***]
Notice served **[***]**.	[***]
Notice served **[***]**.	[***]
Notice served **[***]**.	[***]
Notice served **[***]**.	[***]

The Commencement Date of the production shall be the one as stated in the current version of the Gantt-chart provided by BTPH to CLIENT, being valid at the time when CLIENT submits a cancellation-request.

In addition to the payment of the amounts set forth above for any cancelled scheduled Batch productions, CLIENT shall compensate BTPH for the reasonable out of pocket costs (including disposal costs) associated with any unused or unusable raw materials or process consumables due to such cancellation. BTPH will send CLIENT an invoice to this extent.

13. WORK PRODUCT

13.1 Any and all ideas, materials, documents, reports, information, concepts, inventions, discoveries, data, publications, developments, methods, improvements, CMC dossier or products (including biopharmaceutical products to be used for pre-clinical studies, clinical trials or commercial use), generated by BTPH during and related to the Services performed pursuant to this Agreement ("**Work Product**") shall be and remain the sole and exclusive property of CLIENT and shall be treated by BTPH as CLIENT-owned Confidential Information covered under this Agreement. BTPH hereby assigns any and all rights, title and interest in Work Product to CLIENT, and CLIENT accepts such assignment. BTPH acknowledges that all Services performed hereunder and all Work Product constitute "works made for hire" pursuant to 17 U.S.C. §201(b) (the Copyright Act) and as such is a work specially commissioned for use.

13.2 In the event that any such Work Product becomes the subject of patent applications or patents or other form of intellectual property application or registration, BTPH shall, if CLIENT wishes so in writing, provide CLIENT assistance and execute documents which may be necessary for CLIENT to obtain and secure CLIENT's Intellectual Property Rights. BTPH shall be compensated for such assistance by being paid a daily fee of [***] per skilled and experienced BTPH employee plus expenses.

13.3 Whether the Services and attendant Work Product are ultimately determined to be "works made for hire" (as defined in Section 13.1 above) or an employment to invent, all Work Product shall be and remain the sole property of CLIENT and its assigns. BTPH agrees that CLIENT shall have all copyright, trademark, trade secret and patent rights with respect to any Work Product discovered, created, developed, conceived, reduced to practice, devised or generated under this Agreement without regard to the origin of the Work Product.

If and to the extent that BTPH may, under applicable law, be entitled to claim any ownership interest or Intellectual Property Rights in any Work Product, BTPH hereby transfers, grants, conveys, assigns, and relinquishes exclusively to CLIENT any and all rights, title and interest it now has or may hereafter acquire in and to the Work Product under patent, copyright, trade secret and/or trademark law in perpetuity or for the longest period otherwise permitted by law. BTPH shall assist CLIENT in every reasonable way to obtain and, from time to time, enforce patents, copyrights, trademarks, trade secrets and other rights and protection relating to such Work Product, and to that end, BTPH and its employees will execute all reasonable documents for use in applying for and obtaining such patents, copyrights, trademarks, trade secrets and other rights and protection with respect to any Work Product, as CLIENT may desire, together with any reasonable assignments thereof to CLIENT or persons designated by it. BTPH and its employees' obligations to assist CLIENT in obtaining and enforcing patent, copyrights, trademarks, trade secrets and other rights and protection relating to any Work Product shall continue beyond the expiration or earlier termination of this Agreement. BTPH shall be compensated for such assistance by being paid a daily fee of [***] per skilled and experienced BTPH employee plus expenses.

13.4 All Intellectual Property Rights belonging to CLIENT will remain vested in CLIENT. CLIENT hereby grants to BTPH a non-exclusive, royalty-free license to use its Intellectual Property Rights solely for the purposes of carrying out its obligations under this Agreement only.

13.5 All Intellectual Property Rights belonging to BTPH prior to the Agreement or created not in relation to the Agreement will remain vested in BTPH. BTPH hereby grants to the CLIENT a non-exclusive, royalty-free license to use its Intellectual Property Rights for the purposes of carrying out its obligations under this Agreement only.

13.6 BTPH warrants that it will not knowingly infringe any third party Intellectual Property Rights in the provision of the Services by applying Intellectual Property Rights belonging to BTPH. As of the Effective Date, BTPH is not aware of any third party Intellectual Property Rights that would be infringed by BTPH providing the Services by applying Intellectual Property Rights belonging to BTPH. In order to protect BTPH by executing its obligations under this Agreement, CLIENT ensures that any and all Information and CLIENT Deliverables provided to BTPH by CLIENT do not infringe any third party Intellectual Property Rights and will indemnify BTPH as set forth herein.

14. NONDISCLOSURE

14.1 **Non-Disclosure; Restricted Use.** All information provided by Teva to BTPH under the Teva Agreement and/or by the disclosing Party or its Affiliates hereunder or which becomes known to the receiving Party as a result of entering into this Agreement hereunder, including, without limitation, inventions, discoveries, trade secrets, know-how, technical information, systems, processes, methods, designs, manufacturing practices, specifications, models, formulae, prototypes, samples, laboratory and clinical testing results, compounds, financial and marketing information, business plans, the identity of customers and suppliers, the identity of products under development (collectively the

"**Information**") shall be deemed to be confidential information of the disclosing Party, to be held in strict confidence by the receiving Party. Except as otherwise provided for herein, the receiving Party (including its Affiliates, directors, officers, employees and agents) shall not (a) disclose, use, publish or make available all or any portion of the Information to any third party without the prior written consent of the disclosing Party or (b) commercially exploit the Information or any part thereof.

BTPH shall use CLIENT's Information only to perform the Services and shall communicate CLIENT'S Information only to such of its representatives as are required by their obligations to have knowledge of the Information for the purpose of performing the Services, on the condition that each such representative a) is informed that the Information is the Confidential Information of CLIENT and is subject to the provisions of this Agreement; b) agrees not to disclose the Information to any third party or use it for any purpose other than performing the Services under this Agreement; and c) is subject to a written agreement pursuant to which such representative is bound by such obligations. BTPH shall be responsible for any breach of this Agreement by any of its representatives.

The obligations of confidentiality, non-disclosure and non-use hereunder shall continue unless or until the Information falls within the exceptions provided for in Section 14.2 hereof. Notwithstanding the foregoing, the receiving Party shall be entitled to disclose the Information to the extent required by law or court order provided that the receiving Party furnishes the disclosing Party with prior written notice of the proposed disclosure of the Information in advance of the proposed disclosure so as to provide the disclosing Party with reasonable opportunity to prevent the disclosure of the Information through the obtaining of a protective judicial order for the Information or any other means.

14.2 **Exceptions**. The receiving Party shall not have any obligation hereunder with respect to any Information disclosed by the disclosing Party or its Affiliates which the receiving Party can demonstrate that:

a) at the time of disclosure, is already available or known to the public;

b) after disclosure, becomes available or known to the public through no fault of the receiving Party;

c) except for disclosures by Teva to BTPH under the Teva Agreement, is in the possession of the receiving Party at the time disclosure hereunder is made by the disclosing Party or its Affiliates and such possession is documented by written evidence;

d) except for disclosures by Teva to BTPH under the Teva Agreement, is received from a third party having the right to disclose same; or,

e) can be shown by written evidence to be developed by employees or agents of the receiving Party who had no access to the Confidential Information of the disclosing Party.

Where the above stated exemptions apply, BTPH shall not, in any event, disclose that the Information originated from CLIENT without CLIENT's prior written consent.

Any and all Information disclosed by Teva under the Teva Agreement and/or by CLIENT hereunder shall remain the sole property of CLIENT. Nothing contained in this Agreement shall he deemed to constitute a grant to BTPH of any license or other right under patents, designs, copy rights or other industrial or Intellectual Property Rights, now or hereafter belonging to CLIENT or its Affiliates.

14.3 **Duty to Inform**. If the receiving Party becomes aware or has knowledge of any unauthorized use or disclosure of any Information, it shall promptly notify the disclosing Party of such unauthorized use or disclosure and shall take all reasonable steps to assist the disclosing Party in attempting to minimize any potential or actual damages or losses that may result from such unauthorized disclosure.

14.4 **Injunctive Relief**. BTPH acknowledges that CLIENT will suffer irreparable harm in the event that BTPH breaches or threatens to breach its obligations under this Section 14 and that remedies at law may be inadequate to compensate CLIENT against such actual or threatened breach. Without prejudice to any other rights and remedies otherwise available to CLIENT, BTPH agrees to, in the event of any actual or threatened breach by BTPH of any obligations regarding confidentiality hereunder, the granting of injunctive or other equitable relief.

14.5 **Publicity**. Either Party shall not issue any press release or any other public announcement disclosing the other Party, its Affiliates or products, or this Agreement, without the prior written consent of both Parties, except where such announcements or disclosures are required by law or regulation, in which event the Parties will work together with respect to the wording of any such announcement or disclosure. BTPH agrees that it will not publish any manuscript or other written document based upon information or data resulting from the performance of the Services without the prior written consent of CLIENT. Neither Party shall use the logo or any trademark of the other Party without the prior written consent of such Party.

15. STORAGE OF SAMPLES, CELL BANKS AND OTHER MATERIALS

After completion of the project, CLIENT may elect to have samples, cell banks or other materials including without limitation unpacked columns and cGMP compliant of unpacked column material (if applicable) stored at BTPH for an additional period of time, against the BTPH storage fees as defined in a respective SOW. In case CLIENT fails to inform BTPH of this choice in writing within [***] after completion of the project, BTPH can decide whether to send such materials to CLIENT at CLIENT's expense or to apply a storage fee, initially covering the next twelve (12) months-period. After the expiration of the initial storage period, the storage of such materials will be automatically extended with additional storage periods of [***] each if CLIENT has not informed BTPH in writing [***] prior to the expiration of the current storage period that CLIENT wishes that BTPH sends such materials to CLIENT at CLIENT's expense.

16. INDEMNIFICATION

16.1 BTPH hereby agrees to indemnify, defend and hold harmless the CLIENT and its directors, officers, employees, agents and Affiliates from, against and in respect of, the full amount of any and all liabilities, injuries, damages, claims, deficiencies, fines, assessments, losses, taxes, penalties, interest, costs and expenses, including, without limitation, reasonable fees and disbursements of counsel (collectively "**Claim**"), arising from, in connection with, or incident to (i) any material failure by BTPH to perform any obligations under this Agreement; (ii) any breach or violation of any of the representations, warranties, covenants, terms or conditions, or agreements of BTPH contained in this Agreement; (iii) BTPH's negligence, gross negligence or willful misconduct in the performance of Services under this Agreement; (iv) any failure of the Services or Product to meet Specifications; (v) any product liability claims relating to the Work Product to the extent such claim is based on BTPH's gross negligence or willful misconduct in relation to the Work Product; or (vi) any infringement or alleged infringement or breach of any third party rights by any Party, including without limitation any Intellectual Property Rights, patents, trademarks, copyright, know-how or confidential information, by use of the Work Product provided by BTPH hereunder. The representations and warranties of BTPH set forth in this Agreement and the indemnification provisions hereof shall survive termination or expiration of this Agreement.

16.2 CLIENT hereby agrees to indemnify, defend and hold harmless BTPH and its directors, officers, employees, agents and Affiliates from, against and in respect of, the full amount of any and all liabilities, injuries, damages, claims, deficiencies, fines, assessments, losses, taxes, penalties, interest, costs and expenses, including, without limitation, reasonable fees and disbursements of counsel (collectively "**Claim**"), arising from, in connection with, or incident to (i) any material failure by CLIENT to perform any obligations under this Agreement; (ii) any infringement or alleged infringement or breach of any third party rights by any Party, including without limitation any Intellectual Property Rights, patents, trademarks, copyright, know-how or confidential information, by use of CLIENT's Intellectual Property Rights and/or CLIENT's Confidential Information and/or Materials provided by the CLIENT for the performance of the Services in accordance with the terms and conditions of this Agreement; (iii) any product liability claims relating to the Drug Substance, Drug Product and CLIENT Deliverables including any derivatives of the foregoing, or formulation of the same to the extent such claim is based on the use of the Drug Substance, Drug Product and CLIENT Deliverables following the manufacturer's release, except where such product liability claims arise out of BTPH's failure to meet CLIENT Specifications, gross negligence or willful misconduct; or (iv) the gross negligence or willful misconduct of CLIENT in relation to the use, processing, storage or sale of the Work Product or any derivative or formulation thereof. The representations and warranties of CLIENT set forth in this Agreement and the indemnification provisions hereof shall survive termination or expiration of this Agreement.

16.3 A Party seeking indemnification pursuant to this Section 16 (the "**Indemnitee**") shall give written notice, within [***] from receipt of notice of a such Claim, to the Party from whom indemnification is sought (the "**Indemnitor**"). The Indemnitee shall give the Indemnitor a reasonable opportunity to defend or compromise and settle any Claim with its own

counsel. The Indemnitee shall make available to Indemnitor such information and assistance as Indemnitor may reasonably request in connection with the defense or settlement of any such Claim. The indemnities set forth herein shall include amounts paid in settlement; provided, however, that no such settlement shall be entered into without the Indemnitee's consent, which consent shall not be unreasonably withheld. The Indemnitee may participate in the defense of any such Claim at its own expense.

17. LIMITATION OF LIABILITY

17.1 Neither of the Parties limits its liability:

17.1.1 for fraud;

17.1.2 for death or personal injury caused by its negligence or that of its employees, agents or subcontractors (as applicable);

17.1.3 for any regulatory, fines or penalty, or damages, expenses or other losses arising from a breach by a Party of any law, statute, or regulation;

17.1.4 for its indemnification obligations under Section 16 in case of fault or gross negligence; or for any loss or losses covered within its insurance policies listed in Section 9 above subject to insurance amount and limitation of liability.

17.2 Subject to Section 17.1, the total aggregate liability of CLIENT under or in relation to this Agreement for all claims and losses whether arising under tort (including negligence), breach of contract, or otherwise shall not exceed the maximum amount paid under this Agreement in any calendar year.

17.3 Subject to Section 17.1, the total aggregate liability of BTPH under or in relation to this Agreement for all claims and losses whether arising under tort (including negligence), breach of contract, or otherwise shall not exceed the maximum amount paid under this Agreement in any calendar year.

17.4 Neither of the Parties is liable to the other Party for:

17.4.1 any loss of profit;

17.4.2 any loss of business;

17.4.3 any loss of opportunity;

17.4.4 any loss of revenue; nor

17.4.5 any indirect or consequential loss or damage, in each case whether arising under tort (including negligence), breach of contract or otherwise.

18. CONCLUDING PROVISIONS

18.1 Notices

18.1.1 All notices required hereunder shall be deemed received (i) within five (5) Business Days after being sent by registered or certified mail, postage prepaid, return receipt requested; (ii) within one (1) Business Day after being sent by a nationally recognized overnight courier; (iii) or the same Business Day when delivered personally to the following addresses (unless a Party has provided prior notice of a change of address in accordance herewith):

18.1.2 If to BTPH: to the address set forth above, Attention: General Manager

18.1.3 If to CLIENT: to the address set forth above, Attention: [***]

18.2 Relationship of the Parties

For purposes of this Agreement, the relationship between CLIENT and BTPH shall at all times be that of an independent contractor and nothing contained in this Agreement shall be construed to place them in the relationship of partners, principal and agent, employer/employee or joint venture partners. Consequently, BTPH shall not be entitled to receive any employee benefits which are made available to an employee of CLIENT. BTPH shall have neither actual, apparent, nor implied authority to bind CLIENT to any obligation whatsoever, nor shall BTPH hold itself out as having such authority. CLIENT shall have neither actual, apparent, nor implied authority to bind BTPH to any obligation whatsoever, nor shall CLIENT hold itself out as having such authority. BTPH further acknowledges and accepts responsibility for all the attendant rights and liabilities of such an independent contractor. Any provision in this Agreement or any action by CLIENT which may appear to give CLIENT the right to direct or control BTPH in performing Services means BTPH will follow the desires of CLIENT in the results of Services only. BTPH acknowledges sole responsibility for the provision of BTPH’s pension or welfare benefits and for payment of income and self-employment taxes for BTPH’s earnings under this Agreement.

18.3 Severability

If any provisions herein are found to be unenforceable, it is the intent of the Parties that such provision be replaced, reformed or narrowed so that their original business purpose can be accomplished to the extent permitted by law. The invalidity or unenforceability of any term or provision of this Agreement shall not affect the validity or enforceability of any other term or provision hereof.

18.4 Waiver

Waiver by either Party or the failure by either Party to claim a breach of any provision of this Agreement shall not be deemed to constitute a waiver or estoppel with respect to any subsequent breach of any provision hereof.

18.5 Assignment

18.5.1 Neither Party hereto may assign any of its rights or obligations under this Agreement without the express written consent of the other Party, which consent may not be unreasonably withheld; provided, however, without requiring such consent, CLIENT may assign this Agreement and its rights and duties hereunder to any of its Affiliates and either Party may assign this Agreement in connection with the transfer or sale of all or substantially all of its assets or business or of the assets to which this Agreement refers. Any agreement made in breach of this Article 18.5 is null and void and of no legal force and effect, and the non-breaching Party will have, in addition to all other rights and remedies it may have hereunder, the right to terminate this Agreement immediately.

18.5.2 This Agreement shall inure to the benefit of and be binding upon each Party signatory hereto, its successors and permitted assignees. No assignment shall relieve either Party of the performance of any accrued obligation which such Party may then have under this Agreement.

18.6 Entire Agreement; Amendments

This Agreement constitutes the entire agreement between the Parties with respect to the subject matter herein and supersedes all previous agreements (oral and written), negotiations and discussions. General terms or conditions of either Party are explicitly excluded, in particular in relation to the Services and the supply of Product by BTPH. The Parties may modify any of the provisions hereof only by an instrument in writing duly executed by both Parties.

18.7 Applicable Law and Dispute Resolution

18.7.1 This Agreement is governed by and construed in accordance with the laws of United Kingdom without regard for the conflicts of law principles thereof.

18.7.2 Prior to commencing any litigation with respect to any controversy, claim, counterclaim, dispute, difference or misunderstanding arising out of or relating to the interpretation or application of any term or provisions of this Agreement, a Party shall provide written notice to the other Party of the existence of such dispute. The Parties shall for a period of twenty (20) days following such notice enter into good faith discussions and negotiations in an attempt to resolve such dispute, unless acts or circumstances such as bankruptcy, insolvency, refusal to negotiate in good faith, or repudiation frustrate or make impossible such good faith discussions and negotiations. If, by the end of such twenty (20) day period, unless such period is extended by mutual agreement of the Parties, the Parties have been unable to resolve such dispute, either Party may commence litigation proceedings in the courts of England and Wales.

18.7.3 This Sub-Section shall not prevent a Party from seeking an injunction or urgent interlocutory relief from a court.

18.8 Headings

The headings in this Agreement are intended solely for convenience or reference and shall be given no effect in the construction or interpretation of this Agreement.

18.9 Counterparts

This Agreement may be executed in several counterparts, all of which together shall constitute one agreement binding on both Parties, notwithstanding that both Parties have not signed the same counterpart. The Parties agree that this Agreement may be exchanged by pdf or other electronic means, which upon request of a Party shall be followed up with originals.

18.10 Subcontractors

BTPH shall obtain CLIENT's prior written consent before using any subcontractors to perform Services under a SOW. If written consent to use subcontractors is given by CLIENT, BTPH shall be responsible for ensuring that each subcontractor executes an agreement with BTPH, which agreement shall contain terms and conditions that are consistent with and at least as restrictive as Sections 8, 13 and 14 contained in this Agreement. BTPH shall at all times be liable for the performance of any subcontractor(s).

18.11 Survival

The rights and obligations of CLIENT and BTPH set forth in Clauses 2.8, 2.9, 10, and 13 through 18 and any other provisions which either explicitly or by its nature extend beyond the term of this Agreement of this Agreement shall survive the termination or expiration of this Agreement.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives as of the date first written above.

Biotechpharma UAB		**89bio Ltd.**	
By:	/s/ Vladas Bumelis	By:	/s/ Anat Naschitz
Print Name:	Dr. Vladas Bumelis	Print Name:	Anat Naschitz
Title:	CEO	Title:	Director
Date:	May 8, 2018	Date:	May 27, 2018

[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

AMENDMENT NO. 1

TO

MASTER SERVICES AGREEMENT

THIS AMENDMENT (the "**Amendment**") is made as of the 30 of July 2019, by and between Biotechpharma UAB ("**BTPH**") and 89bio Ltd. ("**CLIENT**").

BACKGROUND

BTPH and CLIENT are parties to that certain Master Services Agreement dated as of the 7th of May, 2018 (the "**Agreement**") and they now desire to amend such Agreement.

NOW, THEREFORE, in consideration of the mutual agreement, BTPH and CLIENT agree to amend the Agreement as follows:

1. **ENZYME INCLUDED IN DEFINED TERMS**.

   a. An additional defined term shall be added to the Agreement as follows:

      "Enzyme" means enzyme intended to be used in the manufacture of a drug product that, when used in the production of a drug, acts as an enzyme in the Manufacturing Process."

   b. Section 1.33 shall be amended and restated as follows:

      "Product" shall mean "the Drug Substance and/or the Drug Product and/or Enzyme and/or Placebo".

   c. Throughout the Agreement, all references (other than definitions) to "Drug Substance" or "Drug Product" shall be amended to be to "Product".

2. **WARRANTIES**.

   a. Section 8.2.1 and Section 8.2.2 shall be amended to delete the following phrase: "As of the Effective Date,".

   b. Section 8.2.5 shall be amended and restated as follows:

      "All Products supplied by BTPH under this Agreement shall (i) conform at the time of Manufacturer's Release to Product Specifications, (ii) be manufactured, packaged, tested and stored in accordance with GMP (other than non-GMP Products if expressly specified in the relevant SOW), the Product Specifications, BTPH SOPs, the Master Batch Record, and the Manufacturing Process, (iii) be free from defects in processing, materials and workmanship, (iv) be merchantable and fit for the purpose of use as human pharmaceutical or consumer health (as relevant) products, (v) not be an article that may not be introduced into interstate commerce under the provisions of Sections 501 or 502 of the United States Federal Food, Drug and Cosmetic Act, as amended from time to time, and shall otherwise comply with applicable laws, and (vi) not be subject to any liens, security interests or any other encumbrances."

3. **GENERAL LIABILITY INSURANCE**. Section 9.1(b) shall be amended and restated as follows:

   "(b) Comprehensive General Liability Insurance, including coverage for product liability, bodily injury, property damage, and personal injury, with limits of [***] and [***]. And Errors and Omissions Liability with limits of [***] and [***]"

4. **PAYMENTS**.

   a. The last paragraph of Section 10.1 shall add the following sentence to the end:

      "[***]."

   b. Section 10.2 shall be amended to change "[***]" to "[***]".

5. **TERMINATION OF SCOPES OF WORK**. In each of Sections 11.2, 11.3 and 11.4 of the Agreement, the following words shall be inserted after the word "Agreement": "and/or any SOWs hereunder".

6. **LIMITATION OF LIABILITY**.

   a. Section 17.1.4 shall be amended and restated as follows: "for its indemnification obligations under Section 16."

   b. Section 17.1.5 shall be added as follows: "for any loss or losses covered by its insurance policies; provided insurance complies with the requirements of Section 9 if applicable, subject to the insurance amount and limitation of liability."

7. **ENTIRE AGREEMENT**. Section 18.6 of the Agreement is amended to add the following sentence: "For clarity, an SOW may vary from the terms of this Agreement if it is explicit and makes reference to the provision superseded."

8. **CONTINUING EFFECTIVENESS**. Except as expressly provided herein, the terms and provisions of the Agreement shall be unchanged and shall continue in full force and effect.

9. **COUNTERPARTS**. This Amendment may be executed in any number of counterparts, each of which shall be an original and all of which, taken together, shall constitute a single agreement.

[Signature Page Follows]

[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

IN WITNESS WHEREOF, BTPH and CLIENT have duly executed this Amendment as of the day and year first above written.

Biotechpharma UAB

By: /s/ Vladas Bumelis
Name: Dr. Vladas Bumelis
Title: Executive Chairman of the Board
Date: July 30, 2019

By: /s/ Giedrius Zunda
Name: Giedrius Zunda
Title: CEO
Date: July 30, 2019

89bio Ltd.

By: /s/ Quoc Le-Nguyen
Print Name: Quoc Le-Nguyen
Title: CTO and Head of QA
Date: August 1, 2019

Exhibit 21.1

Subsidiaries of 89bio, Inc.

1. 89Bio Ltd., a private limited liability company organized and existing under the laws of the State of Israel
2. 89bio Management, Inc., a Delaware corporation
3. UAB 89bio Lithuania, a private limited liability company organized and existing under the laws of the Republic of Lithuania

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the use, in the registration statement on Form S-1, of 89Bio Inc, of our report dated September 19, 2019 on our audit of the financial statements of 89Bio Inc. as of June 28, 2019, and the reference to us under the caption “Experts.”

/s/ Brightman Almagor Zohar & Co.
A Firm in the Deloitte Global Network

Tel Aviv, Israel

October 11, 2019

Exhibit 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the use, in the registration statement on Form S-1, of 89Bio Inc, of our report dated August 15, 2019 on our audit of the financial statements of 89Bio Ltd. as of December 31, 2018, and the related statements of operations and comprehensive loss, change in convertible preferred shares and shareholders' deficit and cash flows from inception January 18, 2018 through December 31, 2018 (which report expresses an unqualified opinion and includes an explanatory paragraph regarding the Company's ability to continue as a going concern), and the reference to us under the caption "Experts."

/s/ Brightman Almagor Zohar & Co.
A Firm in the Deloitte Global Network

Tel Aviv, Israel

October 11, 2019