UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2023

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____to _____

Commission File Number: 001-39122

89bio, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**36-4946844**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
142 Sansome Street, Second Floor San Francisco, California 94104	**94104**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (415) 432-9270

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.001 per share	ETNB	Nasdaq Global Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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.

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 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of May 2, 2023, the registrant had 72,868,455 shares of common stock, $0.001 par value per share, outstanding.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

89bio, Inc.
Condensed Consolidated Balance Sheets
(In thousands)

	March 31, 2023 (Unaudited)	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 350,930	$ 55,255
Short-term available-for-sale securities	129,953	132,905
Prepaid and other current assets	12,747	7,920
Total current assets	493,630	196,080
Operating lease right-of-use asset	322	363
Property and equipment, net	78	92
Other assets	289	289
Total assets	$ 494,319	$ 196,824
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 16,727	$ 12,502
Accrued expenses	7,117	11,944
Operating lease liability, current	171	168
Total current liabilities	24,015	24,614
Operating lease liability, non-current	142	186
Term loan, non-current, net	24,332	20,192
Total liabilities	48,489	44,992
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Common stock	73	51
Additional paid-in capital	790,076	467,374
Accumulated other comprehensive loss	(240)	(350)
Accumulated deficit	(344,079)	(315,243)
Total stockholders' equity	445,830	151,832
Total liabilities and stockholders' equity	$ 494,319	$ 196,824

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

89bio, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2023	**2022**
Operating expenses:		
Research and development	$ 22,306	$ 19,849
General and administrative	6,218	5,259
Total operating expenses	28,524	25,108
Loss from operations	(28,524)	(25,108)
Interest expense	(2,075)	(408)
Interest income and other, net	1,763	(48)
Net loss before income tax	(28,836)	(25,564)
Income tax expense	—	(1)
Net loss	$ (28,836)	$ (25,565)
Other comprehensive income (loss):		
Unrealized gain (loss) on available-for-sale securities	114	(195)
Foreign currency translation adjustments	(4)	3
Total other comprehensive income (loss)	$ 110	$ (192)
Comprehensive loss	$ (28,726)	$ (25,757)
Net loss per share, basic and diluted	$ (0.54)	$ (1.26)
Weighted-average shares used to compute net loss per share, basic and diluted	53,171,370	20,339,416

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

89bio, Inc.
Condensed Consolidated Statements of Stockholders' Equity
For the Three Months Ended March 31, 2023 and 2022
(Unaudited)
(In thousands, except share amounts)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amounts				
Balance as of December 31, 2022	50,560,590	$ 51	$ 467,374	$ (350)	$ (315,243)	$ 151,832
Issuance of common stock in public offering, net of issuance costs	19,461,538	19	296,798	—	—	296,817
Issuance of common stock in at-the-market public offerings, net of issuance costs	968,000	1	13,421	—	—	13,422
Issuance of common stock upon exercise of warrants	1,682,500	2	8,958	—	—	8,960
Issuance of common stock upon exercise of stock options	61,408	—	185	—	—	185
Issuance of common stock upon vesting of restricted stock units, net of withholding taxes	133,669	—	(693)	—	—	(693)
Issuance of common stock warrants in connection with term loan	—	—	482	—	—	482
Stock-based compensation	—	—	3,551	—	—	3,551
Net loss	—	—	—	—	(28,836)	(28,836)
Other comprehensive income	—	—	—	110	—	110
Balance as of March 31, 2023	72,867,705	$ 73	$ 790,076	$ (240)	$ (344,079)	$ 445,830

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amounts				
Balance as of December 31, 2021	20,317,204	$ 20	$ 339,218	$ (64)	$ (213,217)	$ 125,957
Issuance of common stock upon exercise of stock options	12,065	—	29	—	—	29
Issuance of common stock upon vesting of restricted stock units, net	22,115	—	—	—	—	—
Stock-based compensation	—	—	2,512	—	—	2,512
Net loss	—	—	—	—	(25,565)	(25,565)
Other comprehensive loss	—	—	—	(192)	—	(192)
Balance as of March 31, 2022	20,351,384	$ 20	$ 341,759	$ (256)	$ (238,782)	$ 102,741

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

89bio, Inc.
Condensed Consolidated Statements of Cash Flows
(Unaudited)
(In thousands)

	Three Months Ended March 31,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (28,836)	$ (25,565)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	3,551	2,512
Net (accretion) amortization on available-for-sale securities	(1,040)	118
Accretion of final payment fee on term loan	87	121
Amortization of debt issuance costs	132	75
Loss on extinguishment of term loan facility	1,208	—
Noncash operating lease expense	41	—
Depreciation	14	18
Changes in operating assets and liabilities:		
Prepaid and other current assets	(4,599)	1,942
Other assets	—	72
Accounts payable	4,225	(2,422)
Accrued expenses	(4,827)	(1,215)
Operating lease liability	(41)	—
Net cash used in operating activities	(30,085)	(24,344)
Cash flows from investing activities:		
Proceeds from sales and maturities of available-for-sale securities	37,880	36,179
Purchases of available-for-sale securities	(33,774)	(9,401)
Purchases of property and equipment	—	(6)
Net cash provided by investing activities	4,106	26,772
Cash flows from financing activities:		
Proceeds from issuance of common stock in public offering, net of issuance costs	296,817	—
Proceeds from term loan facility, net of issuance costs	24,363	—
Proceeds from issuance of common stock in at-the-market public offering, net of issuance costs	13,422	—
Proceeds from issuance of common stock upon exercise of warrants	8,960	—
Proceeds from issuance of common stock upon exercise of stock options	185	29
Payment of withholding taxes related to restricted stock units	(693)	—
Repayment of term loan facility	(21,400)	—
Net cash provided by financing activities	321,654	29
Net change in cash and cash equivalents, and restricted cash	295,675	2,457
Cash and cash equivalents, and restricted cash at beginning of period	55,255	52,457
Cash and cash equivalents, and restricted cash at end of period	$ 350,930	$ 54,914
Components of cash and cash equivalents, and restricted cash:		
Cash and cash equivalents	$ 350,930	$ 54,889
Restricted cash	—	25
Total cash and cash equivalents, and restricted cash	$ 350,930	$ 54,914
Supplemental disclosures of cash information:		
Cash paid for interest	$ 542	$ 169
Cash paid for operating leases	$ 47	$ —
Supplemental disclosures of noncash information:		
Issuance of common stock warrants in connection with term loan	$ 482	$ —

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

1. Organization and Basis of Presentation

Description of Business

89bio, Inc. ("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, pegozafermin, a specifically engineered glycoPEGylated analog of fibroblast growth factor 21, is currently being developed for the treatment of nonalcoholic steatohepatitis and for the treatment of severe hypertriglyceridemia.

89bio was formed as a Delaware corporation in June 2019 to carry on the business of 89Bio Ltd., which was incorporated in Israel in January 2018.

Liquidity

The accompanying condensed consolidated financial statements have been 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. The Company had cash and cash equivalents and short-term available-for-sale securities of $480.9 million as of March 31, 2023.

The Company expects that its cash and cash equivalents and short-term available-for-sale securities as of March 31, 2023 will be sufficient to fund operating expenses and capital expenditure requirements for a period of at least one year from the date these unaudited condensed consolidated financial statements are filed with the Securities and Exchange Commission ("SEC").

2. Summary of Significant Accounting Policies

Unaudited Condensed Consolidated Financial Statements

The accompanying interim unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States ("U.S. GAAP") and applicable rules and regulations of the SEC regarding interim financial reporting.

The accompanying interim condensed consolidated financial statements are unaudited. The interim unaudited condensed consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements as of and for the year ended December 31, 2022 and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to present fairly the Company's consolidated financial position, results of operations and comprehensive loss, and cash flows. The results of operations for the three months ended March 31, 2023 are not necessarily indicative of the results to be expected for the year ending December 31, 2023 or for any other future annual or interim period. The condensed consolidated balance sheet as of December 31, 2022 was derived from the audited financial statements as of that date. These condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements included in the Annual Report on Form 10-K for the year ended December 31, 2022, which was filed with the SEC on March 15, 2023.

Reclassification

Certain prior period amounts in the Company's condensed consolidated statements of operations and comprehensive loss have been reclassified to conform to the current period presentation. Specifically, interest expense is disclosed separately on the Company's condensed consolidated statements of operations and comprehensive loss, which had no impact on reported net loss, comprehensive loss, or loss per share.

Principles of Consolidation

The accompanying condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

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 accrued research and development expenses and the fair value of stock options. 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 condensed consolidated balance sheets. The carrying values of Company's financial assets and liabilities, including cash and cash equivalents, restricted cash, prepaid and other current assets, accounts payable and accrued expenses approximate to their fair value due to the short-term nature of these instruments. The fair value of the Company's term loan approximates its carrying value, or amortized cost, due to the prevailing market rates of interest it bears. 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 or liabilities in markets that are not active; and

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.

Cash and Cash Equivalents

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 funds and commercial paper that are stated at fair value.

Investments

Investments have been classified as available-for-sale and are carried at estimated fair value as determined based upon quoted market prices or pricing models for similar securities. Management determines the appropriate classification of its available-for-sale investments in debt securities at the time of purchase. Generally, investments with original maturities beyond three months at the date of purchase are classified as short-term because it is management's intent to use the investments to fund current operations or to make them available for current operations. Realized gains and losses, if any, on available-for-sale securities are included in interest income and other, net. The cost of investments sold is based on the specific-identification method. The Company has not experienced any material realized gains or losses in the periods presented.

The Company periodically evaluates whether declines in fair values of its available-for-sale securities below amortized cost are due to credit-related factors or other factors. This evaluation consists of several qualitative and quantitative factors regarding the creditworthiness of the issuers of the security, the severity and duration of the unrealized loss as well as the Company's ability and intent to hold the available-for-sale security until a forecasted recovery occurs. Additionally, the Company assesses whether it has plans to sell the security or it is more likely than not it will be required to sell any available-for-sale securities before recovery of its amortized cost basis. If a credit loss exists, an allowance for credit losses is recorded in interest income and other, net. To date, the Company has not recorded any impairment charges on its available-for-sale securities related to expected credit losses. Any remaining losses related to other factors are excluded from earnings and are reported as a component of comprehensive loss as an unrealized loss.

Comprehensive Loss

The Company's comprehensive loss is comprised of net loss and changes in unrealized gains or losses on available-for-sale securities and foreign currency translation adjustments.

Recently Adopted Accounting Standards

In June 2016, the Financial Accounting Standards Board ("FASB") issued ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326)*: *Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"), which replaces the existing incurred loss impairment model with an expected credit loss model and requires a financial asset measured at amortized cost to be presented at the net amount expected to be collected. The Company adopted this new guidance on January 1, 2023, using a modified retrospective approach and adoption did not have a material impact on the Company's consolidated financial statements and related disclosures.

In August 2020, the FASB issued ASU No. 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40)—Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, which simplifies the accounting for convertible instruments, amends the guidance on derivative scope exceptions for contracts in an entity's own equity, and modifies the guidance on diluted earnings per share calculations as a result of these changes. The Company early adopted ASU 2020-06 as of January 1, 2023, using a modified retrospective approach and adoption did not have a material impact on the Company's consolidated financial statements and related disclosures.

3. Fair Value Measurements

The Company's financial assets measured at fair value on a recurring basis by level within the fair value hierarchy as of March 31, 2023 were as follows (in thousands):

	Valuation Hierarchy	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Money market funds	Level 1	$ 25,143	$ —	$ —	$ 25,143
Commercial paper	Level 2	80,534	10	(119)	80,425
U.S. government bonds	Level 2	18,407	13	(60)	18,360
Agency bonds	Level 2	23,251	8	(55)	23,204
Corporate debt securities	Level 2	11,440	2	(32)	11,410
U.S. treasury bills	Level 2	7,851	4	(13)	7,842
Agency discount securities	Level 2	2,795	—	—	2,795
Non-U.S. debt securities	Level 2	1,496	—	(5)	1,491
Total cash equivalents and available-for-sale securities		$ 170,917	$ 37	$ (284)	$ 170,670
Classified as:					
Cash equivalents					$ 40,717
Short-term available-for-sale securities					129,953
Total cash equivalents and available-for-sale securities					$ 170,670

The Company's financial assets measured at fair value by contractual maturity as of March 31, 2023 were as follows (in thousands):

Within one year	$ 154,706
After one year through two years	15,964
Total cash equivalents and available-for-sale securities	$ 170,670

The Company's financial assets measured at fair value on a recurring basis by level within the fair value hierarchy as of December 31, 2022 were as follows (in thousands):

	Valuation Hierarchy	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Money market funds	Level 1	$ 18,224	$ —	$ —	$ 18,224
Commercial paper	Level 2	104,279	1	(84)	104,196
U.S. government bonds	Level 2	18,225	1	(109)	18,117
Agency bonds	Level 2	13,986	—	(78)	13,908
Corporate debt securities	Level 2	10,488	—	(62)	10,426
U.S. treasury bills	Level 2	7,414	1	(21)	7,394
Agency discount securities	Level 2	5,216	9	—	5,225
Non-U.S. debt securities	Level 2	3,975	—	(20)	3,955
Total cash equivalents and available-for-sale securities		$ 181,807	$ 12	$ (374)	$ 181,445
Classified as:					
Cash equivalents					48,540
Short-term available-for-sale securities					132,905
Total cash equivalents and available-for-sale securities					$ 181,445

The Company's financial assets measured at fair value by contractual maturity as of December 31, 2022 were as follows (in thousands):

Within one year	$ 175,243
After one year through two years	6,202
Total cash equivalents and available-for-sale securities	$ 181,445

4. Balance Sheet Components

Prepaid and other current assets consist of the following as of the periods indicated (in thousands):

	March 31, 2023	December 31, 2022
Prepaid research and development	$ 10,537	$ 5,727
Prepaid taxes	620	646
Prepaid other	1,590	1,547
Total prepaid and other current assets	$ 12,747	$ 7,920

Accrued expenses consist of the following as of the periods indicated (in thousands):

	March 31, 2023	December 31, 2022
Accrued research and development expenses	$ 4,048	$ 6,499
Accrued employee and related expenses	1,800	4,165
Accrued professional and legal fees	1,016	1,052
Accrued other expenses	253	228
Total accrued expenses	$ 7,117	$ 11,944

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 (pegozafermin), 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 upon 120 days' written notice to Teva, (ii) by either party, if the other party materially breaches any of its obligations under the Teva 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.

During the three months ended March 31, 2023 and 2022, none of the development and commercial milestones were met and accordingly, there were no milestone payments related to the Teva Agreements.

6. Term Loan

2021 Loan Agreement

In April 2020, the Company entered into a Loan and Security Agreement, (the "Loan Agreement") with the lenders referred to therein, and Silicon Valley Bank ("SVB"), as collateral agent. The Loan Agreement as amended in May 2021 (the "2021 Loan Agreement") provided for (i) a secured term A loan facility (the "Term A Loan Facility") of up to $20.0 million and (ii) a secured term B loan facility (the "Term B Loan Facility") of up to $5.0 million. The Term A Loan Facility of $20.0 million was fully drawn as of December 2022 and the Term Loan B Loan Facility expired unused.

In January 2023, the Company executed a loan and security agreement with new lenders (the "2023 Loan Agreement") and from the proceeds repaid $21.4 million in outstanding principal, final payment fee, prepayment fee and interest due under the 2021 Loan Agreement. Repayment of the 2021 Loan Agreement was accounted for as an extinguishment as the 2023 Loan Agreement was with new lenders. The Company recorded a loss on extinguishment of $1.2 million, which was recognized as a component of interest expense on the Company's condensed consolidated statements of operations and comprehensive loss.

2023 Loan Agreement

In January 2023, the Company executed the 2023 Loan Agreement with the lenders referred to therein, K2 HealthVentures LLC ("K2HV") as administrative agent and Ankura Trust Company, LLC as collateral agent. The 2023 Loan Agreement provides for up to $100.0 million in aggregate principal in term loans, consisting of a first term loan of $25.0 million that was funded at closing, two subsequent term loans totaling $25.0 million that may be funded upon the achievement of certain time-based, clinical and regulatory milestones, and a fourth term loan of up to $50.0 million that may be funded upon discretionary approval by the lenders.

The term loans are secured by substantially all of the assets of the Company, excluding the Company's intellectual property. The 2023 Loan Agreement contains customary representations and warranties, restricts certain activities and includes customary events of default, including payment default, breach of covenants, change of control, and material adverse effects. In addition, starting January 1, 2024, the Company is required to maintain minimum unrestricted cash and cash equivalents equal to 5.0 times the average change in cash and cash equivalents measured over the trailing three-month period.

The term loans mature on January 1, 2027, provided that the maturity date may be extended to July 1, 2027, if the second and third term loans are funded and the Company achieves certain other financing milestones. The 2023 Loan Agreement provides for interest-only payments to February 1, 2025 that could be extended to February 1, 2026, provided that the maturity date is extended. Consecutive equal payments of principal and interest are due once the interest-only period has elapsed. The term loans bear interest equal to the greater of (i) 8.45% and (ii) the sum of (a) the Prime Rate as reported in The Wall Street Journal plus (b) 2.25%. The interest rate on the term loan was 9.75% at inception and 10.25% as of March 31, 2023. In addition, a final payment fee of 5.95% of the principal amount of the term loans is due upon the earlier of prepayment or maturity of the term loans. The Company has the option to prepay the entire outstanding balance of the term loans subject to a prepayment fee ranging from 3.0% to 1.0% depending on the timing of such prepayment. A commitment fee equal to 0.6% of the principal amount of the fourth term loan is also payable should such loan be funded.

At any time prior to full repayment of the term loans, the lenders may elect to convert up to an aggregate of $7.5 million of the principal amount of the term loans then outstanding into shares of the Company's common stock at a conversion price of $12.6943 per share. The embedded conversion option qualifies for a scope exception from derivative accounting because it is both indexed to the Company's own stock and meets the conditions for equity classification.

Total debt issuance costs related to the first term loan were $0.8 million, including the fair value of the warrant related to the first term loan (discussed below) were recorded as a debt discount since the first term loan was funded at inception. The debt discount, together with the final payment fee, are recognized as interest expense using the effective interest method over the term of the loan.

The expected repayments of principal amount due on the term loans as of March 31, 2023 are as follows (in thousands):

Remainder of 2023	$	—
2024		—
2025		10,805
2026		13,012
2027		1,183
Total principal repayments		25,000
Final payment fee		87
Total principal repayments and final payment fee		25,087
Unamortized debt discount		(755)
Total term loan, non-current, net	$	24,332

Warrants

In January 2023, in connection with the 2023 Loan Agreement, the Company issued the lenders a warrant to purchase up to an aggregate of 204,815 shares of the Company's common stock at an exercise price of $9.7649 per share (the "warrant shares") that expires in January 2033. The warrant shares become exercisable upon the funding of each term loan. In connection with the first term loan that was funded at closing, 51,204 of the warrant shares became exercisable. The warrant shares cannot be settled for cash and include a cashless exercise feature allowing the holder to receive shares net of shares withheld in lieu of the exercise price. The warrant shares also provide for automatic cashless exercise under certain specific conditions and settlement is permitted in unregistered shares. The 51,204 warrant shares meet the requirements for equity classification.

The Company determined the fair value of the 51,204 warrant shares issued using the Black-Scholes option-pricing model with the following assumptions: risk-free interest rate of 3.9%, no dividends, expected volatility of 93.8% and expected term of 10.0 years.

The remaining 153,611 warrant shares are contingently exercisable upon the funding of each subsequent term loan and have the same exercise price and contractual term (the "contingent warrants"). The contingent warrants did not meet the derivative scope exception or equity classification criteria and were accounted for as a derivative liability. The initial fair value and the fair value as of March 31, 2023 of the contingent warrants was insignificant. The contingent warrants derivative liability will be remeasured each reporting period until settled or extinguished with subsequent changes in fair value recorded as interest expense in the condensed consolidated statements of operations and comprehensive loss. The initial fair value of the contingent warrants derivative liability was determined using a probability weighted Black-Scholes option pricing model based on the same input assumptions above.

7. Stockholders' Equity

As of March 31, 2023, the Company's shares of common stock available for future issuance were as follows:

Shares available for future grant under the equity incentive plans	2,144,800
Shares available for future issuance under the employee stock purchase plan	1,234,824
Shares available for future issuance upon the exercise of warrants and pre-funded warrants	12,488,597
Total available for future issuance	15,868,221

Public Offerings

At-the-Market Offerings

In March 2021, the Company entered into a sales agreement (the "Sales Agreement") with SVB Securities LLC and Cantor Fitzgerald & Co. (the "Sales Agents") pursuant to which it may offer and sell up to $75.0 million of the Company's common stock,

from time to time, in “at-the-market” offerings (the “ATM Facility”). The Sales Agents are entitled to compensation at a commission equal to 3.0% of the aggregate gross sales price per share sold under the Sales Agreement.

During the three months ending March 31, 2023, the Company received aggregate proceeds of $13.4 million, net of commissions from sales of 968,000 shares of its common stock pursuant to the ATM Facility.

On February 15, 2023, the Company entered into Amendment No. 1 to the Sales Agreement with the Sales Agents, pursuant to which the Company may offer and sell up to $150.0 million of its common stock, from time to time, through the ATM Facility.

July 2022 Public Offering

In July 2022, the Company completed an underwritten public offering of its common stock, warrants to purchase shares of its common stock and pre-funded warrants to purchase shares of its common stock. The Company sold 18,675,466 shares of its common stock with accompanying warrants to purchase up to 9,337,733 shares of its common stock at a combined public offering price of $3.55 per share. The Company also sold 7,944,252 pre-funded warrants to purchase shares of its common stock with accompanying warrants to purchase up to 3,972,126 shares of its common stock at a combined public offering price of $3.549 per pre-funded warrant, which represents the per share public offering price for the common stock less $0.001 per share, the exercise price for each pre-funded warrant. The Company raised aggregate proceeds of $88.2 million, net of underwriting discounts and commissions of $5.7 million and other offering costs of $0.6 million.

The exercise of the outstanding warrants is subject to a beneficial ownership limitation of 9.99%, or at the election of the holder prior to the issuance of the warrant, 4.99%. The exercise of the outstanding pre-funded warrants is subject to a beneficial ownership limitation of 9.99%, or at the election of the holder prior to the issuance of the pre-funded warrant, 4.99%, which a holder may increase or decrease from time to time but shall not exceed 19.99%. The exercise price and number of shares of common stock issuable upon the exercise of the warrants and pre-funded warrants are subject to adjustment in the event of any stock dividends, stock splits, reverse stock split, recapitalization, or reorganization or similar transaction, as described in the agreements. Under certain circumstances, the warrants and pre-funded warrants may be exercisable on a “cashless” basis. The warrants and pre-funded warrants were classified as a component of stockholders’ equity and additional paid-in capital because such warrants and pre-funded warrants (i) are freestanding financial instruments that are legally detachable and separately exercisable from the equity instruments, (ii) are immediately exercisable, (iii) do not embody an obligation for the Company to repurchase its shares, (iv) permit the holders to receive a fixed number of common shares upon exercise, (v) are indexed to the Company’s common stock and (vi) meet the equity classification criteria. In addition, the warrants and pre-funded warrants do not provide any guarantee of value or return.

March 2023 Public Offering

In March 2023, the Company completed an underwritten public offering of its common stock. The Company sold 19,461,538 shares of its common stock at a public offering price of $16.25 per share. The Company raised aggregate proceeds of $296.8 million, net of underwriting discounts and commissions of $19.0 million and other offering costs of $0.5 million.

Common Stock Warrants

As of March 31, 2023, the Company’s outstanding warrants to purchase shares of its common stock were as follows:

	Shares of Common Stock Underlying Warrants	Exercise Price Per Share	Expiration Date
Warrant issued with term loan to SVB	25,000	$ 22.06	June 30, 2025
Warrant issued with term loan to SVB	33,923	19.12	May 28, 2031
Warrants issued with term loan to K2HV	204,815	9.76	January 27, 2033
Warrants issued in public offering	11,424,859	5.325	July 1, 2024
Pre-funded warrants issued in public offering	800,000	0.001	Do not Expire
Total outstanding	12,488,597		

8. Stock-Based Compensation

Equity Incentive Plans

In September 2019, the Company's board of directors adopted the 2019 Equity Incentive Plan (the "2019 Plan"), which also became effective in September 2019. The Company initially reserved 2,844,193 shares of common stock for issuance under the 2019 Plan. In addition, the number of shares of common stock reserved for issuance under the 2019 Plan will automatically increase on the first day of January for a period of up to ten years in an amount equal to 4% of the total number of shares of the Company's capital stock outstanding on the immediately preceding December 31, or a lesser number of shares determined by the Company's board of directors.

In February 2023, the Company's board of directors adopted the 2023 Inducement Plan (the "2023 Plan"), which also became effective in February 2023. The Company initially reserved 1,500,000 shares of common stock for issuance under the 2023 Plan. Under the 2023 Plan, new employees are eligible to receive equity awards as a material inducement to the commencement of employment with the Company. As of March 31, 2023, no awards had been granted under the 2023 Plan.

Employee Stock Purchase Plan

In October 2019, the Company's board of directors adopted the 2019 Employee Stock Purchase Plan ("ESPP"), which became effective in November 2019. The Company initially reserved 225,188 shares of common stock for purchase under the ESPP. The number of shares of common stock reserved for issuance under the ESPP will automatically increase on the first day of January for a period of up to ten years in an amount equal to 1% of the total number of shares of the Company's common stock outstanding on the immediately preceding December 31, or a lesser number of shares determined by the Company's board of directors. Purchases are accomplished through the participation of discrete offering periods and each offering is expected to be six months in duration. For each offering period, ESPP participants will purchase shares of common stock at a price per share equal to 85% of the lesser of the fair market value of the Company's common stock on (1) the first trading day of the applicable offering period or (2) the last trading day of the applicable offering period.

Stock Options

The following table summarizes stock option activity for the three months ended March 31, 2023:

	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, 2022	3,161,917	$ 12.80	7.9	$ 16,612
Granted	1,366,200	14.61		
Exercised	(61,408)	3.01		
Cancelled and forfeited	(3,250)	17.85		
Balance outstanding as of March 31, 2023	4,463,459	$ 13.49	8.2	$ 21,278
Exercisable as of March 31, 2023	1,686,003	$ 14.32	7.0	$ 10,573

The fair value of stock 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:

	Three Months Ended March 31,	
	2023	2022
Expected term (years)	5.5-6.1	6.0-6.1
Expected volatility	91.6-93.2%	90.6-91.0%
Risk-free interest rate	3.4-3.8%	1.6-1.9%
Expected dividend	—	—

Restricted Stock Units ("RSUs")

The Company has granted certain employees service-based RSUs that generally vest annually over a two or three-year period. The restrictions lapse over time for these service-based RSUs. In the event of termination of the holder's continuous service to the Company, any unvested portion of the service-based RSUs is cancelled. For the three months ended March 31, 2023 and 2022, the Company recognized $0.7 million and $0.2 million, respectively, in expense related to the service-based RSUs.

In February 2021, the Company granted performance-based RSUs that vest as to one-third on each one-year anniversary date, subject to achievement of a development milestone and continued service to the Company. In each of February 2022 and 2023, a portion of the performance-based RSUs vested upon achievement of the development milestone and satisfaction of the continued service condition.

In February and September 2022, the Company granted performance-based RSUs that vest during the applicable performance period, subject to the achievement of certain corporate or department targets and continued service to the Company. In September 2022 and March 2023, a portion of the performance-based RSUs that were granted in February 2022 vested upon achievement of specific targets and satisfaction of the continued service condition.

As of March 31, 2023, it was probable that the remaining performance conditions would be met for the Company's performance-based RSUs and expense was recognized using the accelerated attribution method. For the three months ended March 31, 2023 and 2022, the Company recognized expense of $0.3 million in each period related to performance-based RSUs.

The following table summarizes RSU activity for the three months ended March 31, 2023:

	Number of RSUs	Weighted Average Fair Value at Date of Grant per Unit
Balance outstanding as of December 31, 2022	1,095,738	$ 5.77
Granted	339,075	14.70
Vested / released	(133,669)	7.31
Cancelled / forfeited	(82,767)	7.31
Balance outstanding as of March 31, 2023	1,218,377	$ 7.98

The Company recorded stock-based compensation for the periods indicated as follows (in thousands):

	Three Months Ended March 31,	
	2023	2022
Research and development	$ 1,486	$ 884
General and administrative	2,065	1,628
Total stock-based compensation	$ 3,551	$ 2,512

9. Net Loss Per Share

The following outstanding potentially dilutive common stock equivalents have been excluded from the calculation of diluted net loss per share for the periods indicated due to their anti-dilutive effect:

	Three Months Ended March 31,	
	2023	2022
Stock options to purchase common stock	4,463,459	3,125,486
Unvested RSUs	1,218,377	632,065
Warrants to purchase common stock[1]	11,688,597	58,923
Conversion shares under the term loan with K2HV	590,816	—
Employee stock purchase plan	7,721	19,258
Total	17,968,970	3,835,732

[1] The table above excludes pre-funded warrants issued in connection with the July 2022 public offering (see Note 7).

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Forward Looking Statements

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited condensed consolidated financial statements and related notes and other financial information included elsewhere in this Quarterly Report on Form 10-Q and our consolidated financial statements and related notes and other financial information included in our Annual Report on Form 10-K for the year ended December 31, 2022. Some of the information contained in this discussion and analysis 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 Quarterly Report on Form 10-Q.

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, pegozafermin, a specifically engineered glycoPEGylated analog of fibroblast growth factor 21 ("FGF21"), is currently being developed for the treatment of nonalcoholic steatohepatitis ("NASH") and severe hypertriglyceridemia ("SHTG").

NASH is a severe form of nonalcoholic fatty liver disease, characterized by inflammation and fibrosis in the liver that can progress to cirrhosis, liver failure, hepatocellular carcinoma and death. There are currently no approved products for the treatment of NASH. In 2020 and 2022, we presented positive topline results from cohorts 1 through 6 and cohort 7 respectively, in our Phase 1b/2a trial of pegozafermin in NASH patients which has informed the advancement of our clinical strategy in NASH. We initiated a Phase 2b trial (ENLIVEN) evaluating pegozafermin in fibrosis stage 2 or 3 NASH patients in June 2021. Patients received weekly doses (15 mg and 30 mg) or an every two-week dose (44 mg) of pegozafermin or placebo for 24 weeks followed by a blinded extension phase of an additional 24 weeks for a total treatment period of 48 weeks, with some of the placebo patients re-randomized to receive pegozafermin in the extension phase. In August 2022, we reported the completion of enrollment in ENLIVEN with 219 patients. We reported topline data from ENLIVEN in March 2023. The 44 mg every-two-week and the 30 mg weekly dose groups both met with high statistical significance, both of the primary histology endpoints per the U.S. Food and Drug Administration ("FDA") guidance on endpoints for accelerated approval in non-cirrhotic NASH patients. The 44 mg every two-week and the 30 mg weekly dose groups both demonstrated at least one-stage fibrosis improvement without worsening of NASH (27% and 26%, respectively) at 3.5 times the placebo rate (7%) and NASH resolution without worsening of fibrosis (26% and 23%, respectively), between 12 to 14 times the placebo rate (2%). These dose groups also demonstrated statistically significant and clinically meaningful improvements in liver fat, non-invasive markers of liver fibrosis and inflammation as well as meaningful improvements in other metabolic and lipid markers. Pegozafermin was generally well tolerated with a favorable safety profile consistent with prior studies.

The ENLIVEN study also included 14 biopsy-confirmed NASH patients with compensated cirrhosis (F4 patients) who were not part of the primary analysis but continued in the study. 12 of these 14 patients underwent a follow-up biopsy at week 24. In a descriptive analysis of these data, five out of 11 pegozafermin-treated patients experienced at least one-stage improvement in liver fibrosis with no worsening of NASH by week 24 compared with zero out of 1 patient on placebo. An additional two pegozafermin-treated patients experienced at least one-stage improvement in liver fibrosis with no worsening of ballooning or inflammation.

The Company intends to meet with the FDA in the second half of 2023 and to pursue EU scientific advice in parallel. Subject to regulatory approval, the Company's proposed clinical development plans include a Phase 3 trial evaluating F2/F3 patients with a histology endpoint for accelerated approval and a Phase 3 trial evaluating F4 patients in parallel with an outcomes endpoint for full approval. The planned SHTG Phase 3 trials are expected to satisfy database requirements.

We are also developing pegozafermin for the treatment of SHTG. In June 2022, we announced positive topline results from the ENTRIGUE Phase 2 trial of pegozafermin in SHTG patients. SHTG is a condition identified by severely elevated levels of triglycerides (≥500 mg/dL), which is associated with an increased risk of NASH, cardiovascular events and acute pancreatitis. The trial met its primary endpoint demonstrating statistically significant and clinically meaningful reductions in triglycerides from baseline and key secondary endpoints. We have received feedback from the FDA supporting the advancement of pegozafermin into Phase 3 and are planning to initiate the first of two recommended Phase 3 trials in the second quarter of 2023.

We commenced operations in 2018 and have devoted substantially all of our resources to raising capital, acquiring our initial product candidate, identifying and developing pegozafermin, licensing certain related technology, conducting research and development activities (including preclinical studies and clinical trials) and providing general and administrative support for these operations.

As of March 31, 2023, our cash and cash equivalents and short-term available-for-sale securities totaled $480.9 million. Based on our current operating plan, we believe that our cash and cash equivalents and short-term available-for-sale securities as of March 31, 2023 will be sufficient to meet our anticipated cash requirements for a period of at least one year from the date this Quarterly Report on Form 10-Q is filed with the Securities and Exchange Commission ("SEC").

We have incurred net losses since our inception. Our net losses for the three months ended March 31, 2023 and 2022 were $28.8 million and $25.6 million, respectively. As of March 31, 2023, we had an accumulated deficit of $344.1 million. We expect to continue to incur significant expenses and increasing operating losses as we advance pegozafermin and any future product candidates through clinical trials, seek regulatory approval for pegozafermin 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 pegozafermin 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.

Components of Results of Operations

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for the development of our lead product candidate, pegozafermin. 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 stock-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 services are provided by monitoring the status of specific activities and invoices received from our external service providers. We adjust our accrued expenses 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 for the foreseeable future as we continue the development of pegozafermin 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 pegozafermin and any future product candidates is highly uncertain. To the extent that pegozafermin 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 pegozafermin 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 pegozafermin or any future product candidate.

General and Administrative Expenses

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 stock-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.

Interest Expense

Interest expense primarily consists of interest expense, accretion of final payment fees and amortization of deferred debt issuance costs related to our term loan facility.

Interest Income and Other, Net

Interest income and other, net primarily consists of interest income including accretion of discount on available-for-sale securities, offset by amortization of premium on available-for-sale securities**.**

Results of Operations

Three Months Ended March 31, 2023 and 2022

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

	Three Months Ended March 31,		
	2023	2022	Change
Operating expenses:			
Research and development	$ 22,306	$ 19,849	$ 2,457
General and administrative	6,218	5,259	959
Total operating expenses	28,524	25,108	3,416
Loss from operations	(28,524)	(25,108)	(3,416)
Interest expense	(2,075)	(408)	(1,667)
Interest income and other, net	1,763	(48)	1,811
Net loss before tax	$ (28,836)	$ (25,564)	$ (3,272)

Research and Development Expenses

The following table summarizes the period-over-period changes in research and development expenses for the periods presented (in thousands):

	Three Months Ended March 31,		
	2023	2022	Change
Clinical development	$ 8,966	$ 11,185	$ (2,219)
Contract manufacturing	7,906	4,314	3,592
Personnel-related expenses	5,026	3,945	1,081
Other expenses	408	405	3
Total research and development expenses	$ 22,306	$ 19,849	$ 2,457

Research and development expenses increased by $2.5 million, or 12%, to $22.3 million for the three months ended March 31, 2023 from $19.8 million for the three months ended March 31, 2022. The change was due to an increase of $3.6 million in contract manufacturing costs related to manufacturing and scale-up activities, and an increase of $1.1 million in personnel-related costs mainly due to higher payroll costs and stock-based compensation, offset in part by a decrease of $2.2 million in clinical development costs, mainly as a result of approaching the end of one of our on-going trials.

General and Administrative Expenses

General and administrative expenses increased by $1.0 million, or 18%, to $6.2 million for the three months ended March 31, 2023 from $5.3 million for the three months ended March 31, 2022. The change was primarily due to an increase in costs related to professional services and stock-based compensation.

Interest Expense

Interest expense increased by $1.7 million to $2.1 million for the three months ended March 31, 2023 compared to $0.4 million for the three months ended March 31, 2022, primarily due to a $1.2 million loss on extinguishment upon repayment of our previous term loan and due to higher interest rates during the three months ended March 31, 2023 as compared to the three months ended March 31, 2022.

Interest Income and Other, Net

Interest income and other, net increased to $1.8 million for the three months ended March 31, 2023 compared to a $48,000 net expense for the three months ended March 31, 2022, which was due to higher interest income from our cash equivalents and short-term available-for-sale securities as a result of higher investment balances and favorable interest rates during the three months ended March 31, 2023 as compared to the three months ended March 31, 2022.

Liquidity and Capital Resources

To date, we have incurred significant net losses and negative cash flows from operations. As of March 31, 2023, we had available cash and cash equivalents and short-term available-for-sale securities of $480.9 million and an accumulated deficit of $344.1 million.

In March 2021, we entered into a sales agreement (the "Sales Agreement") with SVB Securities LLC and Cantor Fitzgerald & Co. (the "Sales Agents") pursuant to which we may offer and sell up to $75.0 million of our common stock, from time to time, in "at-the-market" offerings (the "ATM Facility"). The Sales Agents are entitled to compensation at a commission equal to 3.0% of the aggregate gross sales price per share sold under the Sales Agreement. During the three months ending March 31, 2023, pursuant to our ATM Facility, we received aggregate proceeds of $13.4 million, net of commissions from sales of 968,000 shares of our common stock. In February 2023, we entered into Amendment No. 1 to the Sales Agreement with the Sales Agents, pursuant to which we may offer and sell up to $150.0 million of our common stock, from time to time, through the ATM Facility.

In July 2022, we completed an underwritten public offering of our common stock, warrants to purchase shares of our common stock and pre-funded warrants to purchase shares of our common stock and raised aggregate proceeds of $88.2 million, net of underwriting discounts and commissions of $5.7 million and other offering costs of $0.6 million. As of March 31, 2023, warrants to purchase 11,424,859 shares of our common stock at an exercise price of $5.325 per share remain outstanding. Our pre-funded warrants to purchase shares of our common stock are exercisable for a nominal amount. In March 2023, we completed an underwritten public offering of our common stock and sold 19,461,538 shares of our common stock at a public offering price of $16.25 per share. We raised aggregate proceeds of $296.8 million, net of underwriting discounts and commissions of $19.0 million and other offering costs of $0.5 million.

In January 2023, we entered into a loan and security agreement (the "2023 Loan Agreement") with the lenders named therein (the "Lenders"). The 2023 Loan Agreement provides up to $100.0 million principal in term loans, consisting of a first term loan of $25.0 million that was funded at closing, two subsequent term loans totaling $25.0 million that may be funded upon the achievement of certain time-based, clinical and regulatory milestones, and a fourth term loan of up to $50.0 million that may be funded upon discretionary approval by the Lenders. The proceeds of the first term loan were primarily used to repay our obligations under our prior term loan facility.

Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures related to our lead product candidate, pegozafermin. We plan to increase our research and development expenses 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 our existing cash and cash equivalents and short-term available-for-sale securities as of March 31, 2023 will be sufficient to fund our anticipated cash requirements for a period of at least one year from the date this Quarterly Report on Form 10-Q is filed with the SEC. 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 pegozafermin 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 pegozafermin 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 to advance our current product candidate through clinical development, to develop, acquire or in-license other potential product candidates and to fund operations for the foreseeable future. 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. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies.

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.

Cash Flows

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

	Three Months Ended March 31,	
	2023	2022
Net cash (used in) provided by		
Operating activities	$ (30,085)	$ (24,344)
Investing activities	4,106	26,772
Financing activities	321,654	29
Net change in cash and cash equivalents, and restricted cash	$ 295,675	$ 2,457

Operating Activities

During the three months ended March 31, 2023, net cash used in operating activities was $30.1 million, which consisted of a net loss of $28.8 million and a net change of $5.2 million in our net operating assets and liabilities, offset in part by non-cash charges of $4.0 million. The non-cash charges are primarily comprised of $3.6 million in stock-based compensation, $1.2 million in loss recognized on extinguishment of our prior term loan, $0.1 million in amortization of debt issuance costs and $0.1 million in accretion of final payment fee related to our new term loan facility, offset in part by $1.0 million of net accretion on available-for-sale securities. The change in our operating assets and liabilities was primarily due to a $4.6 million increase in prepaid and other current assets due to higher contract manufacturing costs related to manufacturing and scale-up related spend and a net decrease of $0.6 million in accounts payable and accrued expenses due to the timing of payments.

During the three months ended March 31, 2022, net cash used in operating activities was $24.3 million, which consisted of a net loss of $25.6 million, and a net change of $1.6 million in our net operating assets and liabilities, offset in part by non-cash charges of $2.8 million. The non-cash charges are primarily comprised of $2.5 million in stock-based compensation and $0.1 million in accretion of the final payment fee related to our term loan facility, $0.1 million in amortization of premium on available-for-sale securities and $0.1 million in amortization of debt issuance costs. The change in our operating assets and liabilities was primarily due to a $3.6 million decrease in accounts payable and accrued expenses due to the timing of our payables, offset in part by a $2.0 million decrease in prepaid and other current assets due to the timing of payments.

Investing Activities

During the three months ended March 31, 2023, net cash provided by investing activities was $4.1 million, which primarily consisted of $37.9 million in proceeds from sales and maturities of available-for-sale securities, offset in part by $33.8 million in purchases of available-for-sale securities.

During the three months ended March 31, 2022, net cash provided by investing activities was $26.8 million, which consisted of $36.2 million in proceeds from maturities of available-for-sale securities, offset in part by $9.4 million in purchases of available-for-sale securities.

Financing Activities

During the three months ended March 31, 2023, net cash provided by financing activities was $321.7 million, which primarily consisted of net proceeds of $296.8 million from the sale of our common stock from our public offering, net proceeds of $24.4 million from our new term loan facility, net proceeds of $13.4 million pursuant to the sale of our common stock under our ATM Facility and $9.0 million from the exercise of warrants. This was offset in part by the repayment of $21.4 million on our prior term loan, including the final payment and prepayment fees.

During the three months ended March 31, 2022, net cash provided by financing activities consisted of proceeds from the issuance of common stock upon exercise of stock options.

Debt Obligations

Our 2023 Loan Agreement provides for term loans up to $100.0 million. As of March 31, 2023, we had drawn the first term loan of $25.0 million. The term loans mature on January 1, 2027, provided that the maturity date may be extended to July 1, 2027, if the second and third term loans are funded and we achieve certain other financing milestones. The 2023 Loan Agreement provides for interest-only payments to February 1, 2025 that could be extended to February 1, 2026, provided that the maturity date is extended. Consecutive equal payments of principal and interest rates are due once the interest-only period has elapsed. The term loans bear interest equal to the greater of (i) 8.45% and (ii) the sum of (a) the Prime Rate as reported in The Wall Street Journal plus (b) 2.25%. The interest rate on the term loan was 10.25% as of March 31, 2023. In addition, a final payment fee of 5.95% of the principal amount of the term loans is due upon the earlier of prepayment or maturity of the term loans. We have the option to prepay not less than all of the outstanding term loans subject to a prepayment fee ranging from 3.0% to 1.0% depending on the timing of such prepayment. A 0.6% commitment fee is also payable should the fourth term loan be funded.

Other Contractual Obligations and Commitments

See Note 5 to our condensed consolidated financial statements for additional disclosures. There have been no other material changes from the contractual obligations disclosed in our Annual Report on Form 10-K for the year ended December 31, 2022.

Critical Accounting Estimates

There have been no significant changes in our critical accounting estimates as compared to the critical accounting estimates disclosed in our Annual Report on Form 10-K for the year ended December 31, 2022.

Recent Accounting Pronouncements

See Note 2 to our condensed consolidated financial statements for more information.

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.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company, as defined by Rule 12b-2 under the Securities and Exchange Act of 1934 and in Item 10(f)(1) of Regulation S-K, and are not required to provide the information under this item.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As of March 31, 2023, our management, with the participation and supervision of our principal executive officer and our principal financial officer, evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost benefit relationship of possible controls and procedures. Based on this evaluation, our principal executive officer and our principal financial officer concluded that our disclosure controls and procedures were effective as of March 31, 2023 to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and our principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the quarter ended March 31, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. 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.

Item 1A. 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 make an investment decision with respect to shares of our common stock. You should also refer to the other information contained in this Quarterly Report on Form 10-Q, including "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our unaudited condensed consolidated financial statements and related notes. 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. We caution you that the risks, uncertainties and other factors referred to below and elsewhere in this Quarterly Report on Form 10-Q 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.

Risk Factor Summary

Investing in our common stock involves significant risks. You should carefully consider the risks described below before making a decision to invest in our common stock. If we are unable to successfully address these risks and challenges, our business, financial condition, results of operations, or prospects could be materially adversely affected. In such case, the trading price of our common stock would likely decline, and you may lose all or part of your investment. Below is a summary of some of the risks we face.

- 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.
- Our business depends on the success of pegozafermin, our only product candidate under clinical development, which has not completed a pivotal trial. If we are unable to obtain regulatory approval for and successfully commercialize pegozafermin 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.
- 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 pegozafermin or develop new product candidates.
- The ongoing COVID-19 pandemic has resulted and may in the future result in significant disruptions to our clinical trials or other business operations, which could have a material adverse effect on our business.
- If we experience delays in clinical testing, our commercial prospects will be adversely affected, our costs may increase and our business may be harmed.
- If we encounter difficulties in enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- We have relied on, and expect to continue to rely on, third-party manufacturers and vendors to produce and release pegozafermin or any future product candidates. Any failure by a third-party to produce and release 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.
- Pegozafermin 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 are developing pegozafermin for the treatment of NASH, an indication for which there are no approved products, and the treatment of SHTG. The requirements for approval of pegozafermin by the FDA and comparable foreign regulatory authorities may be difficult to predict and may change over time, which makes it difficult to predict the timing and costs of the clinical development.
- 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.
- 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.
- 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.
- We face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than us.
- Unstable market and economic conditions may have serious adverse consequences on our business and financial condition.
- Our Loan and Security Agreement contains certain covenants that could adversely affect our operations and, if an event of default were to occur, we could be forced to repay any outstanding indebtedness sooner than planned and possibly at a time when we do not have sufficient capital to meet this obligation.
- Pegozafermin has not received regulatory approval. If we are unable to obtain regulatory approvals to market pegozafermin or any future product candidates, our business will be adversely affected.
- 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 and a sublicense from ratiopharm to patents and know-how related to glycoPEGylation technology that are used in the development, manufacture and commercialization of pegozafermin. 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.

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 focused on organizing and staffing our company, raising capital, acquiring our initial product candidate, pegozafermin and licensing certain related technology, conducting research and development activities, including preclinical studies and 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.

Pegozafermin is in development and, to date, we have not generated any revenue from the licensing or commercialization of pegozafermin. We will not be able to generate product revenue unless and until pegozafermin or any future product candidate, alone or with future partners, successfully completes clinical trials, receives regulatory approval and is successfully commercialized. As pegozafermin is in 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.

We are not profitable and have incurred net losses since our inception. 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, pegozafermin and any future product candidates. We expect to incur substantial and increasing operating losses over the next several years as our research and development, clinical trials and manufacturing

activities increase. In addition, because of the numerous risks and uncertainties associated with pharmaceutical product development, including that our product candidates may not advance or may take longer than expected to advance through development or may not 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. 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. 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.

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

The primary focus of our product development is pegozafermin for the treatment of patients with NASH and the treatment of patients with SHTG. Currently, pegozafermin 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 pegozafermin for the treatment of NASH or 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 pegozafermin. If we cannot successfully develop, obtain regulatory approval for and commercialize pegozafermin, we may not be able to continue our operations. The future regulatory and commercial success of pegozafermin is subject to a number of risks, including that if approved for NASH or SHTG, pegozafermin will likely compete with products that may reach approval for the treatment of NASH prior to pegozafermin, products that are currently approved for the treatment of SHTG and the off-label use of currently marketed products for NASH and SHTG.

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.

Pegozafermin 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 pegozafermin, may not prove to be safe and effective in clinical trials. We have no direct experience as a company in conducting pivotal trials required to obtain regulatory approval and we expect that the Phase 3 trials we plan to conduct will be more expansive and complex than the trials we've conducted to date. We may be unable to conduct clinical trials at preferred sites, enlist clinical investigators, enroll sufficient numbers of participants, procure sufficient supply 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. We may be unable to design and execute a clinical trial to support regulatory approval. Even if a current clinical trial is successful, it may be insufficient to demonstrate that pegozafermin 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 pegozafermin 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 pegozafermin 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, pegozafermin 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, Phase 1b/2a and Phase 2 clinical trials have involved small patient populations and, because of the small sample size in such trials, the results of these clinical trials may be subject to substantial variability, including the inherent variability associated with biopsies in NASH patients, and may not be indicative of either future interim results or final results in future trials of patients with liver or cardio-metabolic diseases. If we are unable to successfully demonstrate the safety and efficacy of pegozafermin or other future product candidates and receive the necessary regulatory approvals, our business will be materially harmed.

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 pegozafermin 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 in connection with our ongoing activities, particularly as we conduct clinical trials of and seek regulatory approvals for pegozafermin. We believe that our existing cash and cash equivalents and short-term available-for-sale securities will fund our projected operating requirements for a period of at least one year from the date this Quarterly Report on Form 10-Q is filed with the SEC.

We will require additional capital to discover, develop, obtain regulatory approval for and commercialize pegozafermin and any future product candidates. Our ability to complete new and ongoing clinical trials for pegozafermin may be subject to our ability to raise additional capital. We do not have any committed external source of funds other than as a result of any sales that we may make pursuant to the Sales Agreement for our ATM Facility (defined below) and proceeds from our 2023 Loan Agreement, which are subject to the achievement of certain milestones and/or consent of the lenders. We may also receive additional funds from the exercise of outstanding warrants. 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. The current market environment for small biotechnology companies, like 89bio, and broader macroeconomic factors may preclude us from successfully raising additional capital.

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 pegozafermin receives approval and is commercialized, we will be required to make milestone and royalty payments to Teva Pharmaceutical Industries Ltd (“Teva”), from whom we acquired certain patents and intellectual property rights relating to pegozafermin, and from whom we licensed patents and know-how related to glycoPEGylation technology that is used in the manufacture of pegozafermin. For additional information regarding this license agreement, please see Note 5 of our accompanying unaudited condensed consolidated financial statements.

The ongoing COVID-19 pandemic has resulted and may in the future result in significant disruptions to our clinical trials or other business operations, which could have a material adverse effect on our business.

Our business and its operations, including but not limited to our research and development activities, have been adversely affected by health epidemics in regions where we have business operations, and such health epidemics have caused and could continue to cause significant disruption in the operations of third parties upon whom we rely. In response to COVID-19, we have implemented hybrid work policy. The effects of which may negatively impact our growth, including our ability to recruit and onboard new employees, and productivity.

The COVID-19 pandemic has impacted execution and enrollment of our trials. Given the surges in cases of COVID-19 experienced previously and uncertainty regarding other variants, we cannot predict how our ongoing or future trials may be impacted.

In addition, COVID-19 has impacted and may continue to impact personnel at third-party manufacturing facilities in the United States, Europe and other countries, or the availability or cost of materials we use or require to conduct our business, including product development, which would disrupt our supply chain.

The COVID-19 pandemic continues to evolve. The ultimate impact of the COVID-19 pandemic or a similar public health emergency is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems, or the global economy as a whole. However, any one or a combination of these events could have an adverse effect on the operation of and results from our clinical trials and on our other business operations, including preventing or delaying approval for pegozafermin.

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

We cannot guarantee that we will be able to initiate and complete clinical trials and successfully accomplish all required regulatory activities or other activities necessary to gain approval and commercialize pegozafermin or any future product candidates. We currently have two active investigational new drug (“IND”) applications with the FDA in the United States for pegozafermin. In the future, we may file an additional IND with another division for any future indications or future product candidates. 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. As a result, 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 pegozafermin 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 pegozafermin or any future product candidates and may harm our business, results of operations and prospects. 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 pegozafermin 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 including, for example, a new formulation, 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 future clinical trials, and even once enrolled, we may be unable to retain a sufficient number of patients to complete any of our trials. Furthermore, there are inherent difficulties in diagnosing NASH, which can currently only be definitively diagnosed through a liver biopsy, and identifying SHTG patients. Specifically, identifying patients most likely to meet NASH enrollment criteria on biopsy is an on-going challenge, with existing clinical indicators lacking both sensitivity and specificity. As a result, NASH trials often suffer from high levels of screen failure following central review of the baseline liver biopsy, which can lead to lower enrollment. As a result of such difficulties and the significant competition for recruiting NASH and SHTG 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. 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. 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. 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 pegozafermin and any future product candidates. We plan to leverage the safety database from the SHTG Phase 3 program across both the SHTG and NASH indications. If we are not able enroll enough patients in our trials sufficient to support the safety database, our ability to advance the development of pegozafermin may be adversely affected.

We have relied on, and expect to continue to rely on, third-party manufacturers and vendors to produce and release pegozafermin or any future product candidates. Any failure by a third-party to produce and release 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 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 pegozafermin and any future product candidates. We currently have a sole source relationship with BTPH pursuant to which they supply us with pegozafermin. 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 pegozafermin and other operations while we work to identify and qualify an alternate supply source. In addition, we will require large quantities of pegozafermin for large clinical trials and to commercialize pegozafermin. Our current manufacturer may not be able to produce the larger quantities required for Phase 3 studies. We have identified a manufacturing partner for commercial-scale manufacturing, however, we cannot guarantee that such partner will be able to scale up and produce the quantities we would require to commercialize pegozafermin.

We do not have a long-term supply agreement with any third-party manufacturer and there is no guarantee that our third-party manufacturers will be able to fulfill our supply needs. 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.

We have begun producing certain of the reagents required for the glycoPEGylation at BTPH using the know-how transferred to us from Teva under our Reagent Supply and Technology Transfer Agreement. We have not completed the manufacturing process for all these reagents and cannot guarantee that we will be able to produce them successfully, or scale up our production for the quantities needed for commercialization.

Teva supplied us with certain reagents until December 31, 2022. We transferred the manufacturing of such reagents to new suppliers prior to the end of 2022. Any significant delay in the acquisition or decrease in the availability of these raw materials from suppliers could considerably delay the manufacture of pegozafermin, which could adversely impact the timing of any planned trials or the regulatory approvals of pegozafermin.

We rely on third-party vendors for our assay development and testing. If such third-party vendors are unable to successfully produce or test such assays, it may substantially increase our cost or could adversely impact the timing of any planned trials or the regulatory approvals of pegozafermin.

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 cGMP. We 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 pegozafermin 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.

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. Supply chain issues, including those resulting from the COVID-19 pandemic and the ongoing war in Ukraine, may affect our third-party vendors and cause delays. Furthermore, since we have engaged a manufacturer located in China, we are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies of the United States or Chinese governments, political unrest or unstable economic conditions in China. 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 pegozafermin from BTPH, which is our sole manufacturing source for pegozafermin, 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.

Pegozafermin 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 pegozafermin 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 pegozafermin or any future product candidates. As with other drugs, we have seen evidence of adverse effects in animal and human studies and it is possible that other adverse effects will become apparent in ongoing or future animal or human safety studies. 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 pegozafermin 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 pegozafermin or any future product candidates or approved products. Further, we expect that pegozafermin will require multiple administrations via subcutaneous injection in the course of a clinical trial. This chronic administration increases the risk that rare adverse events or chance findings are discovered in the commercial setting, where pegozafermin would be administered to more patients or for greater periods of time, that were not uncovered by our clinical drug development programs.

We are developing pegozafermin for the treatment of NASH, an indication for which there are no approved products, and the treatment of SHTG. The requirements for approval of pegozafermin by the FDA and comparable foreign regulatory authorities may be difficult to predict and may change over time, which makes it difficult to predict the timing and costs of the clinical development.

We are developing pegozafermin for the treatment of NASH, an indication for which there are no approved products. Although there are guidelines issued by the FDA for the development of drugs for the treatment of NASH, the development of a novel product candidates such as pegozafermin may 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. In particular, regulatory authority expectations about liver biopsy data may evolve especially as more information is published about the inherent variability in liver biopsy data. Certain of our competitors have experienced regulatory setbacks for NASH therapies following communications from the FDA. We currently do not know the impact, if any, that these setbacks could have on the path for regulatory approval for NASH therapies generally or for pegozafermin. Furthermore, the histology endpoints from our Phase 2b ENLIVEN trial may not be accepted as primary endpoints for a pivotal Phase 3 trial or for FDA approval.

We are also developing pegozafermin for the treatment of SHTG. Clinical trials for the treatment of SHTG may be relatively costly and time-consuming. In addition, the requirements for approval by the FDA and comparable foreign regulatory authorities may change over time. If the FDA disagrees with our trial and program design for our planned Phase 3 program for SHTG or requires additional evidence to support a successful submission for approval, we may be required to make changes to our program design that could impact timelines and cost.

Our anticipated development costs would likely increase if development of pegozafermin 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, or make changes to ongoing or future clinical trial designs. In addition, if we are unable to leverage our safety database for both SHTG and NASH indications, we may be required to perform additional trials, which would result in increased costs and may affect the timing or outcome of our clinical trials.

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, Novo Nordisk, Akero Therapeutics, Inc. and Boston Pharmaceuticals 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 clinical development plans for pegozafermin or even the viability or prospects of pegozafermin 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.

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, pegozafermin has been manufactured by a single third-party manufacturer, BTPH, solely for preclinical studies and clinical trials. The process of manufacturing pegozafermin, and in particular, the glycoPEGylation process, is complex, highly regulated and subject to several risks and requires significant expertise and capital investment, including for the development of advanced manufacturing techniques and process controls. Manufacturers of biologic products often encounter difficulties in production, including 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 pegozafermin 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.

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. 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. Certain of these companies have recently published positive data regarding their clinical trials, which may further increase the competition we face. 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.

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 pegozafermin in NASH. 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. This may make it difficult for us to differentiate our products from currently approved therapies, which may adversely impact our business strategy. We expect that if pegozafermin or any future product candidates are approved, they will be priced at a significant premium over competitive generic products, including

branded generic products. Insurers and other third-party payors may also encourage the use of generic products or specific branded products prior to utilization of pegozafermin. In addition, many companies are developing new therapeutics, and we cannot predict what the standard of care will be as pegozafermin or any future product candidates progress through clinical development. In addition, to the extent pegozafermin or any future product candidates are approved for liver or 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 pegozafermin 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.

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. 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. 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.

Unstable market and economic conditions, inflation, increases in interest rates, natural disasters, public health crises such as the COVID-19 pandemic, political crises, geopolitical events, such as the crisis in Ukraine, or other macroeconomic conditions, may have serious adverse consequences on our business and financial condition.

The global economy, including credit and financial markets, have experienced extreme volatility and disruptions at various points over the last few decades, including, among other things, diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, supply chain shortages, increases in inflation rates, higher interest rates, and uncertainty about economic stability. For example, the COVID-19 pandemic resulted in widespread unemployment, economic slowdown and extreme volatility in the capital markets. The Federal Reserve has raised interest rates multiple times in response to concerns about inflation and it may raise them again. Higher interest rates, coupled with reduced government spending and volatility in financial markets, may increase economic uncertainty and affect consumer spending. Similarly, the ongoing military conflict between Russia and Ukraine and the rising tensions between China and Taiwan have created extreme volatility in the global capital markets and may have further global economic consequences, including disruptions of the global supply chain. Any such volatility and disruptions may adversely affect our business or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a result of political unrest or war, 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 have experienced and may in the future experience disruptions as a result of such macroeconomic conditions, including delays or difficulties in initiating or expanding clinical trials and manufacturing sufficient quantities of materials. Any one or a combination of these events could have a material and adverse effect on our results of operations and financial condition.

The 2023 Loan Agreement contains certain covenants that could adversely affect our operations and, if an event of default were to occur, we could be forced to repay any outstanding indebtedness sooner than planned and possibly at a time when we do not have sufficient capital to meet this obligation.

Pursuant to the 2023 Loan Agreement, we have pledged substantially all of our assets, other than our intellectual property rights, and have agreed that we may not sell or assign rights to our patents and other intellectual property without the prior consent of our lenders. Additionally, the 2023 Loan Agreement contains certain affirmative and negative covenants that could prevent us from taking certain actions without the consent of our lenders. These covenants may limit our flexibility in operating our business and our ability to take actions that might be advantageous to us and our stockholders. The 2023 Loan Agreement also includes customary events of default, including, among other things, an event of default upon a change of control. Upon the occurrence and continuation of an event of default, all amounts due under the 2023 Loan Agreement become automatically (in the case of a bankruptcy event of default) or may become (in the case of all other events of default and at the option of the administrative agent), immediately due and payable. If an event of default under the 2023 Loan Agreement should occur and be continuing, we could be required to immediately repay any outstanding indebtedness. If we are unable to repay such debt, the lenders would be able to foreclose on the secured collateral, including our cash accounts, and take other remedies permitted under the 2023 Loan Agreement. Even if we are able to repay such accelerated debt amount under the 2023 Loan Agreement upon an event of default, the repayment of these sums may significantly reduce our working capital and impair our ability to operate as planned.

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

We are in the early stages of building the full team that we anticipate we will need to complete the development pegozafermin and other future product candidates. 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 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. 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 experience difficulty in adjusting to our growth and strategic focus.

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 in the biotechnology and pharmaceutical industries. If we are not able to attract and retain necessary personnel and consultants to accomplish our business objectives, it may significantly impede the achievement of our development and commercial objectives and our ability to implement our business strategy. In addition, we are highly dependent on the development, regulatory, manufacturing, commercialization and financial 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.

We are developing new presentations for the liquid formulation of pegozafermin 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 or obtain new drug product, which would require additional costs and cause delay.

We are developing a pre-filled syringe and plan to begin development of a pen-type autoinjector to deliver the liquid formulation of pegozafermin. Any formulation and presentation intended for commercialization is subject to regulatory approval. While the FDA has approved our new drug product formulation, there is no assurance that we will be successful in developing and receiving approval of a pre-filled syringe or an autoinjector on a timely basis or at all, any of which could impede our development and commercialization strategy for pegozafermin. In addition, there is no assurance comparable foreign regulatory authorities will approve our new drug product formulation. The FDA or other comparable foreign regulatory authorities could require nonclinical studies or clinical trials to support introduction of any new formulation, pre-filled syringe 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 pegozafermin and jeopardize our ability to commence product sales and generate revenue from pegozafermin, if approved.

We rely on third parties for certain aspects of our product candidate development process and 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, contract research organizations, 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 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. 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 pegozafermin or any future product candidates, producing additional losses and depriving us of potential revenue.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our contract research organizations, CMO, suppliers, and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, acts of war, medical pandemics or epidemics, such as the novel coronavirus, and other natural or man-made disasters or business interruptions. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

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

Although the development and commercialization of pegozafermin 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.

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.

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. Collaborations are complex and time-consuming to negotiate and document. 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.

We may not be successful in our efforts to identify, in-license or acquire, discover, develop or commercialize additional product candidates.

We may seek to identify, in-license or acquire, discover, develop and commercialize additional product candidates. We cannot assure you that our effort to in-license or acquire additional product candidates will be successful. Even if we are successful in in-licensing or acquiring additional product candidates, their requisite development activities may require substantial resources, and we cannot assure you that these development activities will result in regulatory approvals.

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 subjects us to U.S. and foreign governmental trade, import and export, and customs regulations and laws including various economic and trade sanctions regulations administered by the U.S. Treasury Department’s Office of Foreign Assets Controls and the U.S. Export Administration Regulations. Compliance with these regulations and laws is costly and exposes us to penalties for non-compliance. Doing business internationally potentially involves a number of risks, any of which 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.

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. Our clinical trial liability insurance coverage may not adequately cover all liabilities that we may incur.

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. 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 laws.

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. From time to time, we are subject to periodic phishing attempts. In the third quarter of 2021, we discovered a business email compromise caused by phishing. The phishing attack did not result in the misappropriation of any funds and we do not believe that it had a material adverse effect on our business. We implemented remedial measures promptly following this incident, however, we cannot guarantee that our implemented remedial measures will prevent additional related, as well as unrelated, incidents. If a material system failure, accident or security breach 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.

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. 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.

Risks Related to Regulatory Approvals

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

We do not expect pegozafermin or any future product candidate to be commercially available for several years, if at all. Pegozafermin 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 pegozafermin 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 guidelines issued by the FDA for the development of drugs for the treatment of NASH, it is unclear whether the requirements for approval will change in the future or whether the FDA will rely on regulatory precedent for future regulatory approvals. Any such changes may require us to conduct new trials that could delay our timeframe and increase the costs of our programs related to pegozafermin or any future product candidate for the treatment of NASH or SHTG. In addition, we cannot be certain which efficacy endpoints or presentation thereof clinical or regulatory agencies may require in a Phase 3 clinical trial of NASH or for approval of our product candidates.

Even if we are able to obtain regulatory approvals for pegozafermin 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 pegozafermin 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 guidelines issued by the FDA for the development of drugs for the treatment of NASH, if pegozafermin 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 pegozafermin 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 pegozafermin 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 pegozafermin 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 pegozafermin or any future product candidates will ever obtain regulatory approval. Pegozafermin or any future product candidate could fail to receive regulatory approval from the FDA or comparable foreign regulatory authorities for many reasons, including those referenced in Part I, Item 1. "Business— Government Regulation and Product Approval" in our Annual Report on Form 10-K. 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 the product candidate.

We plan to conduct clinical trials for pegozafermin at sites outside the United States, and the FDA may not accept data from trials conducted in such locations.

We have conducted and expect in the future to conduct one or more of our clinical trials outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with ethical principles. The trial population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will depend on its determination that the trials also complied with all applicable U.S. laws and regulations. If the FDA does not accept the data from any trial that we conduct outside the United States, it would likely result in the need for additional trials, which would be costly and time-consuming and would delay or permanently halt our development of the applicable product candidates. Even if the FDA accepted such data, it could require us to modify our planned clinical trials to receive clearance to initiate such trials in the United States or to continue such trials once initiated.

Further, conducting international clinical trials presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs that could restrict or limit our ability to conduct our clinical trials, the administrative burdens of conducting clinical trials under multiple sets of foreign regulations, foreign exchange fluctuations, diminished protection of intellectual property in some countries, as well as political and economic risks relevant to foreign countries.

Even if pegozafermin 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. 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.

Current and future legislation may increase the difficulty and cost for us, and any collaborators, to obtain marketing approval of and commercialize our drug candidates and affect the prices we, or they, may obtain.

Heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare therapies, which could result in reduced demand for our product candidates or additional pricing pressures. Most recently, on August 16, 2022, President Biden signed into law the Inflation Reduction Act of 2022 (“IRA”), which, among other provisions, included several measures intended to lower the cost of prescription drugs and related healthcare reforms. We cannot be sure whether additional legislation or rulemaking related to the IRA will be issued or enacted, or what impact, if any, such changes will have on the profitability of any of our drug candidates, if approved for commercial use, in the future.

Healthcare insurance coverage and reimbursement may be limited or unavailable for our product candidate, if approved, which could make it difficult for us to sell our product candidate or other therapies profitably.

The success of pegozafermin, if approved, depends on the availability of coverage and adequate reimbursement from third-party payors including governmental healthcare programs, such as Medicare and Medicaid, commercial payors, and health maintenance organizations. We cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, our product candidates or assure that coverage and reimbursement will be available for any product that we may develop.

Governments outside the United States tend to impose strict price controls, which may adversely affect our revenue, if any.

In some countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations. To obtain coverage and reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our drug candidate to other available procedures. If reimbursement of our drugs is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

Risks Related 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 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. 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.

Any changes we make to our pegozafermin 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 pegozafermin or any future product candidates.

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. 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.

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. 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 pegozafermin or any future product candidates and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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 pegozafermin. 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 pegozafermin. Under this agreement, we were granted a perpetual, non-exclusive (but exclusive as to pegozafermin), non-transferable, worldwide license to patents and know-how related to glycoPEGylation technology used in the development, manufacture and commercialization of pegozafermin and products containing pegozafermin. The FGF21 Agreement also contains numerous covenants with which we must comply, including the utilization of commercially reasonable efforts to develop and ultimately commercialize pegozafermin, as well as certain reporting covenants and the obligation to make royalty payments, if and when pegozafermin 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 pegozafermin and products containing pegozafermin. 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.

We may be unable to obtain intellectual property rights or technology necessary to develop and commercialize pegozafermin 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 pegozafermin. 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 pegozafermin 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.

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. 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.

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 pegozafermin or any future product candidates or force us to cease some of our business operations, which could materially harm our business.

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 product candidates. Thus, we cannot guarantee that our product candidates, or our commercialization thereof, do not and will not infringe any third party's intellectual property.

Risks Related to Ownership of Our Common Stock

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 price you paid for your shares. Those fluctuations could be based on various factors in addition to those otherwise described in this Quarterly Report on Form 10-Q, 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.

Sales of our common stock, or the perception that such sales may occur, or issuance of shares of our common stock upon exercise of warrants 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, could depress the market price of our common stock. Certain holders of shares of our common stock 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, we have filed a registration statement registering under the Securities Act the shares of our common stock reserved for issuance under our 2019 Equity Incentive Plan, including shares issuable upon exercise of outstanding options. These shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates. Further, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt or equity securities.

In addition, we must settle exercises of our outstanding warrants in shares of our common stock. The issuance of shares of our common stock upon exercise of the warrants will dilute the ownership interests of our stockholders, which could depress the trading price of our common stock. In addition, the market's expectation that exercises may occur could depress the trading price of our common stock even in the absence of actual exercises. Moreover, the expectation of exercises could encourage the short selling of our common stock, which could place further downward pressure on the trading price of our common stock.

Raising additional capital may cause dilution to existing stockholders, restrict our operations or require us to relinquish rights to our technologies.

Existing stockholders 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, including under the ATM Facility (defined below), 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.

Hedging activity by investors in the warrants could depress the trading price of our common stock.

We expect that many investors in our warrants will seek to employ an arbitrage strategy. Under this strategy, investors typically short sell a certain number of shares of our common stock and adjust their short position over time while they continue to hold the warrants. Investors may also implement this type of strategy by entering into swaps on our common stock in lieu of, or in addition to, short selling shares of our common stock. This market activity, or the market's perception that it will occur, could depress the trading price of our common stock.

General Risk Factors

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

As of March 31, 2023, our executive officers, directors and other holders of 5% or more of our common stock beneficially owned a majority of our outstanding common stock. As a result, 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.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Our amended and restated certificate of incorporation, amended and restated 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 and restated certificate of incorporation and our amended and restated 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. In addition, as a Delaware corporation, we are 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 and restated certificate of incorporation 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 and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for certain actions or proceedings under Delaware statutory or common law. Our amended and restated certificate of incorporation 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. 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 and restated certificate of incorporation to be inapplicable or unenforceable, we may incur additional costs associated with resolving such action in other jurisdictions.

Our ability to use our net operating loss carryforwards and other tax attributes may be limited.

As of December 31, 2022, we had U.S. federal and state net operating loss ("NOL") carryforwards of $160.9 million and $169.8 million, respectively, which may be available to offset future taxable income. As of December 31, 2022, we also had gross federal tax credits of $4.3 million, which may be used to offset future tax liabilities. These NOLs and tax credit carryforwards will begin to expire in 2040. Use of our NOL carryforwards and tax credit carryforwards depends on many factors, including having current or future taxable income, which cannot be assured. In addition, the Company is currently under examination by the Israeli tax authorities for 2018 and 2019, which could impact our NOL carryforwards.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

Item 3. Defaults upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Description
2.1	Contribution and Exchange Agreement, dated as of September 17, 2019, by and among 89Bio Ltd., the Company and its shareholders (filed with the SEC as Exhibit 2.1 to the Company's Form S-1 filed on October 11, 2019).
3.1	Second Amended and Restated Certificate of Incorporation (filed with the SEC as Exhibit 3.1 to the Company's Form 8-K filed on November 15, 2019).
3.2	Second Amended and Restated Bylaws (filed with the SEC as Exhibit 3.2 to the Company's Form 8-K filed on November 15, 2019).
4.1	Specimen common stock certificate of the registrant (filed with the SEC as Exhibit 4.1 to the Company's Form S-1/A filed on October 28, 2019).
4.2	Form of Warrant to Purchase Common Stock for Silicon Valley Bank (filed with SEC as Exhibit 4.1 to the Company's Form 8-K filed on April 13, 2020).
4.3	Form of Warrant (filed with the SEC as Exhibit 4.1 to the Company's Form 8-K filed on July 1, 2022).
4.4	Form of Pre-Funded Warrant (filed with the SEC as Exhibit 4.2 to the Company's Form 8-K filed on July 1, 2022).
4.5	Form of Warrant to Purchase Common Stock for K2 HealthVentures LLC (filed with the SEC as Exhibit 4.1 to the Company's Form 8-K/A filed on February 2, 2023).
10.1	Loan and Security Agreement, dated as of January 4, 2023, among 89bio, Inc., 89bio Management, Inc., 89Bio Ltd., K2 HealthVentures LLC and Ankura Trust Company, LLC (filed with the SEC as Exhibit 10.1 to the Company's Form 8-K filed on January 6, 2023).
10.2	Amendment No. 1 to Sales Agreement, dated February 15, 2023, by and among the Company, SVB Securities LLC and Cantor Fitzgerald & Co. (filed with the SEC as Exhibit 1.2 to the Company's Current Report on Form 8-K filed on February 16, 2023).
10.3+	2023 Inducement Plan (filed with the SEC as Exhibit 99.3 to the Company's Registration Statement on Form S-8 filed on March 15, 2023).
10.4†*	Master Contract Services Agreement by and between 89bio, Inc. and BiBo Biopharma Engineering Co., Ltd., dated as of February 10, 2023, as amended.
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934.
32#	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350.
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	The cover page for the Company's Quarterly Report on Form 10-Q has been formatted in Inline XBRL and contained in Exhibit 101

* Filed herewith.
+ Indicates management contract or compensatory plan.
† Portions of the exhibit have been omitted for confidentiality purposes.
# Furnished herewith and not deemed to be "filed" for purposes of Section 18 of the Exchange Act, and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

89bio, Inc.

Date: May 5, 2023

By: /s/ Rohan Palekar

Rohan Palekar

Chief Executive Officer

(principal executive officer)

Date: May 5, 2023

By: /s/ Ryan Martins

Ryan Martins

Chief Financial Officer

(principal financial and accounting officer)

Exhibit 10.4

[***] = 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.

MASTER SERVICES AGREEMENT

This Master Services Agreement (the "**Agreement**") is entered into as of February 10th, 2023 (the "**Effective Date**") by and between **89BIO, INC.**, a Delaware corporation ("**89bio**"), with its principal place of business located at 142 Sansome Street, 2nd Floor, San Francisco, CA 94104, USA, and BiBo Biopharma Engineering Co., Ltd. with its principal place of business located at Building 6,22,28, No.356 Zhengbo Road, China (Shanghai) Pilot Free Trade Zone LIN-GANG Special Area, Shanghai 201413, P.R. China ("**Provider**"). 89bio and Provider are sometimes referred to herein individually as a "***Party***" and collectively as the "***Parties***."

Recitals

Whereas, 89bio is engaged in the development of pharmaceutical products and intends to perform development and scale up work and then to manufacture 89bio Product (defined below), which is formulated bulk drug substance so that 89bio may further process the formulated bulk drug substance to make 89bio Drug Product (as defined below), which would be used to conduct clinical trials of the 89bio Drug Product;

Whereas, Provider has represented that it has the requisite infrastructure, licenses, permits and capabilities, including trained and experienced personnel and technical skills, to develop, manufacture and supply the 89bio Product (as defined below) to 89bio in accordance with this Agreement; and

Whereas, the Parties desire that Provider develop, manufacture and supply 89bio with the 89bio Product under this Agreement on the terms and subject to the conditions set forth below.

Agreement

Now, Therefore, in consideration of the foregoing and the mutual covenants and premises contained in this Agreement, the receipt and sufficiency of which are hereby expressly acknowledged, the Parties hereto agree as follows:

1. Definitions.

1.1"**89bio Drug Product**" means the finished drug product, incorporating the 89bio Product.

1.2"**89bio Materials**" means the materials stated in the applicable Work Order to be provided by 89bio to Provider with respect to the applicable Services.

1.3"**89bio Product**" means the formulated bulk drug substance as specified in the applicable Work Order.

1.4"**Affiliate**" means, with respect to a Party, any individual, corporation, partnership, company, association, joint venture, firm, or other entity which controls, is controlled by or is

under common control with such Party. For purposes of this definition only, "control" means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such individual, corporation, partnership, company, association, joint venture, firm, or other entity, whether by the ownership of more than fifty percent (50%) of the securities entitled to be voted generally or in the election of directors of such individual, corporation, partnership, company, association, joint venture, firm, or other entity, or by contract or otherwise.

1.5"**Applicable Law**" means all federal, national, state, provincial and local laws, ordinances, rules and regulations, statutes, administrative codes, ordinances, decrees, orders, decisions, injunctions, awards, judgments or permits and licenses of or from governmental authorities relating to or governing the use or regulation of the subject item, as amended from time to time, applicable to the Services or any aspect thereof and the obligations of Provider or 89bio, as the context requires, under this Agreement, including, but not limited to, (A) all applicable federal, state and local laws and regulations of the United States, (B) the U.S. Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301 et seq., (the "**Act**") together with any regulations promulgated thereunder, and (C) cGMPs (as defined in Section 1.9 below).

1.6"**Batch**" means a defined quantity of 89bio Product that is intended to have uniform character and quality and is manufactured during a single cycle of Manufacturing.

1.7"**Certificate of Analysis**" means a document listing the results of testing a representative sample drawn from a Batch to be delivered in accordance with the sampling plan set forth in the applicable master batch records and signed by a suitably qualified employee of Provider.

1.8"**Certificate of Compliance**" means a document signed by Provider's quality assurance department confirming the Batch meets the Specifications and was Manufactured and tested in conformance with cGMP and signed by a suitably qualified employee of Provider.

1.9"**cGMPs**" means current Good Manufacturing Practices promulgated by the Regulatory Authorities, including within the meaning of 21 C.F.R. Parts 210 and 211, as amended, and any applicable current good manufacturing practices requirements and pharmaceutical industry standards for the manufacture and testing of clinical investigational products in force from time-to-time in the European Union (including 2003/94/EEC Directive as supplemented by Volume 4 of EudraLex published by the European Commission), as amended.

1.10"**Confidential Information**" means all information relating to (a) a disclosing Party's business or business plans, including, but not limited to, suppliers, customers, prospective customers, contractors, clinical data, the content and format of various clinical and medical databases, utilization data, cost and pricing data, disease management data, software products, programming techniques, data warehouse and methodologies, all proprietary information, know-how, trade secrets, technical and non-technical materials, products, methods, specifications, processes, sales and marketing plans and strategies, designs, and any such information developed by the disclosing Party or its personnel for or on behalf of the disclosing Party, (b) information of

any Third Parties, and (c) any discussions or proceedings relating to any of the foregoing information, whether disclosed in oral, electronic, visual, written or any other form. Confidential Information includes the terms and conditions of this Agreement. Confidential Information shall also include information of the disclosing Party that a reasonable Person would consider confidential or proprietary under the circumstances. The fact that the disclosing Party may have marked or identified as confidential or proprietary any specific information shall be indicative that the disclosing Party believes such information to be confidential or proprietary, but the failure to so mark information shall not conclusively determine that such information is or is not considered Confidential Information by the disclosing Party. All information that is specifically related to the 89bio Products or 89bio Materials and is developed or generated by or on behalf of Provider as a result of performing the Services or the Manufacture of 89bio Products hereunder including master production and control records, Batch production and control records, 89bio Arising IP, and results of quality control tests for Batches, in each case will be deemed to be 89bio's Confidential Information and Provider will be deemed to be the receiving party of such Confidential Information. All information that is specifically related to the Provider's facility or premise which Provider utilize to perform the Services or the Manufacture of 89bio Products hereunder including parameters of bioreactors. Provider Arising IP and/or improvement during the services, in each case will be deemed to be Provider's Confidential Information and 89bio will be deemed to be the receiving party of such Confidential Information; provided however, nothing herein shall prohibit 89bio from disclosing Provider Arising IP as needed to exercise its rights under the non-exclusive license set forth in Section 9.3.

1.11"**Dedicated Equipment**" means the equipment, if any, identified on a Work Order that is purchased for the exclusive dedicated use by Provider in the provision of the Services.

1.12"**Facility**" means the facility of Provider located at the location set forth in the Work Order.

1.13"**Intellectual Property**" means all (i) trademarks, service marks, trade names, trade dress and logos and any applications for registrations, registrations and renewal thereof; (ii) patent, patent rights, industrial and other designs, including any and all applications, divisions, continuation- in-part, extensions, validations, re-examinations or reissues; (iii) copyrights and moral rights, any original work or authorship fixed in any tangible medium of expression, including literary works, all forms and types of computer software, all source code, object code, firmware, development tools, files, records and data, and all documentation related to any of the foregoing, all musical, dramatic, pictorial, graphic and artistic works; (iv) trade secrets, technology, discoveries and improvements, know-how, proprietary rights, formulae, technical information, techniques, inventions, designs, drawings, procedures, processes, models, manufacturing, manuals and systems, whether or not patentable or copyrightable, including all biological, chemical, biochemical, toxicological, pharmacological and metabolic material and information and data relating thereto, clinical, analytical and stability information and data which have actual or potential commercial value and are not available in the public domain; and (v) all other intellectual property or proprietary rights, in each case whether or not subject to statutory registration or protection.

1.14"**Latent Defect**" means a defect existing at the time of delivery of the 89bio Product in question to 89bio, but which could not reasonably be discovered by a visual inspection of its outer packaging.

1.15"**Manufacture**" and "**Manufacturing**" means any steps, processes and activities necessary to produce the 89bio Product including, the development, manufacturing, processing, filling, finishing, packaging, labeling, storage, quality control testing, sample retention, stability testing, release, and delivery of the 89bio Product.

1.16"**Permitted Recipients**" means the directors, officers, employees, testing laboratories or professional advisers who are required, on a need to know basis, in the course of their duties to receive and consider the Confidential Information for the purpose of enabling the relevant Party to perform its obligations under this Agreement; provided, that those persons are under obligations of confidence and non-use no less stringent than those set out in Section 10.

1.17"**Project**" shall have the meaning provided in Section 2.2.

1.18"**Regulatory Authority**" means any governmental or regulatory authority, department, body, or agency or any court, tribunal, bureau, commission or similar body, whether federal, state, provincial, county or municipal, including but not limited the FDA, EMA, and Health Canada and any other foreign regulatory agencies involved in regulating any aspect of the conduct, development, Manufacture, market approval, sale, distribution, packaging or use of the Services or 89bio Product.

1.19"**Results**" shall have the meaning provided in Section 2.7.

1.20"**Services**" means any or all parts of the services to be conducted by Provider as described in the relevant Work Order.

1.21"**Specifications**" means (a) with respect to 89bio Product to be Manufactured and supplied hereunder, the applicable 89bio Product specifications, including: (i) specifications for Components and 89bio Materials; (ii) Manufacturing specifications, directions, and processes; (iii) storage requirements; (iv) lists of tests, analytical procedures, and acceptance criteria that the applicable 89bio Product must meet; and (b) with respect to other Services, any requirements, acceptance criteria, quality guidelines and other specifications set forth in the applicable Work Order.

1.22"**Third Party**" means any individual, corporation, partnership, company, association, joint venture, firm, or other entity that is not a Party, or an Affiliate of a Party.

2. SCOPE OF WORK.

2.1Scope of Agreement. As a master form of contract, this Agreement allows the Parties to contract for multiple projects through the issuance of multiple work orders without having to re-negotiate the basic terms and conditions contained herein. Subject to the terms and

conditions of this Agreement, 89bio hereby agrees to retain Provider as a non-exclusive manufacturer of the 89bio Product, and Provider agrees to Manufacture the 89bio Product for 89bio at the Facility. Provider further agrees to Manufacture and supply the 89bio Product exclusively to 89bio.

2.2Performance of Services. The Parties shall set forth in writing the specific Services to be performed by Provider for each project under this Agreement (each, a "**Project**") on a Project-by-Project basis, and such writing shall further set forth the time line and schedule for the performance of such Services, the applicable Specifications, any agreed-upon subcontractor or Provider Affiliate performing any part of the Services, the Facility where the Services will be carried out, and the compensation to be paid by 89bio to Provider for the provision of such Services, as well as any other relevant terms and conditions acceptable to the Parties (each such writing, a "**Work Order**"). Each Work Order shall be signed by both Parties. The Parties shall attach a copy of each executed Work Order to this Agreement and each such Work Order is hereby incorporated herein by reference. The Work Order for the initial Services to be performed by Provider is attached hereto as ***Exhibit A***. Each Work Order shall be subject to all of the terms and conditions of this Agreement and the Quality Agreement. To the extent any terms or provisions of a Work Order conflict with the terms and provisions of this Agreement, the terms and provisions of this Agreement shall control, except for quality and compliance related issues, including compliance with cGMP, wherein the Quality Agreement shall control, unless 89bio and Provider agree otherwise in writing.

2.3Quality Agreement. Within [***] of any request by 89bio to enter into a Quality Agreement, and in any event prior to the first cGMP Manufacturing of 89bio Product hereunder, 89bio and Provider shall enter into a quality agreement (the "**Quality Agreement**") in such form and containing such terms as mutually agreed upon by the Parties. To the extent any of the terms of the Quality Agreement conflict with the terms of this Agreement with respect to any commercial matters, including allocation of risk, liability and financial responsibility, the terms of this Agreement shall control, provided with respect to quality-related activities, including compliance with cGMP, the provisions of the Quality Agreement shall govern, unless 89bio and Provider agree otherwise in writing.

2.4Provider Responsibilities. Provider agrees to perform the Services set forth in each Work Order in a competent and professional manner and in strict accordance with the terms and conditions contained in this Agreement and the Work Order, the Quality Agreement and Applicable Law. Provider shall Manufacture the 89bio Products in accordance with the Specifications.

2.5Resources, Equipment and Capacity. Provider shall maintain and reserve for 89bio's benefit sufficient qualified personnel, time, manufacturing equipment and cGMP production capacity to enable Provider to Manufacture and package 89bio Products in accordance with the Specifications and Applicable Laws and the applicable Work Order, unless otherwise agreed in the Work Order.

2.6Use of Affiliates and Subcontractors. Provider may use subcontractors or its Affiliates to perform any obligations of Provider under this Agreement and the applicable Work Order only to the extent the applicable Work Order explicitly contemplates such use of the subcontractor or Affiliates and specifically names such subcontractor and/or Affiliate, provided that with respect to Services to be provided on a cGMP basis, no such delegation or subcontracting of Services to an Affiliate of Provider or subcontractor shall occur until 89bio also has completed a cGMP audit. Provider will at all times be solely responsible and liable for any Services performed by such permitted subcontractors or Affiliates to the same extent as if the performance of such Services was that of Provider and for the compliance of its permitted subcontractors or its Affiliates with the terms and conditions of this Agreement, including the applicable Work Order. 89bio shall remit payment for any Services performed by any such permitted subcontractors or Affiliate to Provider and Provider shall be solely responsible and liable for payment of all fees owed to such subcontractors or Affiliate.

2.7Results. All information, documents, records, data, specimens, and other work product developed or generated by Provider or its employees, agents, consultants, subcontractors, Affiliates or other representatives in the course of conducting the Services (including, documents, records, data, specimens, and other work product pertaining to Manufacturing, handling, storing, analyzing, testing, filling, finishing, packaging, inspecting, labeling, and preparing for shipment of 89bio Product as well as pertaining to developing and optimizing the processes by which 89bio Product are made, release Specifications, analytical test methods and results, master and lot manufacturing instructions, data from testing and inspections, original records of experimental work performed to establish capability to Manufacture and test the 89bio Product, lists and inventory of raw materials, components and equipment used in the Manufacturing, handling, storing, analyzing, testing, filling, finishing, packaging, inspecting, labeling, and preparing for shipment of 89bio Product, approved qualification reports for such equipment, and process trend and variability data), whether in written, graphic or electronic form or contained in any computer database or in any computer readable form (collectively, the "**Results**"), will be the sole and exclusive property of 89bio and shall be deemed 89bio Confidential Information. Any copyrightable work created in connection with the performance of a Project and contained in or relating to the Results will be considered a work made for hire, whether published or unpublished, and all rights therein will be the property of 89bio and Provider irrevocably and unconditionally waives any provision of law known as "moral rights." Provider shall assign and hereby does assign Provider's entire right, title and interest in and to the Results, including all Intellectual Property rights therein, to 89bio. Nothing herein is intended to limit Sections 9.1 and 9.4.

2.8Records. Provider shall record, or cause to be recorded, all Results in a timely, accurate and complete manner. Copies of all Results collected shall be delivered to 89bio by Provider in a timely manner throughout the performance of the Project, and in no event later than [***] after the date of completion or termination of such Project or later than [***]after the date on which 89bio otherwise requests delivery of the Results. Provider shall maintain all original documents comprising the Results (subject to its confidentiality, non-disclosure and non-use obligations set forth in Section 10). Provider shall store these original documents in a safe and organized manner so that they may be provided upon request to 89bio or to the FDA, Drug

Enforcement Agency or other Federal or State agency. Upon 89bio's request, or in the event of termination of this Agreement or in the event that 89bio elects not to pursue marketing, sale, license, or transfer of the 89bio Product, Provider shall surrender copies of documents to 89bio upon receipt of written request for such from 89bio. 89bio shall have the sole right to publish, disclose and use any Results as 89bio, in its sole discretion, deems appropriate, including in submission to any U.S. or foreign regulatory authority.

2.989bio Materials.

(a) 89bio agrees to provide at no cost to Provider the 89bio Materials necessary for performance of a Project as specified in the applicable Work Order, in amounts sufficient for the conduct of the applicable Project. Any shipment from 89bio to Provider of 89bio Materials will be made [***]. Provider shall handle, sample and test the 89bio Material in accordance with the Specifications for the 89bio Material and in accordance with cGMP. Provider shall perform the acceptance tests specified in the applicable Work Order (or as otherwise specified by 89bio in writing) on all 89bio Materials before it uses such 89bio Materials in Manufacturing of 89bio Product, and shall notify 89bio within [***] of delivery of the 89bio Materials to Provider of any defects in the 89bio Materials that are detected through the performance of such acceptance tests. Provider shall be responsible for the storage of the 89bio Materials and Components while in Provider's possession at Provider's own cost. The storage of the 89bio Materials and Components by Provider shall comply with cGMP, the Specifications for the 89bio Materials, any Specifications for Components, and such other storage instructions provided by 89bio in writing.

(b) All 89bio Materials will remain the sole property of 89bio. Provider will use the 89bio Materials only in furtherance of the Services in accordance with this Agreement and Work Orders, and will not use or deliver the 89bio Materials to or for the benefit of any Third Party without the prior written consent of 89bio, and Provider will use the 89bio Material only in compliance with Applicable Laws. Unless any authorities would raise the request to access in an inspection that is governed by Section 3.3 hereof and in compliance therewith, Provider may allow access to the 89bio Materials only to those of its employees or its permitted contractors' or Affiliates' employees who require such access in order to perform their duties in connection with the performance of the Services, provided that such employees are bound by written agreements with Provider (or permitted contractor or Affiliate, as applicable) containing confidentiality and non-use obligations that are at least as restrictive as those this Agreement and intellectual property assignments consistent with Provider's commitments hereunder.

(c) Provider shall keep all 89bio Materials segregated from other materials within its reasonable control in order to maintain the integrity of the 89bio Materials and shall not allow any samples of the 89bio Materials to be used or tested by any person who is not under its direct supervisory control for any purposes. Provider shall not, and shall not permit and, attempt to analyze in any manner, reverse engineer, derivatize, deconstruct or in any way determine the structure or composition of the 89bio Materials, except as is

necessary to perform the Services. Provider shall perform only such tests and analysis as is necessary to meet its obligations under this Agreement and shall maintain the confidentiality of the results of such test in compliance with the terms of this Agreement. Provider covenants that it will: (i) take all necessary care to prevent damage to or loss or theft of 89bio Materials; (ii) clearly identify all such 89bio Materials and Components in storage and in its books as goods belonging to 89bio; and (iii) when possible use first-expiry, first out methods of usage with respect to the 89bio Materials. Provider hereby grants to 89bio a right for 89bio, its employees, its external counsel, including legal counsel or financial auditors and any Third Party contractors approved by Provider, which approval shall not be unreasonably withheld or delayed, to enter any premises where the 89bio Materials are stored in order to inspect and/or repossess the 89bio Materials for cause or during scheduled audits as provided for in Section 3.2.

(d) Provider will reimburse 89bio for 89bio's cost to replace the 89bio Materials, together with any additional out-of-pocket expense, including transportation fees and transportation insurance fees which, as a result of the negligence, intentional misconduct, or breach of obligations under this Agreement by Provider, cannot be used for Manufacturing 89bio Products or are lost, damaged, destroyed or stolen at any time after delivery of such 89bio Materials to the Facility. Provider will immediately inform 89bio of any loss or damage to 89bio Materials and promptly provide in writing all explanations and evidence.

(e) In the event that Provider determines that 89bio Material is not in compliance with the Specifications for the 89bio Material, Provider shall notify 89bio within [***]of such determination. Thereafter if 89bio agrees, after reviewing Provider's documentation, that the 89bio Material is out-of-specification, Provider shall return such non-conforming 89bio Material at [***] cost.

(f) Any 89bio Materials remaining at the termination or expiration of a Work Order shall be returned to 89bio.

(g) Except as expressly provided in Section 9, nothing in this Agreement shall be construed as conferring on Provider any express or implied license or option to license the 89bio Materials, the Confidential Information of 89bio, or any patent, patent application or other Intellectual Property owned or controlled by 89bio.

2.10Components. Should Provider be required to purchase any material (other than the 89bio Materials) under an applicable Work Order, such as [***], necessary to perform the Services (collectively, "***Components***"). Provider shall procure such Components from suppliers who are authorized or approved by 89bio if such authorization or approval is requested by 89bio or if such authorization or approval is required by Regulatory Authorities. The costs of all [***] fee for such Components will be charged to [***] at [***] cost plus handling fee following the table below for any item per transaction; provided however, that the handling fee for [***] will be [***] regardless of the price per item per transaction.

Price per item per transaction	Handling fee (%)
[***]	[***]
[***]	[***]
[***]	[***]

For example, one item per transaction is [***], then the handling fee will be [***].

89bio shall be deemed to be the owner of all such Components, upon payment of the relevant invoice issued by Provider. Provider shall manage the use of Components in accordance with cGMP "first in-first out" rules. The Components shall meet the specifications agreed upon by the Parties. Provider shall perform testing and evaluation of the Components as required to meet the foregoing obligations. Any Components paid for by 89bio that are remaining at the termination or expiration of a Work Order shall be delivered to 89bio.

2.11Dedicated Equipment. If Dedicated Equipment is identified in a Work Order, an amendment to this Agreement covering the selection, procurement, handling fee (if any), warranties, use, storage, ownership, risk of loss, and option to purchase (if not paid as a pass-through cost) of the Dedicated Equipment, among other things will be negotiated by the Parties at that time. In any event, upon termination or expiration of the Work Order for any reason, if the cost of the Dedicated Equipment has been paid by 89bio (typically as a pass-through cost), or 89bio has paid the option purchase price for the Dedicated Equipment, then 89bio shall have the right to, upon reasonable notice, reclaim possession of such Dedicated Equipment [***] (including all costs of disconnection, removal, physical transfer, and any subsequent reinstallation and requalification costs). Provider shall reasonably cooperate with 89bio to remove and return such Dedicated Equipment to 89bio or its designee in accordance with 89bio's written instructions and shall invoice 89bio for direct costs incurred.

2.12Communications. For each Work Order, each Party shall appoint a project representative (each, a "***Representative***") who shall have primary responsibility for day-to-day interactions with the other Party's Representative concerning the Services under the relevant Work Order. Either Party may appoint a substitute or successor Representative by providing written notice thereof to the other Party.

3. CHANGE ORDERS; AUDITS; INSPECTIONS

3.1Change Orders. Any material change to a Work Order shall require a written amendment to the relevant Work Order (a "***Change Order***") executed by each Party. Each Change Order shall be generated by Provider and shall detail the changes to the applicable task, responsibility, duty, fees, timeline or other matters. Each Change Order shall be effective upon the written approval of such Change Order by 89bio.

3.2Audits. Representatives of 89bio may audit Provider's Facility(ies) and Provider's documentation, including Results, and visit and/or meet with Provider at reasonable times during normal business hours, with reasonable advance notice. Provider shall also ensure that representatives of 89bio may inspect the facilities of any subcontractor and Affiliate of Provider that is providing Services at reasonable times during normal business hours, with reasonable advance notice. 89bio may not conduct an inspection more than once during any 12-month period, unless reasonable grounds exist, including but not limited to, a material quality or compliance issue concerning the 89bio Product or its Manufacture, including filling, labeling, or packaging, Facility issues affecting the Services, a forthcoming inspection by a Regulatory Authority in connection with 89bio Product or Services, an inspection required by a strategic partner of 89bio, or proposed process or Manufacturing changes. Provider shall assist 89bio in scheduling such audit or visit at mutually agreeable times at no extra charge. Provider agrees to identify a representative of their independent Quality Assurance unit to act as a liaison to a representative of 89bio Quality Unit. Provider will participate in 89bio's audit and will respond to any reasonable issues raised by 89bio based on such audit, with a corrective action plan mutually acceptable to the Parties.

3.3Inspections. If any governmental or Regulatory Authority conducts, or gives notice to Provider of its intent to conduct, an inspection of the Facilities or of any other facilities where any Services are being performed or to take any other regulatory action with respect to any Services, Provider will notify 89bio within the period set forth in the Quality Agreement of receiving notice thereof and prior to complying with such a demand or request. Provider will also notify 89bio of receipt of any form 483's or warning letters or any other significant regulatory action which Provider's quality assurance group determines could impact the regulatory status of the 89bio Product. Provider and 89bio will cooperate in resolving any concerns with any Regulatory Authority, and 89bio may review Provider's responses to any such reports and communications, and Provider shall in its reasonable discretion incorporate into such responses any comments received from 89bio. Provider will also inform 89bio of any action taken by any Regulatory Authority against Provider or any of its officers or employees which may be reasonably expected to adversely affect the 89bio Product or Provider's ability to provide the Services or Manufacture and supply the 89bio Product hereunder within the period set forth in the Quality Agreement after the action is taken.

4. TESTING; SHIPPING; DELIVERY; ACCEPTANCE

4.1Batch Release. Provider shall be responsible for the technical release to 89bio of each Batch of 89bio Product Manufactured. The Batch of 89bio Product can be released once Provider has performed or has had performed under its supervision by an independent Third Party, all customary tests as per the Specifications and each of the 89bio Products meets the Specifications and Applicable Laws. As part of the release of each Batch of 89bio Product, Provider will provide 89bio with a Certificate of Analysis and a Certificate of Compliance. Provider agrees to further provide a copy of the Batch production records, a BSE/TSE statement and a Nitrosamine statement certifying that the 89bio Product does not contain, and was not Manufactured with, any animal products or any materials of animal origin and do not contain any Nitrosamines or precursors.

4.2Storage. Provider shall store all 89bio Product, 89bio Materials and Components at the Facility with due care and identifiably distinct from other raw material and finished or filled product stocks and shall comply with all storage requirements set forth in the Specifications and all Applicable Laws, including cGMPs. If any 89bio Materials and/or 89bio Product are damaged due to the failure of Provider to comply with all storage requirements set forth in the Specifications and all Applicable Laws, including cGMPs, then Provider shall indemnify 89bio for any losses, claims, penalties, damages, expenses, liabilities, or costs incurred by 89bio as a result of such failure.

4.3Shipping. Shipment of 89bio Product shall be in accordance with Applicable Laws, including cGMP, Good Distribution Practices (GDP), and the instructions for shipping and packaging specified in the relevant Work Order and/or Quality Agreement or as otherwise agreed to in writing by the Parties. Delivery terms are [***]. Title to and risk for the 89bio Products Manufactured by Provider under this Agreement shall pass to 89bio after the 89bio Product has been passed to the carrier assigned by 89bio. Provider shall arrange for the shipment of the 89bio Products in accordance with 89bio's instructions and using a carrier that has been approved by 89bio in writing. [***] shall retain the carrier for transportation of the 89bio Products. Provider will be responsible for customs clearance in China ([***] will be responsible for out-of-pocket costs, invoiced to [***] without mark-up, for customs clearance in China), schedule freight pick up with the carrier, and schedule freight pick up and complete the documentation [***] at [***] expense for shipment of 89bio Products. Shipment of all 89bio Products shall be made at [***] cost and expense. Provider shall use commercially reasonable efforts to effect delivery of 89bio Product on the applicable delivery date specified in the relevant Work Order or as otherwise specified by 89bio in writing.

4.4Manufacturing Problem. In the event that Provider becomes aware of any matter, circumstance or event (a "**Manufacturing Problem**") which (i) would reasonably be expected to give rise to a material delay in the shipment of 89bio Product; (ii) reasonably indicate that the quality standards set forth herein and in the Quality Agreement have been materially compromised or (iii) may reasonably give rise to a material breach hereunder or the right of 89bio to terminate this Agreement, Provider shall promptly give written notice to 89bio of such Manufacturing Problem, the cause thereof, the anticipated length of such Manufacturing Problem, and the action to be taken to reduce, minimize or remove the adverse effects of any such Manufacturing Problem. Within [***] of receipt of the notice given pursuant to this Section 4.4, 89bio and Provider shall meet with a view to agreeing to any actions necessary to ensure that no interruption to supply or shortfall in quantities of 89bio Product occurs.

4.5Inspection and Rejection.

(a) Shortages. 89bio shall inform Provider in writing of any claim relating to a shortage in the quantity of 89bio Products delivered within [***] from the receipt by 89bio or 89bio's designee of each Batch of 89bio Products received and 89bio shall provide Provider with copies of any appropriate documents in 89bio's possession relating to such shortages. At 89bio's election, (i) Provider shall, at its own cost, including, shipment, customs, duties, taxes and insurance cost, provide 89bio with any missing quantity of any

89bio Product, as far as possible within the timeline specified by 89bio, or (ii) 89bio shall have the right to deduct from payment of any invoice any missing quantity of 89bio Products shipped. If it does not notify Provider in writing about a shortage within [***] of receipt, 89bio shall be deemed to have accepted the Batch regardless of whether 89bio has actually performed any inspection of a shipment of such Batch, and to have waived any claims in respect of quantitative defects for that Batch.

(b) Defects. After receipt of a shipment of 89bio Product by 89bio or 89bio's designee, 89bio shall have [***] to analyze such 89bio Product for conformity with (i) the Certificate of Analysis and the Certificate of Compliance, (ii) the Quality Agreement, (iii) the Specifications, and (iv) cGMPs, and to accept or reject the shipment. Payment for 89bio Product prior to such final acceptance or rejection by 89bio shall not constitute acceptance thereof. If 89bio does not reject a shipment of 89bio Product within [***] of receipt of the 89bio Product by 89bio or 89bio's designee, 89bio shall be deemed to have accepted such shipment. However, 89bio's acceptance of a Batch shall not preclude a subsequent rejection of such Batch or any portion thereof following discovery of a Latent Defect in such Batch, including discovery of any substance that would cause the 89bio Product to be adulterated within the meaning of the United States Food, Drug, and Cosmetic Act. 89bio must notify Provider in writing within [***] of discovery of a Latent Defect, including the reasons therefor (including supporting information). 89bio will return the rejected Batch of 89bio Product in accordance with Provider's reasonable instructions and at Provider's expense. For the purpose of clarity, the manufacture or delivery of defective 89bio Product itself shall not constitute a material breach of this Agreement.

4.6Dispute of Rejected Batch(es). If Provider disagrees with the reasons for the rejection, within [***] from the receipt of the 89bio rejection notice, the quality assurance representatives of the Parties will attempt in good faith to resolve any such disagreement. If the Parties are unable to resolve the disagreement in a reasonable time (which will not exceed a period of [***]), the dispute shall be resolved by an independent testing organization of recognized repute within the United States pharmaceutical industry agreed upon by the Parties (which agreement shall not be unreasonably withheld or delayed by either Party); the decision of this organization shall be final and binding upon the Parties. The fees and expenses of such independent testing organization shall be borne by the Party against whom the decision is made.

4.7Replacement. If the Provider agrees with (or chooses not to contest) the reasons for such rejection or the independent testing organization upholds the reasons for such rejection, Provider shall provide 89bio with a corrective action plan within [***] of receiving notice from 89bio of its rejection or of receiving the testing organization's decision and shall supply 89bio, at Provider's expense, with a like quantity of replacement 89bio Product that conforms to the applicable Specifications, the Quality Agreement and cGMPs as soon as practicable, but in any case, within [***], contingent upon the timely receipt from 89bio of all 89bio Materials (at Provider's expense) required for the Manufacture of such replacement 89bio Product.

5. QUALITY ASSURANCE

5.1Validation and Stability Studies. Provider shall perform validation and stability studies as agreed between the Parties in writing, or to the extent required by the ICH regulations and Applicable Laws to Manufacture the 89bio Products at the Facility for use in clinical trials.

5.2Release Testing. Prior to release of the 89bio Products to finished goods inventory, Provider shall test the 89bio Products in accordance with the testing procedures described in the Specifications.

5.3Analytical Reference Standards. 89bio shall provide (either directly or from the 89bio Product cGMP Batches performed hereunder), without charge to Provider, analytical reference standards for the 89bio Products. The reference standards shall be provided in quantities reasonably required for Provider to perform its obligations relating to the Manufacture, stability testing or any other testing of the 89bio Products under this Agreement.

5.4Technical and Quality Matters. The respective responsibilities of each Party in relation to technical and quality matters are further set out in the Quality Agreement.

6. PAYMENT.

6.1 Provider shall invoice 89bio at the time of delivery of the shipment FCA at the Facility for the 89bio Product delivered in accordance with Section 4.3. Each such invoice shall include the invoice number, unit price, and total price of the 89bio Product contained in the shipment in question. All sales of the 89bio Product to 89bio shall be controlled by the terms and conditions of this Agreement. Any preprinted terms contained in any invoice and any other business forms used by either Party for the purposes of ordering, invoicing, shipping or order acceptance or acknowledgment that modifies, are in addition to or are inconsistent with any of the terms of this Agreement shall not form part of this Agreement and shall be null and void and have no force or effect (unless, in each case, as may be otherwise expressly agreed upon by 89bio and Provider in writing).

6.2Fees and Payments. 89bio shall pay each undisputed invoice within [***] of receipt thereof. Each invoice will contain enough detail about the activities under each Work Order during the invoiced period to enable 89bio to determine the accuracy of the amounts invoiced, including copies of all documentation relating to any pass-through expenses. Provider may not exceed the budget set forth in a Work Order without the prior written consent of 89bio. The fees and costs set forth in the applicable Work Order comprise 89bio's entire payment obligation under this Agreement for Provider's performance of the Services set forth in that Work Order, and include compensation for all of Provider's direct and indirect costs of materials and labor, and all overhead related thereto, in connection with such Services. Provider shall keep accurate records of all Services performed, and expenses incurred (including any Components used in performance of the Services and invoice calculations).

6.3Business Review. Upon the written request of 89bio and not more than [***] during the Term and for a period of [***] thereafter, Provider shall permit 89bio or its representative, at 89bio's expense, to have access during normal business hours to such of the records of Provider as may be reasonably necessary for external manufacturing management regarding a CDMO related to any Work Orders for any Calendar Year ending not more than [***] prior to the date of such request.

6.4Taxes. Any use, sales, excise or value added tax, duty custom, inspection or testing fee, or any other tax, fee or any charge of any nature whatsoever imposed by any governmental authority on or measured by the transaction between 89bio and Provider (other than Provider's income tax), shall be paid by 89bio in addition to the prices quoted or invoiced by Provider. In the event that Provider is required to pay any such tax, fee or charge, 89bio shall reimburse Provider for such payment, or in lieu of such payment, 89bio shall provide Provider at the time the order is submitted an exemption certificate or other document acceptable to the authority imposing the tax, fee or charge.

7. REGULATORY.

7.1Maintenance of Permits. Provider shall maintain, at its sole costs, all manufacturing licenses and other regulatory and governmental permits, licenses and approvals that may be necessary to Manufacture and ship 89bio Product.

7.2Approvals. 89bio shall be responsible for obtaining, at its expense, all regulatory and governmental approvals and permits necessary for 89bio to use the 89bio Product Manufactured hereunder, including but not limited to all submissions filed with the FDA or other Regulatory Authorities, other than those necessary licenses, permits or approvals, including any site establishment fees imposed by FDA or other Regulatory Authority, as required by Applicable Laws in order for Provider to perform the Services at the applicable Facility which shall be [***].

7.3Notification of Adverse Manufacturing Activities. Provider shall advise 89bio of any information arising out of its Manufacturing activities that has adverse regulatory compliance and/or reporting consequences concerning the 89bio Product.

7.4Activities at the Manufacturing Site and Machinery Used to Manufacture Products. Provider agrees to disclose to 89bio upon 89bio's request, subject to Provider's confidentiality obligations to its other customers and Third Parties, the nature of any relevant products manufactured or packaged by Provider for itself or Third Parties which use the same machinery as that used by Provider for the Manufacture of 89bio Products under this Agreement or that are stored in the same location where the 89bio Products or 89bio Materials are stored in order that Provider and 89bio may identify any potential effects on quality, safety or efficacy of the 89bio Products which may result.

7.5Storage and Warehousing. Provider shall store and warehouse all 89bio Materials, Components and 89bio Products in premises that are secure, clean, compliant with the Specifications, manufacturing licenses and the Quality Agreement. Provider shall comply with

any agreed upon requirements of 89bio relating to the security of controlled drug substances. Provider shall be responsible for the safe storage and handling of the 89bio Product until delivery to 89bio in accordance with Section 4.3. The Provider shall keep records of the storage conditions in relation to each batch of 89bio Products in accordance with the requirements set forth in the Quality Agreement.

7.6Handling of Materials; Wastes. Provider shall inform its employees, contractors and other personnel of any known or reasonably ascertainable chemical hazards associated with the 89bio Product or any wastes (including, Hazardous Materials) generated through performance of the Manufacturing of the 89bio Product, and to provide such persons with reasonable training in the proper methods of handling and disposing of such items. In addition, Provider shall handle, accumulate, label, package, ship and dispose of all wastes (including, Hazardous Materials) generated through performance of the Manufacturing of the 89bio Product in accordance with all Applicable Laws.

7.7Documentation for Regulatory Authority Requirements. Provider shall maintain in accordance with and for the period specified in the Quality Agreement (unless Applicable Laws, including cGMP, require a longer period), complete and accurate records relating to the Manufacture of 89bio Products and performance of Services as it may be required to hold under such Applicable Law. Provider shall make such documentation available to 89bio (in so far as they are applicable to the 89bio Product and excluding or redacted to remove Provider's Confidential Information, including its proprietary SOPs) promptly upon 89bio's request or its representative for inspection pursuant to obligations of confidentiality upon reasonable request. Provider will provide to 89bio an inventory of records and record types pertaining to the Services, and upon request, a copy of all such records. Following expiration or termination of this Agreement, Provider shall (a) continue to make such records available to 89bio for a period of [***] from the date of such expiration or termination or (b) upon 89bio's prior written request, transfer ownership of such records to 89bio. After expiration of such retention period, Provider will either transfer such records to 89bio or destroy such records as determined by 89bio in its sole discretion.

7.8Assistance with Regulatory Filing. Provider shall provide 89bio with reasonable regulatory support. Any regulatory support activities provided by Provider and associated solely and directly with the Facility will be provided at [***]. For the avoidance of doubt, any other costs for regulatory support activities provided by Provider, including but not limited to those associated to the Manufacturing process or the 89bio Product, shall be [***]. The reports related to the Services shall be established to capture the process development activities ("**Development Reports**"). The quality and the details captured in such Development Reports should be such that information and data on the Manufacturing process can be incorporated into CTD modules for submission to the Regulatory Authorities. Provider shall prepare and provide to 89bio, at no additional cost (unless otherwise agreed to in writing by the Parties), a report describing the Manufacturing processes for the 89bio Product (including any changes to the analytical methods) (in so far as they are applicable to the 89bio Product and excluding Provider's Confidential

Information, including its proprietary SOPs) for 89bio's use in updating the CMC Section of the applicable IND/IMPD and/or NDA/BLA.

8. LABELING

8.1Labeling. 89bio shall provide Provider with any labeling which 89bio requires to be included on the packaging for the 89bio Products (the "**89bio's Labeling**"). All 89bio's Labeling shall be provided by 89bio to Provider in a form appropriate for Manufacture of the 89bio Products in accordance with cGMP, the Specifications and Applicable Laws.

8.2Responsibility for and Changes to Labeling. 89bio shall be responsible for the design of 89bio's Labeling and for ensuring that such labeling is accurate and complies with all Applicable Laws. In the event that 89bio requests a change to 89bio's Labeling for any 89bio Product the Parties will mutually agree on the timing for the introduction of any such change.

9. INTELLECTUAL PROPERTY.

9.1Background IP. Each Party shall, at all times throughout and after the Term, remain the owner of any and all Intellectual Property that it owned (or was licensed to use) prior to the Effective Date, and which Intellectual Property shall, for the purposes of this Agreement, be defined as "**Background IP**". For the purposes of this Section, Background IP vested in 89bio (or its Affiliates) shall be defined as "**89bio Background IP**" and Background IP vested in Provider (or its Affiliates) shall be defined as "**Provider Background IP**".

9.289bio Arising IP. Neither Provider, its Affiliates, nor any of their respective subcontractors shall acquire any rights of any kind whatsoever with respect to the 89bio Product by conducting Manufacturing activities hereunder. All rights to any Intellectual Property (whether or not patentable) conceived (whether or not reduced to practice) in the performance of Services conducted under this Agreement by Provider's or its Affiliates' employees, or independent contractors, either solely or jointly with employees, agents, consultants or other representatives of 89bio relating to the 89bio Product or the Manufacturing, processing, testing, packaging, or storing thereof to the extent relating to the 89bio Product and not useful for general pharmaceutical manufacturing activity, will be owned solely and exclusively by 89bio ("**89bio Arising IP**"). Provider shall assign and hereby assigns its entire right, title and interest in and to the 89bio Arising IP, including all Intellectual Property rights therein, to 89bio. For purposes of clarity, scale-up and scale-down strategies relating to the 89bio Product shall be deemed 89bio Arising IP.

9.3Provider Arising IP. All rights to any Intellectual Property (whether or not patentable) conceived (whether or not reduced to practice) in the performance of work conducted under this Agreement by Provider or its Affiliates' employees, or independent contractors, either solely or jointly with employees, agents, consultants or other representatives of 89bio which is not 89bio Arising IP will be owned solely and exclusively by Provider ("**Provider Arising IP**"). Provider hereby grants to 89bio a non-exclusive and royalty free, perpetual, irrevocable and sub- licensable license to use the Provider Arising IP for the Manufacture of 89bio Product, 89bio Drug Product.

9.4Use of Intellectual Property. Provider will not use, or allow others to use, any 89bio Background IP or 89bio Arising IP for any purpose other than the Manufacture of the 89bio Products for 89bio. 89bio will not use, or allow others to use, any Provider Background IP for any purpose other than in relation to clinical trials for the 89bio Product. 89bio hereby grants Provider and any Affiliates and subcontractors approved by 89bio a non-exclusive and royalty free license for the Term to use the 89bio Background IP and 89bio Arising IP to the extent necessary to Manufacture the 89bio Product under this Agreement.

9.5Assistance. Provider shall, [***], reasonably cooperate in the preparation, filing, prosecution and maintenance of all patent rights of any 89bio Arising IP. Such cooperation shall include as reasonably appropriate execution of all papers and instruments appropriate so as to enable 89bio to prepare, file, prosecute and maintain such rights in any country.

10. CONFIDENTIALITY.

10.1Non-Use, Non-Disclosure. The receiving Party shall (i) use the Confidential Information of the disclosing Party only during the Term and only as reasonably necessary to carry out the purpose of this Agreement, (ii) protect the Confidential Information of the disclosing Party against unauthorized use or disclosure applying standards of care reasonably expected and no less stringent than the standards applied to protection of the receiving Party's own confidential information of a similar nature and (iii) not disclose any Confidential Information of the disclosing Party to any person or entity except to its Permitted Recipients but then only on a need to know basis to those Permitted Recipients who are bound by confidentiality restrictions as restrictive as this Section 10. The Background IP and Arising IP of each Party shall be considered Confidential Information. Notwithstanding the forgoing, 89bio may disclose Confidential Information of Provider as is requested by Regulatory Authorities or as is necessary to be included in regulatory filings or regulatory and ethical authorizations and approvals required for the lawful conduct of clinical trials by 89bio or to the extent reasonably necessary, to sublicensees, licensees, collaborators, vendors, consultants, agents, attorneys, contractors and clinicians under written agreements of confidentiality at least as stringent as those set forth in this Agreement, who have a need to know such information or to existing or potential acquirers, merger partners, collaborators, licensees, sublicensees and sources of financing or to professional advisors (e.g., attorneys, accountants and prospective investment bankers) involved in such activities, for the limited purpose of evaluating such transaction, collaboration, or license or sublicense and under appropriate conditions of confidentiality, only to the extent necessary and with the agreement by those individuals to maintain such Confidential Information in strict confidence.

10.2Standard of Care. Manufacturing performed under this Agreement shall take place in a secure area and access to such area shall be obtained by key or keycard. In addition and without limiting the foregoing, Provider shall maintain security practices (which include appropriate administrative, physical and technical safeguards, including underlying operating system and network security controls) designed to meet or exceed generally accepted industry practice (meaning those reasonably expected of a diligent provider providing services similar to Provider when in possession of highly sensitive information belonging to its clients and are designed to ensure the security, confidentiality and integrity of Confidential Information).

10.3Required Disclosures. The obligations of confidentiality, non-disclosure and non- use hereunder shall continue until the relevant Confidential Information falls within the exceptions provided for in Section 10.4 hereof. Notwithstanding the foregoing, the receiving Party shall be entitled to disclose the Confidential Information of the disclosing Party to the extent required by Applicable Law or court order or requirements of a stock exchange on the condition that the receiving Party provides the disclosing Party with written notice that the Confidential Information is required to be disclosed sufficiently in advance of the disclosure so as to provide the disclosing Party with reasonable opportunity to seek to prevent the disclosure of or to obtain a protective order for the Confidential Information; and provided further that the receiving Party makes any required disclosures in consultation with disclosing Party.

10.4Exclusions to Confidentiality. The receiving Party shall not have any obligation hereunder with respect to any Confidential Information if such Confidential Information (a) is, at the time of disclosure or becomes after disclosure, general or public knowledge through no breach of the Agreement by the receiving Party; (b) was, at the time of disclosure, already known by the receiving Party, as established by written record; (c) is received by the receiving Party from a Third Party having the right to disclose same and who is not bound by a confidentiality agreement or obligations; or (d) is independently developed by the receiving Party without reference to or reliance on the disclosing Party's Confidential Information.

10.5Notification. In the event the receiving Party or its Permitted Recipients become aware or has knowledge of any unauthorized use or disclosure of Confidential Information under the disclosing Party's control, the receiving Party shall promptly notify the disclosing Party of such unauthorized use or disclosure and, thereafter, shall take all reasonable steps to assist the disclosing Party in attempting to minimize any potential or actual damages or losses resulting from such unauthorized use or disclosure.

10.6Return. Upon receipt of a written request from the disclosing Party, or upon termination or expiration of this Agreement, the receiving Party shall promptly return to the disclosing Party all Confidential Information, including all reproductions and copies thereof together with all internal material and documents generated by receiving Party containing Confidential Information or references thereto and the receiving Party shall delete all such Confidential Information and references thereto stored electronically. Notwithstanding the foregoing, each Party may retain a single copy of any Confidential Information as is reasonably necessary for regulatory or insurance purposes, subject to such Party's obligations of confidentiality under this Agreement. Neither Party is obligated to destroy back-up tapes securely archived provided that the back-up tapes are subject to the confidentiality and non-use obligations under this Agreement and are not readily accessible to users.

10.7Public Announcements. Neither Party shall make any press or other public announcement concerning any aspect of this Agreement unless the text of such announcement is first approved in writing by all the Parties to this Agreement.

11. Representations And Warranties.

11.1Mutual Representations and Warranties. 89bio and Provider each represent and warrant to the other that:

(a) Organization and Authority. It has full corporate right, power and authority to enter into this Agreement and to perform its respective obligations under this Agreement;

(b) No Conflicts or Violations. The execution and delivery of this Agreement by such Party and the performance of such Party's obligations hereunder (a) do not conflict with or violate any requirement of Applicable Laws existing as of the Effective Date and applicable to such Party and (b) do not conflict with, violate, breach or constitute a default under, and are not prohibited or materially restricted by, any contractual obligations of such Party or any of its Affiliates existing as of the Effective Date; and

(c) Valid Execution. Such Party is duly authorized, by all requisite corporate action, to execute and deliver this Agreement and the execution, delivery and performance of this Agreement by such Party does not require any shareholder action or approval or the approval or consent of any Third Party, and the person executing this Agreement on behalf of such Party is duly authorized to do so by all requisite corporate action.

11.2 Provider Representations and Warranties for the 89bio Product. Provider represents and warrants to 89bio that:

(a) Conformance with Specifications. The Product supplied under this Agreement shall conform to the Specifications and the Quality Agreement.

(b) Conformance with Labeling Instructions and Free from Defects. All 89bio Product shall be in accordance with 89bio's Labeling, shall be free from defects in materials and workmanship, and shall not be adulterated or misbranded within the meaning of the Act, and is not an article which may not, under the Act, be introduced into interstate commerce.

(c) Manufacture of the 89bio Product. The 89bio Product shall be Manufactured in accordance with applicable cGMP, applicable Specifications, Applicable Laws and the Quality Agreement.

(d) Good Title, No Encumbrances. It will convey good title to the 89bio Product supplied under this Agreement, free from any lawful security, interest, lien or encumbrances.

(e) Right to Provider Background IP. It has the title and/or right to any and all Provider Background IP used to Manufacture the 89bio Product in accordance with this Agreement; and the use of the Provider Background IP to Manufacture the 89bio Product will not infringe the Intellectual Property or any other rights of any Third Party.

(f) Bribery. It will neither offer to give nor give money or gifts to 89bio employees or members of their families in exchange for business from 89bio.

(g) No Debarment. Provider hereby certifies that it has not been debarred under the provisions of the 21 U.S.C. §335(a) or (b), or any similar regulation in China. In the event that Provider: (a) becomes debarred; or (b) receives notice of action or threat of action with respect to its debarment, during the term of this Agreement, Provider agrees to notify 89bio immediately. In the event that Provider becomes debarred as set forth in clause (a) above or Provider receives notice of action or threat of action as set forth in clause (b) above, 89bio will have the right to terminate this Agreement immediately upon written notice to Provider.

(h) No Services of Debarred Persons. Provider hereby certifies that it has not and will not use in any capacity the services of any individual, corporation, partnership, institution or association which has been debarred under 21 U.S.C. §30. In the event Provider becomes aware of the debarment or threatened debarment of any individual, corporation, partnership, institution or association providing services to Provider which directly or indirectly relate to Provider's activities under this Agreement, Provider will notify 89bio immediately. 89bio will have the right, upon receipt of such notice, to terminate this Agreement immediately upon written notice to Provider.

11.3Provider Representations and Warranties for the Services. Provider represents and warrants to 89bio that:

(a) Conformance with Specifications. The Services provided under this Agreement shall conform to the Specifications where required by a Work Statement;

(b) Performance. The Services shall be performed in accordance with applicable cGMP and Applicable Laws with respect to the performance of Services;

(c) Right to Provider Background IP. It has the title and/or right to any and all Provider Background IP used to perform the Services in accordance with this Agreement; and the use by Provider or its Affiliates of Provider Background IP will not infringe the Intellectual Property or any other rights of any Third Party.

11.489bio Representations and Warranties. 89bio represents and warrants to Provider that:

(a) Clinical Trial Authorizations. It holds all necessary clinical trial authorizations to conduct the clinical trials for which the 89bio Product Manufactured under the Agreement will be used.

(b) Right to 89bio Background IP. It has the title and/or right to any and all 89bio Background IP and 89bio Materials supplied to Provider in accordance with this Agreement for the Manufacture and packaging of the 89bio Products or 89bio Drug

Product, and further that it has the title and/or right to grant Provider the right to use such Intellectual Property in accordance with the terms of this Agreement and the use by Provider or its Affiliates of those items (89bio Background IP and 89bio Materials) will not infringe the Intellectual Property or any other rights of any Third Party.

(c) Provision of Information. It has provided and shall provide to Provider all pertinent information in its possession relative to physical, environmental and human health hazards involving the 89bio Product.

11.5 Disclaimer of All Other Warranties. TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, EXCEPT FOR THOSE EXPRESS WARRANTIES IN THIS SECTION 11, NEITHER PARTY MAKES OR GIVES ANY OTHER WARRANTIES, EXPRESS OR IMPLIED (WHETHER BY STATUTE, CUSTOM, COURSE OF DEALING OR OTHERWISE) AND EACH PARTY HEREBY DISCLAIMS ALL OTHER EXPRESS OR IMPLIED WARRANTIES, INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE OR USE, NON INFRINGEMENT AND TITLE.

12. TERM, TERMINATION.

12.1Term. The term of this Agreement shall commence on the Effective Date and shall continue for ten (10) years from the Effective Date, unless terminated earlier by one of the Parties in accordance herewith.

12.2Termination for Convenience. 89bio shall have the right to terminate this Agreement or any Work Order at any time in its sole discretion by giving six (6) months' advance written notice to Provider, which termination shall be subject to Section 12.11. Section 12.2 is not intended to be exclusive. Additional cancelation and termination clauses may be included in the Work Order.

12.3Termination of Agreement for Material Breach. Either Party may terminate this Agreement or a Work Order immediately upon written notice to the other Party in the event of a material breach by the other Party of this Agreement or a Work Order, which breach remains uncured for [***] following written notice to such breaching Party of such material breach. If such notice is for breach of a Work Order, such notice shall note the specific Work Order under which such breach is claimed. For clarity, any notice for breach related to a Work Order shall not affect the Agreement or any other Work Order, all of which will remain in full force and effect.

12.4Termination of Agreement for Bankruptcy. Either Party may terminate this Agreement upon notice to the other Party, if the other Party makes an assignment for the benefit of its creditors of all or substantially all of its assets, is adjudged bankrupt, becomes insolvent, ceases to carry on business, files or consents to the filing of a petition in bankruptcy that is not dismissed within [***], seeks to take advantage of any legislation relating to insolvency, arrangement or relief of debtors, winds-up or liquidates, or if any receiver, trustee, liquidator or similar official is appointed of such other Party or any of its property.

12.5Regulatory Concerns. 89bio may terminate the Agreement immediately upon written notice to Provider pursuant to Section 11.2(g), Section 11.2(h) or if Provider is subject to any Regulatory Authority warning letter or sanction related to the Facility.

12.6Payment upon Early Termination. If this Agreement or any relevant Work Order is completed, expires, or is terminated in whole or in part for any reason, then:

(a) In all cases, Provider shall cease the performance of the Service, including the Manufacture of 89bio Product, and shall terminate any unfilled orders with Third Parties that Provider may have previously submitted with respect to Components, to the extent such orders may be terminated or revoked;

(b) If this Agreement or any Work Order is terminated by 89bio pursuant to Section 12.2, and the termination results in the cancelation of any Orders, the cancelation fees set forth in Section 12.11 will apply to the cancelation of said Orders.

(c) Without limiting 89bio's rejection rights set forth in Section 4, if this Agreement is terminated by 89bio pursuant to Section 12.3, 12.4, or 12.5, 89bio shall have (i) the option but not the obligation to take delivery of and pay for any undelivered 89bio Product, at the price in effect at the time the order for such 89bio Product was placed, and (ii) to take delivery of any unused 89bio Materials, and Components; and provided further that Provider shall cooperate with 89bio in the surrender, delivery and transfer of such items as promptly as is commercially reasonable, with any shipping and related expenses to be borne equally by both parties;

(d) Without limiting 89bio's rejection rights set forth in Section 4, if this Agreement is terminated for any reason other than a termination by 89bio pursuant to Section 12.3, 12.4, or 12.5:

(i) 89bio will [***].

(ii) 89bio will [***];

(iii)Provider will [***].

(e) If this Agreement is terminated for any reason other than by Provider pursuant to Section 12.3, and if the 89bio Product has been manufactured successfully and the process is reproducible and robust, then at 89bio's request Provider. will continue to manufacture 89bio Product for a period of [***] post termination.

(f) In all cases, subject to that 89bio has fulfilled obligation of payment of undisputed amounts hereunder, Provider will promptly deliver to 89bio any and all Results produced as the result of Services performed by Provider up until the effective date of such termination or the expiration of this Agreement as well as all retained samples and all records held by Provider pursuant to Section 7.7 (except for samples and records Provider

is required to retain pursuant to Applicable Law) and Provider will cooperate with 89bio and assist in the transfer to 89bio of all relevant legal, regulatory and technical documents concerning the 89bio Materials and 89bio Product including, but not limited to, master and executed Batch records, validation protocols and reports, stability protocols and reports and relevant manufacturer authorizations, existing retention samples and all such other documents and materials as may be reasonably necessary or useful for 89bio to source 89bio Product from other qualified Third Parties.

12.7Confidential Information. Upon expiration or termination of this Agreement for any reason, each Party shall return or destroy all of the other Party's Confidential Information which it has in its possession or under its control pursuing to Section 10.6.

12.8Regulatory Assistance. After expiration or termination of this Agreement, Provider agrees to provide 89bio with reasonable support in relation to any investigation required by any Regulatory Authority with respect to Manufacture of the 89bio Product carried out at the Facility during the Term, provided that 89bio shall reimburse Provider for its reasonable direct costs and expenses.

12.9Technology Transfer Assistance. Starting no later than [***] following expiration or termination of this Agreement for any reason other than when 89bio is the breaching Party under Section 12.3 and until the successful completion of the Technology Transfer, or, at any time during the Term of the Agreement upon 89bio's request, Subject to that 89bio has fulfilled payment obligation for undisputed fees hereunder, Provider will provide, upon the request of 89bio, its assistance and cooperation in transferring the then-current Manufacturing process to a single skilled alternative manufacturing site, designated by 89bio for the purpose of Manufacturing 89bio Product for 89bio ("**Technology Transfer**"). As part of the Technology Transfer Provider will make available for collection, all 89bio Materials and Components and one copy of all documentation (to the extent not previously delivered to 89bio) generated pursuant to the Services (exclusive of Provider's SOPs) up to the date of termination. 89bio shall reimburse Provider for its reasonable direct costs and expenses, and will arrange a separate Technology Transfer Agreement to govern above mentioned activities.

12.10Survival Upon Termination. Termination or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of any Party prior to such termination or expiration. Such termination or expiration shall not relieve any Party from obligations which are expressly or by implication intended to survive termination or expiration of this Agreement and shall not affect or prejudice any provision of this Agreement which is expressly or by implication provided to come into effect on, or continue in effect after, such termination or expiration. Sections 2.7, 2.8, 7.7, 9, 10, 12.6, 12.7, 12.8, 12.9, 12.10, 13, and 14 will survive expiration or termination of this Agreement.

12.11Cancelation.

If 89bio at any time cancels (for convenience) any campaign set forth in the Work Oder for the manufacture of Product in the [***], the following cancelation charge shall apply.

Cancelation of Services (other than batches or campaigns in the [***]) and the first cGMP run shall be permitted without cost or fee in any event.

Notice of cancelation prior to start of scheduled manufacture of batch or campaign (on a batch by batch basis)	Cancelation charge as a percentage of fees
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

For clarity, the date that is deemed to be the scheduled start of manufacture of the batch or campaign must be agreed by both parties in writing. Email writing will be deemed sufficient for confirmation of the date of the scheduled start of manufacture of the batch or campaign.

Provider shall seek to reuse the reserved capacity as soon as practicable, and if Provider is successful in using the reserved capacity, Provider will reduce the cancellation charge proportionately based upon the number of days the capacity was repurposed.

12.12Delay.

89bio may delay the manufacture of batches or campaigns under a Work Order up to [***] without any cost or fee by providing notice at least [***] prior to the scheduled start of manufacture of batch or campaign, on a batch-by-batch basis (a "Permitted Manufacturing Delay"). If 89bio gives notice of a [***] Permitted Manufacturing Delay, a fee of [***] will be charged. If 89bio provides notice less than [***] prior to such scheduled start date such delay shall be assessed a cancelation charge equivalent to if 89bio had canceled the batch or campaign under Section 12.11. Provided however that in the event of that the delay is due to material supplies (including without limitation capital equipment., Components, or 89bio Materials), facility readiness, process readiness, or analytical readiness, regardless of whether such delay results from responsibilities of Provider, 89bio, both or neither Party, such delay shall be excluded from this Section 2.12, and shall be permitted without any fee and without restriction on number of delays. By way of example, if 89bio provides notice of delay [***] prior to the scheduled start date of manufacture of a batch under a Work Order, this would not be a Permitted Manufacturing Delay and shall be assessed a fee equivalent to a cancelation fee of [***] of the fees for such batch (if such capacity cannot be reused). As a second example, if 89bio provides notice [***] days prior to the scheduled start of the manufacture of a batch under a Work Order, this would be a Permitted Manufacturing Delay and shall be [***] for the first and second time, and if it occurred a third or more time would be assessed a [***]. As a third example, if 89bio provides notice [***] prior to the scheduled start of the manufacture of a batch under a Work Order due to the unavailability of Components needed

for manufacture, the fees under this Section 12.11 would be inapplicable, and there would be [***] due whether it was the first or third such delay. For clarity, this Section 12.12 is applicable solely to the manufacture of batches or campaigns under a Work Order. Delays of other Services shall be [***] in any event.

For clarity, the date that is the scheduled start of manufacture of batch or campaign must be in writing and agreed by both parties. Email writing will be deemed sufficient for confirmation of the date of the scheduled start of manufacture of batch or campaign.

Provider shall seek to reuse the reserved capacity as soon as practicable, and if Provider is successful in using the reserved capacity, Provider will reduce the delay charge proportionately based upon the number of days the capacity was repurposed.

13. INDEMNIFICATION; INSURANCE.

13.189bio Indemnification. 89bio hereby agrees to defend, indemnify and hold harmless Provider, its Affiliates and its and their officers, directors, employees, consultants and agents ("**Provider Indemnitees**") from and against any and all losses, damages, liabilities, expenses and costs, including reasonable legal expense and attorneys' fees ("**Losses**"), to which any such Provider Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any Third Party to the extent such Losses arise out of: (a) a breach by 89bio of any of its representations, warranties, covenants, agreements or obligations under this Agreement, (b) alleged or actual infringement or misappropriation of any Intellectual Property rights of any third party arising from Provider's use of the 89bio Background IP or 89bio Materials in the performance of the Services, (c) the administration, use, handling, storage or other disposition of the 89bio Product after receipt of such Products by 89bio from Provider; provided, however, that 89bio shall not be required to indemnify, hold harmless or defend any Provider Indemnitees against any claim to the extent that Provider has an obligation to indemnify the 89bio Indemnitees under Sections 13.2(a), (b) or (c).

13.2Provider Indemnification. Provider hereby agrees to defend, indemnify and hold harmless 89bio, its Affiliates and its and their officers, directors, employees, consultants, contractors and agents ("**89bio Indemnitees**") from and against any and all Losses to which any such 89bio Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any Third Party to the extent such Losses arise out of: (a) the failure of 89bio Product to meet the warranties set forth in Section 11.2 or the failure of the Services to meet the warranty set forth in Section 11.3, (b) any other breach by Provider of any of its representations, warranties, covenants, agreements or obligations under this Agreement, or (c) the negligence, recklessness or willful misconduct of Provider (or its Affiliates or contractors) in the performance of its obligations hereunder; provided, however, that Provider shall not be required to indemnify, hold harmless or defend any 89bio Indemnitees against any claim to the extent that 89bio has an obligation to indemnify the Provider Indemnitees under Sections 13.1(a), (b) or (c).

13.3General Conditions of Indemnification. If either Party is seeking indemnification under Section 13.1 or 13.2 (the "**Indemnified Party**"), it shall inform the other

Party (the "**Indemnifying Party**") of the claim giving rise to the obligation to indemnify pursuant to such Section as soon as reasonably practicable after receiving notice of the claim (provided, however, any delay or failure to provide such notice shall not constitute a waiver or release of, or otherwise limit, the Indemnified Party's rights to indemnification under, as applicable, Section 13.1 or 13.2, except to the extent that such delay or failure materially prejudices the Indemnifying Party's ability to defend against the relevant claims). The Indemnifying Party shall have the right to assume the defense of any such claim for which it is obligated to indemnify the Indemnified Party. The Indemnified Party shall cooperate with the Indemnifying Party and the Indemnifying Party's insurer as the Indemnifying Party may reasonably request, and at the Indemnifying Party's cost and expense. The Indemnified Party shall have the right to participate, at its own expense and with counsel of its choice, in the defense of any claim or suit that has been assumed by the Indemnifying Party. The Indemnifying Party shall not settle any claim without the prior written consent of the Indemnified Party, not to be unreasonably withheld, delayed or conditioned. The Indemnified Party shall not settle or compromise any such claim without the prior written consent of the Indemnifying Party, which it may provide in its sole discretion. If the Parties cannot agree as to the application of Section 13.1 or 13.2 to any claim, the Parties may conduct separate defenses of such claims, with each Party retaining the right to claim indemnification from the other Party in accordance with Section 13.1 or 13.2 upon resolution of the underlying claim.

13.4Limitations of Liability. EXCEPT FOR A BREACH BY EITHER PARTY OF ARTICLE 9 OR ARTICLE 10 AND THE PARTIES' RESPECTIVE INDEMNIFICATION OBLIGATIONS UNDER SECTION 13.1 AND 13.2 FOR LOSSES IN CONNECTION WITH THIRD PARTY CLAIMS, NEITHER PARTY'S AGGREGATE LIABILITY TO THE OTHER PARTY UNDER ANY RELEVANT WORK ORDER SHALL IN ANY EVENT EXCEED THE TOTAL FEES PAID BY 89BIO TO PROVIDER UNDER THE AGREEMENT. FOR THE AVOIDANCE OF DOUBT, NOTHING IN THIS AGREEMENT IS INTENDED TO LIMIT EITHER PARTY'S LIABILITY FOR DEATH OR PERSONAL INJURY CAUSED BY ITS NEGLIGENCE OR FOR FRAUDULENT MISREPRESENTATION.

13.5No Consequential Damages. EXCEPT FOR BREACH OF ARTICLE 7 OR ARTICLE 8, AND THE PARTIES' RESPECTIVE INDEMNIFICATION OBLIGATIONS UNDER SECTION 13.1 AND 13.2 FOR LOSSES IN CONNECTION WITH THIRD PARTY CLAIMS, IN NO EVENT SHALL EITHER PARTY OR ANY OF ITS AFFILIATES BE LIABLE TO THE OTHER PARTY OR ANY OF ITS AFFILIATES FOR SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES, INCLUDING LOSS OF PROFITS, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY, INDEMNITY CLAIM OR OTHERWISE ARISING OUT OF OR RELATING TO THIS AGREEMENT, THE TRANSACTIONS CONTEMPLATED HEREIN OR ANY BREACH HEREOF.

13.6Insurance. During the Term, each Party shall obtain and maintain, at its sole cost and expense, insurance (including any self-insured arrangements) in types and amounts, that are reasonable and customary in the pharmaceutical and biotechnology industry for companies engaged in comparable activities in the jurisdiction where such activities are being performed.

Without prejudice to the foregoing, Provider shall maintain a minimum product liability insurance covering its liability and claims arising or manufacture and supply the Product within a limit liability of [***]. 89bio shall during the Term and for the longer of (a) [***] after the termination of this agreement and (b) [***] after the last use of the 89bio Product maintain general liability insurance and product liability insurance (for commercial use) and clinical trials insurance covering liability and claims arising or that may arise from the use, supply, licensing or distribution of the 89bio Product with insurance companies and in amounts as customarily maintained. It is understood and agreed that this insurance shall not be construed to limit either Party's liability with respect to its indemnification obligations hereunder. Each Party will, provide to the other Party upon request a certificate evidencing the insurance, or if self-insured, a certificate of self-insurance, such Party is required to obtain and keep in force under this Section 13.6.

14. GENERAL PROVISIONS.

14.1Independent Contractor Relationship. Each Party is an independent contractor under this Agreement. Nothing contained herein will be deemed, for the purpose of any law, to create an employment, agency, joint venture or partnership relationship between the Parties or any of their agents or employees, or any other legal arrangement that would impose liability upon one Party for the act or failure to act of the other Party. The Parties will operate their own businesses separately and independently and they will hold themselves out as, act as, and constitute independent contractors in all respects and not as principal and agent, partners or joint venturers. Neither Party will have any express or implied power to enter into any contracts or commitments or to incur any liabilities in the name of, or on behalf of, the other Party, or to bind the other Party in any respect whatsoever. Neither Party shall make any filing or initiate any communication with a governmental authority that is inconsistent with this Section 14.1 and each Party shall notify the other Party within [***] of receiving any written communication from a governmental authority that asserts a position that is inconsistent with this Section 14.1.

14.2Use of Names. Neither Party shall use the other Party's name or the names of the other Party's employees in any advertising or sales promotional material or in any publication without prior written permission of the other Party. Notwithstanding the above, 89bio may represent Provider's role in reports to or filings with government or regulatory agencies.

14.3Choice of Law. This Agreement shall be governed by the laws of the State of Delaware, excluding its conflicts of laws principles.

14.4Attempts to Amicably Resolve Disputes.

(a) To avoid litigation and to resolve any conflicts that arise during the performance of the Services or thereafter, 89bio and Provider agree that, prior to the commencement of litigation by either Party, the Parties shall engage in executive mediation. Either Party may seek executive mediation by delivering a written request for such mediation to the other. Delivery of such request may be made by hand or by electronic mail.

(b) Within [***] of the delivery of such request, each Party shall appoint a company executive who is not directly involved in the dispute to meet with the other Party's company executive for the purpose of resolving the dispute. No later than [***] of their appointment, the two executives shall meet to consider the dispute. They may request such information as either deems necessary and may meet jointly or separately with party representatives involved in the dispute. The two appointed executives shall use good faith efforts to reach a resolution of the dispute.

(c) If a resolution is reached, it shall be reduced to writing and shall be final and binding on the Parties.

(d) If the two executives cannot reach agreement within [***] of their initial meeting, unless the two executives agree to additional review time, either Party may thereafter pursue any remedy at law or in equity.

14.5Force Majeure. Neither Party shall be liable for failure to perform its obligations under this Agreement (or for a delay in the performance of such obligations), and neither shall be deemed in breach of its obligations, if such failure or delay is due to Force Majeure. In event of Force Majeure, the Party affected thereby shall use commercially reasonable efforts to cure or overcome the same and resume performance of its obligations hereunder. For purposes hereof, "**Force Majeure**" means causes beyond the reasonable control of a Party (or its Affiliates) including acts of God (including earthquake, tornado or hurricane), laws, regulations or actions of any government or agency thereof, war, terrorism, civil commotion, damage to or destruction of production facilities or materials, scientific or technical events, labor disturbances (whether or not any such labor disturbance is within the power of the affected Party to settle) and pandemic or epidemic events. If an event of Force Majeure continues and causes a Party to delay its performance of its obligations for more than [***], then the other Party shall have the right upon written notice to terminate this Agreement without any liability to the other Party; provided that if 89bio terminates hereunder, Provider shall provide reasonable transition assistance as set forth in Section 12.9 hereof.

14.6Injunctive Relief. Each Party hereby agrees that breach of the intellectual property and confidentiality provisions of this Agreement will cause the other Party irreparable damage for which recovery of damages would be inadequate, and that the other Party shall therefore be entitled to obtain timely injunctive relief under this Agreement without the necessity of proving actual damages and without posting bond, as well as such further relief as may be granted by a court of competent jurisdiction.

14.7Entire Agreement; Amendment. This Agreement, together with all Exhibits attached hereto and the Quality Agreement, constitutes the final, complete and exclusive agreement of the Parties with respect to the subject matter hereof and supersedes all prior understandings and agreements relating to its subject matter. This Agreement may not be changed, modified, amended or supplemented except by a written instrument signed by both Parties.

14.8Construction. 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 words "include", "includes" and "including" will be deemed to be followed by the phrase "without limitation". The word "or" is used in the inclusive sense (and/or). The word "will" shall be construed to have the same meaning and effect as the word "shall". 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: (i) 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); (ii) any reference to any Applicable Law herein will be construed as referring to such Applicable Law as from time to time enacted, repealed or amended; (iii) any reference herein to any person will be construed to include the person's permitted successors and assigns; (iv) 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 (v) all references herein to Articles, Sections, or Schedules, unless otherwise specifically provided will be construed to refer to Articles, Sections or Schedules of this Agreement.

14.9Severability. If any provision of this Agreement should be held invalid or unenforceable, the remaining provisions shall be unaffected and shall remain in full force and effect, to the extent consistent with the intent of the Parties as evidenced by this Agreement as a whole.

14.10Third Party Beneficiaries. Except as expressly provided with respect to Provider Indemnitees or 89bio Indemnities in Section 13, there are no Third-Party beneficiaries intended hereunder and no Third Party will have any right or obligation hereunder.

14.11Assignment; Delegation. This Agreement shall inure to the benefit of and be binding upon the successors and assigns of the Parties hereto. Neither Party may assign any of its rights or obligations under this Agreement to any Third Party without the express, written consent of the other Party; *provided*, *however*, that 89bio may assign its interest in this Agreement to an Affiliate or in connection with a merger or sale of substantially all of its business or that portion of its business pertaining to the subject matter of this Agreement, whether by merger, sale of stock, sale of assets or otherwise or under a license or collaboration in connection with the 89bio Materials or 89bio Product(s) or 89bio Drug Product. For the avoidance of doubt, in case the merger or sales of substantially business of 89bio and the new party take control would form any conflict of interest with Provider, assignment and/or delegation of this agreement should have Provider's express, written consent. Conflict of interest here means a company's main activities are contract manufacturing in biologics industry. Provider may not subcontract or otherwise delegate its obligations to any other parties under this Agreement without 89bio's prior written consent.

14.12Headings. Section headings are for convenience of reference only and shall not be considered in the interpretation of this Agreement.

14.13Force Majeure. Neither Party will be liable for delay or failure in the performance of any of its obligations hereunder (other than the payment of money) to the extent such delay or failure is due to causes beyond its reasonable control, including acts of God, fires, floods, earthquakes, labor strikes, hostilities, acts of war, terrorism, civil unrest, national emergencies, epidemics, or pandemics; provided that the affected Party promptly notifies the other Party in writing (and continues to provide monthly status updates to the other Party for the duration of the effect); and provided further that the affected Party uses its commercially reasonable efforts to avoid or remove such causes of non-performance and to mitigate the effect of such occurrence, and will continue performance with reasonable dispatch whenever such causes are removed.

14.14Further Assurances. Each Party shall act in good faith in its performance of this Agreement and shall: (i) not unreasonably delay or withhold the giving of any consent, decision or approval that is either requested or reasonably required by the other Party in order to perform its responsibilities and/or obligations under this Agreement; and (ii) do such other acts and things the other Party may reasonably request for the purpose of carrying out the intent of this Agreement.

14.15Notices. Any notice required or permitted to be given by this Agreement will be in writing, in English, and will be delivered by hand, overnight courier with tracking capabilities, mailed postage prepaid by registered or certified mail addressed as set forth below unless changed by notice so given:

If to 89bio:
89bio, Inc.
142 Sansome Street, 2nd Floor
San Francisco, CA 94104

Attn: [***]

If to Provider:

BiBo Biopharma Engineering Co., Ltd.
Building 6,22,28, No.356 Zhengbo Road,
China (Shanghai) Pilot Free Trade Zone
LIN-GANG Special Area, Shanghai 201413
P. R. China

Attn: [***]

Any such notice will be deemed given on the date delivered. A Party may add, delete (so long as at least one person is remaining), or change the person or address to which notices should be sent at any time upon written notice delivered to the other Party in accordance with this Section 14.15.

14.16Counterparts. This Agreement may be executed in two or more counterparts, each of which will be considered an original, but all of which together will constitute one and the same instrument. A facsimile, PDF (or any electronic signature complying with the U.S. federal ESIGN Act of 2000, e.g., www.docusign.com) or any other type of copy of an executed version of this Agreement signed by a Party is binding upon the signing Party to the same extent as the original of the signed agreement.

14.17Non-Waiver. No failure or delay of one of the Parties to insist upon strict performance of any of its rights or powers under this Agreement shall operate as a waiver thereof, nor shall any other single or partial exercise of such right or power preclude any other further exercise of any rights or remedies provided by law. No waiver, modification, release or amendment of any right or obligation under or provision of this Agreement will be valid or effective unless in writing and signed by the Parties.

[Remainder Of This Page Intentionally Left Blank]

[***] = 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 duly executed this Master Services Agreement on the Effective Date.

89bio, Inc.	**BiBo Biopharma Engineering Co., Ltd.**
By: /s/ Quoc Le-Nguyen (Signature)	By: /s/ Qi Xu (Signature)
Printed Name: Quoc Le-Nguyen	Printed Name: Qi Xu
Title: CTO & Head of Quality	Title: SVP

[Signature Page To Master Services Agreement]

[***] = 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.

EXHIBIT A

WORK ORDER NO.___

AMENDMENT NO. 1
TO
MASTER CONTRACT SERVICES AGREEMENT

This Amendment (the "Amendment") is made as of the 24th of February 2023, by between 89bio, Inc., a Delaware corporation ("**89bio**"), with its principal place of business located at 142 Sansome Street, 2nd Floor, San Francisco, CA 94104, USA, and BiBo Biopharma Engineering Co., Ltd. with its principal place of business located at Building 6,22,28, No.356 Zhengbo Road, China (Shanghai) Pilot Free Trade Zone LIN-GANG Special Area, Shanghai 201413, P.R. China ("**Provider**").

BACKGROUND

Provider and 89bio are parties to that certain Master Services Agreement dated as February 10, 2023 (the "**Agreement**") and they now desire to amend such Agreement to clarify responsibility with respect to dedicated equipment and to clarify venue for any disputes.

NOW, THEREFORE, in consideration of the mutual agreement, Provider and 89bio agree to amend the Agreement as follows:

The Agreement shall be amended as follows.

Section 2.11 is hereby amended and restated Section 2.11 as follows:

2.11 Dedicated Equipment

(a) Selection, **Procurement**, **Warranties.** To the extent set forth in a Work Order, Provider shall select and procure the Dedicated Equipment at [***] as set forth more explicitly in the Work Order. Dedicated Equipment shall be charged to 89bio at cost (plus any applicable VAT tax and/or customs duty paid or payable by Provider) and without any markup. Provider shall determine whether the Dedicated Equipment conforms to the applicable specifications and will work in the Facility for purpose set forth in the applicable Work Order. Unless explicitly set forth in the Work Order, Provider warrants that the Dedicated Equipment shall be new, not previously used by Provider, nor purchased by Provider as "used equipment" by Provider. Provider shall pass through any all manufacturer's warranties for the Dedicated Equipment. Provider shall use Dedicated Equipment only for services performed for 89bio, including the Services for as long as it shall remain Dedicated Equipment.

(b) Use and Storage of Dedicated Equipment. Provider shall use and store the Dedicated Equipment in accordance with any written instructions prescribed by 89bio or the manufacturer of the Dedicated Equipment, and shall performed such routine maintenance and storage for the Dedicated Equipment in accordance with such written instructions at Provider's expense as set forth in a Work Order. All costs for any -, extraordinary or non-routine maintenance that may be required will be approved in advance by 89bio, and the appropriate Work Order will be revised to reflect any additional maintenance costs that may be required during the Term. Except: (i) in connection with such routine maintenance and

storage, (ii) as required by the Services; or (iii) as directed in writing by 89bio, Provider shall not make any alterations, additions or improvements to the Dedicated Equipment.

(c) Ownership and Risk of Loss; Disposition of Equipment; Option. 89bio shall own and continue to own all right, title and interest in and to any Dedicated Equipment. Provider shall not permit any liens or encumbrances to be made on the Dedicated Equipment. Provider is responsible for risk of loss, damage, theft or destruction of the Dedicated Equipment while that Dedicated Equipment is in Provider's possession or on Provider's premises, and shall provide customary and appropriate insurance therefor. Upon termination or expiration of the Work Order for any reason, if the cost of the Dedicated Equipment has been paid by 89bio, or 89bio has paid the option purchase price for the Dedicated Equipment, then 89bio shall have the right to, upon reasonable notice, reclaim possession of such Dedicated Equipment at its sole expense (including all costs of physical transfer and any subsequent reinstallation and requalification costs). Provider shall reasonably cooperate with 89bio to remove and return such Dedicated Equipment to 89bio or its designee in accordance with 89bio's written instructions and shall invoice 89bio for direct costs incurred. Notwithstanding the above, upon termination or expiration of this Agreement, 89bio may offer to sell to Provider, or Provider may offer to purchase from 89bio, the Dedicated Equipment at [***]. Neither Provider nor 89bio shall be obligated to make or accept such offers. In the event that 89bio has not removed the Dedicated Equipment within [***] after reasonable notice, the Dedicated Equipment shall be deemed to be abandoned and Provider may dispose of it or use it as it sees fit. If for any reason, the cost of Dedicated Equipment was not passed through to 89bio under a Work Order, upon termination of the Agreement, 89bio shall have option to purchase such Dedicated Equipment at the initial cost paid for such equipment by Provider, or such lesser amount as the Parties may agree on.

Section 12.10 is hereby amended and restated as follows:

12.10 Survival Upon Termination. Termination or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of any Party prior to such termination or expiration. Such termination or expiration shall not relieve any Party from obligations which are expressly or by implication intended to survive termination or expiration of this Agreement and shall not affect or prejudice any provision of this Agreement which is expressly or by implication provided to come into effect on, or continue in effect after, such termination or expiration. Sections 2.7, 2.8, 2.9, 2.11, 7.7, 9, 10,12.6, 12.7, 12.8, 12.9, 12.10, 13 and 14 will survive expiration or termination of this Agreement.

Section 14.3 is hereby amended and restated as follows:

14.3 Choice of **Law and Venue.** This Agreement shall be governed by the laws of the State of Delaware, United States, excluding its conflicts of laws principles. The Parties hereby agree that any action arising out of this Agreement will be brought solely in any state or federal court located in Delaware, United States. Both Parties hereby submit to the exclusive jurisdiction and venue of any such court.

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.

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.

Defined Terms. Capitalized terms shall have the meanings given to them in the Agreement.

[*Signature Page Follows*]

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

BiBo Biopharma Engineering Co., Ltd.	**89bio, Inc.**
By: /s/ Qi Xu	By: /s/ Quoc Le-Nguyen
Name: Qi Xu	Name: Quoc Le-Nguyen
Title: SVP	Title: Chief Technical Operations Officer & Head of Quality

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Rohan Palekar, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of 89bio, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 5, 2023

By: /s/ Rohan Palekar

Rohan Palekar
Chief Executive Officer
(principal executive officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Ryan Martins, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of 89bio, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 5, 2023

By: /s/ Ryan Martins

Ryan Martins
Chief Financial Officer
(principal financial and accounting officer)

Exhibit 32

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of 89bio, Inc. (the "Company") for the period ending March 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 5, 2023

By: /s/ Rohan Palekar

Rohan Palekar
Chief Executive Officer
(principal executive officer)

Date: May 5, 2023

By: /s/ Ryan Martins

Ryan Martins
Chief Financial Officer
(principal financial and accounting officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. §1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Note: A signed original of this written statement required by §906 has been provided to 89bio, Inc. and will be retained by 89bio, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.