UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 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 June 30, 2024

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 July 29, 2024, the registrant had 105,909,991 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
(Unaudited)
(In thousands, except share and per share amounts)

	June 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 212,218	$ 316,161
Marketable securities	319,166	262,709
Prepaid and other current assets	48,470	14,664
Total current assets	579,854	593,534
Operating lease right-of-use assets	1,942	2,293
Property and equipment, net	27	46
Other assets	315	396
Total assets	$ 582,138	$ 596,269
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 17,461	$ 8,585
Accrued expenses	18,663	20,530
Operating lease liabilities, current	759	496
Term loan, current	4,770	—
Total current liabilities	41,653	29,611
Operating lease liabilities, noncurrent	1,463	1,817
Term loan, noncurrent, net	20,355	24,795
Other noncurrent liabilities	3,750	3,740
Total liabilities	67,221	59,963
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Common stock, $0.001 par value: 200,000,000 shares authorized; 104,915,176 and 93,269,377 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively	105	93
Additional paid-in capital	1,072,579	993,455
Accumulated other comprehensive (loss) income	(683)	190
Accumulated deficit	(557,084)	(457,432)
Total stockholders' equity	514,917	536,306
Total liabilities and stockholders' equity	$ 582,138	$ 596,269

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 June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 44,865	$ 34,915	$ 92,293	$ 57,221
General and administrative	8,571	7,214	18,420	13,432
Total operating expenses	53,436	42,129	110,713	70,653
Loss from operations	(53,436)	(42,129)	(110,713)	(70,653)
Interest expense	(874)	(894)	(1,737)	(2,969)
Interest income and other, net	6,473	4,630	13,029	6,393
Net loss before income tax	(47,837)	(38,393)	(99,421)	(67,229)
Income tax expense	(134)	—	(231)	—
Net loss	$ (47,971)	$ (38,393)	$ (99,652)	$ (67,229)
Other comprehensive (loss) income:				
Unrealized loss on marketable securities	(169)	(355)	(883)	(241)
Foreign currency translation adjustments	5	1	10	(3)
Total other comprehensive loss	$ (164)	$ (354)	$ (873)	$ (244)
Comprehensive loss	$ (48,135)	$ (38,747)	$ (100,525)	$ (67,473)
Net loss per share, basic and diluted	$ (0.48)	$ (0.52)	$ (1.02)	$ (1.06)
Weighted-average shares used to compute net loss per share, basic and diluted	99,831,111	74,126,569	97,838,926	63,706,856

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

89bio, Inc.
Condensed Consolidated Statements of Stockholders' Equity
(Unaudited)
(In thousands, except share amounts)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amounts				
Balance as of December 31, 2023	93,269,377	$ 93	$ 993,455	$ 190	$ (457,432)	$ 536,306
Issuance of common stock in at-the-market public offerings, net of issuance costs	1,396,888	2	21,047	—	—	21,049
Issuance of common stock upon exercise of common stock warrants	337,713	—	1,798	—	—	1,798
Issuance of common stock upon exercise of stock options	1,626	—	7	—	—	7
Issuance of common stock upon vesting of restricted stock units, net of tax withholding for net share settlement	194,120	—	(1,229)	—	—	(1,229)
Stock-based compensation	—	—	4,998	—	—	4,998
Net loss	—	—	—	—	(51,681)	(51,681)
Other comprehensive loss	—	—	—	(709)	—	(709)
Balance as of March 31, 2024	95,199,724	95	1,020,076	(519)	(509,113)	510,539
Issuance of common stock upon exercise of common stock warrants	8,854,576	9	47,142	—	—	47,151
Issuance of common stock upon cashless exercise of pre-funded warrants	799,906	1	(1)	—	—	—
Issuance of common stock upon exercise of stock options	26,355	—	54	—	—	54
Issuance of common stock upon vesting of restricted stock units, net of tax withholding for net share settlement	8,490	—	(39)	—	—	(39)
Issuance of common stock under employee stock purchase plan	26,125	—	178	—	—	178
Stock-based compensation	—	—	5,169	—	—	5,169
Net loss	—	—	—	—	(47,971)	(47,971)
Other comprehensive loss	—	—	—	(164)	—	(164)
Balance as of June 30, 2024	104,915,176	$ 105	$ 1,072,579	$ (683)	$ (557,084)	$ 514,917

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

89bio, Inc.
Condensed Consolidated Statements of Stockholders' Equity
(Unaudited)
(In thousands, except share amounts)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	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 offerings, 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 common stock 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 tax withholding for net share settlement	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
Issuance of common stock in at-the-market public offerings, net of issuance costs	1,200,539	1	23,666	—	—	23,667
Issuance of common stock upon exercise of common stock warrants	1,245,070	1	6,629	—	—	6,630
Issuance of common stock upon exercise of stock options	107,832	—	327	—	—	327
Issuance of common stock upon vesting of restricted stock units, net of tax withholding for net share settlement	31,527	—	—	—	—	—
Issuance of common stock under employee stock purchase plan	13,927	—	142	—	—	142
Stock-based compensation	—	—	4,137	—	—	4,137
Net loss	—	—	—	—	(38,393)	(38,393)
Other comprehensive loss	—	—	—	(354)	—	(354)
Balance as of June 30, 2023	75,466,600	$ 75	$ 824,977	$ (594)	$ (382,472)	$ 441,986

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)

	Six Months Ended June 30,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (99,652)	$ (67,229)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	10,167	7,688
Net accretion of discounts on investments in marketable securities	(5,406)	(2,188)
Amortization of debt discount and accretion of deferred debt costs	330	456
Loss on extinguishment of debt	—	1,208
Noncash operating lease expense	351	83
Depreciation	21	24
Other	113	—
Changes in operating assets and liabilities:		
Prepaid and other assets	(14,319)	(5,816)
Accounts payable	9,002	(1,787)
Accrued expenses	(1,410)	3,112
Operating lease liabilities	(91)	(83)
Other noncurrent liabilities	10	—
Net cash used in operating activities	(100,884)	(64,532)
Cash flows from investing activities:		
Proceeds from sales and maturities of marketable securities	178,090	82,880
Purchases of marketable securities	(230,139)	(180,582)
Net cash used in investing activities	(52,049)	(97,702)
Cash flows from financing activities:		
Proceeds from issuance of common stock in public offerings, net of issuance costs	—	296,817
Payments of deferred offering costs	(116)	—
Proceeds from issuance of common stock in at-the-market public offerings, net of issuance costs	21,049	37,089
Proceeds from term loan facility, net of issuance costs	—	24,363
Proceeds from issuance of common stock upon exercise of common stock warrants	29,543	15,590
Proceeds from issuance of common stock upon exercise of stock options	61	512
Proceeds from issuance of common stock under employee stock purchase plan	178	142
Payments for taxes related to net share settlement upon vesting of restricted stock units	(1,725)	(693)
Repayment of term loan	—	(21,400)
Net cash provided by financing activities	48,990	352,420
Net change in cash and cash equivalents	(103,943)	190,186
Cash and cash equivalents at beginning of period	316,161	55,255
Cash and cash equivalents at end of period	$ 212,218	$ 245,441
Supplemental disclosures of cash information:		
Cash paid for interest	$ 1,368	$ 1,198
Cash paid for amounts included in the measurement of lease liabilities	$ 239	$ 93
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 Liquidity

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 ("FGF21"), is currently being developed for the treatment of metabolic dysfunction-associated steatohepatitis ("MASH"), previously known as nonalcoholic steatohepatitis, and for the treatment of severe hypertriglyceridemia ("SHTG").

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 Company has incurred significant losses and negative cash flows from operations since inception and had an accumulated deficit of $557.1 million as of June 30, 2024. The Company has historically financed its operations primarily through the sale of equity securities, including warrants, and from borrowings under term loan facilities. To date, none of the Company's product candidates have been approved for sale, and the Company has not generated any revenue from commercial products. The Company expects operating losses to continue and increase for the foreseeable future as the Company progresses its clinical development activities for its product candidates.

The Company believes its existing cash, cash equivalents and marketable securities of $531.4 million as of June 30, 2024 will be sufficient to fund its planned operating expense and capital expenditure requirements for a period of at least one year from the date of the issuance of these financial statements.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying interim unaudited condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States ("U.S. GAAP"), the instructions to Form 10-Q and Rule 10-01 of Regulation S-X and applicable rules and regulations of the Securities and Exchange Commission ("SEC") regarding interim financial reporting.

Unaudited Interim Condensed Consolidated Financial Statements

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, 2023 and reflect all normal recurring adjustments that are necessary to present fairly the results for the interim periods presented. Interim results are not necessarily indicative of the results to be expected for the full year ending December 31, 2024 or for any other future annual or interim period. The condensed consolidated balance sheet as of December 31, 2023 was derived from the audited financial statements as of that date and, due to its summary nature, does not include all the disclosures required by U.S. GAAP in audited financial statements. 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, 2023, which was filed with the SEC on March 1, 2024.

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. For the Company and its subsidiary in Israel, the functional currency has been determined to be the U.S. Dollar.

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 accruals for uncertain tax positions, accrued research and development expenses and the valuation 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

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.

Assets Measured at Fair Value on a Recurring Basis

As of June 30, 2024 and December 31, 2023, cash equivalents and marketable securities were the only financial instruments measured and recorded at fair value on a recurring basis on the Company's condensed consolidated balance sheets.

Financial Instruments Not Carried at Fair Value

The Company's financial instruments, including cash, other current assets, accounts payable and accrued expenses are carried at cost which approximates their fair value because of the short-term nature of these financial 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.

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 primarily consist of amounts invested in money market funds, commercial paper and U.S. government Treasury securities and are carried at fair value.

Marketable Securities

The Company invests its excess cash in marketable securities with high credit ratings including money market funds, commercial paper, securities issued by the U.S. government and its agencies and corporate debt securities. The Company accounts for all marketable securities as available-for-sale, as the sale of such securities may be required prior to maturity. These marketable securities are carried at fair value, with unrealized gains and losses reported as accumulated other comprehensive income (loss) until realized. The cost of debt securities is adjusted for accretion of premiums and amortization of discounts to maturity. Such amortization and accretion, as well as interest and dividends, are included in interest income and other, net. Realized gains and losses from the sale of marketable securities, if any, are determined on a specific identification basis and are also included in interest income and other, net. The Company's marketable securities are classified as current assets, which reflects management's intention to use the proceeds from sales of these securities to fund its operations, as necessary, even though the stated maturity date may be one year or more beyond the current balance sheet date.

The Company periodically assesses its marketable securities for impairment. For marketable securities in an unrealized loss position, this assessment first takes into account the Company's intent to sell, or whether it is more likely than not that it will be required to sell the security before recovery of its amortized cost basis. If either of these criteria are met, the marketable security's amortized cost basis is written down to fair value through interest income and other, net. For marketable securities in an unrealized loss position that do not meet the aforementioned criteria, the Company assesses whether the decline in fair value has resulted from credit losses or other factors. In making this assessment, the Company considers the extent to which fair value is less than amortized cost, any changes to the rating of the security by a rating agency, and any adverse conditions specifically related to the security, among other factors. If this assessment indicates that a credit loss may exist, the present value of cash flows expected to be collected from the security are compared to the amortized cost basis of the security. If the present value of cash flows expected to be collected is less than the amortized cost basis, a credit loss exists and an allowance for credit losses will be recorded in interest income and other, net, limited by the amount that the fair value is less than the amortized cost basis. Any additional impairment not recorded through an allowance for credit losses is recognized in other comprehensive loss. Changes in the allowance for credit losses are recorded as provision for (or reversal of) credit loss expense. Losses are charged against the allowance when management believes the uncollectability of a security is confirmed or when either of the criteria regarding intent or requirement to sell is met. These changes are recorded in interest income and other, net.

Income Taxes

The Company accounts for uncertain tax positions using a more-likely-than-not threshold for recognizing and resolving uncertain tax positions. This evaluation is based on factors including, but not limited to, changes in facts or circumstances, changes in tax law, effectively settled issues under audit, and new audit activity. Interest and penalties related to unrecognized tax benefits are included within income tax expense. For the three and six months ended June 30, 2024, the Company recorded income tax expense related to its foreign operations in Israel of $0.1 million and $0.2 million, respectively.

Basic and Diluted Net Loss per Share

Basic and diluted net loss per share is calculated based upon the weighted-average number of shares of common stock outstanding during the period. Shares of common stock that are potentially issuable for little or no cash consideration at issuance, such as the Company's pre-funded warrants issued in July 2022 and December 2023, are included in the calculation of basic and diluted net loss per share, even if they are antidilutive. During periods of income, participating securities are allocated a proportional share of income determined by dividing total weighted-average participating securities by the sum of the total weighted-average common shares and participating securities (the "two-class method"). Shares of the Company's common stock warrants participate in any dividends that may be declared by the Company and are therefore considered to be participating securities. Participating securities have the effect of diluting both basic and diluted earnings per share during periods of income. During periods of loss, no loss is allocated to participating securities since they have no contractual obligation to share in the losses of the Company. Diluted loss per share is computed after giving consideration to the dilutive effect of stock options, restricted stock units ("RSUs"), performance stock units ("PSUs") and common stock warrants, except where such non-participating securities would be anti-dilutive. As the Company incurred net losses for the periods presented, basic net loss per share is the same as diluted net loss per share since the effects of potentially dilutive securities are antidilutive.

Recently Adopted Accounting Standards

The Company did not adopt any new standards or updates issued by the Financial Accounting Standards Board ("FASB") during the six months ended June 30, 2024 that had a material impact on the Company's consolidated financial statements and related disclosures.

Accounting Pronouncements Not Yet Adopted

In November 2023, the FASB issued ASU No. 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures* ("ASU 2023-07"), which is intended to improve reportable segment disclosure requirements, primarily through enhanced disclosures about significant expenses. ASU 2023-07 requires disclosures to include significant segment expenses that are regularly provided to the chief operating decision maker ("CODM"), a description of other segment items by reportable segment, and any additional measures of a segment's profit or loss used by the CODM when deciding how to allocate resources. The ASU also requires all annual disclosures required by Topic 280 to be included in interim periods. All disclosure requirements under this ASU are also required for public entities with a single reportable segment. The ASU is effective for the Company's annual periods beginning on January 1, 2024 and interim periods beginning on January 1, 2025. Early adoption is permitted and requires retrospective application to all prior periods presented in the financial statements. The Company expects to adopt ASU 2023-07 in its Annual Report on Form 10-K for the year ending December 31, 2024 and in the interim periods thereafter. The Company is in the process of evaluating the requirements of this update, which is expected to result in expanded disclosures within the consolidated financial statements upon adoption.

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* ("ASU 2023-09"), which requires companies to disclose, on an annual basis, specific categories in the effective tax rate reconciliation and provide additional information for reconciling items that meet a quantitative threshold. In addition, ASU 2023-09 requires companies to disclose additional information about income taxes paid. The ASU is effective for the Company's annual periods beginning on January 1, 2025 and will be applied on a prospective basis with the option to apply the standard retrospectively. Early adoption is permitted. The Company expects to adopt ASU 2023-09 in its Annual Report on Form 10-K for the year ending December 31, 2025 and in annual periods thereafter. The Company is in the process of evaluating the requirements of this update, which is expected to result in expanded disclosures within the consolidated financial statements upon adoption.

3. Fair Value Measurements

The following tables present the Company's financial assets measured at fair value on a recurring basis by level within the fair value hierarchy for the periods indicated (in thousands):

		June 30, 2024			
	Valuation Hierarchy	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Money market funds	Level 1	$ 35,433	$ —	$ —	$ 35,433
Commercial paper	Level 2	114,406	—	(66)	114,340
U.S. government bonds	Level 2	192,073	29	(511)	191,591
Agency bonds	Level 2	47,296	2	(120)	47,178
Corporate debt securities	Level 2	6,606	—	(29)	6,577
U.S. Treasury securities	Level 2	40,165	—	(3)	40,162
Agency discount securities	Level 2	4,992	—	—	4,992
Total cash equivalents and marketable securities		$ 440,971	$ 31	$ (729)	$ 440,273
Classified as:					
Cash equivalents					$ 121,107
Marketable securities					319,166
Total cash equivalents and marketable securities					$ 440,273

		December 31, 2023			
	Valuation Hierarchy	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Money market funds	Level 1	$ 493	$ —	$ —	$ 493
Commercial paper	Level 2	94,261	—	(55)	94,206
U.S. government bonds	Level 2	137,976	250	(142)	138,084
Agency bonds	Level 2	45,481	152	(44)	45,589
Corporate debt securities	Level 2	3,177	—	(12)	3,165
U.S. Treasury securities	Level 2	71,754	36	(1)	71,789
Agency discount securities	Level 2	7,975	1	—	7,976
Total cash equivalents and marketable securities		$ 361,117	$ 439	$ (254)	$ 361,302
Classified as:					
Cash equivalents					$ 98,593
Marketable securities					262,709
Total cash equivalents and marketable securities					$ 361,302

The valuation techniques used to measure the fair values of the Company's Level 2 financial instruments, which generally have counterparties with high credit ratings, are based on quoted market prices when available. If quoted market prices are not available, the fair value for the security is estimated under the market or income approach using pricing models with market observable inputs.

The following table summarizes the estimated fair value of investments in marketable securities by effective contractual maturity dates as of June 30, 2024 (in thousands):

Within one year	$ 340,064
After one year through two years	100,209
Total cash equivalents and marketable securities	$ 440,273

As of June 30, 2024, the Company's marketable securities in an unrealized loss position include primarily fixed-rate debt securities of varying maturities, which are sensitive to changes in the yield curve and other market conditions. Substantially all of the fixed-rate debt securities in a loss position are investment-grade debt securities. The Company has the intent and ability to hold such securities until recovery of the unrealized losses. Based on the Company's assessment, the unrealized losses as of June 30, 2024 were primarily due to changes in interest rates and not due to increased credit risks associated with specific securities. No allowance for credit losses was recorded as of June 30, 2024 and December 31, 2023.

4. Balance Sheet Components

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

	June 30, 2024	December 31, 2023
Prepaid research and development	$ 26,148	$ 11,579
Prepaid taxes	388	614
Prepaid other	2,528	2,471
Common stock warrant exercise receivable	19,406	—
Total prepaid and other current assets	$ 48,470	$ 14,664

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

	June 30, 2024	December 31, 2023
Accrued research and development expenses	$ 13,145	$ 13,017
Accrued employee and related expenses	3,752	6,248
Accrued professional and legal fees	1,511	1,110
Accrued other expenses	255	155
Total accrued expenses	$ 18,663	$ 20,530

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, under which the Company is not actively developing product candidates and does not have any current plans to do so. Pursuant to the Teva Agreements, the Company paid Teva an initial nonrefundable upfront payment of $6.0 million. Under each license agreement, the Company is required to pay Teva $2.5 million upon the achievement of a specified clinical development milestone, and additional payments totaling up to $65.0 million upon achievement of certain commercial milestones. Each milestone payment shall be payable once, upon the first occurrence of the applicable milestone. The Company is also 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 their 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.

In the fourth quarter of 2023, the Company made a $2.5 million milestone payment to Teva following the achievement of a clinical development milestone under the FGF21 program in SHTG. As of June 30, 2024, the timing and likelihood of achieving any remaining milestones are uncertain. Milestone payment obligations will be recognized when payment becomes probable and reasonably estimable, which is generally upon achievement of the applicable milestone.

BiBo Collaboration Agreement

On April 4, 2024, the Company entered into a collaboration agreement (the "Collaboration Agreement") with BiBo Biopharma Engineering Co., Ltd., a company incorporated under the laws of the People's Republic of China ("BiBo"), pursuant to which BiBo will construct a production facility specifically designed to supply the Company with pegozafermin for commercialization, if approved (the "Production Facility").

Pursuant to the Collaboration Agreement, BiBo will build the Production Facility at BiBo's facility in the Lin-gang Special Area of China (Shanghai) Pilot Free Trade Zone to manufacture the bulk active ingredient (the "Drug Substance") required to produce pegozafermin for commercial supply. The platform is expected to provide the Company with manufacturing capacity to meet its commercial needs based on current projections. Under the Collaboration Agreement, the Company is required to pay BiBo an aggregate of $135.0 million toward the construction of the Production Facility (collectively, the "Payment"), of which $60.0 million was paid subsequent to June 30, 2024 (see Note 10—*Subsequent Events*) to initiate the project. The remainder of the Payment will become payable upon achievement of certain specified milestones, of which up to an additional $61.5 million of the Payment could become payable within the next 12 months. If the actual costs of the Production Facility are substantially greater than the estimated budget, the parties will negotiate a means of allocating such cost overruns.

6. Term Loan Facility

In January 2023, the Company entered into a Loan and Security Agreement ("the Loan Agreement") with the lender parties thereto (the "Lenders"), K2 HealthVentures LLC as administrative agent and Ankura Trust Company, LLC as collateral agent. The Loan Agreement provides for up to $100.0 million in aggregate principal in term loans, consisting of an initial tranche of $25.0 million that was funded at closing, second and third tranches of $15.0 million and $10.0 million, respectively, that may be funded upon the achievement of certain time-based, clinical and regulatory milestones, and a fourth tranche of up to $50.0 million that may be funded upon discretionary approval by the Lenders. As of June 30, 2024, the second and third tranches expired undrawn and the fourth tranche remains available at the sole discretion of the Lenders.

Borrowings under the Loan Agreement are secured by substantially all of the assets of the Company, excluding the Company's intellectual property. The 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. As of June 30, 2024, the Company was in compliance with all covenants under the Loan Agreement.

Borrowings under the Loan Agreement mature on January 1, 2027 and provide for interest-only payments until February 1, 2025. Consecutive equal payments of principal and interest are due once the interest-only period has elapsed. Borrowings under the Loan Agreement 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 stated interest rate on the term loan was 9.75% at inception and 10.75% as of June 30, 2024. 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 borrowings under the Loan Agreement, subject to a prepayment fee ranging from 1.0% to 3.0% depending on the timing of such prepayment. A commitment fee equal to 0.6% of the principal amount of the fourth tranche is also payable if drawn.

At any time prior to full repayment of outstanding borrowings under the Loan Agreement, the Lenders may elect to convert up to an aggregate of $7.5 million of the principal amount of outstanding borrowings 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 met the conditions for equity classification.

Total debt issuance costs related to the term loan facility of $0.8 million, which includes the fair value of warrants issued in connection with the facility, were recorded as debt discount. 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 facility.

The expected repayments of principal amount due on borrowings as of June 30, 2024 are as follows (in thousands):

2024 (remaining six months)	$	—
2025		10,774
2026		13,036
2027		1,190
Total principal outstanding		25,000
Plus accumulated accretion of final payment fee		602
Less unamortized debt discount		(477)
Total net carrying value		25,125
Term loan, current		(4,770)
Term loan, noncurrent, net	$	20,355

In connection with the 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"). The warrant shares become exercisable upon the funding of each tranche and have a 10-year term. In connection with the first tranche 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 met 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.

Of the remaining 153,611 warrant shares (the "contingent warrants"), 102,407 warrant shares associated with the fourth tranche remain outstanding and 51,204 warrant shares associated with the second and third tranches were forfeited as of June 30, 2024. 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 June 30, 2024 of the contingent warrants was insignificant. The contingent warrants derivative liability is 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 Black-Scholes input assumptions described above.

7. Stockholders' Equity

Common Stock Reserved for Issuance

The Company had the following shares of common stock reserved for future issuance, on an as-if-converted basis, as of the periods presented:

	June 30, 2024	December 31, 2023
Stock options outstanding	7,044,951	4,686,577
RSUs and PSUs outstanding	1,452,123	987,550
Shares available for future grants under equity incentive plans	2,468,467	1,790,684
Shares available for future issuance under the employee stock purchase plan	1,181,482	1,207,607
Warrants to purchase common stock outstanding	1,200,034	10,412,806
Pre-funded warrants to purchase common stock outstanding	1,081,081	1,881,081
Conversion feature related to outstanding term loan	590,816	590,816
Total available for future issuance	15,018,954	21,557,121

At-the-Market ("ATM") Offerings

In March 2021, the Company entered into an ATM sales agreement (as amended, the "Sales Agreement") with Leerink Partners LLC and Cantor Fitzgerald & Co. (the "Sales Agents") pursuant to which the Company may offer and sell shares up to $75.0 million of its common stock (the "2021 ATM Facility") from time to time pursuant to an effective registration statement. The Sales Agents are entitled to compensation at a commission of up to 3.0% of the aggregate gross sales price per share sold under the Sales Agreement. In February 2023, the Company entered into an amendment to the Sales Agreement, establishing a new ATM facility with an aggregate offering amount of up to $150.0 million of its common stock (the "2023 ATM Facility") pursuant to an effective registration statement.

During the six months ended June 30, 2023, the Company sold 2,168,539 shares of its common stock under its 2021 ATM Facility and 2023 ATM Facility and received net proceeds of $37.1 million.

During the six months ended June 30, 2024, the Company sold 1,396,888 shares of its common stock under the 2023 ATM Facility resulting in net proceeds of $21.0 million. However, there were no sales under the 2023 ATM Facility for the three months ended June 30, 2024. As of June 30, 2024, there was $104.4 million remaining for future sales under the 2023 ATM Facility.

Underwritten Public Offerings

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 and received net 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 June 30, 2024, 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 in connection with term loan (SVB)	25,000	$ 22.06	June 30, 2025
Warrant issued in connection with term loan (SVB)	33,923	19.12	May 28, 2031
Warrants issued in connection with term loan facility	153,611	9.76	January 27, 2033
Warrants issued in connection with public offering	987,500	5.325	July 1, 2024
Pre-funded warrants issued in connection with public offerings	1,081,081	0.001	Do not expire
Total outstanding	2,281,115		

Warrants to purchase 2,927,570 shares of common stock were exercised during the six months ended June 30, 2023, generating $15.6 million in cash proceeds.

Warrants to purchase 9,192,289 shares of common stock were exercised during the six months ended June 30, 2024, generating $48.9 million in cash proceeds. Of this amount, $19.4 million was received after June 30, 2024 and recorded as a receivable on the balance sheet as of that date. The remaining warrants to purchase 987,500 shares of common stock as of June 30, 2024 were exercised on July 1, 2024, resulting in additional cash proceeds of $5.3 million.

8. Stock-Based Compensation

Equity Incentive Plans

The Company has issued stock-based awards from various equity incentive and stock purchase plans, as more fully described in Note 8—*Stock-Based Compensation* of the Company's Notes to Consolidated Financial Statements section in its Annual Report on Form 10-K for the year ended December 31, 2023.

Equity Incentive Plans Activity

Stock Options

The following table summarizes stock option activity under the Company's equity incentive plans for the six months ended June 30, 2024:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
			(In years)	(In thousands)
Balance outstanding as of December 31, 2023	4,686,577	$ 14.11	7.9	$ 11,712
Granted	2,530,900	9.96		
Exercised	(27,981)	2.20		
Forfeited	(144,545)	12.49		
Balance outstanding as of June 30, 2024	7,044,951	$ 12.70	8.1	$ 6,409
Exercisable as of June 30, 2024	2,783,861	$ 14.89	6.6	$ 5,140

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:

	Six Months Ended June 30,	
	2024	2023
Expected term (years)	5.5–6.1	5.5–6.1
Expected volatility	87.3–90.4%	91.6–98.2%
Risk-free interest rate	3.8–4.6%	3.4–3.8%
Expected dividend	—	—

As of June 30, 2024, total unrecognized stock-based compensation expense related to unvested stock options was $32.5 million, which is expected to be recognized over a weighted-average period of 2.8 years.

RSU and PSUs

RSUs generally vest annually over a two or three-year period. PSUs generally contain performance conditions associated with corporate goals, such as achievement of certain development milestones, that vests upon achievement over a one to three-year period.

The following table summarizes RSU and PSU activity for the six months ended June 30, 2024:

	RSUs		PSUs	
	Number of Shares	Weighted-Average Grant Date Fair Value per Share	Number of Shares	Weighted-Average Grant Date Fair Value per Share
Balance outstanding as of December 31, 2023	688,382	$ 10.72	299,168	$ 5.96
Granted	656,950	9.96	192,000	9.98
Vested	(170,372)	13.76	(159,168)	7.00
Forfeited	(44,837)	8.50	(10,000)	9.98
Balance outstanding as of June 30, 2024	1,130,123	$ 9.91	322,000	$ 7.72

As of June 30, 2024, total unrecognized stock-based compensation expense related to RSUs and PSUs was $10.4 million, which is expected to be recognized over a weighted-average period of 1.7 years.

Stock-Based Compensation

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Research and development	$ 2,342	$ 1,712	$ 4,657	$ 3,199
General and administrative	2,827	2,425	5,510	4,489
Total stock-based compensation	$ 5,169	$ 4,137	$ 10,167	$ 7,688

9. Net Loss Per Share

The following table presents the weighted-average shares outstanding used to calculate basic and diluted net loss per share for the periods indicated:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Common stock	98,495,085	73,326,569	96,230,372	62,906,856
Pre-funded warrants	1,336,026	800,000	1,608,554	800,000
Total	99,831,111	74,126,569	97,838,926	63,706,856

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:

	June 30,	
	2024	2023
Stock options outstanding	7,044,951	4,441,690
RSUs and PSUs outstanding	1,452,123	1,201,500
Warrants to purchase common stock	1,200,034	10,443,527
Conversion feature related to outstanding term loan	590,816	590,816
Total	10,287,924	16,677,533

10. Subsequent Events

In July 2024, pursuant to the terms of the Collaboration Agreement, the Company made a $60.0 million payment to BiBo to initiate the project. Refer to Note 5—*Commitments and Contingencies* above for additional details.

On July 1, 2024, outstanding warrants to purchase 987,500 shares of common stock as of June 30, 2024 were exercised by the warrant holders, resulting in additional cash proceeds of $5.3 million.

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, 2023. 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 metabolic dysfunction-associated steatohepatitis ("MASH"), previously known as nonalcoholic steatohepatitis, and for the treatment of severe hypertriglyceridemia ("SHTG").

MASH is a severe form of metabolic dysfunction-associated steatotic liver disease, previously known as nonalcoholic fatty liver disease, and is characterized by inflammation and fibrosis in the liver that can progress to cirrhosis, liver failure, hepatocellular carcinoma and death. In 2020 and 2022, we presented positive topline results from our Phase 1b/2a trial of pegozafermin in MASH patients, which have informed the advancement of our subsequent clinical strategy in MASH. In our Phase 2b ENLIVEN trial of pegozafermin in MASH patients, patients received weekly doses or an every-two-week dose 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. We reported topline 24 week 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 definitions on endpoints for accelerated approval in non-cirrhotic MASH patients. In September 2023, the FDA granted Breakthrough Therapy Designation to pegozafermin in patients with MASH. In addition, in March 2024, the EMA granted Priority Medicines ("PRIME") designation to pegozafermin in patients with MASH, based on clinical data from the Phase 2b ENLIVEN trial. In November 2023, we announced positive topline data from the blinded extension phase of our Phase 2b ENLIVEN trial at 48 weeks. Both the 44 mg every-two-week and 30 mg weekly dose groups demonstrated statistically significant improvements across Non-Invasive Tests ("NITs") representing key markers of liver health. The benefits observed at week 48 represented by NITs were consistent with the histology and NITs results observed at week 24, indicating sustained benefits over time.

In the fourth quarter of 2023, we held successful end-of-Phase 2 meetings with the FDA, supporting the advancement of pegozafermin into a Phase 3 program and future biologics license application ("BLA") filing. We received scientific advice from the European Medicines Agency ("EMA"), which generally aligned with the feedback from the FDA.

The Phase 3 ENLIGHTEN program includes two Phase 3 clinical trials evaluating patients with MASH: (i) ENLIGHTEN-Fibrosis, in patients with fibrosis stage F2-F3 (F2-F3), which we initiated in the first quarter of 2024 and (ii) ENLIGHTEN-Cirrhosis, in patients with compensated cirrhosis (F4), which we initiated in the second quarter of 2024.

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 MASH, 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 received feedback from the FDA supporting the advancement of pegozafermin and initiated our Phase 3 ENTRUST trial, the first of two recommended Phase 3 trials, in the second quarter of 2023. We expect to report topline results from our Phase 3 ENTRUST trial in 2025. Safety data from the ongoing SHTG Phase 3 program is expected to support the safety database requirements for MASH and vice versa.

In April 2024, we entered into a collaboration agreement (the "Collaboration Agreement") with BiBo Biopharma Engineering Co., Ltd., pursuant to which BiBo will construct a production facility specifically designed to supply us with pegozafermin for commercialization, if approved (the "Production Facility"). Pursuant to the Collaboration Agreement, BiBo will build the Production Facility at BiBo's facility in the Lin-gang Special Area of China (Shanghai) Pilot Free Trade Zone to manufacture the bulk active ingredient (the "Drug Substance") required to produce pegozafermin for commercial supply. The platform is expected to provide us with manufacturing capacity to meet our commercial needs based on current projections.

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. We currently have contractual relationships with Northway Biotechpharma ("BTPH") and BiBo pursuant to which they supply us with pegozafermin for our clinical trials.

We have incurred net losses since our inception. Our net losses for the six months ended June 30, 2024 and 2023 were $99.7 million and $67.2 million, respectively. As of June 30, 2024, we had an accumulated deficit of $557.1 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.

Based on our current operating plan, we expect our existing cash, cash equivalents and marketable securities of $531.4 million as of June 30, 2024 will be sufficient to fund our operations 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").

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 based on invoices and statements received from our external service providers and by monitoring the status of their activities. 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 payment becomes probable and reasonably estimable, which is generally upon achievement of the milestone.

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, employee benefits and stock-based compensation for personnel in executive, finance, commercial 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 consists of interest expense, accretion of final payment fees and amortization of deferred debt issuance costs related to our term loan facility, and loss on extinguishment of debt.

Interest Income and Other, Net

Interest income and other, net primarily consists of interest income including accretion of discount on marketable securities, offset by amortization of premium on marketable securities.

Results of Operations

Three Months Ended June 30, 2024 and 2023

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

	Three months ended June 30,		
	2024	2023	Change
Operating expenses:			
Research and development	$ 44,865	$ 34,915	$ 9,950
General and administrative	8,571	7,214	1,357
Total operating expenses	53,436	42,129	11,307
Loss from operations	(53,436)	(42,129)	(11,307)
Interest expense	(874)	(894)	20
Interest income and other, net	6,473	4,630	1,843
Net loss before tax	$ (47,837)	$ (38,393)	$ (9,444)

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 June 30,		
	2024	2023	Change
Contract manufacturing	$ 17,018	$ 15,229	$ 1,789
Clinical development	18,949	14,088	4,861
Personnel-related expenses	7,847	5,289	2,558
Other expenses	1,051	309	742
Total research and development expenses	$ 44,865	$ 34,915	$ 9,950

Research and development expenses increased by $10.0 million for the three months ended June 30, 2024 compared to the same period in 2023. The change in research and development expenses was primarily attributable to increases in clinical development costs of $4.9 million as we initiated two Phase 3 clinical trials, ENLIGHTEN-Fibrosis and ENLIGHTEN-Cirrhosis, and contract manufacturing costs of $1.8 million related to manufacturing and scale-up activities. Also contributing to the change was an increase in personnel-related expenses of $2.6 million including stock-based compensation driven by higher headcount.

General and Administrative Expenses

General and administrative expenses increased by $1.4 million for the three months ended June 30, 2024 compared to the same period in 2023. The change in general and administrative expenses was primarily attributable to an increase of $1.2 million in personnel-related expenses including stock-based compensation driven by higher headcount.

Interest Expense

Interest expense remained flat for the three months ended June 30, 2024 compared to the same period in 2023 as our term loan provides for interest-only payments until February 1, 2025.

Interest Income and Other, Net

Interest income and other, net increased by $1.8 million for the three months ended June 30, 2024 compared to the same period in 2023. The increase was related to a change in market interest rates, as well as an increase in the average invested balances compared to the same period in 2023.

Six Months Ended June 30, 2024 and 2023

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

	Six months ended June 30,		
	2024	2023	Change
Operating expenses:			
Research and development	$ 92,293	$ 57,221	$ 35,072
General and administrative	18,420	13,432	4,988
Total operating expenses	110,713	70,653	40,060
Loss from operations	(110,713)	(70,653)	(40,060)
Interest expense	(1,737)	(2,969)	1,232
Interest income and other, net	13,029	6,393	6,636
Net loss before tax	$ (99,421)	$ (67,229)	$ (32,192)

Research and Development Expenses

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

	Six months ended June 30,		
	2024	2023	Change
Contract manufacturing	$ 38,369	$ 23,135	$ 15,234
Clinical development	36,873	23,054	13,819
Personnel-related expenses	15,580	10,315	5,265
Other expenses	1,471	717	754
Total research and development expenses	$ 92,293	$ 57,221	$ 35,072

Research and development expenses increased by $35.1 million for the six months ended June 30, 2024 compared to the same period in 2023. The change in research and development expenses was primarily attributable to increases in clinical development costs of $13.8 million as we initiated two Phase 3 clinical trials, ENLIGHTEN-Fibrosis and ENLIGHTEN-Cirrhosis, and contract manufacturing costs of $15.2 million related to manufacturing and scale-up activities. Also contributing to the change was an increase in personnel-related expenses of $5.3 million including stock-based compensation driven by higher headcount.

General and Administrative Expenses

General and administrative expenses increased by $5.0 million for the six months ended June 30, 2024 compared to the same period in 2023. The change in general and administrative expenses was primarily attributable to an increase of $2.7 million in personnel-related expenses including stock-based compensation driven by higher headcount and an increase of $2.3 million in professional fees.

Interest Expense

Interest expense decreased by $1.2 million for the six months ended June 30, 2024 compared to the same period in 2023. The decrease was attributable to a $1.2 million loss on extinguishment of debt recognized in the prior year period.

Interest Income and Other, Net

Interest income and other, net increased by $6.6 million for the six months ended June 30, 2024 compared to the same period in 2023. The increase was related to a change in market interest rates, as well as an increase in the average invested balances compared to the same period in 2023.

Liquidity and Capital Resources

To date, we have incurred significant net losses and negative cash flows from operations. As of June 30, 2024, we had cash, cash equivalents and marketable securities of $531.4 million and an accumulated deficit of $557.1 million.

Sources of Liquidity

At-the-Market ("ATM") Offerings

In March 2021, we entered into an ATM sales agreement (as amended, the "Sales Agreement") with Leerink Partners LLC and Cantor Fitzgerald & Co. (the "Sales Agents") pursuant to which we may offer and sell up to $75.0 million of shares of our common stock (the "2021 ATM Facility") from time to time pursuant to an effective registration statement. The Sales Agents are entitled to compensation at a commission of up to 3.0% of the aggregate gross sales price per share sold under the Sales Agreement. In February 2023, we entered into an amendment to the Sales Agreement, establishing a new ATM facility with an aggregate offering amount of up to $150.0 million of shares of our common stock (the "2023 ATM Facility") pursuant to an effective registration statement.

During the six months ended June 30, 2023, we sold 2,168,539 shares of our common stock under our 2021 ATM Facility and 2023 ATM Facility and received net proceeds of $37.1 million.

During the six months ended June 30, 2024, we sold 1,396,888 shares of our common stock under the 2023 ATM Facility resulting in net proceeds of $21.0 million. However, there were no sales under the 2023 ATM Facility for the three months ended June 30, 2024. As of June 30, 2024, there was $104.4 million remaining for future sales under the 2023 ATM Facility.

Underwritten Public Offerings

In March 2023, we completed an underwritten public offering of our common stock and raised net proceeds of $296.8 million, after deducting underwriting discounts and commissions of $19.0 million and other offering costs of $0.5 million.

In December 2023, we completed an underwritten public offering of our common stock and pre-funded warrants to purchase shares of our common stock and raised net proceeds of $161.8 million, after deducting underwriting discounts and commissions of $10.4 million and other offering costs of $0.4 million.

Exercises of Common Stock Warrants

Warrants to purchase 2,927,570 shares of common stock were exercised during the six months ended June 30, 2023, generating $15.6 million in cash proceeds.

Warrants to purchase 9,192,289 shares of common stock were exercised during the six months ended June 30, 2024, generating $48.9 million in cash proceeds. Of this amount, $19.4 million was received after June 30, 2024, and recorded as a receivable on the balance sheet as of that date. The remaining warrants to purchase 987,500 shares of common stock as of June 30, 2024 were exercised on July 1, 2024, resulting in additional cash proceeds of $5.3 million.

Term Loan Facility

In January 2023, we entered into a Loan and Security Agreement (the "Loan Agreement") with the lender parties thereto (the "Lenders"), K2 HealthVentures LLC as administrative agent and Ankura Trust Company, LLC as collateral agent. The Loan Agreement provides for up to $100.0 million in aggregate principal in term loans, consisting of an initial tranche of $25.0 million that was funded at closing, second and third tranches of $15.0 million and $10.0 million, respectively, that may be funded upon the achievement of certain time-based, clinical and regulatory milestones, and a fourth tranche of up to $50.0 million that may be funded upon discretionary approval by the Lenders. As of June 30, 2024, the second and third tranches expired undrawn and the fourth tranche remains available at the sole discretion of the Lenders.

Funding Requirements

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, as well as the funding of a portion of the construction of the Production Facility. 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 current operating plan, we expect our existing cash, cash equivalents and marketable securities of $531.4 million as of June 30, 2024 will be sufficient to fund our operations 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):

	Six months ended June 30,	
	2024	2023
Net cash (used in) provided by		
Operating activities	$ (100,884)	$ (64,532)
Investing activities	(52,049)	(97,702)
Financing activities	48,990	352,420
Net change in cash and cash equivalents	$ (103,943)	$ 190,186

Operating Activities

For the six months ended June 30, 2024, net cash used in operating activities of $100.9 million reflects a net loss of $99.7 million and a net change of $6.8 million in operating assets and liabilities, partially offset by aggregate noncash charges of $5.6 million. Noncash charges primarily included stock-based compensation expense of $10.2 million, noncash operating lease expense of $0.4 million and amortization of debt discount and accretion of deferred debt costs of $0.3 million, offset in part by net accretion of discounts on investments in marketable securities of $5.4 million. The net change in operating assets and liabilities used cash of $6.8 million and was primarily due to an increase in prepaid and other assets of $14.3 million as we made prepayments related to the initiation of two Phase 3 clinical trials, ENLIGHTEN-Fibrosis and ENLIGHTEN-Cirrhosis, partially offset by a net increase in accounts payable and accrued expenses of $7.6 million driven by timing of payments made and an increase in services rendered by contract research organizations and contract manufacturing organizations in connection with the Phase 3 clinical trials.

For the six months ended June 30, 2023, net cash used in operating activities of $64.5 million reflects a net loss of $67.2 million and a net change of $4.6 million in operating assets and liabilities, partially offset by aggregate noncash charges of $7.3 million. Noncash charges primarily included stock-based compensation expense of $7.7 million, a loss on debt extinguishment of $1.2 million related to our prior term loan, amortization of debt discount and accretion of the final payment fee related to our new term loan facility of $0.5 million, offset in part by net accretion of discounts on investments in marketable securities of $2.2 million. The change in our operating assets and liabilities was primarily attributable to a $5.8 million increase in prepaid and other assets due to higher contract manufacturing costs related to manufacturing and scale-up related spend and a net increase of $1.3 million in accounts payable and accrued expenses due to the timing of payments.

Investing Activities

For the six months ended June 30, 2024, net cash used in investing activities was $52.0 million, which consisted of $230.1 million in purchases of marketable securities, offset by $178.1 million in proceeds from sales and maturities of marketable securities.

For the six months ended June 30, 2023, net cash used in investing activities was $97.7 million, which consisted of $180.6 million in purchases of marketable securities, offset by $82.9 million in proceeds from sales and maturities of marketable securities.

Financing Activities

For the six months ended June 30, 2024, net cash provided by financing activities was $49.0 million, which primarily consisted of proceeds of $29.5 million from the exercise of common stock warrants and net proceeds of $21.1 million pursuant to the sale of our common stock under our 2023 ATM Facility. This was offset in part by payments for taxes of $1.7 million related to net share settlement upon vesting of restricted stock units.

For the six months ended June 30, 2023, net cash provided by financing activities was $352.4 million, which primarily consisted of net proceeds of $296.8 million from the sale of common stock in public offerings, net proceeds of $37.1 million pursuant to the sale of common stock under our 2021 ATM Facility and 2023 ATM Facility, net proceeds of $24.4 million from our term loan facility pursuant to our Loan Agreement, and proceeds of $15.6 million from the exercise of common stock warrants. This was offset in part by the repayment in full of $21.4 million on our prior term loan, including the final payment and prepayment fees.

Contractual Obligations and Commitments

Debt Obligations

As of June 30, 2024, the outstanding debt balance of $25.0 million under our Loan Agreement is scheduled to mature on January 1, 2027 and provides for interest-only payments until February 1, 2025. For additional information regarding the terms of the

debt and interest payable, see Note 6 to our unaudited condensed consolidated financial statements under Part I, Item 1 of this Quarterly Report on Form 10-Q.

Asset Transfer and License Agreement with Teva Pharmaceutical Industries Ltd

In April 2018, we concurrently entered into two Asset Transfer and License Agreements (the "Teva Agreements") with Teva Pharmaceutical Industries Ltd ("Teva") under which we 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, under which we are not actively developing product candidates, and do not have any current plans to do so. Pursuant to the Teva Agreements, we paid Teva an initial nonrefundable upfront payment of $6.0 million. Under each license agreement, we are required to pay Teva $2.5 million upon the achievement of a specified clinical development milestone, and additional payments totaling up to $65.0 million upon achievement of certain commercial milestones. Each milestone payment shall be payable once, upon the first occurrence of the applicable milestone. We are also 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 us 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 their glycoPEGylated FGF21 program in the event we, or any of our affiliates or sublicensees, challenges any of the Teva patents licensed to us, and the challenge is not withdrawn within 30 days of written notice from Teva.

In the fourth quarter of 2023, we made a $2.5 million milestone payment to Teva following the achievement of a clinical development milestone under the FGF21 program in SHTG. As of June 30, 2024, the timing and likelihood of achieving any remaining milestones are uncertain. Milestone payment obligations will be recognized when payment becomes probable and reasonably estimable, which is generally upon achievement of the applicable milestone.

Production Facility Funding Commitments

On April 4, 2024, we entered into the Collaboration Agreement. Pursuant to the Collaboration Agreement, BiBo will build the Production Facility at BiBo's facility in the Lin-gang Special Area of China (Shanghai) Pilot Free Trade Zone to manufacture the Drug Substance required to produce pegozafermin for commercial supply. The platform is expected to provide us with manufacturing capacity to meet our commercial needs based on current projections. Under the Collaboration Agreement, we are required to pay BiBo an aggregate of $135.0 million toward the construction of the Production Facility (collectively, the "Payment"), of which $60.0 million was paid in July 2024 to initiate the project. The remainder of the Payment will become payable upon achievement of certain specified milestones, of which up to an additional $61.5 million of the Payment could become payable within the next 12 months. If the actual costs of the Production Facility are substantially greater than the estimated budget, the parties will negotiate a means of allocating such cost overruns.

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, 2023.

Recent Accounting Pronouncements

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

There have been no material changes in market risk from the information provided in Part II, Item 7A "Quantitative and Qualitative Disclosures About Market Risk," in our Annual Report on Form 10-K for the year ended December 31, 2023.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As of June 30, 2024, 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 Securities Exchange Act of 1934, as amended (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 our management, including our 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 June 30, 2024 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) during the quarter ended June 30, 2024 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.
- 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 MASH 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 we do.
- Unstable market and economic conditions, inflation, increases in interest rates, natural disasters, public health crises, political crises, geopolitical events, such as the crisis in Ukraine and Israel, or other macroeconomic conditions, may have serious adverse consequences on our business and financial condition.
- Our 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.
- 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 MASH 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 MASH 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 MASH or SHTG, pegozafermin will likely compete with products that may reach approval for the treatment of MASH prior to pegozafermin, products that are currently approved for the treatment of SHTG and the off-label use of currently marketed products for MASH 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 limited direct experience as a company in conducting pivotal trials required to obtain regulatory approval and we expect that the Phase 3 trials we are conducting will be more expansive and complex than the trials we have conducted to date. We may be unable to conduct clinical trials at preferred sites, enlist clinical investigators, enroll sufficient numbers of participants, procure sufficient drug 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 an ongoing 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 those clinical trials may be subject to substantial variability, including the inherent variability associated with biopsies in MASH 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 Phase 3 clinical trials of, seek regulatory approval for pegozafermin and prepare for commercialization of pegozafermin. We believe our existing cash, cash equivalents and marketable securities will be sufficient to 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 above) and proceeds from our 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, 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 to accompanying unaudited condensed consolidated financial statements.

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 pegozafermin 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 MASH, which can currently only be definitively diagnosed through a liver biopsy, and identifying SHTG patients. Specifically, identifying patients most likely to meet MASH enrollment criteria on biopsy is an ongoing challenge, with existing clinical indicators lacking both sensitivity and specificity. As a result, MASH trials often suffer from high levels of screen failure following central review of the baseline liver biopsy, which can lead to lower enrollment. In addition, we do not have experience enrolling patients with cirrhosis and such enrollment make take longer than we expect. As a result of such difficulties and the significant competition for recruiting MASH 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. Further, in the event one of our competitors receives regulatory approval for their product candidate before we do, we may have difficulty enrolling patients if they choose to take an approved drug, rather than enroll in a clinical trial. 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 MASH 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 contractual relationships with BTPH and BiBo pursuant to which they supply us with pegozafermin for our clinical trials. If there should be any disruption in our supply arrangement with BTPH or BiBo, including any adverse events affecting BTPH or BiBo, 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 our large Phase 3 clinical trials and to commercialize pegozafermin. Accordingly, in April 2024, we entered into the Collaboration Agreement with BiBo, pursuant to which BiBo will construct the Production Facility in China specifically designed to produce pegozafermin for commercial supply, however, we cannot guarantee that BiBo will be able to complete construction of the Production Facility and scale up and produce the quantities we would require to commercialize pegozafermin.

Pursuant to the Collaboration Agreement, BiBo will build the Production Facility at BiBo's facility in the Lin-gang Special Area of China (Shanghai) Pilot Free Trade Zone to manufacture the Drug Substance required to produce pegozafermin for commercial supply. The platform is expected to provide us with manufacturing capacity to meet our commercial needs based on current projections. Under the Collaboration Agreement, we are required to pay BiBo an aggregate of $135.0 million toward the construction of the Production Facility, of which $60.0 million was paid in July 2024 to initiate the project. The remainder of the Payment will become payable upon achievement of certain specified milestones, of which up to an additional $61.5 million of the Payment could become payable within the next 12 months. If the actual costs of the Production Facility are substantially greater than the estimated budget, the parties will negotiate a means of allocating such cost overruns. We may be ultimately responsible for a substantial portion of such overruns and it could negatively impact our financial condition and results of operations. We cannot guarantee that BiBo will complete or make operational the Production Facility in a timely manner or at all.

We expect to continue to rely on third-party manufacturers and suppliers, including BiBo, if we receive regulatory approval for pegozafermin or any other product candidates. The terms of our commercial supply of pegozafermin may not be favorable to us and could have a material impact on our results of operations.

Under the terms of the Collaboration Agreement, we may be ultimately responsible for a substantial portion of cost overruns and it could negatively impact our financial condition and results of operations. See further discussion in Part I, Item 2 "Management's Discussion and Analysis of Financial Condition and Results of Operations—Contractual Obligations and Commitments." We cannot guarantee that BiBo will complete or make operational the Production Facility in a timely manner or at all.

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 any of our third-party manufacturers or vendors, including our fill-finish vendor, are not able to fulfill their supply or manufacturing obligations in a timely manner, our clinical trials may be delayed. In addition, 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.

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 current good manufacturing practices ("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 ongoing war in Ukraine and the acts of piracy and military unrest in the Red Sea, 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 legislation or policies of the United States, including the proposed BIOSECURE bill, or Chinese governments, political unrest or unstable economic conditions in China. These and other risks associated with our collaboration with BiBo, based in China, may materially adversely affect our ability to attain or maintain quantities of pegozafermin needed for commercialization, if approved. In addition, we have agreed to arbitrate claims related to the Collaboration Agreement with BiBo in Shanghai under the laws of the People's Republic of China, which may limit our ability to enforce our contractual rights against BiBo. 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 or BiBo, which are our primary manufacturing sources 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 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 MASH 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 MASH. Although there are guidelines issued by the FDA and comparable foreign regulatory authorities for the development of drugs for the treatment of MASH, 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 MASH therapies, we expect that the path for regulatory approval for MASH 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 MASH therapies following communications from the FDA and comparable foreign regulatory authorities. We currently do not know the impact, if any, that these setbacks could have on the path for regulatory approval for MASH therapies generally or for pegozafermin. In addition, if one of the other companies receives regulatory approval for its MASH therapy before we do, such approval could impact our development of pegozafermin. We may have difficulty enrolling patients in our Phase 3 program for patients with MASH if patients choose to take an approved drug, rather than enroll in a clinical trial. In addition, we expect that the first therapy that is approved for the treatment of MASH will establish initial pricing and labelling expectations, which could impact our pricing and labelling if pegozafermin receives marketing 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 or comparable foreign regulatory authorities require additional evidence in addition to our ongoing Phase 3 program in SHTG 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 and comparable foreign regulatory authorities 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 MASH 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 MASH. 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 third-party manufacturers 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 we do.

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 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 MASH 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 MASH and SHTG, will increase. We may also face competition indirectly from companies developing therapies like the incretins to treat obesity and/or Type 2 diabetes. Some incretin-based therapies are also being developed for the treatment of MASH.

There are numerous currently approved therapies for treating diseases other than MASH and some of these currently approved therapies may exert effects that could be similar to pegozafermin in MASH. 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, political crises, geopolitical events, such as the crisis in Ukraine and Israel, 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, public health crises have 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 conflicts between Russia and Ukraine and between Israel and surrounding areas 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 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 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 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 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 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 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 Loan Agreement. Even if we are able to repay such accelerated debt amount under the 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 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. If these third parties do not successfully perform and comply with regulatory requirements, we may not be able to successfully complete clinical development, obtain regulatory approval, or commercialize our product candidates and our business could be substantially harmed.

We 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 and to manufacture clinical and commercial scale quantities of our drug substance and drug product and expect to depend on these third parties 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.

In addition, we have relied upon and plan to continue to rely upon third party contract research organizations ("CROs") to conduct, monitor, and manage preclinical and clinical programs. We rely on these parties for execution of clinical trials, and we manage and control only some aspects of their activities. We remain responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs and other vendors are required to comply with all applicable laws, regulations, and guidelines, including those required by the FDA, EMA and comparable foreign regulatory authorities for all of our product candidates in clinical development. If we or any of our CROs or vendors fail to comply with applicable and evolving laws, regulations, and guidelines, the results generated in our clinical trials may be deemed insufficient or unreliable, and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications.

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 MASH 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 information technology, 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 MASH, and while there are guidelines issued by the FDA for the development of drugs for the treatment of MASH, 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 MASH or SHTG.

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. Based on guidelines issued by the FDA for the development of drugs for the treatment of MASH, 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 MASH. Under the Food and Drug Omnibus Reform Act of 2022, the FDA may require, as appropriate, that such studies be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval. 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 have received Breakthrough Therapy designation for pegozafermin in MASH from the FDA and PRIME designation for pegozafermin in MASH from the EMA, but such designation may not actually lead to a faster development or regulatory review or approval process, and does not increase the likelihood that pegozafermin will receive marketing approval. In addition, we may seek Breakthrough Therapy, Fast Track or PRIME designation for other indications or future product candidates, but we might not receive such designation.

In September 2023, we received Breakthrough Therapy designation for pegozafermin in MASH from the FDA. However, the receipt of Breakthrough Therapy designation for pegozafermin in MASH may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA.

In March 2024, the EMA granted PRIME status to pegozafermin in patients with MASH, and, in the future, we may seek Fast Track designation or PRIME designation for our other product candidates. If a drug or biologic is intended for the treatment of a serious or life-threatening condition and the drug or biologic demonstrates the potential to address unmet medical needs for this condition, the sponsor may apply for Fast Track designation. The sponsor of a Fast Track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once a BLA is submitted, the application may be eligible for priority review. A Fast Track product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA. The FDA has broad discretion whether or not to grant this designation.

PRIME is a program launched by the EMA to enhance support for research on and development of medicines that have demonstrated preliminary safety and efficacy and thus the potential to target a significant unmet medical need and bring a major therapeutic advantage to patients. This regulatory program offers developers of promising medicines enhanced interaction and early dialogue with the EMA and is designed to optimize development plans and speed evaluation ensuring these medicines reach patients as early as possible. The EMA has broad discretion whether or not to grant this designation.

In addition, we may seek Breakthrough Therapy designation, Fast Track designation or PRIME designation for other indications or future product candidates. Even if we believe a particular product candidate is eligible for these designations, we cannot assure you that the FDA, EMA or similar regulatory agency would decide to grant them. Breakthrough Therapy, Fast Track and PRIME designations may not result in a faster development process, review or approval compared to conventional FDA or EMA procedures, respectively. In addition, even though pegozafermin is designated as a Breakthrough Therapy in MASH, the FDA may later decide that the product candidate no longer meets the conditions for designation and the designation may be rescinded. The Breakthrough Therapy, Fast Track and PRIME designations do not assure ultimate regulatory approval by the FDA or the EMA. Many drugs and biologics that have received Breakthrough Therapy, Fast Track or PRIME designation have failed to obtain approval. See Part I, Item 1. "Business—Expedited Programs for Serious Conditions" in our Annual Report on Form 10-K.

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.

We expect the product candidates we develop will be regulated as biologics, and therefore they may be subject to competition sooner than anticipated.

The BPCIA was enacted as part of the Affordable Care Act to establish an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an approved biologic. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the reference product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when processes intended to implement BPCIA may be fully adopted by the FDA, any of these processes could have a material adverse effect on the future commercial prospects for our biological products.

We believe that any of the product candidates we develop that is approved in the United States as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider the subject product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of the reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

In addition, the first biologic product submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product has exclusivity against other biologics submitted under the abbreviated approval pathway for the lesser of (i) one year after the first commercial marketing, (ii) 18 months after approval if there is no legal challenge, (iii) 18 months after the resolution in the applicant's favor of a lawsuit challenging the biologics' patents if an application has been submitted, or (iv) 42 months after the application has been approved if a lawsuit is ongoing within the 42-month period. The approval of a biologic product biosimilar to one of our product candidates could have a material adverse impact on our business as it may be significantly less costly to bring to market and may be priced significantly lower than our product candidates.

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. 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 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 fluctuate significantly and results announced by us and our collaborators or competitors could cause our stock price to decline, 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. Our stock price could fluctuate significantly due to various factors in addition to those otherwise described in this Quarterly Report on Form 10-Q, including those described in these "Risk Factors," including business developments announced by us and by our collaborators and competitors, or as a result of market trends and daily trading volume. The business developments that could affect our stock price include announcements or disclosures from competitors in the same class or category, new collaborations, clinical advancement, commercial launch or discontinuation of product candidates in the same class or category and regulatory approvals for our product candidates or product candidates in the same class or category. Our stock price could also fluctuate significantly with the level of overall investment interest in small-cap biotechnology stocks or for other reasons unrelated to our business. 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. 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 Plan and 2023 Inducement 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.

Certain of our executive officers and directors have entered or may enter into Rule 10b5-1 plans providing for sales of shares of our common stock from time to time. Under a Rule 10b5-1 plan, a broker executes trades pursuant to parameters established by the executive officer or director when entering into the plan, without further direction from the executive officer or director. A Rule 10b5-1 plan may be amended or terminated in some circumstances. Our executive officers and directors also may buy or sell additional shares outside of a Rule 10b5-1 plan when they are not in possession of material nonpublic information.

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 above), 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 June 30, 2024, 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. If we are unable to maintain effective internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our stock may decrease.

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.

The Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act") requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, we are required to perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting, as required by Section 404(a) of the Sarbanes-Oxley Act. Section 404(b) of the Sarbanes-Oxley Act ("Section 404") also requires our independent auditors to express an opinion on our internal control over financial reporting. Ensuring that we have adequate internal controls in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that will need to be evaluated frequently. If we are unable to maintain effective internal control over financial reporting, we may not have adequate, accurate or timely financial information, our independent registered public accounting firm may issue a report that is adverse, and we may be unable to meet our reporting obligations as a public company or comply with the requirements of the SEC or Section 404. This could result in a restatement of our financial statements, the imposition of sanctions, including the inability of registered broker dealers to make a market in our common stock, or investigation by regulatory authorities. Any such action or other negative results caused by our inability to meet our reporting requirements or comply with legal and regulatory requirements or by disclosure of an accounting, reporting or control issue could adversely affect the trading price of our securities and our business. Material weaknesses in our internal control over financial reporting could also reduce our ability to obtain financing or could increase the cost of any financing we obtain. If we are not able to comply with the requirements of Section 404 or if we or our independent registered public accounting firm are unable to express an opinion as to the effectiveness of our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC, or other regulatory authorities, which would require additional financial and management resources.

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. If we are required to pay any tax assessment, it could impact our net operating loss carryforwards, as well as our results of operations and financial condition.

As of December 31, 2023, we had U.S. federal and state net operating loss ("NOL") carryforwards of $195.0 million and $302.8 million, respectively, which may be available to offset future taxable income. As of December 31, 2023, we also had gross federal tax credits of $7.5 million, which may be used to offset future tax liabilities. Certain NOLs and tax credit carryforwards will begin to expire in 2039. 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, in December 2023, the Israeli Tax Authorities issued a tax assessment claiming our 2019 reorganization and intercompany transaction to license the intellectual property rights from our subsidiary in Israel should be treated as a sale of intellectual property rights. If this matter is litigated and the Israeli Tax Authorities are able to successfully sustain their position and we are required to pay a tax assessment, it could impact our NOL carryforwards and our results of operations and financial condition could be materially and adversely affected. See further discussion in Part II, Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Estimates—Income Taxes" and in Note 9 to our consolidated financial statements appearing under Part II, Item 8 of our Annual Report on Form 10-K for the year ended December 31, 2023.

Litigation costs and the outcome of litigation could have a material adverse effect on our business.

From time to time we may be subject to litigation claims through the ordinary course of our business operations regarding, but not limited to, securities litigation, employment matters, security of patient and employee personal information, contractual relations with collaborators and licensors and intellectual property rights. Litigation to defend ourselves against claims by third parties, or to enforce any rights that we may have against third parties, could result in substantial costs and diversion of our resources, causing a material adverse effect on our business, financial condition, results of operations or cash flows.

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.

Rule 10b5-1 Trading Plans

On June 10, 2024, Rohan Palekar, Chief Executive Officer and a member of the Board of Directors of the Company, terminated a Rule 10b5-1 trading plan, which was previously adopted on July 5, 2023 and scheduled to expire on July 5, 2024. The plan was terminated at a time when Mr. Palekar was not in possession of material, non-public information about the Company. The plan provided for the potential sale of up to 228,490 shares of common stock held by Mr. Palekar.

None of the Company's other directors or Section 16 officers adopted or terminated any Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement (in each case as defined in Item 408(a) of Regulation S-K) during the fiscal quarter ended June 30, 2024.

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	Certificate of Amendment to the Second Amended and Restated Certificate of Incorporation of 89bio, Inc. (filed with the SEC as Exhibit 3.1 to the Company's Form 8-K filed on June 9, 2023).
3.3	Third Amended and Restated Bylaws of the Company (filed with the SEC as Exhibit 3.1 to the Company's Current Report on Form 8-K filed on November 14, 2023).
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 to Purchase Common Stock for Silicon Valley Bank (filed with the SEC as Exhibit 4.1 to the Company's Current Report on Form 8-K filed on June 4, 2021).
4.4	Form of Warrant (filed with the SEC as Exhibit 4.1 to the Company's Form 8-K filed on July 1, 2022).
4.5	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).
4.6	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).
4.7	Form of Pre-Funded Warrant (filed with the SEC as Exhibit 4.1 to the Company's Current Report on Form 8-K filed on December 8, 2023).
10.1*†	Collaboration Agreement, dated as of April 4, 2024, by and between the Company and BiBo Biopharma Engineering Co., Ltd.
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 - the instance document does not appear in the Interactive Data File as its XBRL tags are embedded within the Inline XBRL document
101.SCH*	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
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.
# 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.
† Certain portions of this exhibit were redacted by means of marking such portions with asterisks because the identified portions are (i) not material and (ii) treated as private or confidential by the Company.

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: August 5, 2024

By: /s/ Rohan Palekar

Rohan Palekar

Chief Executive Officer

(principal executive officer)

Date: August 5, 2024

By: /s/ Ryan Martins

Ryan Martins

Chief Financial Officer

(principal financial and accounting officer)

[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE IT IS BOTH (i) NOT MATERIAL AND (ii) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

Exhibit 10.1

DATED: April 4th, 2024

BIBO BIOPHARMA ENGINEERING CO., LTD.

And

89BIO INC.

F-05-MC PROJECT COLLABORATION AGREEMENT

[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE IT IS BOTH (i) NOT MATERIAL AND (ii) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

This Collaboration Agreement (this "**Agreement**") in respect of the Collaboration on the F-05-MC Project (the "**Collaboration**") is made and entered into as of April 4th, 2024 (the "**Effective Date**"):

BY AND BETWEEN:

BIBO BIOPHARMA ENGINEERING CO., LTD. ("**BiBo**"), a company incorporated under the law of P. R. China, having its registered office at Building 6, 22, 28, No. 356 Zhengbo Road, China (Shanghai) Pilot Free Trade Zone LIN-GANG Special Area, 201413, P. R. China,

and

89BIO INC. (hereinafter referred to as "**89bio**"), a company incorporated under the laws of Delaware, USA, having a principal place of business at 142 Sansome Street. 2nd Floor, San Francisco, CA 94104, USA.

BiBo and **89bio** are hereinafter collectively referred to as the "**Parties**" and individually as the "**Party**".

WHEREAS:

A. BiBo is a contract development and manufacturing organization (CDMO) company engaged in the business of manufacture and distribution of biologic drugs in China and other countries, and has substantial expertise and goodwill worldwide;

B. 89bio is a pharmaceutical company engaged in the business of developing and commercializing novel pharmaceutical products;

C. 89bio has developed Pegozafermin (*as defined below*) and has worked with BiBo for manufacturing at BiBo's Lingang manufacturing facility;

D. The Parties have executed a Master Service Agreement dated February 10th, 2023, as amended from time to time (the "**MSA**"), pursuant to which the Parties intend to enter into a Work Order (*as defined therein*) pursuant to which BiBo will Manufacture (*as defined below*) the Drug Substance (*as defined below*) for the purpose of Phase III materials and, subsequently, commercial product, at BiBo's Lingang manufacturing facility; and

E. As requested by 89bio, BiBo has proposed a F-05-MC Project collaboration with 89bio to support 89bio's further manufacturing needs with respect to Pegozafermin, as further described herein.

F. **NOW THEREFORE**, in consideration of the mutual covenants and promises set forth herein and other good and valuable consideration, the receipt and legal sufficiency of which are hereby mutually acknowledged, BiBo and 89bio hereby agree as follows:

1. DEFINITIONS AND INTERPRETATIONS

All definitions and interpretations mentioned in this Agreement shall have the meanings as stipulated herein below:

1.1 "**89bio Product**" means the Drug Substance.

1.2 "**Affiliate**" / "**Affiliates**" 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.

1.3 "**Applicable Law(s)**" 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 F-05-MC Production Platform or any aspect thereof or the obligations of BiBo 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) all applicable country and local laws and regulations of the P. R. China, and (C) cGMPs (as defined in Section 1.4 below).

1.4 "**cGMPs**" means current Good Manufacturing Practices, including applicable requirements under the Federal Food, Drug, and Cosmetic Act (FDCA) and regulations 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 and commercial pharmaceutical 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.

1.5 "**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 (which shall be the Confidential Information of both Parties). 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.

1.6 "**Discount**" has the meaning set forth in Section 5.5.1.

1.7 "**Drug Product**" means the finished dosage form of Pegozafermin.

1.8 "**Drug Substance**" means the bulk active ingredient required to produce the Drug Product, in pegylated or non-pegylated form.

1.9 "**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.

1.10 "**Know-How**" means any scientific or technical information, results and data of any type whatsoever, in any tangible or intangible form whatsoever, that is not in the public domain or otherwise publicly known, including, without limitation, discoveries, inventions (whether patentable or not), trade secrets, databases, practices, protocols, regulatory filings, methods, processes, techniques, specifications, formulations, formulae, data (including pharmacological, biological, chemical, toxicological, clinical, analytical, quality control, and stability

data) dosing and target patient information, studies and procedures, and manufacturing process and development information, results and data, whether or not patentable, in each of the foregoing cases to the extent not claimed or disclosed in a patent.

1.11 "**Manufacture**" and "**Manufacturing**" means any steps, processes and activities necessary to produce the 89bio Product or Drug 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 or Drug Product.

1.12 "**Patents**" means: (i) an issued or granted patent (whether to an invention, the industrial design or other patentable intellectual property), including any extension, supplemental protection certificate, registration, confirmation, reissue, reexamination, extension, or renewal thereof; (ii) a pending patent application, including any continuation, divisional, continuation-in-part, request for continued examination, substitute, or provisional application thereof; (iii) all pending or issued counterparts or foreign equivalents of any of the foregoing; (iv) a patent application in preparation; and / or (v) any similar rights in any country worldwide held by either Party.

1.13 "**Payment**" has the meaning set forth in Section 5.3.

1.14 "**Pegozafermin**" means glycoPEGylated human fibroblast growth factor 21 (FGF21) analog.

1.15 "**Pegozafermin Work Order**" has the meaning set forth in Section 5.4.

1.16 "**Regulatory Authority**" / "**Regulatory Authorities**" 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, the FDA, EMA, NMPA and Health Canada involved in regulating any aspect of the conduct, development, Manufacture, market approval, sale, distribution, packaging or use of the F-05-MC Production Platform, the 89bio Product or the Drug Product. The facility of the F-05-MC Production Platform shall comply with regulatory authority of P. R. China with respect to the facility.

1.17 "**Term**" shall have the meaning as described in Section 4.

1.18 "**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. INTELLECTUAL PROPERTY

2.1 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.

2.2 BiBo owns the trademark, Know-How and Patents for the construction of the F-05-MC Production Platform, including but not limited to "PanFlex®".

3. REPRESENTATIONS AND WARRANTIES

3.1 Representations and Warranties by 89bio

89bio represents, warrants and agrees as follows:

3.1.1 Authority

89bio has necessary permissions, approvals and has authority to enter into this Agreement.

3.1.2 Freedom to Contract

89bio has the legal right to enter into this Agreement and perform its obligations hereunder, and no third parties have the right to prevent it from performing the obligations under this Agreement. In addition, the undersigned signatory for 89bio represents and warrants that he / she has been duly authorized to sign this Agreement on behalf of 89bio and he / she further represents that all requisite corporate actions have been taken on the part of 89bio to approve this Agreement and the transactions contemplated under this Agreement.

3.1.3 Due Authorization and Enforceability

89bio is a company duly organized, validly existing and is in good standing under the laws of its jurisdiction of its incorporation, is qualified to do business and is in good standing as a foreign corporation in each jurisdiction in which the conduct of its business or the ownership of its properties requires such qualification and has all requisite power and authority, corporate or otherwise, to conduct its business as now being conducted, to own, lease and operate its properties and to execute, deliver and perform this Agreement. All requisite actions, corporate and otherwise, have been taken to authorize 89bio's execution, delivery and performance of this Agreement. This Agreement is a legal and valid document and shall have binding obligation on 89bio and be enforceable against 89bio in accordance with the terms agreed herein.

3.2 Representations, Warranties and Agreements of BiBo

BiBo represents, warrants and agrees as follows:

3.2.1 Authority

BiBo has necessary permissions, approvals and has authority to enter into this Agreement.

3.2.2 Freedom to Contract

BiBo has the legal right to enter into this Agreement and perform its obligations hereunder, and no third parties have the right to prevent it from performing the obligations under this Agreement. In addition, the undersigned signatory for BiBo represents and warrants that he / she has been duly authorized to sign this Agreement on behalf of BiBo and he / she further represents that all requisite corporate actions have been taken on the part of BiBo to approve this Agreement and the transactions contemplated under this Agreement.

3.2.3 Due Authorization and Enforceability

BiBo is a company duly organized, validly existing and in good standing under the laws of its jurisdiction of incorporation, is qualified to do business and is in good standing as a foreign corporation in each jurisdiction in which the conduct of its business or the ownership of its properties requires such qualification, and has all requisite power and authority, corporate and otherwise, to conduct its business as now being conducted, to own, lease and operate its properties and to execute, deliver and perform this Agreement. All requisite action, corporate and otherwise, has been taken to authorize BiBo's execution, delivery and performance of this Agreement. This Agreement is a legal and valid document and shall have binding obligation on BiBo and be enforceable against BiBo in accordance with the terms agreed herein.

4. TERM

This Agreement shall be effective as of the Effective Date and shall continue to be in force and effect until the F-05-MC Production Platform is completed in construction and operational, unless terminated earlier by either Party in accordance with the terms hereof ("**Term**").

5. THE COLLABORATION

5.1 **F-05-MC Project**. BiBo will execute the F-05-MC Project and will build and make operational a production platform with [***] production lines (collectively, the "**F-05-MC Production Platform**") at BiBo's Lingang Site located at 360 South Zhengbo Road in Lin-gang Special Area of China (Shanghai) Pilot Free Trade Zone (the "**BiBo Site**") (the "**F-05-MC Project**"). BiBo has the full ownership of the F-05-MC Production Platform. [***] The official kickoff of the F-05-MC Project is upon the [***]. BiBo will execute the F-05-MC Project and BiBo will build the F-05-MC Production Platform in accordance with the schedule set forth in Exhibit 1. The F-05-MC Production Platform shall (a) comply with all Applicable Laws, including the cGMP commercial production requirements for the Drug Substance as well as broader production requirements for general purposes, (b) be

substantially the same as, or improved from, the existing production platform at the BiBo Site, (c) be designed and built by personnel who are skilled, experienced and competent in their respective trades or professions, and who are professionally qualified to perform the obligations under this Agreement and (d) be capable of producing the Drug Substance to 89bio's specifications at the [***].

5.2 **Cost**. BiBo and 89bio will split the cost of [***] of the **F-05-MC Project**. 89bio shall make a payment of 135 million U.S. dollars to BiBo (in accordance with Section 5.3). Such estimated cost is calculated based upon the best information available as of [***]. The actual cost of the F-05-MC Project may be varied along project execution. In case the actual cost of the Project become substantially over the budget of [***], an independent cost evaluation organization mutually agreed by both 89bio and BiBo shall be engaged to reassess the cost. Upon confirmation by both parties, the reassessment will take effect, and the overrun portion exceeding the Payment will be jointly resolved through negotiation between both parties.

5.3 **Payment**. 89bio shall make payments of a total amount equal to 135 million U.S. dollars or a greater amount pursuant to and in accordance with Section 5.2 (collectively, the "Payment") to BiBo, which shall be payable in installments upon the achievement of the applicable milestone set forth in Exhibit 1 to the designated bank account by BiBo. The Payment will not be refunded in any case, except as set forth in this Agreement, including through **Special Preferential Arrangements** as described in Section 5.5 or as a consequence of termination through Section 6.6. Upon the full completion of the Payment of 135 million U.S. dollars, production and supply of the Drug Substance under the Pegozafermin Work Order as described in Section 5.4, the Discount described in Section 5.5 and priority scheduling rights as described in Section 5.6 shall apply. In the situation of material overrun as described in Section 5.2, the overrun portion exceeding the Payment will be jointly resolved through negotiation between both parties.

5.4 **Work Order**. The Parties shall enter into a work order or work orders under the MSA [(or Commercial Manufacturing Agreement)] for the production and supply of the Drug Substance by BiBo for 89bio at the F-05-MC Production Platform (the "**Pegozafermin Work Order**"**),** which shall contain the terms set forth in this Section, Section 5.5, Section 5.6 and Section 5.7. Such Pegozafermin Work Order shall be entered into prior to the production of the Drug Substance.

5.5 **Special Preferential Arrangements**.

The Pegozafermin Work Order shall provide that 89bio will receive a discount of [***] (the "**Discount**"**)** of the Drug Substance purchased by 89bio under the Pegozafermin Work Order; provided that the aggregate amount of Discounts obtained by 89bio shall be capped at the amount of the Payment, and 89bio shall not receive the Discount thereafter. If 89bio ceases to pursue or discontinues commercialization of the Drug Product, or 89bio is bankrupted, auctioned, or liquidated, resulting in the termination of the Pegozafermin Work Order, BiBo shall no longer provide 89bio with

further Discount as no more Pegozafermin Drug Substance manufacturing will occur.

5.6 **Forecasting and Priority Right in Production Scheduling**.

5.6.1 The Pegozafermin Work Order shall provide that: (a) 89bio will, on a [***] basis, provide a [***] production plan to BiBo ([***]) (each a "**Forecast**") ; (b) the [***] of each Forecast shall be binding (each, a "**Binding Forecast**") and 89bio shall be responsible for the production fee for such [***] of each Forecast, of which [***] shall be paid prior to such period as a reservation fee, and the remainder shall be paid according to the payment schedule defined in Work Order; and (c) upon BiBo receiving the Binding Forecast and the reservation fee, then, BiBo shall prioritize and lock F-05-MC Production Platform availability for the capacity required by 89bio's Binding Forecast.

5.6.2 Any time upon receiving BiBo other clients' binding request for use of the production lines of the F-05-MC production platform, and this binding request is in conflict with the Forecast of 89bio, BiBo shall provide 89bio a right of first refusal, subject to 89bio shall convert the corresponding slots to a Binding Forecast within [***] and follow the procedure as set forth in Section 5.6.1 to lock the capacity.

5.6.3 Any time upon receiving 89bio's request for additional production demands on the available production lines of the F-05-MC Production Platform, BiBo shall provide 89bio the priority right over any other Bibo clients by following the procedure as set forth in Section 5.6.1;

5.6.4 In the event that the production lines of the F-05-MC production platform are already in the process of production for other clients' product, 89bio shall have the priority over any other client in the condition of not interrupting the current production process.

5.7 **Use of BiBo Existing Manufacturing Line**. In the event 89bio requires a manufacturing line for clinical or commercial production and the F-05-MC Production Platform is not completed and operational, upon 89bio's request, (a) BiBo shall validate BiBo's existing manufacturing line at the BiBo Site for the commercial production of the Drug Substance, in effect validating the existing manufacturing line as [***] under the Agreement. In total, 89bio will be responsible for the validation fee for [***] lines, and if more validation batches are needed, BiBo will cover the extra validation batches fee. 89bio will be responsible for all the cost of raw materials, (b) BiBo shall produce all volumes requested by 89bio for the Drug Substance under the Pegozafermin Work Order on such manufacturing line until the F-05-MC Production Platform is completed and validated.

6. Termination

6.1 **Termination upon material breach by BiBo**. Material breach by BiBo means failure to execute F-05-MC Project under this agreement due to willful misconduct without any other external conditions (such as third-party equipment delays, force majeure, etc.), also excluding reasonable challenges and risk factors during project implementation processes (such as challenges in regulatory certification), resulting in overall project delivery significantly delayed and material impact on the commercial production of the Pegozafermin. In the event of a material breach of this Agreement by BiBo, 89bio may provide written notice of such breach to BiBo, including a description of the breach, and indicating 89bio's intent to terminate this Agreement. BiBo will have [***] after receipt of such notice to cure the breach, provided the breach is capable of being cured. If the breaching Party fails to cure such breach within such [***] period, or if such breach is not susceptible to cure, then 89bio may terminate this Agreement upon notice to BiBo.

6.2 **Termination 89bio Failure to Pay**. If 89bio breaches its obligation to pay the Payment pursuant to this Agreement, and fails to cure such breach within [***] after receipt by 89bio of notice thereof from BiBo referencing this Section and indicating BiBo's intent to terminate this Agreement, then BiBo may terminate this Agreement upon notice to 89bio. In the event that the termination occurs due to 89bio's failure to make the [***] payment of [***], 89bio shall pay BiBo [***] counting since [***] until the termination date.

6.3 **Termination for Bankruptcy**. A Party may terminate this Agreement, effective immediately upon written notice to the other Party, if such other Party files for bankruptcy, is adjudicated bankrupt under insolvency laws, is dissolved or has a receiver appointed for substantially all of its property.

6.4 **Termination for Change in Law**. 89bio may terminate this Agreement upon notice if a change in Applicable Laws or an applicable Regulatory Authority imposes a binding restriction or requirement that makes, or shall make, it impossible or substantially impracticable for 89bio to purchase the Drug Substance from BiBo (including the BIOSECURE Act).

6.5 **Termination with mutual consent**. The Parties may terminate this Agreement at any time with mutual written consent.

6.6 **Consequences of Termination**. In the event of a termination pursuant to Section 6.1 or Section 6.4, BiBo shall pay to 89bio an amount equal to the amount of Payment paid to BiBo as of the effective date of such termination, less [***] incurred for the F-05-MC Project as of the effective date of such termination (the "**Unspent Refund**"). An independent cost evaluation organization mutually agreed upon by both 89bio and BiBo shall be engaged to issue an assessment of the actual reasonable costs incurred as the basis for calculating the Unspent Refund. Costs incurred shall include amounts actually paid and amounts contractually due in the future although not paid at the time; provided that BiBo shall use reasonable efforts to cancel and minimize such amounts to be paid.

7. INDEMNIFICATION

7.1 BiBo Indemnification

BiBo 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, damages, liabilities, expenses and costs, including reasonable legal expense and attorneys' fees, 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) a breach by BiBo of any of its representations, warranties, covenants, agreements or obligations under this Agreement, (b) infringement of the Intellectual Property rights of a third party as a result of BiBo 's performance under this Agreement, (c) noncompliance with Applicable Law, (d) injury or death of a person or loss of or damage to tangible property, in each case, resulting from the acts or omissions (including breach of contract) of BiBo or (e) the negligence, recklessness or willful misconduct of BiBo (or its Affiliates) in the performance of its obligations hereunder.

7.2 89bio Indemnification

89bio hereby agrees to defend, indemnify and hold harmless BiBo, its Affiliates and its and their officers, directors, employees, consultants and agents ("**BiBo Indemnitees**") from and against any and all losses, damages, liabilities, expenses and costs, including reasonable legal expense and attorneys' fees, to which any such BiBo 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 or (b) injury or death of a person or loss of or damage to tangible property, in each case, resulting from the acts or omissions (including breach of contract) of 89bio or (c) the negligence, recklessness or willful misconduct of 89bio (or its Affiliates) in the performance of its obligations hereunder.

8. MISCELLANEOUS

8.1 **Debarment**. BiBo represents that, consistent with Section 306(a) and Section 306(b) of the FDCA (21 U.S.C. § 335a (a) and 335a (b)) and similar regulations of P. R. China, the EU and relevant EU member states, neither it nor any of its Affiliates, nor its or its Affiliates' employees engaged in the performance of services under this Agreement: (i) is or has been debarred, or (ii) has been under indictment for a crime for which a person or entity could be debarred under §335a (or under an equivalent provision of any jurisdiction), or (iii) engaged in any conduct that would reasonably be expected to result in debarment under § 335a or under an equivalent provision under similar regulations of P. R. China, the EU and relevant EU member states. BiBo will not hire any debarred individual to perform services under this Agreement. If, during the term of this Agreement, BiBo

becomes aware of the debarment or threatened debarment (or any indictment or conduct for which a person could be debarred) of BiBo, any of its Affiliates or of any person or entity retained by it then BiBo will notify 89bio as soon as practicable and will promptly withdraw such person(s) from the performance of any services under this Agreement.

8.2 **Application Integrity Policy**. BiBo represents that neither BiBo, nor any BiBo Affiliates who will perform services under this Agreement, nor any of its officers, employees, contractors, or agents acting for BiBo, nor any officers, employees, contractors, or agents acting for any BiBo Affiliates who will perform services under this agreement, have committed or will commit any act, made any statement or failed to make any statement, relating to the Drug Substance of Pegozafermin or the development or Manufacture thereof, that has or would reasonably be expected to provide a basis for FDA to invoke its policy with respect to "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities" set forth in 56 Fed. Reg. 46191 (September 10, 1991) and any amendments thereto, or for any Regulatory Authority to invoke any similar regulations of P. R. China, the EU and relevant EU member states.

8.3 **Disqualification; Exclusion**. BiBo warrants that neither BiBo, nor any BiBo Affiliates who will perform services under this Agreement, nor any of its officers, employees, contractors, or agents acting for BiBo, nor any officers, employees, contractors, or agents acting for any BiBo Affiliates who will perform services under this Agreement, have been suspended, debarred or convicted of any crime or engaged in any conduct that would reasonably be expected to result in (i) disqualification from clinical trials under the FDCA, FDA regulations, or an equivalent provision in any jurisdiction in the U.S., P. R. China, the EU or relevant EU member states, or (ii) exclusion from federal health care programs under 42 U.S.C. Section 1320a-7 or an equivalent provision in any jurisdiction in the U.S., P. R. China, the EU or relevant EU member states.

8.4 **Amendments**

This Agreement will not in any way be modified, changed or amended except by an instrument in writing duly executed by the Parties hereto. This Agreement constitutes the entire agreement between the Parties with respect to the subject matter hereof and supersedes any prior negotiations, understandings or agreements, whether oral or in writing, concerning the subject matter hereof.

8.5 **Governing Law and Dispute Resolution**

8.5.1 This Agreement and any non-contractual obligations arising out of or in connection with the same will be governed by the laws of P. R. China.

8.5.2 If any dispute, controversy, difference or claim arising out of or relating to this Agreement, including the existence, validity, interpretation, performance, breach or termination thereof or any dispute regarding

non-contractual obligations arising out of or relating to it arises between the Parties during the subsistence of this Agreement or thereafter ("**Dispute**"), the Parties shall endeavor to settle the Dispute amicably, within [***] of the first notification of the Dispute by any Party.

8.5.3 If no amicable settlement is reached within [***] of the first notification of the Dispute by any Party, such Dispute shall be referred to and finally resolved by arbitration administered by Shanghai International Economic and Trade Arbitration Commission ("**SHIAC**") in accordance with the SHIAC Rules for the time being in force, which rules are deemed to be incorporated by reference in this Section. The seat of the arbitration shall be Shanghai and the language of the arbitration shall be English.

8.5.4 Notwithstanding anything to the contrary contained in this Section, the Parties shall continue to perform their respective obligations under this Agreement unless such obligation is disputed by any of the Parties.

8.6 **Survival**

The following Sections shall survive post expiry or termination of this Agreement: Section 1 (*Definitions and Interpretations*), Section 2 (*Intellectual Property*), Section 6.6 (*Consequences of Termination*), Section 7 (*Indemnification*) and Section 8 (*Miscellaneous*).

8.7 **Severability**

If any provision of this Agreement is unenforceable or invalid, no other provision shall be affected thereby, and the remaining provisions shall be construed and reformed to the maximum extent possible and continue with the same effect as if such unenforceable or invalid provision was not a part of this Agreement, it being the intent and agreement of the Parties that this Agreement will be deemed to have been amended by modifying such provision to the extent necessary to render it valid, legal and enforceable while preserving its intent or, if such modification is not possible, by substituting therefor another provision that is legal and enforceable and that achieves the same objective.

8.8 **Notices**

8.8.1 Any notice and other communications provided for in this Agreement shall be in writing and shall be first transmitted by facsimile / electronic transmission, and then confirmed by postage or prepaid registered airmail or by internationally recognized courier to the addresses as mentioned below:

If to BiBo:
BIBO BIOPHARMA ENGINEERING CO., LTD.
Address: Room 207, No. 199 Guoshoujing Road, China (Shanghai) Pilot Free Trade Zone, 201203 Shanghai, P. R. China

For attention of: Qi Xu
E-mail: [***]

If to the 89bio:
89BIO INC.
Address: 142 Sansome Street. 2nd Floor, San Francisco, CA 94104, USA.
For the attention of: Quoc Le-Nguyen
E-mail: [***]

8.8.2 Any notice, demand or other communication so addressed to the other Party shall be deemed to have been delivered with proof of dispatch:

a) if personally delivered, upon delivery at the relevant address;

b) if sent by pre-paid airmail, [***] after the date of posting or, in the case of courier, [***] after the date of delivery to the courier by the sender;

c) if sent by post / speed post, [***] after the date of dispatch;

d) if sent by facsimile, when dispatched, subject to confirmation of uninterrupted transmission by a transmission report, provided that any notice dispatched by facsimile after [***] (at the place where facsimile is to be received) shall be deemed to have been received at [***] (at the place where facsimile is to be received) on the next day; or

e) if sent by electronic mail, when dispatched, provided that any notice dispatched by electronic mail after [***] (at the place where electronic mail is to be received) shall be deemed to have been received at [***] (at the place where electronic mail is to be received) on the next day.

8.8.3 Any Party may, from time to time, change its address or representative for receipt of notices provided for in this Agreement by giving to the other Parties not less than [***] prior written notice.

8.9 **Waiver**

Waiver of or consent to a breach of a provision must be in writing and signed by the Party claimed to have so waived or consented. Waiver of or consent to a breach of a provision shall not constitute a waiver of or consent for any other different or subsequent breach.

8.10 **Relationship of Parties and Other Activities**

The Parties hereto are independent contractors and no Party is an employee, agent, partner or joint venture of the other.

8.11 **Further Actions**

Each Party agrees to execute, acknowledge and deliver such further instruments and to do all such other acts, as may be reasonably necessary or appropriate in order to carry out the purposes and intent of this Agreement.

8.12 **Execution**

This Agreement may be executed in any number of counterparts and via facsimile signature, including PDF / email, each of which shall be deemed to be an original as against any Party whose signature appears thereon, and all of which shall together constitute one and the same instrument. This Agreement shall become binding when one or more counterparts hereof, individually or taken together, shall bear the signatures of all the Parties reflected hereon as the signatories hereto.

8.13 **Titles**

The titles of the Sections and sub-sections of this Agreement are for convenience of reference only and are not to be considered in construing the terms and provisions hereof.

8.14 **Exhibits**

All exhibits to this Agreement are hereby incorporated by reference into, and made a part of, this Agreement.

8.15 **Confidentiality**

8.15.1 During the Term, each Party (the "**Receiving Party**") shall maintain in confidence all information of the other Party (the "**Disclosing Party**") disclosed hereunder and identified as, or acknowledged to be, or by its nature ought to be considered, Confidential Information (as defined in Clause 8.15.2) of the Disclosing Party. The Receiving Party will not use the Disclosing Party's Confidential Information in any manner or disclose the Disclosing Party's Confidential Information to anyone, except: (i) for uses and disclosures expressly permitted by this Agreement or necessary for the receiving Party to perform its obligations or exercise its rights hereunder; or (ii) for disclosures to those of the Receiving Party's Affiliates and the officers, directors, employees, and agents of the Receiving Party or any of its Affiliates (collectively, "**Representatives**") to whom disclosure is reasonably necessary in connection with the Receiving Party's activities contemplated by this Agreement, provided that, prior to such disclosure to a Representative, the Receiving Party will have advised such Representatives of the confidential nature of such Confidential Information and such Representatives shall be bound by obligations of confidentiality at least as restrictive as those of this Clause 8.15. The Receiving Party will be responsible for any breach of this Clause 8.15 arising from the conduct of its Representatives.

8.15.2 As used herein "Confidential Information" of the Disclosing Party shall include all confidential or proprietary information disclosed by or on behalf of the Disclosing Party hereunder, including, without limitation, the Confidential Information described in Section 1.4, information of or regarding the Disclosing Party's or its Affiliates products, advertising, distribution, marketing, strategic plans, cost data, productivity or technological advances, specifications, data, know-how, formulations, technical information, pricing and other transaction terms, customers and suppliers, potential customers and suppliers, and information provided to the Disclosing Party on a confidential basis by a third party; in each case whether in written, electronic, oral, visual or another form. The term Confidential Information will not include information which the Receiving Party establishes that (i) is or becomes generally available to the public other than as result of a disclosure by the Receiving Party or any of its Representatives in breach of this Agreement, (ii) is in the Receiving Party's lawful possession, on a non-confidential basis, prior to disclosure thereof by or on behalf of the Disclosing Party to the Receiving Party, (iii) becomes available to the Receiving Party on a non-confidential basis from a source other than the Disclosing Party, provided that such source is not known to the Receiving Party to be bound by an obligation of confidentiality to the Disclosing Party with respect to such information or (iv) is independently developed or discovered by the Receiving Party without use of or reference to the Confidential Information of the Disclosing Party.

8.15.3 If the Receiving Party or any of its Representatives is required pursuant to Applicable Law, rule or regulation (including, without limitation, subpoena, civil investigative demand, compulsory process or other legal requirement) to disclose any Confidential Information of the Disclosing Party, then (i) the Receiving Party will promptly notify the Disclosing Party in writing thereof and will cooperate with the Disclosing Party, at the Disclosing Party's expense, in seeking a protective order or confidential treatment and (ii) the Receiving party and its Representatives may disclose such Confidential Information to the extent so required.

8.15.4 The Disclosing Party would be irreparably injured by a breach of this Clause 8.15 by the Receiving Party, and such a breach would not be compensable in money damages. Accordingly, in addition to any other rights and remedies of the Disclosing Party pursuant to this Agreement and Applicable Law, the Disclosing Party shall be entitled to seek injunctive and other equitable relief with respect to any breach or threatened breach of this Clause 8.15.

8.15.5 Upon termination and / or expiration of this Agreement, the Receiving Party will, upon written request of the Disclosing Party, promptly return to the Disclosing Party or destroy all Confidential Information of the Disclosing Party in the possession or control of the Receiving Party or any of its Representatives, provided that the Receiving Party may retain one (1) copy

of the Disclosing Party's Confidential Information in order to comply with Applicable Law and determine the rights and obligations of the Receiving Party pursuant to this Clause 8.15, which retained copy of Confidential Information will remain confidential, subject to the terms of this Clause 8.15.

8.16 **Press Release**

Except as may be required under any statutory obligation, no Party will issue a press release or issue a statement to the media in any form whatsoever concerning this Agreement or the other Party without the prior written consent of the other Party.

8.17 **Assignment**

No Party may assign this Agreement or any of its rights, liabilities or obligations hereunder without the prior written consent of the other Party, such consent not to be unreasonably withheld, delayed or conditioned; provided that 89bio may assign its rights under this Agreement or delegate its obligations under this Agreement to: (1) an entity acquiring all or substantially all of the assets of 89bio; (2) the successor in a merger involving 89bio; or (3) an Affiliate of 89bio, including in connection with a corporate reorganization of 89bio. This Agreement shall be binding upon the successors and permitted assigns of the Parties. An assignment or delegation in violation of this Section shall be null and void *ab initio.* .

8.18 **Force Majeure**

8.18.1 Neither Party shall be liable for any failure or delay in the performance of any of its obligations hereunder to the extent such performance is delayed or affected by any earthquake, floods, land-slides, or such other acts of God, war, civil disorder, fire, insurrections, riots, epidemics, pandemics (other than the COVID-19 pandemic), terrorist attack, general, widespread strikes or lockouts, general, widespread shortage of materials, orders, injunctions or directions of government, competent courts, or other statutory authorities of general application or other similar events (collectively referred to as "Force Majeure Condition(s)"); provided that: (a) such Force Majeure Condition is beyond the control of the affected Party and could not be prevented by appropriate precautions; (b) the affected Party is diligently attempting to recommence performance (including through alternate means); and (c) if BiBo is the affected Party, BiBo is implementing appropriate business continuity plans. The affected Party shall immediately notify the other Party of the occurrence of the Force Majeure Condition (but in no event later than [***]) and describe the Force Majeure Condition in sufficient detail.

8.18.2 If the Force Majeure Condition(s) in question prevails for a continuous period in excess of [***] the Parties shall enter into bona fide discussions with a view to alleviating its effects or to agree upon such alternative

arrangements as may be fair and reasonable. In case no such arrangement is agreed upon within [***] from the date of occurrence of Force Majeure Condition(s), 89bio may terminate this Agreement by giving at least [***] written notice to BiBo.

Remainder of page intentionally left blank; signature page follows.

[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE IT IS BOTH (i) NOT MATERIAL AND (ii) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

IN WITNESS WHEREOF, BiBo and 89bio have executed this Agreement by their duly authorized officers on the Effective Date.

For **BIBO BIOPHARMA**	For **89BIO INC.**
ENGINEERING CO., LTD	
Signature: /s/ Peng Jiao	Signature: /s/ Rohan Palekar
Name: Peng Jiao	Name: Rohan Palekar
Title: Chief Executive Officer	Title: Chief Executive Officer

[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE IT IS BOTH (i) NOT MATERIAL AND (ii) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

Exhibit 1: Milestone and Payment Schedule of the Collaboration

Items	***Milestones***	***Milestone/Payment Date***	***% of Total***	***Amount (USD)***
T0	[***]	[***]	[***]	/
1st Milestone/Payment	[***]	[***]	[***]	[***]
2nd Milestone/Payment	[***]	[***]	[***]	[***]
3rd Milestone/Payment	[***]	[***]	[***]	[***]
		Total Payment by 89bio		**135,000,000**

Note:

[***]

[***]

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: August 5, 2024

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: August 5, 2024

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 ended June 30, 2024, 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: August 5, 2024

By: /s/ Rohan Palekar

Rohan Palekar
Chief Executive Officer
(principal executive officer)

Date: August 5, 2024

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.