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 March 31, 2025

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.)**
655 Montgomery Street, Suite 1500	
San Francisco, California	**94111**
(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 April 25, 2025, the registrant had 145,984,182 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)

	March 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 315,396	$ 126,060
Marketable securities	323,384	313,895
Prepaid and other current assets	44,164	36,495
Total current assets	682,944	476,450
Property and equipment, net	85	23
Operating lease right-of-use assets	1,409	1,572
Other assets	593	640
Total assets	$ 685,031	$ 478,685
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 14,790	$ 15,382
Accrued expenses	22,343	20,020
Operating lease liabilities, current	751	727
Total current liabilities	37,884	36,129
Operating lease liabilities, noncurrent	888	1,090
Warrant liability	295	516
Term loan, noncurrent, net	35,940	35,732
Other noncurrent liabilities	4,566	4,429
Total liabilities	79,573	77,896
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Common stock, $0.001 par value: 200,000,000 shares authorized; 145,984,182 and 119,849,436 shares issued and outstanding as of March 31, 2025 and December 31, 2024, respectively	146	120
Additional paid-in capital	1,500,713	1,224,617
Accumulated other comprehensive income	385	563
Accumulated deficit	(895,786)	(824,511)
Total stockholders' equity	605,458	400,789
Total liabilities and stockholders' equity	$ 685,031	$ 478,685

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

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

	Three Months Ended March 31,	
	2025	**2024**
Operating expenses:		
Research and development	$ 64,394	$ 47,428
General and administrative	11,515	9,849
Total operating expenses	75,909	57,277
Loss from operations	(75,909)	(57,277)
Interest expense	(1,267)	(863)
Interest income and other, net	6,038	6,556
Net loss before income tax	(71,138)	(51,584)
Income tax expense	(137)	(97)
Net loss	$ (71,275)	$ (51,681)
Other comprehensive income (loss):		
Unrealized loss on marketable securities	(170)	(714)
Foreign currency translation adjustments	(8)	5
Total other comprehensive loss	$ (178)	$ (709)
Comprehensive loss	$ (71,453)	$ (52,390)
Net loss per share, basic and diluted	$ (0.49)	$ (0.54)
Weighted-average shares used to compute net loss per share, basic and diluted	146,365,115	95,846,740

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	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amounts				
Balance as of December 31, 2024	119,849,436	$ 120	$ 1,224,617	$ 563	$ (824,511)	$ 400,789
Issuance of common stock and pre-funded warrants in public offering, net of issuance costs	25,957,142	26	269,877	—	—	269,903
Issuance of common stock upon exercise of stock options	4,000	—	33	—	—	33
Issuance of common stock upon vesting of restricted stock units, net of tax withholding for net share settlement	173,604	—	(1,030)	—	—	(1,030)
Stock-based compensation	—	—	7,216	—	—	7,216
Net loss	—	—	—	—	(71,275)	(71,275)
Other comprehensive loss	—	—	—	(178)	—	(178)
Balance as of March 31, 2025	145,984,182	$ 146	$ 1,500,713	$ 385	$ (895,786)	$ 605,458

	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 offering, 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

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

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

	Three Months Ended March 31,	
	2025	**2024**
Cash flows from operating activities:		
Net loss	$ (71,275)	$ (51,681)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	7,216	4,998
Net accretion of discounts on investments in marketable securities	(1,898)	(2,822)
Amortization of debt discount and accretion of deferred debt costs	455	162
Noncash operating lease expense	163	175
Depreciation	10	9
Change in fair value of warrant liability	(221)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(7,869)	2,089
Accounts payable	(600)	6,767
Accrued expenses	2,323	457
Operating lease liabilities	(178)	29
Other noncurrent liabilities	137	97
Net cash used in operating activities	(71,737)	(39,720)
Cash flows from investing activities:		
Proceeds from sales and maturities of marketable securities	97,341	72,140
Purchases of marketable securities	(105,102)	(152,038)
Purchases of property and equipment	(72)	—
Net cash used in investing activities	(7,833)	(79,898)
Cash flows from financing activities:		
Proceeds from issuance of common stock and pre-funded warrants in public offering, net of issuance costs	269,903	—
Payments of deferred offering costs	—	(253)
Proceeds from issuance of common stock in at-the-market public offering, net of issuance costs	—	21,067
Proceeds from issuance of common stock upon exercise of common stock warrants	—	1,798
Proceeds from issuance of common stock upon exercise of stock options	33	104
Payments for taxes related to net share settlement upon vesting of restricted stock units	(1,030)	(1,686)
Net cash provided by financing activities	268,906	21,030
Net change in cash and cash equivalents	189,336	(98,588)
Cash and cash equivalents at beginning of period	126,060	316,161
Cash and cash equivalents at end of period	$ 315,396	$ 217,573
Supplemental disclosures of cash information:		
Cash paid for interest	$ 814	$ 679

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

1. Organization and Liquidity

Description of Business

89bio, Inc. (together with its consolidated subsidiaries, herein referred to as 89bio, the company, we, our or us) is 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, is a specifically engineered glycoPEGylated analog of fibroblast growth factor 21 (FGF21). Pegozafermin is currently being developed for the treatment of metabolic dysfunction-associated steatohepatitis (MASH), formerly nonalcoholic steatohepatitis (NASH), 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

We have incurred significant losses and negative cash flows from operations since inception and had an accumulated deficit of $895.8 million as of March 31, 2025. We have historically financed our operations primarily through the sale of equity securities, including warrants, and from borrowings under term loan facilities. To date, none of our product candidates have been approved for sale, and we have not generated any revenue from commercial products. We expect operating losses to continue and increase for the foreseeable future as we progress our clinical development activities for our product candidates.

We believe our existing cash, cash equivalents and marketable securities of $638.8 million as of March 31, 2025 will be sufficient to fund our planned operating expense requirements for a period of at least one year from the issuance date of these condensed consolidated 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, 2024 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, 2025 or for any other future annual or interim period. The condensed consolidated balance sheet as of December 31, 2024 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 our audited consolidated financial statements included in the Annual Report on Form 10-K for the year ended December 31, 2024, which was filed with the SEC on February 27, 2025.

Principles of Consolidation

The accompanying condensed consolidated financial statements include our accounts and those of our wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation. Our functional currency, and that of our subsidiary in Israel (our only significant subsidiary), is 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. We evaluate our estimates and assumptions on an ongoing basis using historical experience and other factors and adjust 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 and Liabilities Measured at Fair Value on a Recurring Basis

Financial instruments measured and recorded at fair value on a recurring basis consist of cash equivalents and marketable securities and common stock warrants issued in connection with a term loan facility that do not meet all of the criteria for equity classification.

Financial Instruments Not Carried at Fair Value

Our 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. We believe the fair value of our term loan is not materially different from its carrying value (amortized cost), as its interest rate adjusts periodically based on the U.S. Prime Rate, reflecting current market conditions for similar variable-rate debt.

Cash and Cash Equivalents

We consider 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

We invest our 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. We classify 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, net of tax, recognized as a component of accumulated other comprehensive income (loss) within stockholders' equity until realized. The amortized cost of debt securities is adjusted for accretion of premiums and amortization of discounts to maturity. Such amortization and accretion, along with interest and dividends earned, 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. We classify our marketable securities as current assets, which reflects our intention to use the proceeds from sales of these securities to fund our operations, as necessary, even though the stated maturity date may be one year or more beyond the current balance sheet date.

We periodically assess our available-for-sale marketable securities for impairment. For marketable securities in an unrealized loss position, this assessment first takes into account our intent to sell, or whether it is more likely than not that we 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, we assess whether the decline in fair value has resulted from credit losses or other factors. In making this assessment, we consider 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. 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 we believe the uncollectability of a marketable 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. To date, we have not experienced any credit-related losses on our marketable securities.

Income Taxes

We account 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 months ended March 31, 2025 and 2024, we recorded income tax expense related to our foreign operations in Israel of $0.1 million and $0.1 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. Pre-funded warrants with a nominal exercise price are considered outstanding and are included in the calculation of basic net loss per share from their issuance date as they are economically equivalent to outstanding common stock. 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. Shares of our common stock warrants participate in any dividends that may be declared by us 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 our losses. Diluted loss per share is computed after considering 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 we 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.

Segment Information

Operating segments are defined as components of an enterprise that have the following characteristics: (i) they engage in business activities from which they may earn revenue and incur expense, (ii) their operating results are regularly reviewed by the chief operating decision maker (CODM) for resource allocation decisions and performance assessment, and (iii) their discrete financial information is available. Our CODM is our Chief Executive Officer (CEO), who manages and allocates resources to our operations on a consolidated basis. We manage our business as a single reportable segment and our operations are focused on the development and commercialization of innovative therapies for the treatment of liver and cardio-metabolic diseases. Segment information is further described in Note 10.

Recently Adopted Accounting Standards

We did not adopt any new standards or updates issued by the Financial Accounting Standards Board (FASB) during the three months ended March 31, 2025 that had a material impact on our consolidated financial statements and related disclosures.

Accounting Pronouncements Not Yet Adopted

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* (ASU 2023-09). ASU 2023-09 requires public business entities 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. ASU 2023-09 is effective for our 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. We expect to adopt ASU 2023-09 in our Annual Report on Form 10-K for the year ending December 31, 2025 and in annual periods thereafter. We are in the process of evaluating the requirements of this update, which is expected to result in expanded disclosures within our consolidated financial statements upon adoption.

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses* (ASU 2024-03). ASU 2024-03 requires public business entities to provide expanded footnote disclosures disaggregating certain specified expense categories, such as purchases of inventory, employee compensation, depreciation, and amortization, included within relevant expense captions presented on the income statement. The objective of this guidance is to provide investors with more detailed information about an entity's cost structure. ASU 2024-03 is effective for our annual periods beginning on January 1, 2027, and interim periods within annual reporting periods beginning January 1, 2028. Application is permitted on either a prospective or retrospective basis, and early adoption is permitted. We expect to adopt the annual disclosure requirements of ASU 2024-03 in our Annual Report on Form 10-K for the year ending December 31, 2027, and the interim disclosure requirements beginning with our Form 10-Q for the quarter ending March 31, 2028. We are currently evaluating the requirements of this update, which is expected to result in significantly expanded disclosures regarding the composition of our expenses within our consolidated financial statements upon adoption.

3. Fair Value Measurements

Assets Measured at Fair Value on a Recurring Basis

The following table presents our financial assets measured at fair value on a recurring basis by level within the fair value hierarchy for the periods indicated (in thousands):

		March 31, 2025			
	Valuation Hierarchy	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Assets:					
Money market funds	Level 1	$ 9,301	$ —	$ —	$ 9,301
Commercial paper	Level 2	101,313	—	(28)	101,285
U.S. government bonds	Level 2	178,916	347	(15)	179,248
Agency bonds	Level 2	52,517	68	(2)	52,583
Corporate debt securities	Level 2	8,331	12	(3)	8,340
U.S. Treasury securities	Level 2	45,551	2	(2)	45,551
Agency discount securities	Level 2	5,784	—	—	5,784
Total cash equivalents and marketable securities		$ 401,713	$ 429	$ (50)	$ 402,092
Classified as:					
Cash equivalents					$ 78,708
Marketable securities					323,384
Total cash equivalents and marketable securities					$ 402,092

		December 31, 2024			
	Valuation Hierarchy	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Assets:					
Money market funds	Level 1	$ 22,645	$ —	$ —	$ 22,645
Commercial paper	Level 2	51,982	14	(5)	51,991
U.S. government bonds	Level 2	169,860	439	(29)	170,270
Agency bonds	Level 2	63,753	111	(5)	63,859
Corporate debt securities	Level 2	6,154	15	(3)	6,166
U.S. Treasury securities	Level 2	44,499	10	—	44,509
Agency discount securities	Level 2	18,940	2	—	18,942
Total cash equivalents and marketable securities		$ 377,833	$ 591	$ (42)	$ 378,382
Classified as:					
Cash equivalents					$ 64,487
Marketable securities					313,895
Total cash equivalents and marketable securities					$ 378,382

The valuation techniques used to measure the fair values of our 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 March 31, 2025 (in thousands):

Within one year	$ 369,008
After one year through two years	33,084
Total cash equivalents and marketable securities	$ 402,092

As of March 31, 2025, 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. All of the fixed-rate debt securities in a loss position are investment-grade debt securities. We have the intent and ability to hold such securities until recovery of the unrealized losses. Based on our evaluation, the unrealized losses as of March 31, 2025 were insignificant and did not reflect increased credit risks within specific securities holdings. No allowance for credit losses was recorded as of March 31, 2025 and December 31, 2024.

Liabilities Measured at Fair Value on a Recurring Basis

Warrant Liability

As of March 31, 2025, our only financial liability measured at fair value on a recurring basis relates to warrants to purchase up to 311,996 shares of our common stock issued in connection with the Term Loan Facility (see Note 6). The number of warrants that become exercisable is contingent on subsequent loan advances drawn by us under the Term Loan Facility. As such, the warrants are not considered to be indexed to our own stock and were accounted for as a liability. We recorded the fair value of the warrants upon issuance using a probability-weighted scenario analysis with a Black-Scholes option-pricing model. We are required to revalue the warrants at each reporting date with any changes in fair value recorded on the consolidated statements of operations and comprehensive loss until the exercise contingencies are resolved. The valuation of the warrants is considered under Level 3 of the fair value hierarchy, taking into account the likelihood of the warrants becoming exercisable in addition to assumptions used in the Black-Scholes option-pricing model.

The reconciliation of our warrant liability measured at fair value on a recurring basis using unobservable inputs (Level 3) is as follows (in thousands):

	Warrant Liability
Balance outstanding as of December 31, 2024	$ 516
Change in fair value	(221)
Balance outstanding as of March 31, 2025	$ 295

The warrants had a fair value of $0.3 million as of March 31, 2025, based on a Black-Scholes valuation with the following assumptions: risk-free interest rate of 4.2%, no dividends, expected volatility of 87.8% and expected term of 9.5 years.

4. Balance Sheet Components

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

	March 31, 2025	December 31, 2024
Prepaid research and development	$ 40,934	$ 32,550
Prepaid taxes	133	368
Prepaid other	3,097	3,577
Total prepaid and other current assets	$ 44,164	$ 36,495

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

	March 31, 2025	December 31, 2024
Accrued research and development expenses	$ 17,208	$ 11,426
Accrued employee and related expenses	3,479	6,872
Accrued professional and legal fees	1,614	1,680
Accrued other expenses	42	42
Total accrued expenses	$ 22,343	$ 20,020

5. Commitments and Contingencies

Asset Transfer and License Agreement with Teva Pharmaceutical Industries Ltd

In April 2018, we acquired certain patents and intellectual property from Teva Pharmaceutical Industries Ltd. (Teva) relating to Teva's former glycoPEGylated FGF21 program, including the compound pegozafermin (the FGF21 Agreement).

Under the FGF21 Agreement, we are obligated to make future payments to Teva. A $2.5 million milestone payment was made in the fourth quarter of 2023 upon achievement of a specified clinical development milestone. Remaining potential payments under the FGF21 Agreement consist of up to $65.0 million upon achievement of specified commercial milestones. We are also obligated to pay Teva tiered royalties at percentages in the low-to-mid single-digits on worldwide net sales of any products containing pegozafermin.

As of March 31, 2025, 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.

The FGF21 Agreement 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 FGF21 Agreement 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. Teva can also terminate the agreement if we, or any of our affiliates or sublicensees, challenge the licensed patents and do not withdraw the challenge within 30 days of written notice from Teva.

BiBo Collaboration Agreement

In April 2024, we entered into a collaboration agreement (the Collaboration Agreement) with BiBo Biopharma Engineering Co., Ltd. (BiBo), under which BiBo will construct a production facility at its site in the Lin-gang Special Area of China (Shanghai) Pilot Free Trade Zone. This manufacturing platform is specifically designed to enable the production of the bulk active ingredient required for pegozafermin's commercial supply, and we expect it to provide capacity sufficient for our projected commercial needs.

Under the Collaboration Agreement, we are required to pay BiBo an aggregate of $135.0 million (exclusive of applicable value-added tax) toward the construction of the production facility, of which $121.5 million (net of applicable value-added tax) in milestone payments have been made as of March 31, 2025. The remaining $13.5 million will become payable upon achievement of certain specified milestones. 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

As of March 31, 2025, our outstanding debt consisted of amounts drawn under a term loan facility (the Term Loan Facility) established pursuant to a Loan and Security Agreement, dated January 2023, as amended in September 2024 (as amended, the Loan Agreement) with certain lenders, K2 HealthVentures LLC serving as administrative agent, and Ankura Trust Company, LLC as collateral agent.

The Term Loan Facility provides for a maximum aggregate principal amount of $150.0 million, available in tranches:

- Tranche 1: Provides for total borrowings of up to $70.0 million. An initial $35.0 million was funded upon closing of the related amendment in September 2024, the proceeds of which included the refinancing of the $25.0 million principal balance then outstanding under the original loan agreement. As of March 31, 2025, the remaining $35.0 million is available for drawdown through June 30, 2025.
- Tranche 2: $30.0 million, the availability of which is contingent upon achievement of a specific clinical development milestone (positive Phase 3 SHTG Data) by December 31, 2025. In February 2025, we announced that we decided to unblind the ENTRUST Phase 3 study in SHTG after study completion at week 52 and not conduct the interim week 26 readout, which interim readout we expected would have occurred before December 31, 2025. Consequently, we expect to report topline data from ENTRUST in the first quarter of 2026, and therefore, we do not anticipate meeting the condition required to access Tranche 2 within the specified timeframe.
- Tranche 3: Up to $50.0 million, which may become available at our request, subject to the lenders' sole discretion.

Our obligations under the Loan Agreement are secured by substantially all of our assets, excluding intellectual property. The Loan Agreement contains customary representations and warranties, restricts certain activities (including requiring prior lender consent for the sale or assignment of rights to our patents and other intellectual property), and includes customary events of default, including payment default, breach of covenants, change of control, and material adverse effects. In addition, commencing January 1, 2026, we are required to maintain minimum unrestricted cash, cash equivalents and marketable securities equal to 5.0 times the average change in such balances over the trailing three-month period. As of March 31, 2025, we were in compliance with all covenants of the Loan Agreement.

Borrowings under the Loan Agreement mature on October 1, 2028 and provide for interest-only payments until January 1, 2027. Thereafter, consecutive equal payments of principal and interest are due. The Term Loan Facility bears interest equal to the greater of (i) 8.95% and (ii) the sum of (a) the Prime Rate as reported in The Wall Street Journal plus (b) 1.75%. On the date the debt was refinanced and on March 31, 2025, the stated interest rate on the outstanding Term Loan Facility was 9.75% and 9.25%, respectively. An end of term fee of 5.95% of the aggregate principal amount of term loans advanced is also payable. We have the option to prepay the entire outstanding balance of borrowings, subject to a prepayment fee ranging from 1.0% to 3.0% depending on the timing of such prepayment.

In connection with the amendment of the original agreement, we issued warrants to purchase up to 406,951 shares of our common stock at an exercise price of $7.3719 per share that expire 10 years from the date of issuance. Of these, 94,955 shares were immediately exercisable and classified as equity. Warrants to purchase the remaining 311,996 shares of common stock become exercisable proportionally with future advances under the term loan tranches. These warrants are classified as a liability and remeasured to fair value at each reporting period (see Note 3).

The lenders also have the right to convert up to an aggregate of $7.5 million of the principal amount from the original term loan then outstanding and an additional aggregate of $5.0 million from the amended term loan then outstanding into shares of our common stock at conversion prices of $12.6943 and $9.5835 per share, respectively.

The expected repayments of principal amounts due on borrowings as of March 31, 2025 were as follows (in thousands):

2025 (remaining nine months)	$	—
2026		—
2027		18,322
2028		16,678
Total principal outstanding		35,000
Plus accumulated accretion of end of term fees		1,476
Less unamortized debt discount		(536)
Total net carrying value		35,940
Term loan, current		—
Term loan, noncurrent, net	$	35,940

7. Stockholders' Equity

Common Stock Reserved for Issuance

Common stock reserved for future issuance, on an as-if-converted basis, were as follows:

	As of March 31, 2025	As of December 31, 2024
Stock options outstanding	11,578,904	7,707,342
RSUs and PSUs outstanding	2,726,824	1,818,994
Shares available for future grants under equity incentive plans	2,018,216	2,181,235
Shares available for future issuance under the employee stock purchase plan	3,285,644	2,087,150
Warrants to purchase common stock outstanding	517,078	517,078
Pre-funded warrants to purchase common stock outstanding	11,231,081	4,331,081
Conversion feature related to outstanding term loan	1,112,546	1,112,546
Total available for future issuance	32,470,293	19,755,426

Underwritten Public Offering

In February 2025, we completed an underwritten public offering consisting of 25,957,142 shares of common stock at an offering price of $8.75 per share, including 4,285,714 shares of common stock issued upon the exercise in full of the overallotment option by the underwriters, as well as pre-funded warrants to purchase 6,900,000 shares of common stock at a public offering price of $8.749 per underlying share. We raised net proceeds of approximately $269.9 million, after deducting underwriting discounts and commissions of $17.3 million and other offering costs of $0.3 million.

Common Stock Warrants

As of March 31, 2025, outstanding warrants to purchase shares of our 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	51,204	$9.7649	January 27, 2033
Warrants issued in connection with amended Term Loan Facility	406,951	$7.3719	September 30, 2034
Pre-funded warrants issued in connection with public offerings	11,231,081	$0.001	Do not expire
Total outstanding	11,748,159		

Exercise of pre-funded warrants is subject to a beneficial ownership limitation, initially capped at 9.99% of our outstanding common stock. Prior to issuance, a holder had the option to decrease this limitation to 4.99%. The holder may subsequently adjust this limitation, provided that it does not exceed 19.99%. The number of shares issuable upon exercise is subject to adjustment for stock dividends, stock splits, recapitalizations, reorganizations, or other similar events, as further specified in the warrant agreements. Under certain conditions, the pre-funded warrants may be exercised on a cashless basis. There were no exercises of common stock warrants or pre-funded warrants for the three months ended March 31, 2025.

8. Stock-Based Compensation

Equity Incentive Plans Activity

Stock Options

The following table summarizes stock option activity under our equity incentive plans for the three months ended March 31, 2025:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (In years)	Aggregate Intrinsic Value (In thousands)
Balance outstanding as of December 31, 2024	7,707,342	$ 12.19		
Granted	4,004,100	9.60		
Exercised	(4,000)	8.25		
Forfeited	(128,538)	12.57		
Balance outstanding as of March 31, 2025	11,578,904	$ 11.29	8.3	$ 5,082
Exercisable as of March 31, 2025	4,082,873	$ 13.90	6.4	$ 4,593

The fair value of stock option awards granted for the periods indicated was estimated at the date of grant using a Black-Scholes option-pricing model with the following assumptions:

	Three Months Ended March 31,	
	2025	2024
Expected term (years)	5.5 - 6.1	5.5 - 6.1
Expected volatility	86.8 - 87.2%	89.4 - 90.4%
Risk-free interest rate	4.4%	3.8 - 4.1%
Expected dividend	—	—

As of March 31, 2025, total unrecognized stock-based compensation expense related to unvested stock options was $52.1 million, which is expected to be recognized over a weighted-average period of 3.1 years.

RSU and PSUs

The following table summarizes RSU and PSU activity for the three months ended March 31, 2025:

	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, 2024	1,503,994	$ 9.65	315,000	$ 7.67
Granted	1,210,375	9.60	—	—
Vested	(269,691)	11.27	(2,500)	9.98
Forfeited	(22,854)	10.24	(7,500)	9.98
Balance outstanding as of March 31, 2025	2,421,824	$ 9.44	305,000	$ 7.59

As of March 31, 2025, total unrecognized stock-based compensation expense related to RSUs and PSUs was $28.9 million, which is expected to be recognized over a weighted-average period of 2.2 years.

Stock-Based Compensation

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

	Three Months Ended March 31,	
	2025	2024
Research and development	$ 3,402	$ 2,315
General and administrative	3,814	2,683
Total stock-based compensation	$ 7,216	$ 4,998

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 March 31,	
	2025	2024
Common stock	137,357,367	93,965,659
Pre-funded warrants	9,007,748	1,881,081
Total	146,365,115	95,846,740

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:

	As of March 31,	
	2025	2024
Stock options outstanding	11,578,904	6,891,349
RSUs and PSUs outstanding	2,726,824	1,508,546
Warrants to purchase common stock	517,078	10,075,092
Conversion feature related to outstanding term loan	1,112,546	590,816
ESPP shares issuable	31,333	13,091
Total	15,966,685	19,078,894

10. Segment Information

We operate and manage our business as a single reportable segment focused on the development and commercialization of innovative therapies for the treatment of liver and cardio-metabolic diseases. Our CEO, as the CODM, uses consolidated net loss to evaluate our expenditures and monitor budget versus actual results. The monitoring of budgeted versus actual results and cash on hand are used in assessing performance of the segment and in establishing resource allocation across the organization.

Factors considered in determining our single reportable segment include the nature of our operating activities, our organizational and reporting structure, and the type of information reviewed by the CODM to allocate resources and evaluate financial performance.

The CODM regularly reviews significant expense categories included within our consolidated net loss to manage our operations. These significant expense categories include research and development, general and administrative, interest expense, interest income and other, net and income tax expense, which are each separately presented on our condensed consolidated statements of operations and comprehensive loss.

Substantially all of our long-lived assets, which primarily consist of right-of-use assets related to operating leases, were located in the United States as of March 31, 2025 and December 31, 2024.

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, 2024. 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, is a specifically engineered glycoPEGylated analog of fibroblast growth factor 21 (FGF21). Pegozafermin is currently being developed for the treatment of metabolic dysfunction-associated steatohepatitis (MASH), formerly nonalcoholic steatohepatitis (NASH), and for the treatment of severe hypertriglyceridemia (SHTG). MASH, a severe form of metabolic dysfunction-associated steatotic liver disease (formerly nonalcoholic fatty liver disease), is characterized by liver inflammation and fibrosis, potentially progressing to cirrhosis, liver failure, hepatocellular carcinoma and death.

Pegozafermin MASH Program

Pegozafermin is currently advancing through Phase 3 clinical development. This follows positive results from the Phase 1b/2a trial and the Phase 2b ENLIVEN trial, which demonstrated statistically significant histological improvements through 24 weeks and benefits across non-invasive tests (NITs) in both non-cirrhotic (F2-F3) and compensated cirrhotic (F4) MASH patients through 48 weeks. The U.S. Food and Drug Administration (FDA) has granted pegozafermin Breakthrough Therapy Designation, and the European Medicines Agency (EMA) has granted it Priority Medicines Designation (PRIME) for MASH.

We are enrolling patients for our Phase 3 ENLIGHTEN program of two global, randomized, double-blind, placebo-controlled trials, which were initiated in 2024, following successful end-of-Phase 2 interactions with the FDA and EMA in 2023:

- ENLIGHTEN-Fibrosis: This trial is actively enrolling patients with MASH and fibrosis stage F2-F3. It evaluates weekly and every-two-week dosing regimens of pegozafermin versus placebo. The co-primary histology endpoints, assessed at week 52, are intended to support potential filings for accelerated approval in the United States and conditional approval in Europe. We currently anticipate reporting topline data from the histology cohort in the first half of 2027. Patients are expected to continue treatment for collection of outcome events for potential full approval in F2-F3 MASH.
- ENLIGHTEN-Cirrhosis: This trial is actively enrolling patients with MASH and compensated cirrhosis (F4). It evaluates a weekly dosing regimen of pegozafermin versus placebo. The primary histology endpoint, assessed at 24 months, is intended to support potential filings for accelerated approval in the United States and conditional approval in Europe for F4 patients. We currently anticipate reporting topline data from the histology cohort in 2028. Patients are expected to continue treatment for collection of outcomes events, primarily decompensation events, which could support potential full approval for F4 and F2-F3 MASH.

Both Phase 3 trials are designed to enroll a proportion of patients on background glucagon-like peptide-1 (GLP-1) based therapies to evaluate the potential incremental benefit of pegozafermin. The trials will stratify patients based on their use of background GLP-1 based therapies. Patients in both trials can self-administer pegozafermin using the planned commercial liquid formulation via subcutaneous injection. We continue to execute on these trials with the goal of generating data to support regulatory submissions for pegozafermin as a potential treatment for patients with MASH.

Pegozafermin SHTG Program

We are also advancing pegozafermin for the treatment of SHTG, based on positive results from our Phase 2 ENTRIGUE trial and supportive feedback from the FDA indicating that two Phase 3 trials are required for registration using triglyceride reduction as the primary endpoint. Enrollment in the first of these Phase 3 trials, ENTRUST, was completed in December 2024 with 369 patients. This 52-week, randomized, double-blind, placebo-controlled global trial is evaluating weekly subcutaneous doses of pegozafermin (20 mg and 30 mg) against placebo. The primary endpoint—percent change from baseline in fasting triglycerides compared to placebo at Week 26—will be analyzed after study completion at Week 52. This timing of analysis aligns with our strategic prioritization of the

MASH program, followed by the SHTG program. We expect to report topline data from the ENTRUST trial in the first quarter of 2026. Safety data from the ongoing ENTRUST trial is expected to support the safety database requirements for MASH and vice versa.

Manufacturing and Commercial Supply Preparedness

In April 2024, we entered into a collaboration agreement (the Collaboration Agreement) with BiBo Biopharma Engineering Co., Ltd. (BiBo), under which BiBo is constructing a production facility at its site in the Lin-gang Special Area of China (Shanghai) Pilot Free Trade Zone. This manufacturing platform is specifically designed to enable the production of the bulk active ingredient required for pegozafermin's commercial supply, and we expect it to provide capacity sufficient for our projected commercial needs. The scalability of our manufacturing process was demonstrated via the successful completion of a large-scale Good Manufacturing Practices (GMP) production run of pegozafermin during the fourth quarter of 2024 at an existing commercial-scale production line at BiBo's facility in Shanghai. The Collaboration Agreement is a component of our broader global manufacturing strategy, which ensures resilience and flexibility by leveraging a diversified supply chain with alternative sources from contract development and manufacturing organizations (CDMOs) for each step, mitigating reliance on any single partner and reducing macro/geopolitical risk exposure.

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 incurred pursuant to the Collaboration Agreement, 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 and manufacturing 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 resources, 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 cash interest related to our term loan facility, noncash interest attributable to the accretion of end of term loan fees, 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 is primarily comprised of interest income derived from marketable securities, including the accretion of discounts and amortization of premiums.

Income Taxes

We make estimates of the amounts to recognize for income taxes in each tax jurisdiction in which we operate. In addition, provisions are established for uncertain tax positions taken.

Results of Operations

Three Months Ended March 31, 2025 and 2024

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

	Three Months Ended March 31,		
	2025	2024	Change
Operating expenses:			
Research and development	$ 64,394	$ 47,428	$ 16,966
General and administrative	11,515	9,849	1,666
Total operating expenses	75,909	57,277	18,632
Loss from operations	(75,909)	(57,277)	(18,632)
Interest expense	(1,267)	(863)	(404)
Interest income and other, net	6,038	6,556	(518)
Net loss before tax	$ (71,138)	$ (51,584)	$ (19,554)

Research and Development Expenses

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

	Three Months Ended March 31,		
	2025	2024	Change
Clinical development	$ 33,795	$ 17,924	$ 15,871
Contract manufacturing	19,057	21,351	(2,294)
Personnel-related expenses	10,673	7,733	2,940
Other expenses	869	420	449
Total research and development expenses	$ 64,394	$ 47,428	$ 16,966

Research and development expenses increased by $17.0 million for the three months ended March 31, 2025 compared to the same period in 2024. The increase was primarily driven by $15.9 million in net additional spending across our Phase 3 clinical programs. This reflects increased investment to advance our ENLIGHTEN-Fibrosis and ENLIGHTEN-Cirrhosis clinical trials, partially offset by a slight decrease in costs for our ENTRUST clinical trial following the completion of patient enrollment in December 2024. Additional factors included a $2.9 million increase in personnel-related expenses including stock-based compensation driven by higher headcount and a $0.5 million increase in other research and development expenses. These increases were partially offset by a $2.3 million decrease in contract manufacturing costs, primarily reflecting expenses incurred in the comparable prior year period for manufacturing activities in preparation for two Phase 3 trials initiated in March and May 2024.

General and Administrative Expenses

General and administrative expenses increased by $1.7 million for the three months ended March 31, 2025 compared to the same period in 2024. The increase was primarily attributable to an increase in personnel-related expenses including stock-based compensation driven by higher headcount.

Interest Expense

Interest expense increased by $0.4 million for the three months ended March 31, 2025 compared to the same period in 2024, driven primarily by $0.2 million from higher average outstanding debt and a $0.2 million write-off of deferred financing fees associated with tranche 2 of the Term Loan Facility.

Interest Income and Other, Net

Interest income and other, net decreased by $0.5 million for the three months ended March 31, 2025 compared to the same period in 2024, primarily reflecting lower average invested balances in cash equivalents and marketable securities.

Liquidity and Capital Resources

To date, we have incurred significant net losses and negative cash flows from operations. As of March 31, 2025, we had cash, cash equivalents and marketable securities of $638.8 million and an accumulated deficit of $895.8 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. In February 2023, we entered into an amendment to the Sales Agreement. This amendment terminated the 2021 ATM Facility and established 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.

In 2024, we sold 1,396,888 shares of our common stock and received net proceeds of $21.0 million.

During the three months ended March 31, 2025, there were no sales of our common stock under the 2023 ATM Facility. As of March 31, 2025, there was $104.4 million remaining for future sales under the 2023 ATM Facility.

Underwritten Public Offerings

In November 2024, we completed an underwritten public offering of our common stock and pre-funded warrants to purchase shares of our common stock, raising net proceeds of $136.3 million after deducting underwriting commissions, discounts, and other offering expenses.

In February 2025, we completed an underwritten public offering of our common stock and pre-funded warrants to purchase shares of our common stock, raising net proceeds of $269.9 million after deducting underwriting commissions, discounts, and other offering expenses.

Exercise of Common Stock Warrants

In 2024, pre-funded warrants to purchase 799,906 shares of our common stock were exercised via cashless exercises and warrants to purchase 10,179,789 shares of our common stock were exercised for cash generating proceeds of $54.2 million resulting in the issuance of a total of 10,979,695 shares of common stock.

Term Loan Facility

As of March 31, 2025, our primary source of debt financing was through a term loan facility (the Term Loan Facility), which provides for a maximum aggregate principal amount of $150.0 million. This facility was established pursuant to a Loan and Security Agreement, dated January 2023, as amended in September 2024 (as amended, the Loan Agreement) with certain lenders, K2 HealthVentures LLC, serving as administrative agent, and Ankura Trust Company, LLC, as collateral agent.

The Term Loan Facility is structured in three tranches:

- Tranche 1: This tranche provides for total borrowings of up to $70.0 million. An initial $35.0 million was funded upon the closing of the related amendment in September 2024, the proceeds of which included the refinancing of the $25.0 million principal balance then outstanding under the original loan agreement. As of March 31, 2025, the remaining $35.0 million is available for drawdown through June 30, 2025.

- Tranche 2: This $30.0 million tranche was contingent upon the achievement of a specific clinical development milestone (positive Phase 3 SHTG Data) by December 31, 2025. In February 2025, we announced that we decided to unblind the ENTRUST Phase 3 study in SHTG after study completion at week 52 and not conduct the interim week 26 readout, which interim readout we expected would have occurred before December 31, 2025. Consequently, we expect to report topline data from ENTRUST in the first quarter of 2026, and therefore, we do not anticipate meeting the condition required to access Tranche 2 within the specified timeframe.
- Tranche 3: This tranche allows for borrowing of up to $50.0 million at our request, subject to the lenders' sole discretion. While this represents a potential future source of capital, its availability is not guaranteed and is dependent on the lenders' approval at the time of any request.

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 pursuant to the Collaboration Agreement. 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. In addition, with a change in the current administration in 2025, there has been an economic policy shift towards increasing tariffs, which in turn has led and could lead to further retaliatory tariffs. These may have the potential to impact expenses as well as our ability to, if ever, generate revenue or 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 $638.8 million as of March 31, 2025 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;
- the cost of preparing, filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and
- the cost overruns under the Collaboration Agreement if the actual costs of construction of the production facility are greater than the estimated budget.

We expect to continue to generate substantial operating losses for the foreseeable future as we expand our research and development activities. We will continue to fund our operations primarily through utilization of our current financial resources and through additional raises of capital to advance our current product candidate through clinical development, to develop, acquire or in-license other potential product candidates and to fund operations for the foreseeable future. However, there is no assurance that such funding will be available to us or that it will be obtained on terms favorable to us or will provide us with sufficient funds to meet our objectives. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies.

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

Cash Flows

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

	Three Months Ended March 31,	
	2025	2024
Net cash (used in) provided by		
Operating activities	$ (71,737)	$ (39,720)
Investing activities	(7,833)	(79,898)
Financing activities	268,906	21,030
Net change in cash and cash equivalents	$ 189,336	$ (98,588)

Operating Activities

For the three months ended March 31, 2025, net cash used in operating activities of $71.7 million reflects a net loss of $71.3 million and a net change of $6.2 million in operating assets and liabilities, partially offset by aggregate noncash charges of $5.7 million. Noncash charges primarily included stock-based compensation expense of $7.2 million, amortization of debt discount and accretion of deferred debt costs of $0.5 million, partially offset in part by net accretion of discounts on investments in marketable securities of $1.9 million. The net change in operating assets and liabilities was primarily driven by a $7.9 million increase in prepaid expenses and other assets, mainly due to higher advance payments (such as site initiation fees and other upfront costs) to support the expansion of our ongoing Phase 3 programs, partially offset by a net increase in accounts payable and accrued expenses of $1.7 million driven by activity levels and timing of vendor payments.

For the three months ended March 31, 2024, net cash used in operating activities of $39.7 million reflects a net loss of $51.6 million, partially offset by a net change of $9.4 million in operating assets and liabilities and aggregate noncash charges of $2.5 million. Noncash charges primarily included stock-based compensation expense of $5.0 million, net accretion of discounts on investments in marketable securities of $2.8 million, amortization of debt discount and accretion of deferred debt costs of $0.2 million and noncash operating lease expense of $0.2 million. The net change in operating assets and liabilities was mainly due to an increase in accounts payable and accrued expenses of $7.2 million and a decrease in prepaid expenses and other assets of $2.1 million, primarily driven by timing of payments made and an increase in services rendered by contract research organizations and contract manufacturing organizations in connection with our clinical trials.

Investing Activities

For the three months ended March 31, 2025, net cash used in investing activities was $7.8 million, which primarily consisted of $105.1 million in purchases of marketable securities, offset in part by $97.3 million in proceeds from sales and maturities of marketable securities.

For the three months ended March 31, 2024, net cash used in investing activities was $79.9 million, which consisted of $152.0 million in purchases of marketable securities, offset in part by $72.1 million in proceeds from sales and maturities of marketable securities.

Financing Activities

For the three months ended March 31, 2025, net cash provided by financing activities was $268.9 million, primarily reflecting $269.9 million in net proceeds from our public offering of common stock and pre-funded warrants. This was offset in part by payments for employee withholding taxes of $1.0 million related to net share settlement upon vesting of restricted stock units.

For the three months ended March 31, 2024, net cash provided by financing activities was $21.0 million, primarily reflecting $21.1 million in net proceeds from sales of common stock under our 2023 ATM Facility and $1.8 million from the exercise of common stock warrants. This was offset in part by payments for taxes of $1.7 million related to net share settlement upon vesting of restricted stock units.

Contractual Obligations and Commitments

Debt Obligations

As of March 31, 2025, the outstanding principal amount of $35.0 million under our Loan Agreement is scheduled to mature on October 1, 2028 and provides for interest-only payments until January 1, 2027. 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

Under our license agreement with Teva Pharmaceutical Industries Ltd. (Teva) for the glycoPEGylated FGF21 program (pegozafermin), we are obligated to pay Teva up to $65.0 million upon the achievement of specified commercial milestones, in addition to a $2.5 million clinical development milestone payment made in the fourth quarter of 2023. We also have an obligation to pay tiered royalties on future worldwide net sales of products containing pegozafermin. As of March 31, 2025, the timing and likelihood of achieving the 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.

Remaining Production Facility Funding Obligation

Under the Collaboration Agreement, we are required to pay BiBo an aggregate of $135.0 million (exclusive of applicable value-added tax) toward the construction of the production facility, of which we have paid $121.5 million (net of applicable value-added tax) as of March 31, 2025. The remaining $13.5 million will become payable upon achievement of a certain specified milestone. 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, 2024.

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, 2024.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As of March 31, 2025, 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 March 31, 2025 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 March 31, 2025 that have materially affected, or are 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, and new risks will emerge from time to time. It is not possible for our management to predict all risks. Moreover, some of the factors, events and contingencies discussed below may have occurred in the past, but the disclosures below are not representations as to whether or not the factors, events or contingencies have occurred in the past, and instead reflect our beliefs and opinions as to the factors, events or contingencies that could materially and adversely affect us in the future.

Risk Factor Summary

- 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 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, fluctuations 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 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 following the filing of this Form 10-Q.

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 under the 2023 ATM Facility and proceeds from our Loan Agreement, which are subject to the achievement of certain milestones and/or consent of the lenders. 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. For example, escalating trade tensions, interest rate uncertainty and regulatory uncertainty have caused significant market volatility in recent months, and particularly in the biotechnology and biopharmaceutical industries, which such volatility can have an adverse effect on the ability to raise 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 our consolidated financial statements appearing under Part II, Item 8 of our Annual Report on Form 10-K for the year ended December 31, 2024.

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 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, enrollment in Phase 3 clinical trials may be adversely affected by the marketing approval for Rezdiffra™ or the potential marketing approvals for one or more investigational MASH drugs if patients choose to take an approved drug rather than enroll in a clinical trial. In addition, our ability to receive accelerated approval of pegozafermin using data from the histology cohorts for non-cirrhotic (F2-F3) and cirrhotic (F4) MASH may be adversely affected if another company's product candidate receives full approval before we receive accelerated approval. 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 either party, it could have a negative effect on the clinical development of pegozafermin if our other manufacturer is not able to produce sufficient quantities of pegozafermin and we need to qualify an alternate supply source.

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. BiBo is constructing a production facility in China specifically designed to produce pegozafermin for commercial supply. We cannot guarantee that BiBo will be able to complete or make operational the production facility in a timely manner or at all, or be able to scale up and produce the quantities we would require to commercialize pegozafermin. Under our Collaboration Agreement with BiBo, we are required to pay BiBo an aggregate of $135.0 million (exclusive of applicable value-added tax) toward the construction of the production facility, however, if the actual costs of the production facility are substantially greater than the estimated budget, we and Bibo 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. For additional information regarding the production facility, please see Part I, Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations—Contractual Obligations and Commitments" and Note 5 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, 2024.

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. 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 and Merck & Cie 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 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 primary source suppliers, BTPH and BiBo, have not yet manufactured a commercial product, and as a result, have 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 or Chinese governments, political unrest or unstable economic conditions in China. For example, WuXi Biologics, which we have engaged as a potential commercial supply chain vendor, is identified in the U.S. legislation known as the BIOSECURE Act, which was proposed in the 118th Congress, as a "biotechnology company of concern." The version of the BIOSECURE Act introduced in the U.S. House of Representatives during the 118th Congress would prohibit federal agencies from entering into procurement contracts with, as well as providing grants and loans to, an entity that uses biotechnology equipment or services from a biotechnology company of concern, and includes a grandfathering provision allowing biotechnology equipment and services provided or produced by named "biotechnology companies of concern" under a contract or agreement entered into before the effective date until January 1, 2032. The pathway and timing for the BIOSECURE Act or its provisions to become law are uncertain. Foreign CMOs may be subject to U.S. legislation, including the proposed BIOSECURE Act, trade restrictions, and other foreign regulatory requirements that could increase the cost or reduce the supply of material available to us, delay the procurement or supply of such material or have an adverse effect on our ability to secure significant commitments from governments to purchase our potential therapies. For example, in April 2025, the United States government imposed significant tariffs on imports from China and other countries and may impose more restrictions on goods, including biologically derived substances, manufactured in or imported from China or other countries or impose other restrictions on companies' ability to work with Chinese or other foreign counterparties. 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. Changes to Chinese regulations or government policies affecting biopharmaceutical companies are unpredictable and may have a material adverse effect on our collaborators in China, which could have an adverse effect on our business, financial condition, results of operations and prospects. Developments in China's public health, economic, political, and social conditions and the uncertainty around China's relationship with other governments, such as the United States and the United Kingdom, could also negatively impact our ability to manufacture our product candidates for our planned clinical trials or have an adverse effect on our ability to secure government funding, which could adversely affect our financial condition and cause delay to our clinical development programs. Furthermore, if the BIOSECURE Act is passed and one or more of our collaborators in China is deemed to be a biotechnology company of concern, our operations and financial condition may be negatively impacted as a result of any delays or increased costs arising from the trade restrictions and other foreign regulatory requirements affecting such collaborators. 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.

While we believe that pegozafermin has been generally well tolerated with a favorable safety profile in our clinical trials, patients have experienced adverse events that have been considered treatment-related. Some of the more common adverse events included diarrhea, nausea, injection site erythema, injection site rash and increase appetite. Undesirable side effects caused by pegozafermin or

any future product candidates or by other companies' similar approved drugs or 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. Our Phase 1 and Phase 2 clinical trials have involved a limited number of patients and limited duration of exposure to pegozafermin. As a result, we cannot be assured that adverse effects of pegozafermin will not be uncovered when a larger number of patients are exposed to the product candidate in our Phase 3 clinical trials. 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 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, another company has received regulatory approval for its MASH therapy, and 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 such approved drug, rather than enroll in a clinical trial. In addition, such approved MASH therapy 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, fluctuations 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, has 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, fluctuating interest rates, and uncertainty about economic stability. In addition, the effects of global economic conditions, including new or increased tariffs and other barriers to trade, especially in light of recent executive orders made by the current administration, trade and other international disputes, slower growth or recession, high unemployment, labor availability constraints, significant natural disasters, including as a result of climate change, changes to fiscal and monetary policy or government budget dynamics, particularly in the pharmaceutical and biotech areas, may have adverse effects on our business and financial condition. In recent months, the United States has announced tariffs on imports from most countries, including significant tariffs on imports from China. Historically, tariffs have led to increased trade and political tensions. In response to tariffs, other countries have implemented retaliatory tariffs on U.S. goods. Political tensions as a result of trade policies could reduce trade volume, investment, technological exchange and other economic activities between major international economies, resulting in a material adverse effect on global economic conditions and the stability of global financial markets. There is substantial uncertainty about the duration of existing tariffs and whether additional tariffs may be imposed, modified or suspended. In addition, the Federal Reserve has previously raised interest rates multiple times in response to concerns about inflation and it may raise them again. Fluctuation in 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 2021, we implemented remedial measures promptly following a business email compromise caused by phishing, 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.

If the market opportunities for our approved product candidates, if any, are smaller than we expect, it could materially and adversely affect our financial condition and results of operation.

If the market opportunity for our products, if approved, is smaller than we expect, we may never become or remain profitable nor generate sufficient revenue growth to sustain our business even if we obtain significant market share for them. The potentially addressable patient population for our products may be limited or may not be amenable to treatment with our products, and new patients may become increasingly difficult to identify or access, which would adversely affect our results of operations and our business.

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.

While the FDA has approved a product for the treatment of MASH and 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. Further, the FDA and comparable foreign regulatory authorities may undergo leadership changes, change their policies, issue additional regulations or revise existing regulations, or take other actions, such as those implemented by the recently established Department of Government Efficiency, which may impact our clinical development plans or prevent or delay approval of our programs under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals and increase the costs of compliance.

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 for the year ended December 31, 2024. 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 and in March 2024, the EMA granted PRIME status to pegozafermin in patients with MASH. We may in the future seek Breakthrough Therapy designation, Fast Track designation or PRIME designation for other indications or future product candidates. However, 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.

In addition, 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. Additionally, changes in the leadership of the FDA and other actions taken by the current administration, including mass layoffs within the federal government, may impose constraints on the FDA's ability to engage in activities in the normal course and may result in reductions to the FDA's budget, employees and operations, which may lead to slower response times and longer review periods, potentially affecting our ability to take advantage of the benefits for Breakthrough Therapy and Fast Track designations and progress development of our programs or obtain regulatory approval for our programs. See Part I, Item 1. "Business—Expedited Programs for Serious Conditions" in our Annual Report on Form 10-K for the year ended December 31, 2024.

We 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 to continue conducting 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.

Disruptions at the FDA and other government agencies could negatively affect the review of our regulatory submissions, which could negatively impact our business.

The ability of the FDA to review and approve regulatory submissions can be affected by a variety of factors, including statutory, regulatory and policy changes, inadequate government budget funding levels or a reduction in the FDA's workforce and its ability to hire and retain key personnel, disruptions caused by government shutdowns and public health crises. There have been mass layoffs of federal employees since the start of the current administration in January 2025, the full impact of which is unclear at this time. Such disruptions could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. In addition, the current administration has made and is expected to continue to make changes in the leadership of various U.S. federal regulatory agencies and changes to U.S. federal government policy that have led to, in some cases, legal challenges and uncertainty around the funding, functioning and policy priorities of the U.S. federal regulatory agencies, including the FDA.

We are unable to predict the extent to which the current administration may impose or seek to impose leadership or policy changes at the FDA or changes to rules and policies impacting our business and operations. It is unclear how these executive actions or other potential actions by the federal government will impact the FDA or other regulatory authorities that oversee our business. Government proposals to reduce or eliminate budgetary deficits may include reduced allocations to the FDA and other related government agencies. These budgetary pressures may reduce the FDA's ability to perform its responsibilities, which could result in delays in our clinical trial timelines. If a significant reduction in the FDA's workforce occurs, the FDA's budget is significantly reduced or a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions or take other actions critical to the development or manufacturing of pegozafermin, or future product candidates, which could have a material adverse effect on our business.

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 ACA 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. The Inflation Reduction Act of 2022 (IRA) includes 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. Historically, 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. Accordingly, even if we or our licensors are able to obtain patents, the patents might be substantially narrower than anticipated. Thus, there is no assurance as to the degree and range of protections any of our patents, if issued, may afford us or whether patents will be issued. 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 (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, 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. For example, escalating trade tensions, interest rate uncertainty and regulatory uncertainty have caused significant market volatility in recent months, and particularly in the biotechnology and biopharmaceutical industries. 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 the Amended and Restated 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, if we issue warrants in the future, we may need to settle exercises of such warrants in shares of our common stock. The issuance of shares of our common stock upon exercise of 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 2023 ATM Facility, 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.

We may issue warrants in the future, and hedging activity by investors in such warrants could depress the trading price of our common stock.

We may issue warrants in the future and investors in such warrants may 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 December 31, 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 (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, 2024, we had U.S. federal and state net operating loss (NOL) carryforwards of $255.5 million and $496.5 million, respectively, which may be available to offset future taxable income. As of December 31, 2024, we also had gross federal tax credits of $19.7 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. As of December 31, 2024, discussions with the Israel Tax Authorities are ongoing. 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, 2024.

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.

Trading Arrangements

None of our directors or executive officers adopted or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement during the three months ended March 31, 2025, as such terms are defined under Item 408(a) of Regulation S-K.

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 of the Company (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 the Company (filed with the SEC as Exhibit 3.1 to the Company's Current Report on 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 Company (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 Current Report on 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 to Purchase Common Stock for K2 HealthVentures LLC (filed with the SEC as Exhibit 4.1 to the Company's Current Report on Form 8-K/A filed on February 2, 2023).
4.5	Form of Warrant to Purchase Common Stock for K2 HealthVentures LLC (filed with the SEC as Exhibit 4.1 to the Company's Current Report on Form 8-K filed on October 3, 2024).
4.6	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).
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 November 14, 2024).
4.8	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 January 29, 2025).
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.

SIGNATURES

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

89bio, Inc.

Date: May 2, 2025

By: /s/ Rohan Palekar
Rohan Palekar
Chief Executive Officer
(principal executive officer)

Date: May 2, 2025

By: /s/ Ryan Martins
Ryan Martins
Chief Financial Officer
(principal financial and accounting officer)

Exhibit 31.1

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

I, Rohan Palekar, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: May 2, 2025

By: /s/ Rohan Palekar

Rohan Palekar
Chief Executive Officer
(principal executive officer)

Exhibit 31.2

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

I, Ryan Martins, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: May 2, 2025

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 March 31, 2025, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

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

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

Date: May 2, 2025

By: /s/ Rohan Palekar

Rohan Palekar
Chief Executive Officer
(principal executive officer)

Date: May 2, 2025

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.