UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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: 001-42272

MBX Biosciences, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**84-1882872**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
11711 N. Meridian Street, Suite 300 Carmel, Indiana	**46032**
(Address of principal executive offices)	**(Zip Code)**

(317) 659-0200

Registrant's telephone number, including area code

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 $0.0001 per share	MBX	The Nasdaq Global Select 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 November 3, 2025, the registrant had 44,902,302 shares of common stock, $0.0001 par value per share, outstanding.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q (this "Quarterly Report") contains forward looking statements, including the sections entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Risk Factors". These sections contain express or implied forward-looking statements that are based on our management's belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future operational or financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements in this Quarterly Report include, but are not limited to, statements about:

- the initiation, timing, progress and results of our current and future research and development programs, preclinical studies and clinical trials;
- our ability to successfully complete our clinical trials;
- our ability to finalize the design or formulation of any product candidate;
- the ability of our platform to optimize pharmacokinetic and/or pharmacologic properties;
- our ability to advance any product candidates that we may identify and successfully complete any clinical studies, including the manufacture of any such product candidates;
- our ability to quickly leverage programs within our initial target indications and to progress additional programs to further develop our pipeline;
- our ability to internalize certain of our discovery capabilities;
- the prevalence of certain diseases and conditions we intend to treat and the size of the market opportunity for our product candidates;
- estimates of the number of patients with certain diseases and conditions we intend to treat and the number of patients that we will enroll in our clinical trials;
- the likelihood of our clinical trials demonstrating safety and efficacy of our product candidates;
- the timing of our investigational new drug applications submissions;
- the timing of announcement of interim and final results from clinical trials;
- our projected operating expenses and capital expenditure requirements;
- the implementation of our strategic plans for our business, programs and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our technology and platform;
- developments related to our competitors and our industry;
- the success of competing therapies that are or may become available;
- our ability to leverage the clinical, regulatory, and manufacturing advancements to accelerate our clinical trials and approval of product candidates;
- our ability to meet future regulatory standards with respect to our product candidates, if approved;
- our ability to identify and enter into future license agreements and collaborations;
- our reliance on third parties to conduct clinical trials of our product candidates;
- our reliance on third parties for the manufacture of our product candidates;
- developments related to our technology and platform;
- regulatory or other geopolitical developments in the United States and foreign countries and their potential impacts, if any, on the Company;
- our commercialization, marketing and manufacturing capabilities;

- our expectations regarding the period during which we will qualify as an emerging growth company under the Jumpstart Our Business Startups Act of 2012 or a smaller reporting company;
- our ability to attract and retain key scientific and management personnel; and
- our anticipated use of our existing cash, cash equivalents and marketable securities, including the proceeds from our public offerings, our financial performance, estimates of our expenses, capital requirements, and need for additional financing.

In some cases, you can identify forward-looking statements by terminology such as "may," "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "continue" or the negative of these terms or other comparable terminology. These statements are only predictions. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, which are, in some cases, beyond our control and which could materially affect results. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under the section entitled "Risk Factors" and elsewhere in this Quarterly Report. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those implied or projected by the forward-looking statements. No forward-looking statement is a guarantee of future performance. You should read this Quarterly Report and the documents that we reference in this Quarterly Report and have filed with the SEC as exhibits to this Quarterly Report and previous filings, completely and with the understanding that our actual future results may be materially different from any future results expressed or implied by these forward-looking statements.

The forward-looking statements in this Quarterly Report represent our views as of the date of this Quarterly Report. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Quarterly Report.

This Quarterly Report also contains estimates, projections and other information concerning our industry, our business and the markets for our product candidates. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. Unless otherwise expressly stated, we obtained this industry, business, market, and other data from our own internal estimates and research as well as from reports, research surveys, studies, and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources. While we are not aware of any misstatements regarding any third-party information presented in this Quarterly Report, their estimates, in particular, as they relate to projections, involve numerous assumptions, are subject to risks and uncertainties and are subject to change based on various factors, including those discussed under the section entitled "Risk Factors" and elsewhere in this Quarterly Report.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

MBX BIOSCIENCES, INC.

CONDENSED BALANCE SHEETS
(in thousands, except share and per share amounts)

	September 30, 2025 (Unaudited)	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 223,125	$ 49,351
Marketable securities	168,548	212,798
Prepaid expenses and other current assets	5,829	5,137
Total current assets	397,502	267,286
Property and equipment, net	2,004	1,080
Right-of-use assets	520	119
Other assets	50	50
Total assets	$ 400,076	$ 268,535
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 3,768	$ 5,335
Accrued expenses	8,140	5,545
Operating lease liability, current	154	171
Total current liabilities	12,062	11,051
Share repurchase liability	7	42
Operating lease liability, net of current	469	—
Total liabilities	12,538	11,093
Commitments and contingencies (Note 9)		
Stockholders' equity (deficit)		
Undesignated preferred stock, $0.0001 par value, 10,000,000 shares authorized and zero issued and outstanding as of September 30, 2025 and December 31, 2024	—	—
Common stock, $0.0001 par value, 500,000,000 shares authorized and 44,715,498 issued and outstanding as of September 30, 2025 and 500,000,000 shares authorized and 33,421,525 issued and outstanding as of December 31, 2024	6	5
Additional paid-in-capital	589,792	394,887
Accumulated deficit	(202,414)	(137,505)
Accumulated other comprehensive income	154	55
Total stockholders' equity	387,538	257,442
Total liabilities and stockholders' equity	$ 400,076	$ 268,535

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

MBX BIOSCIENCES, INC.

CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited - in thousands, except share and per share amounts)

	Three months ended September 30,		Nine months ended September 30,	
	2025	2024	2025	2024
Operating expenses				
Research and development	$ 19,270	$ 16,747	$ 59,400	$ 42,192
General and administrative	4,656	2,865	12,860	7,392
Total operating expenses	23,926	19,612	72,260	49,584
Loss from operations	(23,926)	(19,612)	(72,260)	(49,584)
Interest and other income, net	2,308	1,470	7,351	3,248
Net loss	$ (21,618)	$ (18,142)	$ (64,909)	$ (46,336)
Unrealized gain on marketable securities	143	121	99	46
Total other comprehensive income	143	121	99	46
Total comprehensive loss	$ (21,475)	$ (18,021)	$ (64,810)	$ (46,290)
Net loss attributable to common stockholders	$ (21,618)	$ (18,142)	$ (64,909)	$ (46,336)
Net loss per common share, basic and diluted	$ (0.63)	$ (2.78)	$ (1.93)	$ (15.42)
Weighted average number of common shares outstanding used in computation of net loss per common share, basic and diluted	34,198,597	6,515,616	33,688,669	3,004,382

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

MBX BIOSCIENCES, INC.

CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT) AND CONVERTIBLE PREFERRED STOCK
(Unaudited - in thousands, except share amounts)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Outstanding Shares	Amount				
Balance at January 1, 2025	33,421,525	$ 5	$ 394,887	$ (137,505)	$ 55	$ 257,442
Issuance of common stock upon exercise of stock options	3,019	—	4	—	—	4
Repurchase of restricted stock due to early exercised unvested stock options	(173)	—	19	—	—	19
Stock-based compensation expense	—	—	1,839	—	—	1,839
Net loss	—	—	—	(23,880)	—	(23,880)
Other comprehensive loss	—	—	—	—	(2)	(2)
Balance at March 31, 2025	33,424,371	5	396,749	(161,385)	53	235,422
Issuance of common stock upon exercise of stock options	167,855	—	1,333	—	—	1,333
Stock-based compensation expense	—	—	1,937	—	—	1,937
Net loss	—	—	—	(19,411)	—	(19,411)
Other comprehensive income loss	—	—	—	—	(42)	(42)
Balance at June 30, 2025	33,592,226	5	400,019	(180,796)	11	219,239
Issuance of common stock from public offering, net of issuance costs	11,108,055	1	187,389	—	—	187,390
Issuance of common stock upon exercise of stock options	15,217	—	139	—	—	139
Stock-based compensation expense	—	—	2,245	—	—	2,245
Net loss	—	—	—	(21,618)	—	(21,618)
Other comprehensive income	—	—	—	—	143	143
Balance at September 30, 2025	44,715,498	$ 6	$ 589,792	$ (202,414)	$ 154	$ 387,538

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Common Stock		Additional		Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Deficit
	Outstanding Shares	Amount	Outstanding Shares	Amount	Outstanding Shares	Amount	Outstanding Shares	Amount	Paid-in Capital	Accumulated Deficit		
Balance at January 1, 2024	53,598,587	$ 36,501	129,240,032	$ 6	—	$ —	1,257,080	$ 1	$ 3,054	$ (75,583)	$ 60	$ (72,468)
Issuance of common stock upon exercise of stock options	—	—	—	—	—	—	35,918	—	198	—	—	198
Stock-based compensation expense	—	—	—	—	—	—	—	—	1,623	—	—	1,623
Net loss	—	—	—	—	—	—	—	—	—	(12,337)	—	(12,337)
Other comprehensive loss	—	—	—	—	—	—	—	—	—	—	(63)	(63)
Balance at March 31, 2024	53,598,587	36,501	129,240,032	115,856	—	—	1,292,998	1	4,875	(87,920)	(3)	(83,047)
Issuance of common stock upon exercise of stock options	—	—	—	—	—	—	24,101	1	111	—	—	112
Stock-based compensation expense	—	—	—	—	—	—	—	—	919	—	—	919
Net loss	—	—	—	—	—	—	—	—	—	(15,857)	—	(15,857)
Other comprehensive loss	—	—	—	—	—	—	—	—	—	—	(12)	(12)
Balance at June 30, 2024	53,598,587	36,501	129,240,032	115,856	—	—	1,317,099	2	5,905	(103,777)	(15)	(97,885)
Issuance of Series C Convertible Preferred Stock, net of $279 issuance costs	—	—	—	—	61,650,480	63,221	—	—	—	—	—	—
Conversion of Series A Convertible Preferred stock to common stock upon closing of the initial public offering	(53,598,587)	(36,501)	—	—	—	—	4,458,324	—	36,501	—	—	36,501
Conversion of Series B Convertible Preferred stock to common stock upon closing of the initial public offering	—	—	(129,240,032)	(115,856)	—	—	10,750,183	1	115,855	—	—	115,856
Conversion of Series C Convertible Preferred stock to common stock upon closing of the initial public offering	—	—	—	—	(61,650,480)	(63,221)	5,128,092	1	63,220	—	—	63,221
Issuance of common stock from initial public offering, net of $17,210 issuance costs	—	—	—	—	—	—	11,730,000	1	170,468	—	—	170,469
Issuance of common stock upon exercise of stock options	—	—	—	—	—	—	602	—	35	—	—	35
Repurchase of restricted stock due to early exercised unvested stock options	—	—	—	—	—	—	(8,242)	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	1,192	—	—	1,192
Net loss	—	—	—	—	—	—	—	—	—	(18,142)	—	(18,142)

Other comprehensive income	—	—	—	—	—	—	—	—	—	—	121	121
Balance at September 30, 2024	—	$ —	—	$ —	—	$ —	33,376,058	$ 5	$ 393,176	$ (121,919)	$ 106	$ 271,368

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

MBX BIOSCIENCES, INC.

CONDENSED STATEMENTS OF CASH FLOWS
(Unaudited - in thousands)

	Nine months ended September 30,	
	2025	2024
Cash flows from operating activities:		
Net loss	$ (64,909)	$ (46,336)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	6,021	3,734
Non cash operating lease expense	101	79
Accretion and amortization of marketable securities, net	(3,056)	(1,531)
Depreciation expense	188	186
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(692)	(1,319)
Accounts payable	(1,595)	3,282
Accrued expenses	2,343	3,374
Operating lease right-of-use asset	(501)	—
Operating lease liability	452	(113)
Net cash used in operating activities	(61,648)	(38,644)
Cash flows from investing activities:		
Purchases of property and equipment	(1,136)	(782)
Purchases of marketable securities	(152,718)	(151,968)
Maturities of marketable securities	191,622	59,500
Call redemptions of marketable securities	8,500	—
Net cash provided by (used in) investing activities	46,268	(93,250)
Cash flows from financing activities:		
Proceeds from public offering, net of underwriting discounts and commissions	187,948	—
Proceeds from initial public offering, net of underwriting discounts and commissions	—	174,542
Proceeds from exercise of stock options	1,460	208
Payments related to offering costs	(254)	(3,735)
Proceeds from the issuance of Series C Convertible Preferred Stock	—	63,500
Preferred stock issuance costs	—	(279)
Net cash provided by financing activities	189,154	234,236
Net increase in cash and cash equivalents	173,774	102,342
Cash and cash equivalents, beginning of period	49,351	30,523
Cash and cash equivalents, end of period	$ 223,125	$ 132,865
Supplemental disclosure of non-cash investing and financing activities:		
Vesting of early exercised stock options	$ 34	$ 206
Property and equipment in accounts payable and accrued liabilities	5	16
Conversion of convertible preferred stock to common stock upon initial public offering	—	215,578
Deferred public offering costs included in accounts payable and accrued expenses	304	329

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

MBX BIOSCIENCES, INC.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS

1. NATURE OF BUSINESS AND LIQUIDITY

MBX Biosciences, Inc. (“MBX” or the “Company”) is a clinical-stage biopharmaceutical company focused on the discovery and development of novel precision peptide therapies for the treatment of endocrine and metabolic disorders. The Company is advancing a pipeline of novel candidates for endocrine and metabolic disorders. The Company was organized in August 2018 in Indiana as a Limited Liability Company and converted to a C corporation in the state of Delaware in April 2019. The Company maintains its corporate offices in Carmel, Indiana.

Since inception, the Company has devoted substantially all of its resources to drug discovery and development of its product candidates canvuparatide (MBX 2109), imapextide (MBX 1416) and MBX 4291, and other preclinical programs, building an intellectual property portfolio, organizing and staffing the Company, business planning, raising capital and providing general and administrative support for these operations. The Company does not have any products approved for sale and has not generated any revenue from product sales. The Company has historically funded its operations primarily through the issuance and sale of our common stock, including through our initial public offering (the "IPO"), convertible preferred stock and convertible notes, which generated approximately $401.8 million in aggregate gross proceeds. In September 2025, the Company also completed an underwritten public offering (the "September 2025 Offering") of 11,108,055 shares of its common stock, which generated approximately $199.9 million in aggregate gross proceeds, resulting in $601.7 million in cumulative, aggregate gross proceeds.

Liquidity

From inception and through September 30, 2025, the Company has devoted substantially all of its efforts to drug discovery and development. The Company has a limited operating history, has incurred operating losses since inception and expects to continue to incur significant operating losses for the foreseeable future. The Company incurred net losses of $64.9 million and $61.9 million for the nine months ended September 30, 2025 and the year ended December 31, 2024, respectively. As of September 30, 2025, the Company has an accumulated deficit of $202.4 million and cash, cash equivalents and marketable securities of $391.7 million. Based on the Company’s current business plan, management believes that existing cash and cash equivalents and marketable securities will be sufficient to fund the Company’s obligations for at least 12 months from the date of issuance of these condensed financial statements.

Basis of presentation

The accompanying unaudited condensed financial statements as of September 30, 2025 and for the three and nine months ended September 30, 2025 and 2024 have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP") for interim financial information and pursuant to Article 10 of Regulation of the Securities Act of 1933, as amended. Accordingly, they do not include all of the information and notes required by U.S. GAAP for complete financial statements. These unaudited condensed financial statements include only normal and recurring adjustments that the Company believes are necessary to fairly state the Company’s financial position and the results of its operations and cash flows. The results for the three and nine months ended September 30, 2025 are not necessarily indicative of the results expected for the full fiscal year or any subsequent interim period. The condensed balance sheet at December 31, 2024 has been derived from the audited financial statements at that date but does not include all disclosures required by U.S. GAAP for complete financial statements. Because all of the disclosures required by U.S. GAAP for complete financial statements are not included herein, these unaudited condensed financial statements and the notes accompanying them should be read in conjunction with the Company’s audited financial statements for the year ended December 31, 2024 included in the Company's Annual Report on Form 10-K as filed with the SEC on March 17, 2025 ("2024 Annual Report").

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

There have been no significant changes from the significant accounting policies and estimates disclosed in Note 2 of the "Notes to Financial Statements" in the audited financial statements for the year ended December 31, 2024 and notes thereto, included in the 2024 Annual Report, except as noted below.

Deferred offering costs

The Company capitalizes as deferred offering costs all direct and incremental legal, professional, accounting and other third-party fees incurred in connection with the September 2025 Offering and IPO. The deferred offering costs related to the September

2025 Offering and IPO were each offset against the September 2025 Offering proceeds and IPO proceeds, respectively, upon the consummation of the applicable offerings. As of September 30, 2025, $0.3 million of deferred offering costs were included in accounts payable and accrued expenses in the accompanying balance sheets. As of September 30, 2024, $0.3 million of deferred offering costs were included in accounts payable and accrued expenses in the accompanying balance sheets.

Recently issued accounting pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard-setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on the accompanying financial statements and disclosures.

In December 2023, the FASB issued ASU 2023-09, Income Taxes: Improvements to Income Tax Disclosures (Topic 740), which establishes incremental disaggregation of income tax disclosures pertaining to the effective tax rate reconciliation and income taxes paid. This new standard is effective for fiscal years beginning after December 15, 2024. Early adoption is permitted. The standard should be applied prospectively to financial statements issued for periods after the effective date of this ASU with the option to apply it retrospectively. The Company intends to adopt this standard in its Annual Report on Form 10-K for the year ending December 31, 2025 and is currently assessing the impact ASU 2023-09 (Topic 740) will have on its financial statements, including the footnote disclosures.

In November 2024, the FASB issued ASU 2024-03, Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses, which is intended to provide more detailed information about specified categories of expenses (purchases of inventory, employee compensation, depreciation and amortization) included in certain expense captions presented on the face of our income statements. This new standard is effective for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted. The amendments may be applied either (1) prospectively to financial statements issued for periods after the effective date of this ASU or (2) retrospectively to all prior periods presented in the financial statements. The Company is currently assessing the impact ASU 2024-03 will have on its financial statements, including the footnote disclosures.

Recently enacted legislation

In July 2025, the One Big Beautiful Bill Act (“OBBBA”) was signed into law, which includes significant provisions modifying the U.S. tax framework. The Company is currently assessing the impact these legislative changes will have on its financial statements, including the footnote disclosures.

3. FAIR VALUE MEASUREMENTS

The following table presents information about the Company’s financial instruments as of September 30, 2025 and December 31, 2024, that are measured at fair value on a recurring basis and indicates the fair value hierarchy of the inputs the Company utilized to determine such fair value (*in thousands*):

	September 30, 2025			
	Total	Level 1	Level 2	Level 3
Financial assets:				
Money market funds (cash equivalents)	$ 220,208	$ 220,208	$ —	$ —
Marketable securities	168,548	163,569	4,979	—
Total financial assets measured at fair value	$ 388,756	$ 383,777	$ 4,979	$ —

	December 31, 2024			
	Total	Level 1	Level 2	Level 3
Financial assets:				
Money market funds (cash equivalents)	$ 37,989	$ 37,989	$ —	$ —
Marketable securities (cash equivalents)	9,990	4,997	4,993	—
Marketable securities	212,798	204,385	8,413	—
Total financial assets measured at fair value	$ 260,777	$ 247,371	$ 13,406	$ —

4. MARKETABLE SECURITIES

The fair value of the Company's marketable securities as of September 30, 2025 and December 31, 2024 is based on Level 1 and Level 2 inputs. The Company's investments consist mainly of U.S. government and agency securities. Fair value is determined by taking into consideration valuations obtained from third-party pricing services. The third-party pricing services utilize industry standard valuation models, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities; issuer credit spreads; benchmark securities; and other observable inputs. There were no transfers between levels within the fair value hierarchy during each of the nine months ended September 30, 2025 and 2024. The Company has assessed U.S. government treasuries as Level 1 and all other marketable securities as Level 2 within the fair value hierarchy of ASC 820. The Company classifies its entire investment portfolio as available-for-sale as defined in ASC 320, Debt Securities, and views all investments as available for use in its current operations. The Company has therefore classified all securities as current, even if it does not necessarily intend to dispose of the securities in the following year. Securities are carried at fair value with the unrealized (losses) gains reported in other comprehensive (loss) income.

As of September 30, 2025 and December 31, 2024, none of the Company's investments were determined to be other than temporarily impaired.

The following table summarizes the Company's investments (*in thousands*):

		September 30, 2025			
	Balance Sheet Classification	Amortized Cost	Unrealized Gain	Unrealized (Loss)	Estimated Fair Value
Government and agency securities	Marketable securities	168,394	155	(1)	168,548
Total		$ 168,394	$ 155	$ (1)	$ 168,548

		December 31, 2024			
	Balance Sheet Classification	Amortized Cost	Unrealized Gain	Unrealized (Loss)	Estimated Fair Value
Government and agency securities	Cash equivalents	$ 9,989	$ 1	$ —	$ 9,990
Government and agency securities	Marketable securities	212,744	107	(53)	212,798
Total		$ 222,733	$ 108	$ (53)	$ 222,788

The fair values of available-for-sale debt securities as of September 30, 2025, by contractual maturity, are summarized as follows (*in thousands*):

	September 30, 2025
Due in one year or less	$ 167,033
Due after one year	1,515
Total	$ 168,548

5. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid and other current assets consisted of the following (*in thousands*):

	September 30, 2025	December 31, 2024
Prepaid research and development expenses	$ 3,399	$ 3,652
Interest receivable	1,548	682
Other current assets	882	803
Total prepaid and other current assets	$ 5,829	$ 5,137

6. PROPERTY AND EQUIPMENT, NET

Property and equipment, net consisted of the following *(in thousands)*:

	September 30, 2025	December 31, 2024
Furniture and fixtures	$ 214	$ 214
Computer equipment and software	81	81
Equipment	861	816
Leasehold improvements	490	391
Construction in progress	968	—
Total property and equipment	2,614	1,502
Less accumulated depreciation	(610)	(422)
Property and equipment, net	$ 2,004	$ 1,080

Depreciation expense was $0.1 million for each of the three months ended September 30, 2025 and 2024, respectively. Depreciation expense was $0.2 million for each of the nine months ended September 30, 2025 and 2024.

7. ACCRUED EXPENSES

Accrued expenses consisted of the following (*in thousands*):

	September 30, 2025	December 31, 2024
Compensation and benefits	$ 2,778	$ 2,324
Research and development expenses	4,790	3,063
Other	572	158
Total accrued expenses	$ 8,140	$ 5,545

8. OTHER ASSETS

Other assets consisted of the following (*in thousands*):

	September 30, 2025	December 31, 2024
Security deposits	50	50
Total other assets	$ 50	$ 50

9. COMMITMENTS AND CONTINGENCIES

Leases

In April 2022, the Company entered into an operating lease agreement for a principal executive office in Carmel, Indiana (the “Carmel Lease”). The Carmel Lease commenced in October 2022 and had an initial term of 39 months, a termination date of December 31, 2025, and an option to extend for 36 additional months at the Company’s discretion. The option to extend was not considered reasonably certain as of the lease inception. On May 9, 2025, the Company entered into the first amendment of the Carmel Lease (the "First Amendment"). Pursuant to the terms of the First Amendment, the leased premises were expanded, and the lease term was extended through December 31, 2028 with an option to extend for 36 additional months at the Company’s discretion. The option to extend is not considered reasonably certain as of the date of the First Amendment.

In December 2023, the Company entered into an operating lease agreement for laboratory space in Indianapolis, Indiana (the “Laboratory Lease”). The Laboratory Lease commenced in December 2023 and had a term of 12 months, terminating in December 2024. The Company entered into a new lease for laboratory space in August 2024, commencing in December 2024, and terminating in December 2025. Both laboratory leases are short-term leases with no corresponding lease liability or right-of-use asset recorded, and lease payments are recognized as expense on a straight-line basis over the lease terms.

The Company has no other operating or finance leases as of September 30, 2025 or December 31, 2024.

Pursuant to ASC 842, the Company evaluated the new terms of the First Amendment of the Carmel Lease and determined the First Amendment should be treated as a lease modification of the existing Carmel Lease. In accordance with the accounting guidance, the Company remeasured the lease liability as of May 9, 2025, the First Amendment commencement date, to reflect the changes in the lease payments and the change in the lease term. This resulted in an increase of $0.6 million to the Company's lease liability and a corresponding increase to its right-of-use asset as shown on its condensed balance sheets as of September 30, 2025.

The future minimum rent payments relating to the Carmel Lease under the terms and conditions existing as of September 30, 2025, are summarized as follows (*in thousands*):

(in thousands)	Amount
2025	$ 44
2026	229
2027	234
2028	240
Total lease payments	747
Less: imputed interest	(124)
Present value of lease liabilities	$ 623

The Company incurred $0.1 million of rent expense for each of the three months ended September 30, 2025 and 2024. The Company incurred $0.2 million of rent expense for each of the nine months ended September 30, 2025 and 2024.

The following table summarizes the operating lease term and discount rate for the Carmel Lease as of September 30, 2025 and December 31, 2024:

	September 30, 2025	December 31, 2024
Weighted-average remaining lease term (years)	3.3	1.0
Weighted-average discount rate	11.0%	8.0%

Cash paid for amounts included in the measurement of the Company’s operating lease liability was less than $0.1 million for each of the three months ended September 30, 2025 and 2024. Cash paid for amounts included in the measurement of the Company’s operating lease liability was $0.1 million for each of the nine months ended September 30, 2025 and 2024.

The following table sets forth the amount of right-of-use assets and lease liabilities included on the Company’s balance sheet as of September 30, 2025 and December 31, 2024 (*in thousands*):

	September 30, 2025	December 31, 2024
Right-of use assets	$ 520	$ 119
Operating lease liability, current	154	171
Operating lease liability, net of current	469	—

License agreement

In January 2024, the Company entered into an amendment (the "Amendment") for the Exclusive License Agreement with Indiana University Research and Technology Corporation (“IURTC”) (the “License Agreement”), to license certain intellectual property arising under the Master Research Agreement with The Trustees of Indiana University (the "Research Agreement"). The Amendment specifies IURTC is entitled to the receipt of additional clinical and regulatory milestones, as defined in the Amendment, up to an aggregate of $9.0 million. Following the execution of the Amendment, future remaining clinical and regulatory milestone payments in the License Agreement and all amendments totaled up to $9.3 million. In the three and nine months ended September 30, 2025, the Company triggered a $1.0 million milestone payable to IURTC related to the initiation of the Phase 1 clinical trial of MBX 4291. The $1.0 million milestone payment was included in accounts payable in the condensed balance sheet as of September 30, 2025 and was paid in the fourth quarter of 2025. In consideration for the license, the Company paid no license fees to IURTC during the three and nine months ended September 30, 2024.

Legal proceedings

The Company is not currently a party to any material legal proceedings. At each reporting date, the Company evaluates whether a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. The Company expenses as incurred the costs related to its legal proceedings.

10. CONVERTIBLE PREFERRED STOCK

Prior to its IPO, the Company issued Series A Convertible Preferred Stock, Series B Convertible Preferred Stock and Series C Convertible Preferred Stock.

On August 30, 2024, the Company's board of directors and stockholders approved the fourth amended and restated certificate of incorporation, which was effective immediately prior to the closing of the Company's IPO on September 16, 2024, and which, among other things, authorized 10,000,000 undesignated shares of preferred stock, $0.0001 par value per share.

Immediately prior to the closing of the Company's IPO on September 16, 2024, pursuant to the reverse stock split and a proportional adjustment to the existing conversion ratios of each series of the Company's preferred stock, all of the Company's outstanding shares of convertible preferred stock were converted into an aggregate of 20,336,599 shares of common stock, as follows: 4,458,324 shares of common stock were issued as a result of the conversion of Series A convertible preferred stock; 10,750,183 shares of common stock were issued as a result of the conversion of Series B convertible preferred stock; and 5,128,092 shares of common stock were issued as a result of the conversion of Series C convertible preferred stock. Prior to the conversion of the Company's convertible preferred stock, holders of the Series A, Series B and Series C Convertible Preferred Stock had certain rights and preferences, including voting and conversion rights and dividend and liquidation preferences. The Company had no shares of convertible preferred stock outstanding at September 30, 2025.

11. COMMON STOCK

On August 30, 2024, the Company’s stockholders approved the fourth amended and restated certificate of incorporation, which was filed upon the closing of the IPO on September 16, 2024 and which, among other things, increased the number of shares of common stock authorized for issuance to 500,000,000 shares of common stock, $0.0001 par value.

On September 16, 2024, the Company completed the IPO of its common stock and issued and sold 11,730,000 shares of its common stock at a price of $16.00 per share. As a result, the Company received $170.5 million in net proceeds, after deducting underwriting discounts and commissions and offering costs of $17.2 million.

On September 26, 2025, the Company completed the September 2025 Offering and issued and sold 11,108,055 shares of its common stock at a price of $18.00 per share. As a result, the Company received $187.4 million in net proceeds, after deducting underwriting discounts and commissions and offering costs of $12.5 million.

As of September 30, 2025 and December 31, 2024, there were 44,715,498 and 33,421,525 shares of common stock issued and outstanding, respectively. Shares of common stock issued and outstanding as of September 30, 2025 include 2,514 shares of restricted stock related to the unvested portion of early exercised common stock options. Shares of common stock issued and outstanding as of December 31, 2024 include 12,608 shares of restricted stock related to the unvested portion of early exercised common stock options. These are included in shares of common stock as they are considered to be legally outstanding as of September 30, 2025 and December 31, 2024, respectively. These shares are subject to the Company’s option to repurchase and are not transferable until such time as they are fully vested.

Common stock reserved

The number of shares of common stock that have been reserved for future issuance in connection with outstanding stock options granted under the Company's 2019 Stock Option and Grant Plan (the "2019 Plan") and the 2024 Stock Option and Incentive Plan (the "2024 Plan"), stock options available for grant under the 2019 Plan and 2024 Plan and shares available for future issuance under the 2024 ESPP as of September 30, 2025 and December 31, 2024, are as follows:

	September 30, 2025	December 31, 2024
Outstanding common stock options	4,597,701	3,502,440
Common stock options available for grant	2,993,150	2,603,253
Shares available for issuance under 2024 ESPP	623,651	289,436
Total	8,214,502	6,395,129

12. STOCK-BASED COMPENSATION

2019 Stock Option and Grant Plan

The Company's 2019 Plan, as amended, provides for the Company to sell or issue common stock or restricted common stock or to grant incentive stock options or nonqualified stock options for the purchase of common stock, to employees, members of the Board, and consultants of the Company. The 2019 Plan is administered by the Board or at the discretion of the Board by a committee of the Board. The exercise prices, vesting periods, and other restrictions are determined at the discretion of the Board or a committee of the Board, except that the exercise price per share of stock options may not be less than 100% of the fair market value of the share of common stock on the date of grant and the contractual term of stock option may not be greater than 10 years. Stock options granted to date typically vest and become exercisable over four years from the date of grant.

As of the date the 2024 Plan became effective, there will be no further awards granted under the 2019 Plan, but all outstanding awards under the 2019 Plan will continue to be governed by their existing terms. 2,675,959 stock options to purchase common stock were outstanding under the 2019 Plan as of September 30, 2025.

2024 Stock Option and Incentive Plan

In August 2024, the Company's board of directors adopted, and its stockholders approved, the 2024 Plan, which became effective in September 2024. The 2024 Plan allows the Company to make equity-based and cash-based incentive awards to its officers, employees, directors and consultants. The 2024 Plan provides for the grant of incentive stock options, stock options, stock appreciation rights, restricted shares of common stock, restricted stock units, dividend equivalent rights and cash bonuses. The number of shares initially reserved for issuance under the 2024 Plan is 3,065,000 shares. In addition, the number of shares reserved and available for issuance under the 2024 Plan will automatically increase on January 1, 2025 and each January 1 thereafter, by five percent (5%) of the sum of the outstanding number of shares of common stock and the numbers of shares of common stock issuable pursuant to the exercise of any outstanding warrants to acquire common stock for a nominal exercise price on the immediately preceding December 31 or such lesser number of shares as determined by the compensation committee. The number of shares reserved under the 2024 Plan is subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization. As of September 30, 2025, 1,921,742 stock options to purchase common stock were outstanding under the 2024 Plan, and 2,993,150 shares remained available for future grant under the 2024 Plan. The shares available for issuance under the 2024 Plan may be authorized but unissued shares or shares reacquired by the Company.

The shares of common stock underlying any awards under the 2024 Plan and the 2019 Plan that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by the Company prior to vesting, satisfied without the issuance of stock, expire or are otherwise terminated (other than by exercise) will be added back to the shares of common stock available for issuance under the 2024 Plan.

2024 Employee Stock Purchase Plan

In August 2024, the Company's board of directors adopted, and its stockholders approved, the 2024 ESPP, which became effective in September 2024. A total of 289,436 shares of common stock were initially reserved for issuance under the 2024 ESPP. The 2024 ESPP provides that the number of shares reserved and available for issuance will automatically increase on January 1, 2025 and each January 1 thereafter, by the least of (i) 578,872 shares of common stock, (ii) one percent (1%) of the number of shares of common stock issued and outstanding on the immediately preceding December 31, or (iii) such lesser number of shares of common stock as determined by the administrator of the 2024 ESPP. The number of shares reserved under the 2024 ESPP is subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization. As of September 30, 2025, 623,651 shares remained available for issuance under the 2024 ESPP. No shares were issued under the 2024 ESPP during the three and nine months ended September 30, 2025 and 2024.

Stock option valuation

The determination of the grant date fair value of stock-based awards granted to employees, directors and nonemployees during the three and nine months ended September 30, 2025 and 2024, was estimated using the Black-Scholes option-pricing model and was calculated based on the following assumptions.

	Nine months ended September 30,	
	2025	2024
Fair value of common stock	$6.00 - $18.25	$9.14 - $16.00
Dividend yield	—%	—%
Volatility	93.6% - 97.5%	88% - 110%
Risk-free interest rate	3.87% - 4.42%	3.52% - 5.18%
Expected term (years)	5.50 - 6.08	0.50 - 6.08

Summary of option activity

The Company's stock option activity regarding employees, directors, and nonemployees for the nine months ended September 30, 2025, is summarized as follows (*in thousands except share and per share amounts*):

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (years)	Aggregate intrinsic value
Options outstanding - December 31, 2024	3,502,440	$ 8.70	8.89	$ 34,307
Granted	1,474,871	10.62		
Exercised	(186,091)	7.85		
Forfeited	(193,519)	10.71		
Options outstanding - September 30, 2025	4,597,701	$ 9.27	8.47	38,152
Options vested and expected to vest - September 30, 2025	4,597,701	$ 9.27	8.47	38,152
Options exercisable - September 30, 2025	2,449,642	$ 7.14	7.76	$ 25,409

Additional information with regard to stock option activity involving employees and directors for the nine months ended September 30, 2025 and 2024, is as follows (*in thousands except per share amounts*):

	September 30,	
	2025	2024
Weighted-average grant date fair value per option of total options granted	$ 8.15	$ 4.79
Aggregate intrinsic value of stock options exercised	636	361

As of September 30, 2025, total unrecognized compensation cost related to the unvested awards to employees, directors, and nonemployees is $22.3 million, which is expected to be recognized over a weighted-average period of 2.8 years.

Stock-based compensation

During the three and nine months ended September 30, 2025 and 2024, the Company recorded stock-based compensation expense regarding its employees, directors, and nonemployees as follows (*in thousands*):

	Three months ended September 30,		Nine months ended September 30,	
	2025	2024	2025	2024
Research and development expense	$ 923	$ 529	$ 2,527	$ 1,913
General and administrative expense	1,322	663	3,494	1,821
Total	$ 2,245	$ 1,192	$ 6,021	$ 3,734

13. DEFINED CONTRIBUTION PLAN

The Company established a defined contribution savings plan under Section 401(k) of the Internal Revenue Code. This plan covers substantially all employees who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pretax basis. In the nine months ended September 30, 2025, the Company began contributing to the plan on behalf of its employees. In the three and nine months ended September 30, 2025, the Company made contributions of $0.1 million and $0.2 million, respectively, to the plan. No employer contributions were made during the year ended December 31, 2024.

14. NET LOSS PER SHARE ATTRIBUTABLE TO COMMON STOCKHOLDERS

Net loss per share

The following table summarizes the computation of basic and diluted net loss per share attributable to common stockholders of the Company (in thousands except share and per share amounts).

	Three months ended September 30,		Nine months ended September 30,	
	2025	2024	2025	2024
Net loss and net loss attributable to common stockholders	$ (21,618)	$ (18,142)	$ (64,909)	$ (46,336)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.63)	$ (2.78)	$ (1.93)	$ (15.42)
Weighted average number of common shares outstanding used in computation of net loss per common share, basic and diluted	34,198,597	6,515,616	33,688,669	3,004,382

The Company's potential dilutive securities, which include convertible preferred stock, restricted stock related to early exercise of common stock options, restricted stock related to unvested founder shares and outstanding common stock options, have been excluded from the computation of diluted net loss per share as the effect would be antidilutive. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The potential dilutive securities included in the table below, presented on an as converted basis, were excluded from the calculation of net loss per share due to their anti-dilutive effect:

	September 30,	
	2025	2024
Outstanding common stock options	4,597,701	3,573,385
Restricted stock related to early exercise of options to purchase common stock	2,514	18,039
Total	4,600,215	3,591,424

15. RELATED PARTY TRANSACTIONS

In April 2019, the Company executed the Research Agreement pursuant to which the Company agreed to fund certain research of a former director and former officer of the Company. The period of performance for this agreement is June 1, 2019 through April 30, 2022 and the contract totals approximately $2.8 million. On February 14, 2022, the Research Agreement was amended to extend the period of performance from April 30, 2022 to April 30, 2025 and increase the total contract costs by $3.0 million. On January 16, 2025, the Research Agreement was amended to extend the period of performance from April 30, 2025 through April 1, 2026 and increase the total contract costs by $1.0 million. The Company paid $0.5 million and $0.3 million pursuant to this agreement during the three months ended September 30, 2025 and 2024, respectively, and $1.0 million and $0.8 million during nine months ended September 30, 2025 and 2024, respectively. The Research Agreement also provides the Company an option to license the technology arising under the agreement (see Note 9).

16. SEGMENT INFORMATION

The Company operates as a single reportable segment engaged in the discovery and development of novel precision peptide therapies for the treatment of endocrine and metabolic disorders. The Company's determination that it operates as a single segment is consistent with the nature of its operations and the financial information regularly reviewed by the chief executive officer, in his capacity as the chief operating decision maker ("CODM"), for the purposes of evaluating performance, allocating resources, setting incentive compensation targets, and planning and forecasting for future periods. The Company's purpose is to help people with endocrine and metabolic disorders live fuller and healthier lives. The Company's long-term success is significantly dependent on its

ability to research and develop innovative medicines. The CODM uses net loss to assess performance of the Company, ensuring that it is investing in the research and development of product candidates. The CODM allocates research and development resources based upon several factors, including the likelihood of technical success, unmet medical needs, and the viability of commercial success. A significant component of the CODM's decision-making process is to ensure a balanced investment in the research and development portfolio to drive near-term success and long-term sustainability. During the three months ended June 30, 2025, the Company submitted and IND application for MBX 4291 and thus began tracking and internally reporting the related direct program expenses. As this information is provided to the CODM on a regular basis, it has been separately disclosed within our significant segment expenses below for all periods presented.

The following table summarizes our significant segment expenses and segment net loss for the three and nine months ended September 30, 2025 and 2024 (*in thousands*):

	For the three months ended September 30,		For the nine months ended September 30,	
	2025	2024	2025	2024
Expenses:				
Canvuparatide direct program expense	$ 10,130	$ 5,957	$ 27,390	$ 14,920
MBX 4291 direct program expense	2,669	5,514	10,991	7,659
Imapextide direct program expense	618	2,066	3,411	9,810
Preclinical and other research and development direct expense	1,466	194	4,316	769
Research and development overhead expense	4,387	3,016	13,292	9,034
Other segment items (1)	2,348	1,395	5,509	4,144
Net loss	$ 21,618	$ 18,142	$ 64,909	$ 46,336

(1) Other segment items are primarily comprised of general and administrative expenses and interest and other income.

17. SUBSEQUENT EVENTS

The Company has evaluated subsequent events through November 6, 2025, the date the unaudited condensed financial statements were available to be issued, to ensure these financial statements include appropriate disclosure of events both recognized in the financial statements and events which occurred but were not recognized in the financial statements. The Company has concluded no subsequent events have occurred that require disclosure.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited condensed financial statements and the related notes and other financial information included elsewhere in this Quarterly Report on Form 10-Q (this "Quarterly Report") and with our audited financial statements and the related notes for the year ended December 31, 2024 and the related Management's Discussion and Analysis of Financial Condition and Results of Operation, both of which are included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC") on March 17, 2025 (our "2024 Annual Report"). This discussion and other parts of this Quarterly Report contain forward-looking statements that involve risks and uncertainties, such as statements regarding our plans, objectives, expectations, intentions and projections. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the "Risk Factors" section of this Quarterly Report. You should carefully read the "Risk Factors" section of this Quarterly Report to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see "Special Note Regarding Forward-Looking Statements". Our historical results are not necessarily indicative of the results that may be expected for any period in the future.

Overview

We are a clinical-stage biopharmaceutical company focused on the discovery and development of novel precision peptide therapies for the treatment of endocrine and metabolic disorders. Our company was founded by global leaders with a transformative approach to peptide drug design and development. Leveraging this expertise, we designed our proprietary Precision Endocrine Peptide™ (the "PEP™") platform to overcome the key limitations of unmodified and modified peptide therapies and to improve clinical outcomes and simplify disease management for patients. Our PEPs are selectively engineered to have optimized pharmaceutical properties, including extended time-action profiles and consistent drug concentrations with low peak-to-trough concentration ratios, consistent exposure to target tissues, and less frequent dosing. We are advancing a pipeline of novel candidates for endocrine and metabolic disorders with clinically validated targets, established endpoints for regulatory approval, significant unmet medical needs and large potential market opportunities.

Our lead product candidate, canvuparatide (MBX 2109), is a parathyroid hormone ("PTH") peptide prodrug that is designed as a potential long-acting hormone replacement therapy for the treatment of chronic hypoparathyroidism, ("HP"). Leveraging our proprietary PEP platform, we designed canvuparatide to treat the underlying pathophysiology of HP by providing a continuous, infusion-like exposure to PTH, with convenient once-weekly administration. In a Phase 1 clinical trial, canvuparatide demonstrated a low ratio between the highest concentration of active drug observed after a dose and the concentration of active drug observed immediately prior to the next dose, ("peak-to-trough ratio"), which is consistent with a continuous, infusion-like profile, and an extended half-life, potentially enabling the first once-weekly PTH dosing regimen for patients with HP. Canvuparatide was generally well-tolerated with no drug-related severe or serious adverse effects. In a Phase 2 clinical trial of 64 patients with HP, canvuparatide achieved the primary endpoint with a statistically significant responder rate at Week 12 and further demonstrated positive six-month responder results from the open-label extension portion of the trial. All patients completed the 12-week trial, and canvuparatide was generally well-tolerated, with no treatment-related serious adverse events or discontinuations. We expect to conduct both an End of Phase 2 meeting with the U.S. Food and Drug Administration ("FDA") and Scientific Advice with the European Medicines Agency, in the first quarter of 2026. We also intend to present results from our Phase 2 clinical trial at a medical meeting in the second quarter of 2026; report one-year results from our ongoing open-label extension study in the second quarter of 2026; and initiate a Phase 3 clinical trial of canvuparatide in the third quarter of 2026.

Our lead obesity product candidate, MBX 4291, is designed to be a long-acting and highly potent PEP™ GLP-1 and glucose-dependent insulinotropic polypeptide ("GIP"), receptor co-agonist prodrug with the goal of potential once monthly dosing frequency and improved efficacy and tolerability relative to existing standards of care. In our preclinical studies, the active component of MBX 4291 demonstrated a similar activity profile and body weight loss in mice as tirzepatide, an approved weekly GLP-1/GIP co-agonist, and an extended duration of action of the active component of MBX 4291, supporting the potential for once-monthly administration. During our preclinical studies, the concentration of the active component of MBX 4291 was significantly lower than the concentration of tirzepatide during the comparison period. Although we believe MBX 4291 has the potential to be dosed less frequently, less frequent dosing would require a higher dose of MBX 4291. The results observed from our preclinical studies may not necessarily be predictive of the results of later-stage clinical trials that we may conduct. In addition, the study supporting potential duration of MBX 4291 was conducted separately from studies evaluating its effects. We are conducting a randomized, double-blind, placebo controlled Phase 1 clinical trial designed to evaluate safety, tolerability, pharmacokinetics, and pharmacodynamics of SAD and MAD doses in adults with obesity. Following the SAD and four-week MAD portions of the trial, we plan to evaluate multiple ascending doses of MBX 4291, or matching placebo, administered over 12 weeks in up to two cohorts consisting of thirty participants. Results from the planned 12-week MAD portion are expected in the fourth quarter of 2026. Beyond MBX 4291, we have a robust discovery pipeline including multiple programs in the lead optimization stage of development.

Our program, imapextide (MBX 1416), is designed to be a long-acting glucagon-like peptide-1 ("GLP-1") receptor antagonist, as a potential therapy for post-bariatric hypoglycemia, ("PBH"), a chronic complication of bariatric surgery. Imapextide is designed as a convenient once-weekly therapy to reduce insulin secretion and increase blood glucose to reduce the frequency and severity of hypoglycemic events. The single ascending dose ("SAD") portion of this Phase 1 trial evaluated subcutaneous imapextide doses of 10 milligrams (“mg”), 30 mg, 100 mg and 200 mg, in up to eight healthy adults per cohort randomized 3:1 (six imapextide; two placebo in each cohort). The multiple ascending dose ("MAD") portion of the trial evaluated four weekly subcutaneous doses of placebo and 10 mg, 30 mg (as two injections) and 30 mg (as one injection) imapextide in three cohorts in up to eight healthy adults per cohort (six imapextide; two placebo in each cohort). An additional cohort assessed the clinical relevance of preclinical transporter findings. In January 2025, we announced positive topline results from our Phase 1 SAD and MAD clinical trial of imapextide in healthy adult volunteers. Results from the Phase 1 clinical trial demonstrated dose-proportional increases in imapextide exposure, a median half-life of 90 hours, which is supportive of a once-weekly dosing regimen, and, at steady state, the median T_{max} was between 36 and 48 hours. Imapextide was generally well-tolerated with a favorable safety profile and no treatment-related serious adverse events. We are conducting a Phase 2a, open-label clinical trial evaluating primary efficacy of subcutaneous imapextide in adult patients with PBH. Approximately ten patients with a history of hypoglycemia following Roux-en-Y or sleeve gastrectomy will undergo three mixed-meal tolerance tests after each imapextide administration, to evaluate the pharmacodynamic effect of imapextide. Topline results are expected in the second quarter of 2026.

Since our inception, we have devoted substantially all of our resources to drug discovery and development of our product candidates, canvuparatide, imapextide and MBX 4291, and other preclinical programs, building our intellectual property portfolio, organizing and staffing our company, business planning, raising capital and providing general and administrative support for these operations. We do not have any products approved for sale and have not generated any revenue from product sales. In September 2024, we completed our initial public offering (the "IPO"), pursuant to which we issued and sold 11,730,000 shares of common stock (inclusive of 1,530,000 shares of commons stock sold pursuant to the underwriters' exercise of their option to purchase additional shares). The aggregate net proceeds received by use from the IPO were $170.5 million, after deducting underwriting discounts and commissions and other offering costs of $17.2 million. In September 2025, we completed an underwritten public offering (the "September 2025 Offering") of 11,108,055 shares of our common stock, which generated approximately $187.4 million in aggregate net proceeds, after deducting underwriting discounts and commissions and other offering costs of $12.5 million. We have historically funded our operations primarily from the issuance and sale of our common stock, convertible preferred stock and convertible notes, which have generated approximately $601.7 million in cumulative, aggregate gross proceeds.

We have incurred significant operating losses since inception and we expect to continue to incur substantial losses for the foreseeable future. Our ability to generate revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our product candidates. Our net losses were $21.6 million and $18.1 million for the three months ended September 30, 2025 and 2024, respectively. Our net losses were $64.9 million and $46.3 million for the nine months ended September 30, 2025 and 2024, respectively. We had an accumulated deficit of $202.4 million and $137.5 million as of September 30, 2025 and December 31, 2024, respectively.

We anticipate that our expenses and operating losses will increase substantially for the foreseeable future as we:

- advance the development of our lead product candidates, canvuparatide, imapextide and MBX 4291, and future product candidates;
- advance our current research activities and further develop our platform;
- continue preclinical development and discover and develop future product candidates we may identify;
- seek regulatory approval for any product candidates for which we successfully complete clinical trials;
- establish either internally or through contract manufacturing organizations manufacturing capacity capabilities to supply our clinical trials in our pipeline and eventually for commercialization;
- transition from a company with a research focus to a company capable of supporting commercial activities, including establishing sales, marketing, and distribution infrastructure;
- attract, hire and retain additional research and development, clinical, commercial, general and administrative personnel;
- develop, maintain, expand, protect and enforce our intellectual property portfolio;
- defend against any claims by third parties that we have infringed, misappropriated or otherwise violated any intellectual property of any such third party;
- acquire or in-license product candidates, intellectual property and technologies;
- confirm, maintain or obtain freedom to operate for any of our owned or licensed technologies and product candidates;

- establish and maintain collaborations;
- add operational, financial and management information systems and personnel; or
- incur additional legal, audit, accounting, compliance, insurance, investor relations and other expenses to operate as a public company that we did not incur as a private company.

We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for one or more product candidates. If we obtain regulatory approval for any product candidate and do not enter into a commercialization partnership, we expect to incur significant expenses related to developing our commercialization capability to support product sales, manufacturing, marketing, and distribution. As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances, and marketing, distribution or licensing arrangements with third parties. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, reduce or eliminate the development and commercialization of our platform or delay our pursuit of potential in-licenses or acquisitions.

We had cash, cash equivalents and marketable securities of $391.7 million and $262.1 million as of September 30, 2025 and December 31, 2024, respectively. We believe our existing cash, cash equivalents and marketable securities will be sufficient to fund our operating expenses and capital expenditure requirements into 2029. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See “Liquidity and capital resources” herein and “Risk Factors—Risks related to financial position and need for capital” from Item 1A Risk Factors in our Annual Report.

License agreement

Below is a summary of the key terms for our license agreement.

Indiana University Research And Technology Corporation Exclusive License Agreement

In June 2020, we entered into an Exclusive License Agreement with Indiana University Research and Technology Corporation, or IURTC, a non-profit corporation organized under the laws of the State of Indiana, represented by The Trustees of Indiana University ("IU"), pursuant to which we have been granted an exclusive, royalty-bearing license to certain IURTC patent rights ("the Licensed Intellectual Property") developed by Dr. DiMarchi and other collaborators to further scientific research, for new product development, and for other applications in public interest, such license, the IURTC License Agreement. In particular, we have been granted an exclusive, royalty-bearing license to make, have made, use, have used, offer to sell, have offered for sale, sell, have sold, import and have imported products that are covered by the Licensed Intellectual Property ("Licensed Products"), with the right to sublicense to third parties. IURTC and IU have retained the right to (i) practice and use the Licensed Intellectual Property for non-commercial educational, research, and patient care and treatment purposes, and (ii) permit other non-profit and academic entities to practice and use the Licensed Intellectual Property for the same non-commercial purposes. Under the IURTC License Agreement, we agreed to use commercially reasonable efforts to develop, promote and sell Licensed Products in accordance with the IURTC License Agreement and any applicable laws. The IURTC License Agreement leverages IURTC’s expertise in peptide therapies as well as our scientific, clinical, and regulatory capabilities to accelerate the development of peptide treatments for people with endocrine and metabolic disorders. Canvuparatide (MBX 2109), imapextide (MBX 1416) and MBX 4291 are Licensed Products under the IURTC License Agreement. Any future product candidates developed pursuant to our sponsored research agreement with IU or otherwise covered by the Licensed Intellectual Property may be subject to the IURTC License Agreement.

As initial consideration for the license, we paid IURTC an immaterial issue fee. As additional consideration for the license, we are required to pay IURTC: (i) royalties with a rate based on net sales per calendar year; (ii) an annual maintenance fee of up to $0.1 million beginning in the first year in which the first commercial sale occurs; (iii) a mid-single digits percentage of any sublicensing revenue; and (iv) milestone payments in the event of successful achievement of specified development milestones up to an aggregate of $0.4 million. IURTC is also entitled to receive reimbursement for all patent prosecution and maintenance related expenses. Our tiered royalties are in the low single-digits on annual net sales of the Licensed Products. In the event that we are required to pay a non-affiliate third party consideration for intellectual property owned or controlled by such non-affiliate third party that we or a sublicensee licensed for the development of Licensed Products, we can deduct such amounts from the royalty payments up to a certain amount of the running royalties owed that year. The royalty term will terminate on a country-by-country basis as to each Licensed Product, until the expiration or termination of the last valid claim within the patent rights covering such Licensed Product in that country.

On January 5, 2024, we and IURTC entered into a fourth amendment to the IURTC License Agreement (the "Fourth Amendment"). The Fourth Amendment specifies IURTC is entitled to the receipt of additional clinical and regulatory milestones, as

defined in the Fourth Amendment, up to an aggregate of $9.0 million. Following the execution of the Fourth Amendment, future remaining clinical and regulatory milestone payments in the IURTC License Agreement and all amendments total up to $9.3 million.

The IURTC License Agreement will expire at the expiration of the last of the patent rights covered in the IURTC License Agreement, unless terminated earlier by mutual agreement or by one of the parties. We may terminate the IURTC License Agreement with or without cause upon ninety (90) days prior written notice to IURTC. IURTC may terminate the IURTC License Agreement if we commit a material breach of the IURTC License Agreement and fail to cure the breach within the respective cure period after receipt of the notice of material breach or upon our failure to undertake certain activities in furtherance of commercial development goals. Upon termination of the IURTC License Agreement, all rights granted by IURTC will terminate and automatically revert to IURTC.

Components of results of operations

Operating expenses

Our operating expenses consist of (i) research and development expenses and (ii) general and administrative expenses.

Research and development

The largest component of our total operating expenses since our inception has been research and development activities. Research and development expenses are expensed as incurred and consist primarily of:

- external research and development expenses incurred under agreements with contract research organizations, ("CROs"), consultants and other third parties to conduct our clinical trials;
- costs related to manufacturing our product candidates for preclinical studies and clinical trials, including agreements with contract development and manufacturing organizations ("CDMOs");
- license fees, including any milestone-based payments;
- compensation and benefits, including stock-based compensation expense, for research and development personnel;
- the costs of acquiring research and development supplies and services;
- manufacturing process development costs;
- costs associated with regulatory activities;
- costs incurred in development of intellectual property;
- other outside services and consulting costs; and
- an allocated portion of facilities and other infrastructure costs associated with our research and development activities.

We expect our research and development expenses to increase substantially for the foreseeable future as we continue to invest in research and development activities to advance our programs and conduct clinical trials. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming, and the successful development of our product candidates is highly uncertain. As a result, expenses may vary significantly based on factors such as:

- the timing and progress of research and development, preclinical and clinical development activities;
- the number, scope and duration of clinical trials required for regulatory approval of our existing or future product candidates;
- the costs, timing, and outcome of regulatory review of any of our existing or future product candidates by the FDA and comparable foreign regulatory authorities, including the potential for such authorities to require that we perform more preclinical studies or clinical trials than those that we currently expect or for such authorities to change their requirements on studies that had previously been agreed to;
- the costs of manufacturing clinical and commercial supplies of our existing or future product candidates;
- our ability to maintain existing, and establish new, strategic collaborations, licensing or other arrangements, and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- our implementation of various computerized informational systems and efforts to enhance operational systems;

- expenses incurred to attract, hire and retain skilled research and development personnel;
- per subject clinical trial costs;
- the number of sites included in our clinical trials;
- the countries in which our clinical trials are conducted;
- length of time required to enroll subjects and initiate our clinical trials;
- the number of subjects that participate in our clinical trials;
- the drop-out and discontinuation rate of subjects;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of subject participation in our clinical trials and follow-up, including the duration of open label extensions;
- the timing of license agreement milestone payments related to development, regulatory and commercial events;
- manufacturing success with patient materials;
- mitigation/responses to potential health authority questions and/or inspections;
- the degree to which we obtain, maintain, defend and enforce our intellectual property rights; and
- the extent to which we establish collaboration, licensing or similar arrangements and the performance of any related third parties.

A change in the outcome of any of these variables with respect to the development of any of our existing or future product candidates could significantly change the costs and timing associated with the development of that product candidate.

General and administrative

General and administrative expenses consist primarily of compensation and benefits, including stock-based compensation expense for general and administrative personnel; other expenses for outside professional services, including legal fees relating to intellectual property and corporate matters; professional fees for accounting, auditing, consulting and tax services; insurance costs; administrative travel expenses; website development costs; marketing and public relations costs; and facilities, information technology and other allocated overhead costs.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support continued growth of our research and development activities. We also anticipate that we will incur increased accounting, audit, legal, regulatory, compliance and director and officer insurance costs as well as investor and public relations expenses associated with being a public company. We also expect our intellectual property expenses to increase as we expand our intellectual property portfolio.

Other income

Interest and other income, net

Total other income, net, is comprised of interest income earned on our cash and cash equivalents and marketable securities and amortization expense and accretion income on our marketable securities.

Results of operations

Comparison of the three months ended September 30, 2025 and 2024

The following table summarizes our results of operations for the three months ended September 30, 2025 and 2024 (in thousands):

	Three months ended September 30,		Change
	2025	2024	$
Operating expenses:			
Research and development	$ 19,270	$ 16,747	$ 2,523
General and administrative	4,656	2,865	1,792
Total operating expenses	23,926	19,612	4,315
Loss from operations	(23,926)	(19,612)	(4,315)
Other income			
Interest and other income, net	2,308	1,470	838
Total other income, net	2,308	1,470	838
Net loss	$ (21,618)	$ (18,142)	$ (3,476)

Research and development expenses

The following table summarizes our research and development expenses for the periods indicated (in thousands):

	Three months ended September 30,		Change
	2025	2024	$
Direct research and development program expenses:			
Canvuparatide (MBX 2109)	$ 10,130	$ 5,958	$ 4,172
MBX 4291 (1)	2,669	5,514	(2,845)
Imapextide (MBX 1416)	618	2,066	(1,448)
Preclinical and other (1)	1,466	193	1,273
Indirect research and development costs:			
Personnel related costs (including stock-based compensation)	3,976	2,771	1,205
Facility-related and other	411	245	166
Total research and development expense	$ 19,270	$ 16,747	$ 2,523

(1) Prior period amounts for MBX 4291 have been reclassified to conform to current period presentation.

Research and development expenses were $19.3 million for the three months ended September 30, 2025, as compared to $16.7 million for the three months ended September 30, 2024. The increase of $2.5 million consisted of the following:

Direct research and development program expenses related to canvuparatide increased by $4.2 million, primarily due to increased activities related to conduct of the Phase 2 clinical trial and increased manufacturing in preparation for the Phase 3 clinical trial. Direct program expenses for MBX 4291 decreased by $2.8 million primarily due to the timing of preclinical studies and manufacturing activities, partially offset by a $1.0 million IURTC milestone that was triggered in the three months ended September 30, 2025 related to the initiation of the Phase 1 clinical trial of MBX 4291. Direct program expenses related to imapextide decreased by $1.4 million, primarily due to the completion of the Phase 1 clinical trial in the first quarter of 2025. Direct program expenses for preclinical and other programs increased by $1.3 million primarily due to pipeline candidate development activities. Personnel-related costs (including stock-based compensation), increased by $1.2 million, primarily due to increased headcount and stock-based compensation expense. Facility-related and other expenses, which include allocated overhead, including rent, repairs and maintenance costs, common facilities and information technology-related expenses allocated to research and development increased by $0.2 million.

General and administrative expenses

General and administrative expenses were $4.7 million for the three months ended September 30, 2025, as compared to $2.9 million for the three months ended September 30, 2024. The increase of $1.8 million was primarily due to higher professional fees related to legal and accounting services and higher personnel-related costs, including compensation, benefits and stock-based compensation, as we expanded our infrastructure to support growth in our operations as a public company.

Interest and other income, net

Interest and other income, net, which includes interest income and amortization of premiums and discounts on our investments in marketable securities, were $2.3 million for the three months ended September 30, 2025, as compared to $1.5 million for the three months ended September 30, 2024. The increase of $0.8 million was due to increased interest on our cash, cash equivalents and marketable securities, which increased primarily due to our IPO in September 2024, the Series C Convertible Preferred Stock financing in August 2024 and the September 2025 Offering.

Comparison of the nine months ended September 30, 2025 and 2024

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

	Nine months ended September 30,		Change
	2025	2024	$
Operating expenses:			
Research and development	$ 59,400	$ 42,192	$ 17,208
General and administrative	12,860	7,392	5,468
Total operating expenses	72,260	49,584	22,677
Loss from operations	(72,260)	(49,584)	(22,676)
Other income			
Interest and other income, net	7,351	3,248	4,103
Total other income, net	7,351	3,248	4,103
Net loss	$ (64,909)	$ (46,336)	$ (18,573)

Research and development expenses

The following table summarizes our research and development expenses for the periods indicated (in thousands):

	Nine months ended September 30,		Change
	2025	2024	$
Direct research and development program expenses:			
Canvuparatide (MBX 2109)	$ 27,390	$ 14,920	$ 12,470
MBX 4291 (1)	10,991	7,659	3,332
Imapextide (MBX 1416)	3,411	9,810	(6,399)
Preclinical and other (1)	4,316	769	3,548
Indirect research and development costs:			
Personnel related costs (including stock-based compensation)	11,277	7,461	3,816
Facility-related and other	2,015	1,573	442
Total research and development expense	$ 59,400	$ 42,192	$ 17,209

(1) Prior period amounts for MBX 4291 have been reclassified to conform to current period presentation.

Research and development expenses were $59.4 million for the nine months ended September 30, 2025, as compared to $42.2 million for the nine months ended September 30, 2024. The increase of $17.2 million consisted of the following:

Direct research and development program expenses related to canvuparatide increased by $12.5 million, primarily due to increased activities related to conduct of the Phase 2 clinical trial, costs associated with conducting preclinical studies and an increase in manufacturing costs in preparation for the Phase 3 trial. Direct program expenses for MBX 4291 increased by $3.3 million, primarily due to preclinical studies and manufacturing activities, for which the IND was filed in June 2025, and a $1.0 million IURTC milestone that was triggered in the nine months ended September 30, 2025 related to the initiation of the Phase 1 clinical trial of MBX 4291. Direct program expenses related to imapextide decreased by $6.4 million, primarily due to the completion of the Phase 1 clinical trial in the first quarter of 2025. Direct program expenses for preclinical and other programs increased by $3.5 million, primarily due to pipeline candidate development activities. Personnel-related costs (including stock-based compensation), increased by $3.8 million, primarily due to increased headcount and stock-based compensation expense. Facility-related and other expenses, which include allocated overhead, including rent, repairs and maintenance costs, common facilities and information technology-related expenses allocated to research and development increased by $0.4 million.

General and administrative expenses

General and administrative expenses were $12.9 million for the nine months ended September 30, 2025, as compared to $7.4 million for the nine months ended September 30, 2024. The increase of $5.5 million was primarily due to higher professional fees related to legal, insurance and accounting services and higher personnel-related costs, including compensation, benefits and stock-based compensation, as we expanded our infrastructure to support growth in our operations as a public company.

Interest and other income, net

Interest and other income, net, which includes interest income and amortization of premiums and discounts on our investments in marketable securities, were $7.4 million for the nine months ended September 30, 2025, as compared to $3.2 million for the nine months ended September 30, 2024. The increase of $4.1 million was due to increased interest on our cash, cash equivalents and marketable securities, which increased primarily due to our IPO in September 2024, the Series C Convertible Preferred Stock financing in August 2024 and the September 2025 Offering.

Liquidity and capital resources

Sources of liquidity

Since our inception, we have incurred significant operating losses. We have historically funded our operations primarily through our IPO, the September 2025 Offering, and sales of our convertible preferred stock and convertible notes, which have generated approximately $601.7 million in cumulative, aggregate gross proceeds. As of September 30, 2025 and December 31, 2024, we had $391.7 million and $262.1 million in cash, cash equivalents and marketable securities, respectively. We have not yet generated any revenue from product sales and do not expect to in the foreseeable future as our product candidates are in various phases of clinical and preclinical development.

Future funding requirements

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the development of our product candidates. In addition, we expect to incur additional costs associated with operating as a public company. The timing and amount of our operating expenditures will depend largely on:

- the timing and progress of research and development, preclinical and clinical development activities;
- the number, scope and duration of clinical trials required for regulatory approval of our existing or future product candidates;
- the costs, timing, and outcome of regulatory review of any of our existing or future product candidates by the FDA and comparable foreign regulatory authorities, including the potential for such authorities to require that we perform more preclinical studies or clinical trials than those that we currently expect or for such authorities to change their requirements on studies that had previously been agreed to;
- the costs of manufacturing clinical and commercial supplies of our existing or future product candidates;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our existing or future product candidates for which we receive regulatory approval;
- the cost of filing and prosecuting our patent applications, and maintaining and enforcing our patents and other intellectual property rights;
- our ability to maintain existing, and establish new, strategic collaborations, licensing or other arrangements, and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- any product liability or other lawsuits related to our existing or future product candidates;
- our implementation of various computerized informational systems and efforts to enhance operational systems;
- expenses incurred to attract, hire and retain skilled personnel;
- the costs of operating as a public company;
- our ability to establish a commercially viable pricing structure and obtain approval for coverage and adequate reimbursement from third-party and government payers;

- the extent to which we acquire or invest in businesses, products, and technologies;
- the effect of competing technological and market developments; and
- the impact of other factors, including inflation, economic uncertainty and geopolitical tensions, which may exacerbate the magnitude of the factors discussed above.

We had $391.7 million and $262.1 million in cash, cash equivalents and marketable securities as of September 30, 2025 and December 31, 2024, respectively. We believe that our existing cash, cash equivalents and marketable securities will be sufficient to fund our current operating plan for at least the next 12 months from the date of issuance of the accompanying unaudited condensed financial statements. Based on our current operating plan, we estimate that our existing cash, cash equivalents and marketable securities will be sufficient to fund our projected operating expenses and capital expenditure requirements into 2029. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, and marketing, distribution or licensing arrangements with third parties. To the extent that we raise additional capital through the sale of equity or convertible debt securities, ownership interest for existing investors may be materially diluted, and the terms of such securities could include liquidation or other preferences that adversely affect existing investors' rights as a stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specified actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, reduce or eliminate our product development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Cash flows

The following table summarizes our sources and uses of cash for the periods presented (in thousands):

	Nine months ended September 30,	
	2025	2024
Net cash used in operating activities	$ (61,648)	$ (38,644)
Net cash provided by (used in) investing activities	46,268	(93,250)
Net cash provided by financing activities	189,154	234,236
Net increase in cash and cash equivalents	$ 173,774	$ 102,342

Cash flows from operating activities

Net cash used in operating activities for the nine months ended September 30, 2025 was $61.6 million. This was primarily due to our net loss of $64.9 million, partially offset by non-cash charges of $3.3 million. Non-cash charges primarily consisted of $6.0 million of stock-based compensation expense, $0.2 million of depreciation expense related to our property and equipment and $0.1 million of amortization expense related to our right-of-use asset, partially offset by $3.1 million of net amortization and accretion of marketable securities. The changes in our net operating assets and liabilities primarily consisted of a $0.7 million increase in our prepaid expenses and other current assets related to prepaid balances with CROs and CDMOs offset by a $0.7 million increase in accounts payable and accrued expenses primarily related to balances with CROs and CDMOs.

Net cash used in operating activities for the nine months ended September 30, 2024 was $38.6 million. This was primarily due to our net loss of $46.3 million, partially offset by net cash provided by changes in our operating assets and liabilities of $5.2 million and non-cash charges of $2.5 million. The changes in our net operating assets and liabilities primarily consisted of a $6.7 million increase in accounts payable and accrued expenses primarily related to balances with CDMOs, partially offset by a $1.3 million increase in our prepaid expenses and other current assets related to prepaid balances with CROs. Non-cash charges primarily consisted of $3.7 million of stock-based compensation expense, partially offset by $1.5 million of net amortization and accretion of marketable securities.

Cash flows from investing activities

Net cash provided by investing activities for the nine months ended September 30, 2025 was $46.3 million, which consisted of maturities of marketable securities of $191.6 million and redemptions of marketable securities of $8.5 million, partially offset by purchases of marketable securities of $152.7 million and purchases of property and equipment of $1.1 million.

Net cash used in investing activities for the nine months ended September 30, 2024 was $93.3 million, which consisted of purchases of marketable securities of $152.0 million and purchases of property and equipment of $0.8 million, partially offset by maturities of marketable securities of $59.5 million.

Cash flows from financing activities

Net cash provided by financing activities for the nine months ended September 30, 2025 was $189.2 million, which consisted of proceeds of $187.9 million from the September 2025 Offering, net of underwriting discounts and commissions and $1.5 million of proceeds from the exercise of common stock options, partially offset by payments totaling $0.3 million related to offering costs for the September 2025 Offering.

Net provided by financing activities for the nine months ended September 30, 2024 was $234.2 million, which primarily consisted of proceeds from our IPO, net of underwriting discounts and commissions, of $174.5 million in September 2024, gross proceeds from our issuance of Series C Convertible Preferred Stock of $63.5 million in August 2024 and $0.2 million in proceeds from the exercise of common stock options, partially offset by payments of offering costs related to our IPO of $3.7 million and preferred stock offering costs of $0.3 million.

Contractual obligations and commitments

Leases

We have entered into two separate lease agreements for corporate office space and laboratory space, with terms extending through December 2028 and December 2025, respectively. The lease for our corporate office space was amended in May 2025 as further discussed in Note 9 to our interim unaudited condensed financial statements included elsewhere in this Quarterly Report. As of September 30, 2025, our future remaining operating lease payments were $0.7 million, with $0.2 million payable within the next twelve months, with respect to leases already commenced as of such date. As of December 31, 2024, our future remaining operating lease payments were $0.2 million, with $0.2 million payable within the next twelve months, with respect to leases already commenced as of such date.

Refer to Note 9 in our interim unaudited condensed financial statements included elsewhere in this Quarterly Report for more information on our lease obligations.

License agreement and other agreements

Under the IURTC License Agreement, we have payment obligations that are contingent upon future events, such as the achievement of specified development, regulatory and commercial milestones, and in some cases, we are required to make royalty payments in connection with the sales of products developed under those agreements. Although we could be required to make additional future milestone payments under the IURTC License Agreement, we are unable to estimate the timing or likelihood of achieving the milestones or making future product sales. For additional details regarding the IURTC License Agreement and related obligations, refer to Note 9 in our interim unaudited condensed financial statements included elsewhere in this Quarterly Report, and see the section herein titled “License agreement” included in our 2024 Annual Report.

We enter into contracts in the normal course of business with clinical trial sites and clinical supply manufacturers and with vendors for preclinical studies and clinical trials, research supplies and other services and drugs for operating purposes. These contracts generally provide for termination after a notice period, and, therefore, are cancelable contracts. In addition, certain of our supply agreements contain minimum purchase commitments in certain situations, the timing and likelihood of which we cannot estimate at this time.

Recently issued accounting pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position, results of operations or cash flows is disclosed in Note 2 to our unaudited condensed financial statements included elsewhere in this Quarterly Report.

Critical accounting policies and significant judgments and estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with generally accepted accounting principles, ("GAAP"). The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses incurred during the reporting periods.

On an ongoing basis, we evaluate our estimates and judgments, including but not limited to those related to accrued research and development costs, the fair value of common stock and stock-based compensation expense and other fair value measurements. These estimates and assumptions are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates and assumptions could occur in the future. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ from these estimates under different assumptions or conditions.

During the nine months ended September 30, 2025, there were no material changes to our critical accounting policies and estimates described under Management's Discussion and Analysis of Critical Accounting Policies and Estimates which are included in our 2024 Annual Report.

Off-balance sheet arrangements

During the periods presented we did not have, nor do we currently have, any off-balance sheet arrangements as defined in the rules and regulations of the SEC.

Emerging growth company and smaller reporting company status

We qualify as an "emerging growth company," as defined in the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include: (i) being permitted to present only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's discussion and analysis of financial condition and results of operations" disclosure in this Quarterly Report; (ii) reduced disclosure about our executive compensation arrangements; (iii) not being required to hold advisory votes on executive compensation or to obtain stockholder approval of any golden parachute arrangements not previously approved; (iv) an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002; and (v) an exemption from compliance with the requirements of the Public Company Accounting Oversight Board regarding the communication of critical audit matters in the auditor's report on the financial statements.

We may take advantage of these exemptions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.235 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of our IPO; (iii) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC. We may choose to take advantage of some but not all of these exemptions. We have taken advantage of reduced reporting requirements in this Quarterly Report. Accordingly, the information contained herein may be different from the information you receive from other public companies in which you hold stock. Additionally, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, therefore, while we are an emerging growth company we will not be subject to new or revised accounting standards at the same time that they become applicable to other public companies that are not emerging growth companies. As a result of this election, our audited financial statements and unaudited condensed financial statements may not be comparable to those of other public companies that comply with new or revised accounting pronouncements as of public company effective dates. We may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for private companies.

We are also a “smaller reporting company,” meaning that the market value of our shares held by nonaffiliates is less than $700 million and our annual revenue was less than $100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our shares held by nonaffiliates is less than $250 million or (ii) our annual revenue was less than $100 million during the most recently completed fiscal year and the market value of our shares held by nonaffiliates is less than $700 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our 2024 Annual Report and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company, as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and are not required to provide the information required by this Item.

Item 4. Controls and Procedures.

Management's Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2025. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, mean controls and other procedures of a company that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures.

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 it judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2025 our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable level.

Changes in Internal Control over Financial Reporting

There have been 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 September 30, 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.

From time to time, we may become involved in litigation or other legal proceedings. We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are probable to have material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on our business, financial condition, results of operations and prospects because of defense and settlement costs, diversion of management resources and other factors.

Item 1A. Risk Factors.

Except as set forth below, there have been no material changes to our risk factors previously disclosed in Part I, Item 1A, "Risk Factors" in our 2024 Annual Report. Our business involves significant risks. Stockholders should carefully consider the risks and uncertainties described in our 2024 Annual Report together with all of the other information contained in this Quarterly Report on Form 10-Q (this "Quarterly Report") and in the other documents that we file with the SEC, including our unaudited condensed financial statements and related notes appearing in this Quarterly Report, before deciding to invest in our common stock. If any of the events or developments described were to occur, our business, prospects, operating results and financial condition could suffer materially, the trading price of our common stock could decline and you could lose all or part of your investment. The risks and uncertainties described are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may also adversely affect our business.

Changes in tax laws or in their implementation or interpretation may adversely affect our business and financial condition.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. For example, the One Big Beautiful Bill Act (the "OBBBA") was signed into law on July 4, 2025 and made significant changes to U.S. federal tax law. Changes to tax laws (which changes may have retroactive application) could adversely affect our business and our financial condition. For example, under Section 174 of the IRC, in taxable years beginning after December 31, 2021, expenses that are incurred for research and development performed outside the U.S. will be capitalized and amortized, which may have an adverse effect on our cash flow. The OBBBA provides that for taxable years beginning after December 31, 2024, expenses that are incurred for research and development performed in the U.S. may, at the taxpayer's election, be immediately deducted or capitalized and amortized. In addition, the OBBBA provides that for taxable years beginning after December 31, 2021 and before January 1, 2025, certain eligible taxpayers generally may elect to retroactively deduct expenses for research and development performed in the U.S. in such taxable years generally may elect to accelerate and deduct the remaining unamortized amounts of such research and development expenses (i) in the first taxable year beginning after December 31, 2024, or (ii) ratably over the two-taxable year period beginning with the first taxable year beginning after December 31 2024. In recent years, many such changes have been made and changes are likely to continue to occur in the future. For example, under Section 174 of the Code, currently, in taxable years beginning after December 31, 2021, expenses that are incurred for research and development in the U.S. are capitalized and amortized, which may have an adverse effect on our cash flow. More recently, however, there have been proposals to retroactively reinstate deductibility under Section 174 of the Code. In addition, it is unclear how changes in U.S. federal income tax laws will affect state and local taxation. We cannot predict whether, when, in what form or with what effective dates, tax laws, regulations and rulings may be enacted, promulgated or decided or whether they could increase our or our shareholders' tax liability or require changes in the manner in which we operate in order to minimize any adverse effects of changes in tax laws or in the interpretation thereof.

Ongoing healthcare legislative and regulatory reform measures may have a material adverse effect on our business and results of operations.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example, (1) changes to our manufacturing arrangements, (2) additions or modifications to product labeling, (3) the recall or discontinuation of our products or (4) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business. See the sections titled, "Business–Government regulation–Current and future U.S. healthcare reform" included in this annual report on Form 10-K.

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of products have been a focus in this effort. There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical products, limiting coverage and the amount of reimbursement for drugs and other medical products, government control and other changes to the healthcare system in the United States. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions

with existing controls and measures, could further limit our revenue generated from the sale of any approved products. Even if we do receive a favorable coverage determination for our products by third-party payors, coverage policies and third-party payor reimbursement rates may change at any time.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their commercial products, which has resulted in several Congressional inquiries and proposed and enacted state and federal 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 pharmaceutical products. Congress has indicated that it will continue to seek new legislative measures to control drug costs.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices, which has resulted in several U.S. Congressional inquiries and federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs, and review the relationship between pricing and manufacturer patient programs. The Inflation Reduction Act of 2022 (the "IRA"), for example, includes several provisions that may impact our business to varying degrees, including provisions that reduce the out-of-pocket spending cap for Medicare Part D beneficiaries to $2,000 starting in 2025, eliminating the prescription drug coverage gap; impose new manufacturer financial liability on certain drugs under Medicare Part D, allow the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and biologics without generic or biosimilar competition; require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation; and delay until January 1, 2032 the implementation of an HHS rebate rule that would have limited the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs were previously exempted from the Medicare drug price negotiation program; however, this exemption was restricted to drugs with only one orphan designation and for which the only approved indication is for that disease or condition. If a product received multiple orphan designations or had multiple approved indications, it would not qualify for the orphan drug exemption. Under the OBBBA, this restriction was eliminated; and effective for the 2028 initial price applicability year, all orphan drugs, regardless of the number of orphan designations or indications, are exempt from the Medicare drug price negotiation program. The effects of the IRA on our business and the healthcare industry in general is not yet known.

On April 15, 2025, the Trump Administration published Executive Order 14273, "Lowering Drug Prices by Once Again Putting Americans First," which generally directs the federal government to take measures to reduce drug prices, including eliminating the so-called "pill penalty" under the Inflation Reduction Act that creates a distinction between small molecule and large molecule products for purposes of determining when a drug may be eligible for drug price negotiation. On May 12, 2025, the Trump Administration published Executive Order 14297, "Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients" which generally, among other things, directs the federal government to establish and communicate most-favored-nation price targets to pharmaceutical manufacturers to bring prices for American patients in line with comparably developed nations. Further, the Executive Order directs the federal government to support regulatory paths to allow direct-to-patient sales for companies that meet these targets. It also states that the Administration will take additional aggressive action (for example, examining whether marketing approvals should be modified or rescinded or opening the door for individual drug importation waivers) should manufacturers fail to offer American consumers the most-favored-nation lowest price. It also directs the Secretary of Commerce and the U.S. Trade Representative to "take all necessary and appropriate action to ensure foreign countries are not engaged in any act, policy, or practice that may be unreasonable or discriminatory or that may impair United States national security . . . including by suppressing the price of pharmaceutical products below fair market value in foreign countries." Notably, a similar "Most Favored Nation" pricing rule enacted under the first Trump Administration was subject to an injunction resulting from judicial challenges to the rule, which was formally rescinded by the former Biden Administration in August 2021.

We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our approved products;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

These laws, and future state and federal healthcare reform measures may be adopted in the future, any of which may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

In addition, the U.S. Supreme Court's June 2024 decision in Loper Bright Enterprises v. Raimondo overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The Loper decision could result in additional legal challenges to regulations and guidance issued by federal agencies, including the FDA, on which we rely. Any such legal challenges, if successful, could have a material impact on our business. Additionally, the Loper decision may result in increased regulatory uncertainty, inconsistent judicial interpretations, and other impacts to the agency rulemaking process, any of which could adversely impact our business and operations. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action or as a result of legal challenges, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, our business could be materially harmed.

Changes in the FDA, other government agencies or comparable foreign regulatory authorities could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA or comparable foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies or comparable foreign regulatory authorities on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA, other government agencies or comparable foreign regulatory authorities may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times, including beginning on October 1, 2025, and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities. The duration of the current government shutdown is unknown. If a prolonged government shutdown occurs or a widespread freeze on federal funding continues or occurs in the future, including as a result of reaching the debt ceiling, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, government shutdowns could impact our ability to access the public markets and obtain additional capital in the future.

Item 2. Unregistered Sales of Equity Securities, Use of Proceeds and Issuer Purchases of Equity Securities.

(a) Recent Sales of Unregistered Equity Securities

None.

(b) Use of Proceeds from Initial Public Offering

On September 12, 2024, our Registration Statement on Form S-1 (No. 333-281764) for our initial public offering (the "IPO") was declared effective by the SEC. Refer to the disclosure in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2024, filed on November 7, 2024, which disclosure remains unchanged as of the date of this Quarterly Report.

(c) Issuer Repurchases of Securities

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

(c) None of our directors or "officers," as defined in Rule 16a-1(f) under the Securities Exchange Act of 1934, adopted or terminated a Rule 10b5-1 trading plan or arrangement or a non-Rule 10b5-1 trading plan or arrangement, as defined in Item 408(c) of Regulation S-K, during the fiscal quarter covered by this report.

Item 6. Exhibits.

Exhibit Number	Description
3.1	Fourth Amended and Restated Certificate of Incorporation of MBX Biosciences, Inc. (as currently in effect) (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-42272) filed with the SEC on September 16, 2024).
3.2	Amended and Restated Bylaws of MBX Biosciences, Inc. (as currently in effect) (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-42272) filed with the SEC on September 16, 2024).
4.1+	Second Amended and Restated Investors' Rights Agreement among the Registrant and certain of its stockholders, dated August 2, 2024) (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-281764) filed with the SEC on September 9, 2024).
4.2	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-281764) filed with the SEC on September 9, 2024).
31.1*	Certification of Principal Executive Officer 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.
31.2*	Certification of Principal Financial Officer 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.
32.1**	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH*	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104*	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

**This certification will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent specifically incorporated by reference into such filing.

+ Certain exhibits and schedules to these agreements have been omitted pursuant to Item 601(a)(5) and (6) of Regulation S-K. The registrant will furnish copies of any of the exhibits and schedules to the SEC upon request.

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.

MBX Biosciences, Inc.

Date: November 6, 2025

By: /s/ P. Kent Hawryluk
P. Kent Hawryluk
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 6, 2025

By: /s/ Richard Bartram
Richard Bartram
Chief Financial Officer
(Principal Financial Officer and Principal 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, P. Kent Hawryluk, certify that:

1. I have reviewed this Form 10-Q for the Quarterly Period Ended September 30, 2025 of MBX Biosciences, 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(s) 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)) 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) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

   (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(s) 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: November 6, 2025

By: /s/ P. Kent Hawryluk

P. Kent Hawryluk
President and 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, Richard Bartram, certify that:

1. I have reviewed this Form 10-Q for the Quarterly Period Ended September 30, 2025 of MBX Biosciences, 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(s) 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)) 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) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

   (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(s) 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: November 6, 2025

By: /s/ Richard Bartram

Richard Bartram
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

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 of MBX Biosciences, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: November 6, 2025

By: /s/ P. Kent Hawryluk

P. Kent Hawryluk
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 6, 2025

By: /s/ Richard Bartram

Richard Bartram
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)