# 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, 2024**

**OR**

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

**For the transition period from _____ to _____**

**Commission File Number: 001-42272**

# 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<br>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 1, 2024, the registrant had 33,417,418 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 contains 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 developments in the United States and foreign countries;
- our commercialization, marketing and manufacturing capabilities;

•our expectations regarding the period during which we will qualify as an emerging growth company under the JOBS Act 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 initial public offering (IPO), 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.

## SUMMARY RISK FACTORS

Our business is subject to numerous risks and uncertainties, which include, but are not limited to, the following:

•We have incurred significant losses since inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.

•The results observed from preclinical studies or early-stage clinical trials of our product candidates, including, but not limited to, our preclinical studies of MBX 4291, may not necessarily be predictive of the results of later-stage clinical trials that we may conduct. Similarly, positive results from such preclinical studies or early-stage clinical trials may not be replicated in our subsequent preclinical studies or clinical trials.

•We have never generated revenue from product sales and may never become profitable

•We will need substantial additional funding. If we are unable to raise additional capital when needed on acceptable terms, or at all, we may be forced to delay, reduce, or terminate certain of our research and product development programs, future commercialization efforts or other operations.

•Our business is highly dependent on the success of our product candidates. If we are unable to successfully complete clinical development, obtain regulatory approval for or commercialize one or more of our product candidates, or if we experience delays in doing so, our business will be materially harmed.

•If we fail to discover, develop and commercialize other product candidates, or successfully build out our own internal discovery capacities, we may be unable to grow our business and our ability to achieve our strategic objectives would be impaired.

•We may incur unexpected costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

•Our product candidates may cause undesirable side effects, including injection site reactions, or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following regulatory approval, if obtained.

•We may find it difficult to enroll patients in our clinical trials.

•The number of patients with the diseases and disorders for which we are developing our product candidates has not been established with precision. If the actual number of patients with the diseases or disorders we elect to pursue with our product candidates is smaller than we anticipate, we may have difficulties in enrolling patients in our clinical trials, which may delay or prevent development of our product candidates.

•We face significant competition in an environment of rapid change, and there is a possibility that our competitors may achieve regulatory approval before us or develop therapies that are safer or more advanced or effective than ours, or that we are unable to compete with existing entities that have made substantial investment into novel treatments for disease, which may harm our financial condition and our ability to successfully market or commercialize any product candidates we may develop.

•The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed. We have not yet demonstrated an ability to obtain regulatory approvals.

•If we do not achieve our projected development and commercialization goals in the timeframes we announce and expect, the development and commercialization of our product candidates may be delayed, and our business and results of operations may be harmed.

•We rely on third parties to assist in conducting our clinical trials. If they do not perform satisfactorily, we may not be able to obtain regulatory approval or commercialize our product candidates, or such approval or commercialization may be delayed, and our business could be substantially harmed.

•Our use of third parties to manufacture our product candidates may increase the risk that we will not have sufficient quantities of our product candidates, raw materials, active pharmaceutical ingredients, or APIs, or drug products when needed or at an acceptable cost.

•We are dependent on the services of our management and other clinical and scientific personnel, and if we are not able to retain these individuals or recruit additional management or clinical and scientific personnel, our business will suffer.

•Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent us from obtaining approvals for the commercialization of our product candidates.

•We face significant competition in an environment of rapid change, and there is a possibility that our competitors may achieve regulatory approval before us or develop therapies that are safer or more advanced or effective than ours.

The summary risk factors described above should be read together with the text of the full risk factors in the section titled "Risk Factors" and the other information set forth in this Quarterly Report, as well as in other documents that we file with the SEC. The risks summarized above or described in full elsewhere in this Quarterly Report are not the only risks that we face. Additional risks and uncertainties not presently known to us, or that we currently deem to be immaterial may also materially adversely affect our business, financial condition, results of operations, and future growth prospects.

## PART I—FINANCIAL INFORMATION

**Item 1. Financial Statements.**

**MBX BIOSCIENCES, INC.**

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

| | September 30, 2024 (Unaudited) | December 31, 2023 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 132,865 | $ 30,523 |
| Marketable securities | 144,198 | 50,153 |
| Prepaid expenses and other current assets | 4,107 | 2,789 |
| Total current assets | 281,170 | 83,465 |
| Property and equipment, net | 1,033 | 439 |
| Right-of-use assets | 147 | 226 |
| Other assets | 50 | 50 |
| Total assets | $ 282,400 | $ 84,180 |
| **Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)** | | |
| Current liabilities: | | |
| Accounts payable | $ 5,002 | $ 1,391 |
| Accrued expenses | 5,752 | 2,382 |
| Operating lease liability, current | 166 | 153 |
| Total current liabilities | 10,920 | 3,926 |
| Share repurchase liability | 68 | 194 |
| Operating lease liability, net of current | 44 | 171 |
| Total liabilities | 11,032 | 4,291 |
| Commitments and contingencies (Note 9) | | |
| Convertible preferred stock | | |
| Series A Convertible Preferred Stock, $0.0001 par value, zero shares authorized, issued and outstanding as of September 30, 2024 and 53,598,587 shares authorized, issued and outstanding (liquidation preference of $36,822,229) as of December 31, 2023 | — | 36,501 |
| Series B Convertible Preferred Stock, $0.0001 par value, zero shares authorized, issued and outstanding as of September 30, 2024 and 129,240,032 shares authorized, issued and outstanding (liquidation preference of $116,316,029) as of December 31, 2023 | — | 115,856 |
| Total convertible preferred stock | — | 152,357 |
| Stockholders' equity (deficit) | | |
| Undesignated preferred stock, $0.0001 par value, 10,000,000 shares authorized and zero issued and outstanding as of September 30, 2024 and zero shares authorized, issued and outstanding as of December 31, 2023 | — | — |
| Common stock, $0.0001 par value, 500,000,000 shares authorized and 33,376,058 issued and outstanding as of September 30, 2024 and 237,000,000 shares authorized and 1,257,080 issued and outstanding as of December 31, 2023 | 5 | 1 |
| Additional paid-in-capital | 393,176 | 3,054 |
| Accumulated deficit | (121,919) | (75,583) |
| Accumulated other comprehensive income | 106 | 60 |
| Total stockholders' equity (deficit) | 271,368 | (72,468) |
| Total liabilities, convertible preferred stock and stockholders' equity (deficit) | $ 282,400 | $ 84,180 |

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, | |
|---|---|---|---|---|
| | 2024 | 2023 | 2024 | 2023 |
| Operating expenses | | | | |
| Research and development | $ 16,747 | $ 9,073 | $ 42,192 | $ 20,807 |
| General and administrative | 2,865 | 1,872 | 7,392 | 4,513 |
| Total operating expenses | 19,612 | 10,945 | 49,584 | 25,320 |
| Loss from operations | (19,612) | (10,945) | (49,584) | (25,320) |
| Interest and other income, net | 1,470 | 783 | 3,248 | 1,600 |
| Net loss | $ (18,142) | $ (10,162) | $ (46,336) | $ (23,720) |
| Unrealized gain on marketable securities | 121 | 9 | 46 | 6 |
| Total other comprehensive gain | 121 | 9 | 46 | 6 |
| Total comprehensive loss | $ (18,021) | $ (10,153) | $ (46,290) | $ (23,714) |
| Net loss attributable to common stockholders | $ (18,142) | $ (10,162) | $ (46,336) | $ (23,720) |
| Net loss per common share, basic and diluted | $ (2.78) | $ (9.40) | $ (15.42) | $ (24.28) |
| Weighted average number of common shares outstanding used in computation of net loss per common share, basic and diluted | 6,515,616 | 1,081,349 | 3,004,382 | 976,824 |

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)**

| | Series A Convertible Preferred Stock | | Series B Convertible Preferred Stock | | Series C Convertible Preferred Stock | | Common Stock | | Additional | | Accumulated Other | Total |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Outstanding Shares | Amount | Outstanding Shares | Amount | Outstanding Shares | Amount | Outstanding Shares | Amount | Paid-in Capital | Accumulated Deficit | Comprehensive Income (Loss) | Stockholders' Deficit |
| **Balance at January 1, 2024** | 53,598,587 | $ 36,501 | 129,240,032 | $ 115,856 | — | $ — | 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 income (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 income (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 (loss) | — | — | — | — | — | — | — | — | — | — | 121 | 121 |
| **Balance at September 30, 2024** | — | $ — | — | $ — | — | $ — | 33,376,058 | $ 5 | $ 393,176 | $ (121,919) | $ 106 | $ 271,368 |

| | Series A Convertible Preferred Stock | | Series B Convertible Preferred Stock | | Common Stock | | Additional | | Accumulated Other | Total |
|---|---|---|---|---|---|---|---|---|---|---|
| | Outstanding Shares | Amount | Outstanding Shares | Amount | Outstanding Shares | Amount | Paid-in Capital | Accumulated Deficit | Comprehensive Income (Loss) | Stockholders' Deficit |
| **Balance at January 1, 2023** | 53,598,587 | $ 36,501 | 53,118,933 | $ 47,378 | 1,007,995 | $ 1 | $ 411 | $ (43,020) | $ 3 | $ (42,605) |
| Issuance of common stock upon exercise of stock options | — | — | — | — | 27,344 | — | 77 | — | — | 77 |
| Stock-based compensation expense | — | — | — | — | — | — | 204 | — | — | 204 |
| Net loss | — | — | — | — | — | — | — | (5,949) | — | (5,949) |
| Other comprehensive income (loss) | — | — | — | — | — | — | — | — | 1 | 1 |
| **Balance at March 31, 2023** | 53,598,587 | 36,501 | 53,118,933 | 47,378 | 1,035,339 | 1 | 692 | (48,969) | 4 | (48,272) |
| Issuance of common stock upon exercise of stock options | — | — | — | — | 198,806 | — | 269 | — | — | 269 |
| Stock-based compensation expense | — | — | — | — | — | — | 225 | — | — | 225 |
| Net loss | — | — | — | — | — | — | — | (7,608) | — | (7,608) |
| Other comprehensive income (loss) | — | — | — | — | — | — | — | — | (4) | (4) |
| **Balance at June 30, 2023** | 53,598,587 | 36,501 | 53,118,933 | 47,378 | 1,234,145 | 1 | 1,186 | (56,577) | — | (55,390) |
| Issuance of Series B Convertible Preferred Stock, net of $30 issuance costs | — | — | 76,121,099 | 68,478 | — | — | — | — | — | — |
| Issuance of common stock upon exercise of stock options | — | — | — | — | 14,902 | — | 129 | — | — | 129 |
| Stock-based compensation expense | — | — | — | — | — | — | 595 | — | — | 595 |
| Net loss | — | — | — | — | — | — | — | (10,162) | — | (10,162) |
| Other comprehensive income (loss) | — | — | — | — | — | — | — | — | 9 | 9 |
| **Balance at September 30, 2023** | 53,598,587 | $ 36,501 | 129,240,032 | $ 115,856 | 1,249,047 | $ 1 | $ 1,910 | $ (66,739) | $ 9 | $ (64,819) |

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, | |
|---|---|---|
| | **2024** | **2023** |
| **Cash flows from operating activities:** | | |
| Net loss | $ (46,336) | $ (23,720) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Stock-based compensation expense | 3,734 | 1,025 |
| Non cash operating lease expense | 79 | 70 |
| Accretion and amortization of marketable securities, net | (1,531) | (444) |
| Depreciation expense | 186 | 116 |
| Changes in operating assets and liabilities: | | |
| Prepaid expenses and other current assets | (1,319) | 275 |
| Accounts payable | 3,282 | 722 |
| Accrued expenses | 3,374 | 1,226 |
| Operating lease liability | (113) | (102) |
| Net cash used in operating activities | (38,644) | (20,832) |
| **Cash flows from investing activities:** | | |
| Purchases of property and equipment | (782) | (74) |
| Purchases of marketable securities | (151,968) | (29,898) |
| Maturities of marketable securities | 59,500 | 28,000 |
| Net cash used in investing activities | (93,250) | (1,972) |
| **Cash flows from financing activities:** | | |
| Proceeds from exercise of common stock options | 208 | 720 |
| Proceeds from initial public offering, net of underwriting discounts and commissions | 174,542 | — |
| Payments related to offering costs | (3,735) | — |
| Proceeds from the issuance of Series C Convertible Preferred Stock | 63,500 | — |
| Proceeds from the issuance of Series B Convertible Preferred Stock | — | 68,509 |
| Preferred stock issuance costs | (279) | (30) |
| Net cash provided by financing activities | 234,236 | 69,199 |
| Net increase in cash and cash equivalents | 102,342 | 46,395 |
| Cash and cash equivalents, beginning of period | 30,523 | 24,210 |
| Cash and cash equivalents, end of period | 132,865 | |
| | $ | $ 70,605 |
| **Supplemental disclosure of non-cash investing and financing activities:** | | |
| Vesting of early exercised stock options and founder shares | $ 206 | $ 389 |
| Property and equipment in accounts payable and accrued liabilities | 16 | — |
| Conversion of convertible preferred stock to common stock upon initial public offering | 215,578 | — |
| Deferred initial public offering costs included in accounts payable and accrued expenses | 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 MBX 2109, 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, convertible preferred stock and convertible notes, which generated approximately $401.8 million in aggregate gross proceeds.

### *Initial Public Offering*

On September 16, 2024, the Company completed its initial public offering ("IPO"), pursuant to which it sold 11,730,000 shares of its common stock at a public offering price of $16.00 per share, resulting in net proceeds of approximately $170.5 million, after deducting underwriting discounts, commissions and other offering costs. Immediately prior to the closing of the IPO, the Company's outstanding convertible preferred stock automatically converted into 20,336,599 shares of common stock. Following the closing of the IPO, zero shares of convertible preferred stock were authorized, issued or outstanding.

### *Reverse Stock Split*

On September 6, 2024, the Company effected a one-for-12.0221 reverse stock split of its issued and outstanding shares of common stock and a proportional adjustment to the existing conversion prices for the Company's convertible preferred stock (see Note 10). Accordingly, all issued and outstanding share and per share amounts of common stock and stock option awards for all periods presented in the accompanying condensed financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect this reverse stock split. The par value and the number of authorized shares of the common stock and convertible preferred stock were not adjusted in connection with the reverse stock split.

### *Liquidity*

From inception and through September 30, 2024, 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 $46.3 million and $32.6 million for the nine months ended September 30, 2024 and the year ended December 31, 2023, respectively. As of September 30, 2024, the Company has an accumulated deficit of $121.9 million and cash, cash equivalents and marketable securities of $277.1 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, 2024 and for the three and nine months ended September 30, 2024 and 2023 have been prepared in accordance with U.S. generally accepted accounting principle ("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, 2024 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, 2023 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, 2023 included in the Company's final IPO prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on September 12, 2024 (the "IPO Prospectus").

## 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, 2023 and notes thereto, included in the IPO prospectus, 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 Company's IPO. The deferred offering costs were offset against the IPO proceeds upon the consummation of the offering on September 16, 2024. 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.

***Segments***

Operating segments are defined as components of an entity for which separate financial information is made available and is regularly evaluated by the chief operating decision maker ("CODM") in making decisions regarding resource allocation and assessing performance. The Company's CODM is the chief executive officer and operations are managed as a single segment for the purposes of assessing performance and making operating decisions. All of the Company's assets are located in the United States.

***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 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 consolidated 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 consolidated financial statements. We are currently assessing the impact ASU 2024-03 will have on our financial statements, including our footnote disclosures.

## 3.FAIR VALUE MEASUREMENTS

The following table presents information about the Company's financial instruments as of September 30, 2024 and December 31, 2023, 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, 2024 | | | |
|---|---|---|---|---|
| | Total | Level 1 | Level 2 | Level 3 |
| **Financial assets:** | | | | |
| Money market funds (cash equivalents) | $ 89,201 | $ 89,201 | $ — | $ — |
| Marketable securities (cash equivalents) | 43,422 | 24,752 | 18,670 | — |
| Marketable securities | 144,198 | 144,198 | — | — |
| Total financial assets measured at fair value | $ 276,821 | $ 258,151 | $ 18,670 | $ — |

| | December 31, 2023 | | | |
|---|---|---|---|---|
| | Total | Level 1 | Level 2 | Level 3 |
| **Financial assets:** | | | | |
| Money market funds (cash equivalents) | $ 30,359 | $ 30,359 | $ — | $ — |
| Marketable securities | 50,153 | 40,231 | 9,922 | — |
| Total financial assets measured at fair value | $ 80,512 | $ 70,590 | $ 9,922 | $ — |

**4.MARKETABLE SECURITIES**

The fair value of the Company's marketable securities as of September 30, 2024 and December 31, 2023 is based on Level 1 and Level 2 inputs. The Company's investments consist mainly of U.S. government and agency securities, government-sponsored bond obligations and certain other corporate debt 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 the nine months ended September 30, 2024 and year ended December 31, 2023. 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. We have therefore classified all securities as current, even if we do not necessarily intend to dispose of the securities in the following year. Securities are carried at fair value with the unrealized gains (losses) reported in other comprehensive income (loss).

As of September 30, 2024 and December 31, 2023, 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, 2024 | | | |
|---|---|---|---|---|
| | Amortized Cost | Unrealized Gain | Unrealized (Loss) | Estimated Fair Value |
| Government and agency securities | $ 187,514 | $ 121 | $ (15) | $ 187,620 |
| Total | $ 187,514 | $ 121 | $ (15) | $ 187,620 |

| | December 31, 2023 | | | |
|---|---|---|---|---|
| | Amortized Cost | Unrealized Gain | Unrealized (Loss) | Estimated Fair Value |
| Government and agency securities | $ 50,093 | $ 62 | $ (2) | $ 50,153 |
| Total | $ 50,093 | $ 62 | $ (2) | $ 50,153 |

The fair values of available-for-sale debt securities as of September 30, 2024, by contractual maturity, are summarized as follows (*in thousands*):

| | September 30, 2024 |
|---|---|
| Due in one year or less | $ 187,620 |
| Due after one year | — |
| Total | $ 187,620 |

**5.PREPAID EXPENSES AND OTHER CURRENT ASSETS**

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

| | September 30, 2024 | December 31, 2023 |
|---|---|---|
| Prepaid research and development expenses | $ 2,411 | $ 2,448 |
| Interest receivable | 858 | 208 |
| Other current assets | 838 | 133 |
| Total prepaid and other current assets | $ 4,107 | $ 2,789 |

**6.PROPERTY AND EQUIPMENT, NET**

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

| | September 30, 2024 | December 31, 2023 |
|---|---|---|
| Furniture and fixtures | $ 181 | $ 162 |
| Computer equipment and software | 62 | 59 |
| Equipment | 760 | 21 |
| Leasehold improvements | 391 | 372 |
| Construction in progress | 3 | 3 |
| Total property and equipment | 1,397 | 617 |
| Less accumulated depreciation | (364) | (178) |
| Property and equipment, net | $ 1,033 | $ 439 |

Depreciation expense was $0.1 million and an immaterial amount for the three months ended September 30, 2024 and 2023, respectively, and $0.2 million and $0.1 million for the nine months ended September 30, 2024 and 2023, respectively.

**7.ACCRUED EXPENSES**

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

| | September 30, 2024 | December 31, 2023 |
|---|---|---|
| Compensation and benefits | $ 1,850 | $ 1,365 |
| Research and development expenses | 3,717 | 903 |
| Other | 185 | 114 |
| Total accrued expenses | $ 5,752 | $ 2,382 |

**8.OTHER ASSETS**

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

| | September 30, 2024 | December 31, 2023 |
|---|---|---|
| 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 has an initial term of 39 months, terminating in December 2025, 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 lease inception.

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 has a term of 12 months, terminating in December 2024. The lease does not contain an option to extend the term. Due to the lease term being only one year, we have elected to account for it as a short-term lease with no corresponding lease liability or right-of-use asset recorded, and lease payments recognized as expense on a straight-line basis over the lease term.

The Company has no other operating or finance leases as of September 30, 2024 or December 31, 2023.

The future minimum rent payments relating to the Carmel Lease under the terms and conditions existing as of September 30, 2024, are summarized as follows (*in thousands*):

| (in thousands) | Amount |
|---|---|
| 2024 (remaining three months) | $ 43 |
| 2025 | 178 |
| Total lease payments | 221 |
| Less: imputed interest | (11) |
| Present value of lease liabilities | $ 210 |

The Company incurred $0.1 million and an immaterial amount of rent expense for the three months ended September 30, 2024 and 2023, respectively, and $0.2 million and $0.1 million for the nine months ended September 30, 2024 and 2023, respectively.

The following table summarizes the operating lease term and discount rate for the Carmel Lease as of September 30, 2024 and December 31, 2023:

| | September 30, 2024 | December 31, 2023 |
|---|---|---|
| Weighted-average remaining lease term (years) | 1.3 | 2.0 |
| Weighted-average discount rate | 8.0% | 8.0% |

Cash paid for amounts included in the measurement of the Company's operating lease liability was $0.1 million for the nine months ended September 30, 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, 2024 and December 31, 2023 (*in thousands*):

| | September 30, 2024 | December 31, 2023 |
|---|---|---|
| Right-of use assets | $ 147 | $ 226 |
| Operating lease liability, current | 166 | 153 |
| Operating lease liability, net of current | 44 | 171 |

***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 total up to $9.3 million. In consideration for the license, during the nine months ended September 30, 2024 and year ended December 31, 2023, the Company paid immaterial licensing fees to IURTC.

***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**

The Company has 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 (the "Board") and stockholders approved the fourth amended and restated certificate of incorporation, which was effective immediately prior to the closing of the 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 as discussed further below,

all of the Company's outstanding shares of convertible preferred stock were converted into an aggregate of 20,336,599 shares of common stock.

***Issuances of convertible preferred stock***

In July 2020, the Company entered into a Series A convertible preferred stock purchase agreement ("Series A SPA") under which it issued 29,112,081 shares of Series A Convertible Preferred Stock, for cash, at a price of $0.687 per share, for gross proceeds of $20.0 million (the "Initial Series A Closing"). The Company incurred issuance costs of $0.3 million in relation to the issuance of Series A Convertible Preferred Stock, which have been recorded as a reduction to the value of the Series A Convertible Preferred Stock in mezzanine equity in the accompanying balance sheets. The Series A SPA contained provisions that potentially obligated the Company to sell an additional 14,556,039 shares of Series A Convertible Preferred Stock at $0.687 per share in an additional closing contingent upon either the achievement of a regulatory milestone defined in the Series A SPA or upon the agreement of the Company's Board and lead investor to waive the requirement to achieve the milestone. In the event that an Initial Series A Closing purchaser failed to purchase all of their required shares in the subsequent Series A closing, each of the Series A Convertible Preferred Stock held by such purchaser automatically converted into one-half of a share of common stock.

Concurrently with the Initial Series A Closing, convertible notes issued by the Company in 2019 and 2020, including accrued interest and accrued deferred compensation, plus interest, were converted into 8,474,865 shares of Series A convertible preferred stock at a conversion price equal to 90% of the Series A financing, or $0.6183, representing a total of $5.4 million.

On November 12, 2021, the Company sold 16,011,641 additional shares of Series A convertible preferred stock at the same terms and conditions as those contained in the initial Agreement. The gross proceeds from the sale of Series A Convertible Preferred Stock upon achieving the milestone event was $11.0 million at $0.687 per share. The Company incurred immaterial issuance costs in relation to the issuance of Series A Convertible Preferred Stock, which have been recorded as a reduction to the value of the Series A Convertible Preferred Stock in mezzanine equity in the accompanying balance sheets.

On November 7, 2022 (the "Initial Series B Closing"), the Company entered into a Series B preferred stock purchase agreement to issue certain investors Series B Convertible Preferred Stock at a purchase price of $0.90 per share ($0.0001 par value). The Company amended the Certificate of Incorporation ("Charter") on November 7, 2022, which authorized the issuance of 129,240,032 shares of Series B Convertible Preferred Stock, in addition to 53,598,587 shares of Series A Convertible Preferred Stock issued and outstanding. The Company also executed the Amended and Restated Right of First Refusal and Co-Sale Agreement and the Amended and Restated Investors' Rights Agreement.

The Initial Series B Closing resulted in the issuance of 40,545,552 shares of Series B Convertible Preferred Stock, at a price of $0.90 per share, for gross cash proceeds of $36.5 million. The Company incurred issuance costs of $0.4 million in relation to the issuance of Series B Convertible Preferred Stock, which have been recorded as a reduction to the value of the Series B Convertible Preferred Stock in mezzanine equity in the accompanying balance sheets. Concurrently with the Initial Series B Closing, the 2022 Notes, including accrued interest, were converted into 12,573,381 shares of Series B Convertible Preferred Stock at a conversion price equal to 90% of the Series B financing. After the Initial Closing, the Company agreed to sell on the same terms and conditions as the first sale, an additional 76,121,099 shares of Series B Preferred Stock (the "Series B Milestone Issuance") upon achieving certain development milestones.

On August 15, 2023, the Company issued 76,121,099 shares of Series B Convertible Preferred Stock, at a price of $0.90 per share, for gross cash proceeds of $68.5 million in the Series B Milestone Issuance. The Company incurred immaterial issuance costs in relation to this issuance of Series B Convertible Preferred Stock, which have been recorded as a reduction to the value of the Series B Convertible Preferred Stock in mezzanine equity in the accompanying balance sheets.

On August 2, 2024, the Company entered into a Series C convertible preferred stock purchase agreement under which it issued 61,650,480 shares of Series C Convertible Preferred Stock, for cash, at a price of $1.03 per share, for gross proceeds of $63.5 million. The Company incurred issuance costs of $0.3 million in relation to the issuance of Series C Convertible Preferred Stock, which were initially recorded as a reduction to the value of Series C Convertible Preferred Stock.

The holders of the Series A, Series B and Series C Convertible Preferred Stock have the following rights and preferences:

***Voting rights***

Series A, Series B and Series C Convertible Preferred Stock are entitled to cast the number of votes equal to the number of whole shares of common stock into which the shares of Series A, Series B and Series C Convertible Preferred Stock held by such holder are convertible as of the record date for determining stockholders entitled to vote on such matter.

***Election of directors***

The holders of record of shares of Series A Convertible Preferred Stock, exclusively and as a separate class, shall be entitled to elect three directors of the Company. The holders of record of shares of Series B Convertible Preferred Stock, exclusively and as a separate class, shall be entitled to elect one director of the Company. The holders of record of shares of Series C Convertible Preferred Stock, exclusively and as a separate class, are not entitled to elect any directors of the Company.

***Non-cumulative dividend***

Holders of Series A, Series B and Series C Convertible Preferred Stock, in preference to the holders of common stock, are entitled to receive, when, as and if declared by the Board of the Company, but only out of funds that are legally available therefor, cash dividends at the rate of eight percent (8%) of the Series A, Series B and Series C original issue price per annum on each outstanding share of Series A, Series B and Series C Convertible Preferred Stock (the "Preferred Dividends"). All such Preferred Dividends shall be payable only when, as and if declared by the Board of the Company and shall be non-cumulative. No dividends have been declared to-date as of September 30, 2024.

***Conversion right***

Each share of Series A, Series B and Series C Convertible Preferred Stock is automatically converted into common stock upon either (a) the closing of the sale of shares of common stock to the public at a price of at least $2.061, $2.25 or $2.25, respectively, per share (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the common stock), in a firm-commitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, resulting in at least $50,000,000 of gross proceeds to the Corporation and in connection with such offering the common stock is listed for trading on the Nasdaq Stock Market's National Market, the New York Stock Exchange or another exchange or marketplace approved the Board or (b) the affirmative vote or written consent of the majority preferred stockholders. All outstanding convertible preferred stock was converted into common stock immediately prior to the closing of the Company's IPO.

***Liquidation preference***

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company, the holders of shares of Series A, Series B and Series C Convertible Preferred Stock then outstanding shall be entitled to be paid out of the assets of the Company available for distribution to its stockholders, and in the event of a Deemed Liquidation Event (as defined in the Company's Charter), the holders of shares of Series A, Series B and Series C Convertible Preferred Stock then outstanding shall be entitled to be paid out of the consideration payable to stockholders in such Deemed Liquidation Event or out of the available proceeds, as applicable, before any payment shall be made to the holders of common stock by reason of their ownership thereof, an amount per share equal to the greater of (i) the Series A, Series B and Series C Convertible Preferred Stock original issue prices, plus any dividends declared but unpaid thereon, or (ii) such amount per share as would have been payable had all shares of Series A, Series B and Series C Convertible Preferred Stock been converted into common stock immediately prior to such liquidation, dissolution, winding up or Deemed Liquidation Event.

**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.

As of September 30, 2024 and December 31, 2023, there were 33,376,058 and 1,257,080 shares of common stock issued and outstanding, respectively. Shares of common stock issued and outstanding as of September 30, 2024, include 18,039 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, 2023 include 90,324 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, 2024 and December 31, 2023, respectively. These shares are subject to the Company's option to repurchase and are not transferrable until such time as they are fully vested.

***Common stock reserved***

The number of shares of common stock that have been reserved for the potential conversion of Preferred Stock, and 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") and stock options available for grant under the 2019 Plan and 2024 Plan as of September 30, 2024 and December 31, 2023, are as follows:

| | September 30, 2024 | December 31, 2023 |
|---|---|---|
| Conversion of Series A Preferred Stock | — | 4,458,324 |
| Conversion of Series B Preferred Stock | — | 10,750,183 |
| Outstanding common stock options | 3,573,385 | 2,493,777 |
| Common stock options available for grant | 2,577,775 | 684,284 |
| Shares available for issuance under 2024 ESPP | 289,436 | — |
| Total | 6,440,596 | 18,386,568 |

**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 December 31, 2023, the total number of shares of common stock authorized and issuable under the 2019 Plan was 3,728,169. The remaining shares reserved for issuance under the 2019 Plan ceased to be available for issuance at the time that 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. 3,086,160 stock options to purchase common stock were outstanding under the 2019 Plan as of September 30, 2024.

***2024 Stock Option and Incentive Plan***

In August 2024, the Company's Board 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, 2024, 2,577,775 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 directors adopted, and its stockholders approved, the 2024 Employee Stock Purchase Plan (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.

No shares were issued under the 2024 ESPP during the three and nine months ended September 30, 2024.

***Stock option valuation***

The determination of the grant date fair value of stock-based awards granted to employees, directors and nonemployees during the nine months ended September 30, 2024 and 2023, is estimated using the Black-Scholes option-pricing model and was calculated based on the following assumptions.

| | Nine months ended September 30, | |
|---|---|---|
| | 2024 | 2023 |
| Fair value of common stock | $9.14 - $16.00 | $4.09 - $7.81 |
| Dividend yield | —% | —% |
| Volatility | 88% - 110% | 80% - 90% |
| Risk-free interest rate | 3.52% - 5.18% | 3.42% - 4.34% |
| Expected term (years) | 0.50 - 6.08 | 6.02 - 6.08 |

***Summary of option activity***

The Company's stock option activity regarding employees, directors, and nonemployees for the nine months ended September 30, 2024, 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, 2023 | 2,493,777 | $ 6.00 | 9.26 | $ 4,543 |
| Granted | 1,333,901 | 12.18 | | |
| Exercised | (63,194) | 3.68 | | |
| Forfeited | (198,696) | 6.40 | | |
| Cancelled | (3,217) | 3.25 | | |
| Repurchased | 10,814 | 2.41 | | |
| Options outstanding and exercisable - September 30, 2024 | 3,573,385 | $ 8.31 | 8.97 | $ 63,134 |

Additional information with regard to stock option activity involving employees and directors for the nine months ended September 30, 2024 and 2023, is as follows (*in thousands except per share amounts*):

| | September 30, | |
|---|---|---|
| | 2024 | 2023 |
| Weighted-average grant date fair value per option of total options granted | $ 4.79 | $ 0.48 |
| Aggregate intrinsic value of stock options exercised | 361 | 320 |

As of September 30, 2024, total unrecognized compensation cost related to the unvested awards to employees, directors, and nonemployees is $18.2 million, which is expected to be recognized over a weighted-average period of 3.3 years.

***Stock-based compensation***

During the nine months ended September 30, 2024 and 2023, 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, | |
|---|---|---|---|---|
| | 2024 | 2023 | 2024 | 2023 |
| Research and development expense | $ 529 | $ 227 | $ 1,913 | $ 402 |
| General and administrative expense | 663 | 369 | 1,821 | 623 |
| Total | $ 1,192 | $ 596 | $ 3,734 | $ 1,025 |

## 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. As of September 30, 2024, the Company has not made any contributions to the plan on behalf of our employees.

## 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, | |
|---|---|---|---|---|
| | 2024 | 2023 | 2024 | 2023 |
| Net loss and net loss attributable to common stockholders | $ (18,142) | $ (10,162) | $ (46,336) | $ (23,720) |
| Net loss per share attributable to common stockholders, basic and diluted | $ (2.78) | $ (9.40) | $ (15.42) | $ (24.28) |
| Weighted average number of common shares outstanding used in computation of net loss per common share, basic and diluted | 6,515,616 | 1,081,349 | 3,004,382 | 976,824 |

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, | |
|---|---|---|
| | 2024 | 2023 |
| Series A Convertible Preferred Stock (as converted to common stock) | — | 4,458,324 |
| Series B Convertible Preferred Stock (as converted to common stock) | — | 10,750,183 |
| Outstanding common stock options | 3,573,385 | 2,406,109 |
| Restricted stock related to early exercise of options to purchase common stock | 18,039 | 135,631 |
| Total | 3,591,424 | 17,750,247 |

## 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 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. The Company paid $0.2 million and $0.3 million pursuant to this agreement during the three months ended September 30, 2024 and 2023, respectively, and $0.9 million and $0.7 million during the nine months ended September 30, 2024 and 2023, respectively. The Research Agreement also provides the Company an option to license the technology arising under the agreement (see Note 9).

## 16.SUBSEQUENT EVENTS

The Company has evaluated subsequent events through November 7, 2024, 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 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, 2023 included in our final prospectus dated September 12, 2024, filed with the Securities and Exchange Commission pursuant to rule 424(b) under the Securities Act of 1933, as amended (the "IPO Prospectus"). 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, MBX 2109, is a parathyroid hormone 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 MBX 2109 to treat the underlying pathophysiology of HP by providing a continuous, infusion-like exposure to parathyroid hormone, ("PTH"), with convenient once-weekly administration. In a Phase 1 clinical trial, MBX 2109 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. MBX 2109 was generally well-tolerated with no drug-related severe or serious adverse effects. We are currently evaluating MBX 2109 in a Phase 2 clinical trial in patients with HP and dosed our first patient in this trial in August 2024. Enrollment is ongoing and expected to complete in the first quarter of 2025 and we anticipate reporting top-line data in the third quarter of 2025.

Our second program is MBX 1416, which is designed to be a long-acting glucagon-like peptide-1, ("receptor antagonist"), as a potential therapy for post-bariatric hypoglycemia, ("PBH"), a chronic complication of bariatric surgery. MBX 1416 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. In our ongoing Phase 1 clinical trial, the single ascending dose portion of this Phase 1 trial evaluates subcutaneous MBX 1416 doses of 10 milligrams ("mg"), 30 mg, 100 mg and 200 mg, in up to eight healthy adults per cohort randomized 3:1 (six MBX 1416; two placebo in each cohort). The multiple ascending dose portion of the trial evaluates four weekly subcutaneous doses of placebo and 10 mg, 30 mg (as two injections) and 30 mg (as one injection) MBX 1416 in three cohorts in up to eight healthy adults per cohort (six MBX 1416; two placebo in each cohort). An additional cohort will assess the clinical relevance of preclinical transporter findings. Preliminary data regarding the way the compound is absorbed, distributed, metabolized and excreted, ("pharmacokinetics") from the single ascending dose portion demonstrated that weekly subcutaneous injections resulted in dose-proportional increases in MBX 1416 exposure and a half-life supporting a once-weekly dosing regimen. We anticipate the last subject visit to occur in late November 2024 and plan to announce the Phase 1 top-line data in early January of 2025.

Our third program is our lead obesity product candidate, MBX 4291, is designed to be a long-acting and highly potent and glucose-dependent insulinotropic polypeptide receptor prodrug with the goal of reducing dosing frequency and improving efficacy and tolerability relative to existing standards of care. MBX 4291 is currently being evaluated in preclinical studies, with an anticipated investigational new drug, ("IND") submission in the second quarter of 2025. Beyond MBX 4291, we have a robust discovery pipeline including additional programs in the lead optimization stage for the treatment of obesity and associated comorbidities.

Since our inception, we have devoted substantially all of our resources to drug discovery and development of our product candidates, MBX 2109, MBX 1416 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. We have historically funded our operations primarily from the issuance and sale of our common stock, convertible preferred stock and convertible notes, which generated approximately $401.8 million in 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 $18.1 million and $10.2 million for the three months ended September 30, 2024 and 2023, respectively. Our net losses were $46.3 million and $23.7 million for the nine months ended September 30, 2024 and 2023, respectively. We had an accumulated deficit of $121.9 million and $75.6 million as of September 30, 2024 and December 31, 2023, 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, MBX 2109, MBX 1416 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 $277.1 million and $80.7 million as of September 30, 2024 and December 31, 2023, respectively. We believe that our existing cash, cash equivalents and marketable securities will be sufficient to fund our operating expenses and capital expenditure requirements into mid-2027. 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” and “Risk Factors—Risks related to financial position and need for capital.”

**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. MBX 2109, 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 U.S. Food and Drug Administration ("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 (expense)***

*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, 2024 and 2023***

The following table summarizes our results of operations for the three months ended September 30, 2024 and 2023 (in thousands):

| | Three months ended September 30, 2024 | 2023 | Change $ |
|---|---|---|---|
| Operating expenses: | | | |
| Research and development | $ 16,747 | $ 9,073 | $ 7,674 |
| General and administrative | 2,865 | 1,872 | 993 |
| Total operating expenses | 19,612 | 10,945 | 8,667 |
| Loss from operations | (19,612) | (10,945) | (8,667) |
| Other income (expense) | | | |
| Interest and other income, net | 1,470 | 783 | 687 |
| Total other income, net | 1,470 | 783 | 687 |
| Net loss | $ (18,142) | $ (10,162) | $ (7,980) |

***Research and development expenses***

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

| | Three months ended September 30, 2024 | 2023 | Change $ |
|---|---|---|---|
| Direct research and development program expenses: | | | |
| MBX 2109 | $ 5,958 | $ 2,973 | $ 2,985 |
| MBX 1416 | 2,066 | 4,155 | (2,089) |
| Preclinical and other | 5,708 | 439 | 5,269 |
| Indirect research and development costs: | | | |
| Personnel related costs (including stock-based compensation) | 2,771 | 1,413 | 1,358 |
| Facility-related and other | 244 | 93 | 151 |
| Total research and development expense | $ 16,747 | $ 9,073 | $ 7,674 |

Research and development expenses were $16.7 million for the three months ended September 30, 2024, as compared to $9.1 million for the three months ended September 30, 2023. The increase of $7.7 million consisted of the following:

Direct research and development program expenses related to MBX 2109 increased by $3.0 million, primarily due to the ongoing Phase 2 clinical trial and costs associated with conducting preclinical studies. Direct program expenses related to MBX 1416 decreased by $2.1 million, primarily due to the timing of costs associated with conducting preclinical studies, partially offset by an increase in costs associated with conduct of the Phase 1 clinical trial. Direct program expenses for preclinical and other programs increased by $5.3 million primarily due to pipeline candidate development activities, specifically including investigational new drug application ("IND")-enabling preclinical studies related to MBX 4291. Personnel-related costs (including stock-based compensation), increased by $1.4 million, primarily due to increased headcount and stock-based compensation expense. Facility-related and other, 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 $2.9 million for the three months ended September 30, 2024, as compared to $1.9 million for the three months ended September 30, 2023. The increase of $1.0 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.

***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 $1.5 million for the three months ended September 30, 2024, as compared to $0.8 million for the three months ended September 30, 2023. The increase of $0.7 million was due to increased interest on our cash, cash equivalents and marketable securities, which increased primarily due to our IPO in September 2024 and the Series C Convertible Preferred Stock financing in August 2024.

***Comparison of the nine months ended September 30, 2024 and 2023***

The following table summarizes our results of operations for the nine months ended September 30, 2024 and 2023 (in thousands):

| | Nine months ended September 30, | | Change |
|---|---|---|---|
| | 2024 | 2023 | $ |
| Operating expenses: | | | |
| Research and development | $ 42,192 | $ 20,807 | $ 21,385 |
| General and administrative | 7,392 | 4,513 | 2,879 |
| Total operating expenses | 49,584 | 25,320 | 24,264 |
| Loss from operations | (49,584) | (25,320) | (24,264) |
| Other income (expense) | | | |
| Interest and other income, net | 3,248 | 1,600 | 1,648 |
| Total other income, net | 3,248 | 1,600 | 1,648 |
| Net loss | $ (46,336) | $ (23,720) | $ (22,616) |

***Research and development expenses***

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

| | Nine months ended September 30, 2024 | 2023 | Change $ |
|---|---|---|---|
| Direct research and development program expenses: | | | |
| MBX 2109 | $ 14,920 | $ 7,649 | $ 7,271 |
| MBX 1416 | 9,810 | 7,405 | 2,405 |
| Preclinical and other | 8,428 | 1,746 | 6,682 |
| Indirect research and development costs: | | | |
| Personnel related costs (including stock-based compensation) | 7,461 | 3,655 | 3,806 |
| Facility-related and other | 1,573 | 352 | 1,221 |
| Total research and development expense | $ 42,192 | $ 20,807 | $ 21,385 |

Research and development expenses were $42.2 million for the nine months ended September 30, 2024, as compared to $20.8 million for the nine months ended September 30, 2023. The increase of $21.4 million consisted of the following:

Direct research and development program expenses related to MBX 2109 increased by $7.3 million, primarily due to the initiation of the Phase 2 clinical trial. Direct program expenses related to MBX 1416 increased by $2.4 million, primarily due to the ongoing execution of the Phase 1 clinical trial, costs associated with conducting preclinical trials and costs associated with manufacturing drug supply. Direct program expenses for preclinical and other programs increased by $6.7 million primarily due to pipeline candidate development activities, specifically related to IND-enabling preclinical studies for MBX 4291. 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, which include allocated overhead, including rent, repairs and maintenance costs, common facilities and information technology-related expenses allocated to research and development increased by $1.2 million, primarily due to a one-time cash gift to Indiana University to support research in macromolecular chemistry and peptide therapeutics and related areas in the Department of Chemistry, and other infrastructure costs to support organizational growth.

***General and administrative expenses***

General and administrative expenses were $7.4 million for the nine months ended September 30, 2024, as compared to $4.5 million for the nine months ended September 30, 2023. The increase of $2.9 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.

***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 $3.2 million for the nine months ended September 30, 2024, as compared to $1.6 million for the nine months ended September 30, 2023. The increase of $1.6 million was due to increased interest on our cash, cash equivalents and marketable securities, which increased primarily due to our IPO in September 2024 and the Series C Convertible Preferred Stock financing in August 2024.

**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 and sales of our convertible preferred stock and convertible notes, which have generated approximately $401.8 million in aggregate gross proceeds. As of September 30, 2024 and December 31, 2023, we had $277.1 million and $80.7 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 $277.1 million and $80.7 million in cash, cash equivalents and marketable securities as of September 30, 2024 and December 31, 2023, 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 mid-2027. 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, | |
|---|---|---|
| | 2024 | 2023 |
| Net cash used in operating activities | $ (38,644) | $ (20,832) |
| Net cash used in investing activities | (93,250) | (1,972) |
| Net cash provided by financing activities | 234,236 | 69,199 |
| Net increase in cash and cash equivalents | $ 102,342 | $ 46,395 |

***Cash flows from operating activities***

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.

Net cash used in operating activities for the nine months ended September 30, 2023 was $20.8 million. This was primarily due to our net loss of $23.7 million, partially offset by net cash provided by changes in our operating assets and liabilities of $2.1 million and non-cash charges of $0.8 million. The changes in our net operating assets and liabilities primarily consisted of a $1.9 million increase in accounts payable and accrued expenses and a $0.3 million decrease in our prepaid expenses and other current assets. Non-cash charges primarily consisted of $1.0 million of stock-based compensation expense, partially offset by $0.4 million of net amortization and accretion of marketable securities.

***Cash flows from investing activities***

Net cash used in investing activities for the nine months ended September 30, 2024 was $93.3 million, which consisted of maturities 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.

Net cash used in investing activities for the nine months ended September 30, 2023 was $2.0 million, which consisted of purchases of marketable securities of $30.0 million and purchases of property and equipment of $0.1 million, partially offset by maturities of marketable securities of $28.0 million.

***Cash flows from financing activities***

Net cash 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 proceeds from the exercise of stock options of $0.2 million, partially offset by payments related to IPO costs of $3.7 million and preferred stock offering costs of $0.3 million.

Net cash provided by financing activities for the nine months ended September 30, 2023 was $69.2 million, which consisted of proceeds from our issuance of Series B Convertible Preferred Stock of $68.5 million in August 2023 and proceeds from the exercise of common stock options of $0.7 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 2025. As of September 30, 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. As of December 31, 2023, our future remaining operating lease payments were $0.4 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 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 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, see the section herein titled “License agreement” included in our IPO Prospectus.

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, 2024, 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 IPO Prospectus, except that our common stock is now publicly traded and we therefore no longer require common stock valuations.

**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 Annual Report on Form 10-K 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, 2024. 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, 2024 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, 2024 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.

*Our business involves significant risks. Stockholders should carefully consider the risks and uncertainties described below 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 below 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 below 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.*

#### Risks related to financial position and need for capital

***We have incurred significant losses since inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.***

Since inception, we have incurred significant operating losses. Our net loss was $46.3 million and $32.6 million for the nine months ended September 30, 2024 and the year ended December 31, 2023, respectively. As of September 30, 2024, we had an accumulated deficit of $121.9 million. As of December 31, 2023, we had an accumulated deficit of $75.6 million. We have financed our operations primarily through our issuance and sale of our common stock, convertible preferred stock and convertible promissory notes. Substantially all of our losses have resulted from expenses incurred in connection with our research and development and from general and administrative costs associated with our operations. We expect to continue to incur significant expenses and increasing operating 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 our current product candidates and potential future product candidates. The net losses we incur may fluctuate significantly from quarter to quarter. We anticipate that our expenses will increase substantially for the foreseeable future if and as we:

- advance our current research activities and further develop our platform;
- continue preclinical development and progress clinical trials for our product candidates and any future product candidates we may identify;
- seek regulatory approval for any product candidates for which we successfully complete clinical trials;
- establish our manufacturing capacity capabilities to supply our clinical trials in our pipeline and eventually for commercialization;
- commercialize our product candidates, if approved, which will require significant marketing, sales, and distribution infrastructure expenses;
- hire additional research and development, clinical, commercial, and general and administration personnel;
- develop, maintain, expand, protect, and enforce our intellectual property portfolio;
- 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 continue to operate as a public company that we did not incur as a private company.

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 the sale of equity, debt financings, or other capital sources, which may include collaborations with other companies or other strategic transactions. 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, product candidates or delay our pursuit of potential in-licenses or acquisitions.

We have not yet demonstrated an ability to successfully complete any pivotal clinical trials, advance any product candidate beyond Phase 2, obtain regulatory approvals, manufacture our product candidates at commercial scale, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. To become and remain profitable, we must develop and, either directly or through collaborators, eventually commercialize a therapy or therapies with market potential. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of product candidates, obtaining regulatory approval for these product candidates, manufacturing, marketing and selling those therapies for which we may obtain regulatory approval and satisfying any post-marketing requirements. We may never succeed in these activities and, even if we do, may never generate revenues that are significant or large enough to achieve profitability.

Because of the numerous risks and uncertainties associated with developing our technology, platform and our product candidates, we are unable to predict the extent of any future losses or when we will become profitable, if at all. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

***We have never generated revenue from product sales and may never become profitable.***

Our ability to generate revenue from product sales and achieve profitability depends on our ability, alone or with collaborative partners, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize, our product candidates. We may not generate revenues from product sales for many years, if ever. Our ability to generate future revenues from product sales depends heavily on our or our collaborators' ability to successfully:

- complete research and development of our product candidates;
- identify new product candidates;
- seek and obtain regulatory approvals for any product candidates for which we successfully complete clinical trials;
- launch and commercialize any product candidates for which we may obtain regulatory approval by establishing a sales force, marketing and distribution infrastructure, or alternatively, collaborating with a commercialization partner;
- qualify for adequate coverage and reimbursement by government and third-party payors for any product candidates for which we may obtain regulatory approval;
- establish and maintain supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and the market demand for any product candidates for which we obtain regulatory approval;
- develop, maintain and enhance a sustainable, scalable, reproducible and transferable manufacturing process for the product candidates we may develop;
- address competing technological and market developments;
- negotiate favorable terms in any collaboration, licensing or other arrangements into which we may enter and performing our obligations in such collaborations;
- receive market acceptance by physicians, patients, healthcare payors, and others in the medical community;
- maintain, protect, enforce, defend and expand our portfolio of intellectual property and other proprietary rights, including patents, trade secrets and know-how;
- defend against third-party intellectual property claims of infringement, misappropriation or other violation; and
- attract, hire and retain qualified personnel.

Our expenses could increase beyond expectations if we are required by the U.S. Food and Drug Administration ("FDA") or other regulatory authorities to perform preclinical studies or clinical trials in addition to those that we currently anticipate. Even if one or more of our product candidates are approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Additionally, such products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives. Even if we are able to generate revenues from the sale of any approved product candidates, we may not become profitable and may need to obtain additional funding to continue operations.

***We will need substantial additional funding. If we are unable to raise additional capital when needed on acceptable terms, or at all, we may be forced to delay, reduce, or terminate certain of our research and product development programs, future commercialization efforts or other operations.***

Developing product candidates, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception, and we expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, continue, initiate and conduct clinical trials of, and seek regulatory approval for, our product candidates. In addition, if we obtain regulatory approval for our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing, and distribution to the extent that such sales, marketing, manufacturing, and distribution are not the responsibility of a collaborator. Other unanticipated costs may also arise. Furthermore, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on acceptable terms, we would be forced to delay, reduce, or eliminate our research and product development programs, future commercialization efforts or other operations.

As of September 30, 2024, our cash, cash equivalents and marketable securities were $277.1 million. We expect that our existing cash, cash equivalents, and marketable securities will enable us to fund our operating expenses and capital expenditure requirements into mid-2027. However, our operating plan may change as a result of factors currently unknown to us, and we may need to seek funding sooner than planned. Our future capital requirements will depend on many factors, including:

- 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 product candidates;
- the costs, timing, and outcome of regulatory review of any of our product candidates;
- the costs of manufacturing clinical and commercial supplies of our product candidates;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive regulatory approval;
- the costs of preparing, filing and prosecuting our patent applications, maintaining and enforcing our patents and other intellectual property rights and defending intellectual property-related claims;
- 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;
- the extent to which we acquire or in-license other product candidates and technologies;
- any product liability or other lawsuits related to our 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 economic uncertainty, global health crises and geopolitical tensions, which may exacerbate the magnitude of the factors discussed above.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive, and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends, and possibly other restrictions.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. We have no committed sources of additional capital and, if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our future product candidates or other research and development initiatives. Without sufficient funding, our license agreements and any future collaboration agreements may also be terminated if we are unable to meet the payment or other obligations under such agreements.

If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce, or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Additionally, if we raise funds through additional collaborations, strategic alliances, 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 we may have to grant licenses on terms that may not be favorable to us and/or that may reduce the value of our common stock.

***Our short operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.***

We are an early-stage company. We commenced our operations in August 2018. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, and research and development activities such as developing our platform and technology and identifying and beginning to advance preclinical and clinical testing of our product candidates. Two of our product candidates, MBX 2109 and MBX 1416 are in clinical development, while MBX 4291 is in the IND-enabling phase and our other development programs in our obesity portfolio remain in the research or lead optimization stage of development. We have not yet demonstrated an ability to complete any large-scale, pivotal clinical trials, advance any product candidate beyond Phase 2, obtain regulatory approvals, manufacture our product candidates at commercial scale, arrange for a third party to do so on our behalf or conduct sales and marketing activities necessary for successful commercialization.

Our limited operating history, particularly in light of the evolving field of peptide therapies, may make it difficult to evaluate our platform, technology and industry and predict our future performance. Our short history as an operating company makes any assessment of our future success or viability subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by very early stage companies in rapidly evolving fields. If we do not address these risks successfully, our business will suffer.

In addition, as a new business that is rapidly growing, we may encounter other unforeseen expenses, difficulties, complications, and delays in our product development. We will need to transition from a company with a focus on research and conducting clinical trials to a company capable of supporting commercial activities if any of our product candidates are approved. We may not be successful in such a transition.

***Our future ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.***

Since our inception, we have incurred losses and we may never achieve profitability. As of December 31, 2023, we had U.S. federal net operating loss carryforwards of $30.1 million which are not subject to expiration and state net operating loss carryforwards of $71.3 million which begin to expire in various amounts in 2039, and $4.7 million of U.S. federal research and development carryforwards which begin to expire in various amounts in 2039, and $1.2 million of research credit carryforwards for state income tax purposes which begin to expire in various amounts in 2029. To the extent that we continue to generate taxable losses, under current law, our unused U.S. federal net operating losses ("NOLs") may be carried forward to offset a portion of future taxable income, if any. Additionally, we continue to generate business tax credits, including research and development tax credits, which generally may be

carried forward to offset a portion of future taxable income, if any, subject to expiration of such credit carryforwards. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended ("the Code"), if a corporation undergoes an “ownership change,” generally defined as one or more shareholders or groups of shareholders who own at least 5 percent of the corporation’s equity increasing their equity ownership in the aggregate by more than 50 percentage points (by value) over a three-year period, the corporation’s ability to use its pre-change NOLs and other pre-change tax attributes (such as research and development tax credits) to offset its post-change income or taxes may be limited. Similar rules may apply under state tax laws. To date, we have not completed an analysis under Section 382 of the Code. It is possible that our prior equity offerings and other changes in our stock ownership could have resulted in such ownership changes in the past. In addition, we may experience ownership changes in the future or subsequent shifts in our stock ownership, some of which are outside of our control. As a result, if we earn net taxable income, our ability to use our pre-change NOLs or other pre-change tax attributes to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. There is a risk that due to changes under the tax law, regulatory changes or other unforeseen reasons, our existing NOLs or business tax credits could expire or otherwise be unavailable to offset future income tax liabilities. At the state level, there may also be periods during which the use of NOLs or business tax credits is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. For these reasons, we may not be able to realize a tax benefit from the use of our NOLs or tax credits, even if we attain profitability.

***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. Changes to tax laws (which changes may have retroactive application) could adversely affect our business and our financial condition. 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.

**Risks related to our business and industry**

***Our business is highly dependent on the success of our product candidates. If we are unable to successfully complete clinical development, obtain regulatory approval for or commercialize one or more of our product candidates, or if we experience delays in doing so, our business will be materially harmed.***

We are in the early stages of our development efforts and have only two product candidates, MBX 2109 and MBX 1416, in clinical development. All of our other development programs are still in the preclinical or drug discovery stage. To date, as an organization, we have not completed the development of any product candidates. Our future success and ability to generate revenue from our product candidates is dependent on our ability to successfully develop, obtain regulatory approval for and commercialize one or more of our product candidates. All of our product candidates will require substantial additional investment for clinical development, regulatory review and approval in one or more jurisdictions. If any of our product candidates encounters safety or efficacy problems, development delays or regulatory issues or other problems, our development plans and business would be materially harmed.

We may not have the financial resources to continue development of our product candidates if we experience any issues that delay or prevent regulatory approval of, or our ability to commercialize, our product candidates, including:

- our inability to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our product candidates are safe and effective;
- insufficiency of our financial and other resources to complete the necessary clinical trials and preclinical studies;
- negative or inconclusive results from our clinical trials, preclinical studies or the clinical trials of others for product candidates similar to ours, leading to a decision or requirement to conduct additional clinical trials or preclinical studies or abandon a program;
- product-related adverse events experienced by subjects in our clinical trials, including unexpected toxicity results or drug-drug interactions, or by individuals using drugs or therapeutic biologics similar to our product candidates;

•delays in submitting an Investigational New Drug ("IND"), application or comparable foreign applications or delays or failure in obtaining the necessary approvals from regulators to commence a clinical trial or a suspension or termination, or hold, of a clinical trial once commenced;

•conditions imposed by the FDA or comparable foreign regulatory authorities regarding the scope or design of our clinical trials;

•poor effectiveness of our product candidates during clinical trials;

•better than expected performance of control arms, such as placebo groups, which could lead to negative or inconclusive results from our clinical trials;

•delays in enrolling or inability to enroll subjects in our clinical trials;

•high drop-out rates of subjects from our clinical trials;

•inadequate supply or quality of product candidates or other materials necessary for the conduct of our clinical trials;

•higher than anticipated clinical trial or manufacturing costs;

•our inability to timely or adequately finalize the design or formulation of any product candidate or demonstrate that a formulation of any product candidate will be stable for commercially reasonable time periods;

•unfavorable FDA or comparable regulatory authority inspection and review of our clinical trial sites;

•failure of our third-party contractors or investigators to comply with regulatory requirements or the clinical trial protocol or otherwise meet their contractual obligations in a timely manner, or at all;

•failure to acquire patent rights over our product candidates;

•delays and changes in regulatory requirements, policies and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our therapies in particular; or

•varying interpretations of data by the FDA and comparable foreign regulatory authorities.

***If we fail to discover, develop and commercialize other product candidates, or successfully build out our own internal discovery capacities, we may be unable to grow our business and our ability to achieve our strategic objectives would be impaired.***

Although the development and commercialization of MBX 2109, MBX 1416 and MBX 4291 and the other development candidates in our obesity portfolio are our initial focus, as part of our longer-term growth strategy, we plan to continue to develop our additional assets in earlier stages of development and to build fully functional internal discovery capabilities to develop other product candidates. We intend to evaluate internal opportunities from our existing product candidates or other potential product candidates. We have historically relied on the discovery capabilities of our co-founder, Dr. Richard DiMarchi, but we are currently continuing to build fully functional internal discovery capabilities, including laboratory space, and internalizing our ability to develop other product candidates. Dr. DiMarchi is a current consultant to the Company, as well as the principal investigator under our research agreement with the Trustees of Indiana University, under which we retain intellectual property developed on our behalf by Dr. DiMarchi, but the consulting agreement and research agreement are both terminable by either party. We have leased laboratory and office space at a research facility suitable for peptide chemistry, in vitro pharmacology and bioanalytical chemistry. We have built a team devoted to peptide chemistry and in vitro pharmacology, and are continuing to expand that team. The peptide chemistry lab will be based around a state-of-the-art peptide synthesizer capable of synthesizing up to 106 peptides of variable scales and chemistries simultaneously. We are equipping the laboratories currently and expect to continue to enhance our internal discovery efforts. If we are unable to complete this expansion and internalization, we may not be able to add internally-developed product candidates to our pipeline and will have to rely on our existing product candidates, additional product candidates we may in-license, or additional candidates we may develop through third-party research partners.

We also may choose to in-license or acquire other product candidates to treat patients suffering from other disorders with significant unmet medical needs and limited treatment options. These in-licensed or internally developed potential product candidates will require additional, time-consuming development efforts prior to commercial sale, including preclinical studies, clinical trials and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to the risks of failure that are inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot be certain that any such products that are approved will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace or be more effective than other commercially available alternatives.

These research programs to discover and identify additional product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified, and all efforts are as of now completed externally as we continue our efforts to internalize certain of our discovery capabilities. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including the following:

- the research methodology used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidates obsolete;
- product candidates that we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- a product candidate may, on further study, be shown to have harmful side effects, interactions with other drugs, or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- a product candidate may not be sufficiently differentiated or offer substantial improvement over the currently available treatment options or standard of care in a given therapeutic category;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors.

In the future, we may also seek to in-license or acquire product candidates or the underlying technology. The process of proposing, negotiating and implementing a license or acquisition is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of product candidates. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable, or at all.

In addition, future acquisitions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of management's time and attention to develop acquired products or technologies;
- incurrence of substantial debt, dilutive issuances of securities or depletion of cash to pay for acquisitions;
- higher than expected acquisition and integration costs;
- difficulty assimilating or integrating acquired or licensed technologies, products, employees or business operations;
- issues maintaining uniform standards, procedures, controls and policies;
- unanticipated costs associated with acquisitions or strategic alliances, including the assumption of unknown or contingent liabilities and the incurrence of debt or future write-offs of intangible assets or goodwill;
- increased amortization expenses;
- risks associated with entering new markets in which we have limited or no experience;
- potential losses related to investments in other companies;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to motivate key employees of any acquired businesses.

If we are unsuccessful in identifying and developing additional product candidates, either through internal development or licensing or acquisition from third parties, our potential for growth and achieving our strategic objectives may be impaired and we may not be able to increase our revenues in future periods, which could harm our business, results of operations and prospects, and the value of our shares.

***The successful development of pharmaceutical products is highly uncertain.***

Successful development of pharmaceutical products is highly uncertain and is dependent on numerous factors, many of which are beyond our control. Product candidates that appear promising in the early phases of development may fail to reach the market for several reasons, including:

- clinical trial results may show the product candidates to be less effective than expected (for example, a clinical trial could fail to meet its primary or key secondary endpoint(s)) or have an unacceptable safety or tolerability profile;
- failure to receive the necessary regulatory approvals or a delay in receiving such approvals, which, among other things, may be caused by patients who fail the trial screening process, slow enrollment in clinical trials, patients dropping out of trials, patients lost to follow-up, length of time to achieve trial endpoints, additional time requirements for data analysis or New Drug Application ("NDA"), preparation, discussions with the FDA, an FDA request for additional preclinical or clinical data (such as long-term toxicology studies) or unexpected safety or manufacturing issues;
- preclinical study results may show the product candidate to be less effective than desired or to have harmful side effects;
- post-marketing approval requirements; or
- the proprietary rights of others and their competing products and technologies that may prevent our product candidates from being commercialized.

The length of time necessary to complete clinical trials and submit an application for marketing approval for a final decision by a regulatory authority varies significantly from one product candidate to the next and from one country or jurisdiction to the next and may be difficult to predict.

Even if we are successful in obtaining marketing approval, commercial success of any approved products will also depend in large part on the availability of coverage and adequate reimbursement from third-party payors, including government payors such as the Medicare and Medicaid programs and managed care organizations in the United States or country-specific governmental organizations in foreign countries, which may be affected by existing and future healthcare reform measures designed to reduce the cost of healthcare. Third-party payors could require us to conduct additional studies, including post-marketing studies related to the cost effectiveness of a product, to qualify for reimbursement, which could be costly and divert our resources. If government and other healthcare payors were not to provide coverage and adequate reimbursement for our products once approved, market acceptance and commercial success would be reduced.

In addition, if any of our product candidates receive marketing approval, we will be subject to significant regulatory obligations regarding the submission of safety and other post-marketing information and reports and registration, and will need to continue to comply (or ensure that our third-party providers comply) with current Good Manufacturing Practices ("cGMPs") and Good Clinical Practices ("GCPs"), for any clinical trials that we conduct post-approval. In addition, there is always the risk that we, a regulatory authority or a third-party might identify previously unknown problems with a product post-approval, such as adverse events of unanticipated severity or frequency. Compliance with these requirements is costly, and any failure to comply or other issues with our product candidates post-approval could adversely affect our business, financial condition and results of operations.

***We may incur unexpected costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.***

To obtain the requisite regulatory approvals to commercialize any of our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe and effective in humans. We may experience delays in completing our clinical trials or preclinical studies and initiating or completing additional clinical trials or preclinical studies, including as a result of regulators not allowing or delay in allowing clinical trials to proceed under an IND, or not approving or delaying approval for any clinical trial grant or similar approval we need to initiate a clinical trial. We may also experience numerous unforeseen events during our clinical trials that could delay or prevent our ability to receive marketing approval or commercialize the product candidates we develop, including:

- regulators, institutional review boards ("IRBs") or other reviewing bodies may not authorize us or our investigators to commence a clinical trial, or to conduct or continue a clinical trial at a prospective or specific trial site;
- we may not reach agreement on acceptable terms with prospective contract research organizations ("CROs") and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- we may experience challenges or delays in recruiting principal investigators or study sites to lead our clinical trials;

•the number of subjects or patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, including because of the small number of patients for certain of our rare disease indications, and the number of clinical trials being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical trials at a higher rate than we anticipate;

•our third-party contractors, including those manufacturing our product candidates or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;

•we may have to amend clinical trial protocols submitted to regulatory authorities or conduct additional studies to reflect changes to incorporate adjustments in our planned analysis or in regulatory requirements or guidance, which may be required to resubmit to an IRB and regulatory authorities for re-examination;

•regulators or other reviewing bodies may find deficiencies with, fail to approve or subsequently find fault with the manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for clinical and commercial supplies, or the supply or quality of any product candidate or other materials necessary to conduct clinical trials of our product candidates may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply; and

•the potential for approval policies or regulations of the FDA or the applicable foreign regulatory agencies to significantly change in a manner rendering our clinical data insufficient for approval.

Regulators or IRBs of the institutions in which clinical trials are being conducted may suspend, limit or terminate a clinical trial, or data monitoring committees may recommend that we suspend or terminate a clinical trial, due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Negative or inconclusive results from our clinical trials or preclinical studies could mandate repeated or additional clinical trials and, to the extent we choose to conduct clinical trials in other indications, could result in changes to or delays in clinical trials of our product candidates in such other indications. We do not know whether any clinical trials that we conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market our product candidates for the indications that we are pursuing. If later-stage clinical trials do not produce favorable results, our ability to obtain regulatory approval for our product candidates will be adversely impacted.

Our failure to successfully initiate and complete clinical trials and to demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates would significantly harm our business. Our product candidate development costs will also increase if we experience delays in testing or regulatory approvals and we may be required to obtain additional funds to complete clinical trials. We cannot be certain that our clinical trials will begin as planned or be completed on schedule, if at all, or that we will not need to restructure or otherwise modify our trials after they have begun. For instance, we have adjusted our protocol for MBX 2109 to take into account feedback from our CRO. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates, which may harm our business and results of operations. In addition, many of the factors that cause, or lead to, delays of clinical trials may ultimately lead to the denial of regulatory approval of our product candidates.

***Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent us from obtaining approvals for the commercialization of our product candidates.***

Any product candidate we develop and the activities associated with its development and commercialization, including its design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities in the United States and by comparable authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction. We have not received approval to market any product candidates from regulatory authorities in any jurisdiction and it is possible that none of the product candidates we are developing or may seek to develop in the future will ever obtain regulatory approval.

We have no experience in submitting and supporting the applications necessary to gain marketing approvals and expect to rely on third-party CROs or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication

to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Any product candidates we develop may not be effective, may be only moderately effective, or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude its obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity, and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit, or prevent marketing approval of a product candidate. Any marketing approval that we may ultimately obtain could be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If we experience delays in obtaining approval or if we fail to obtain approval of any product candidates we may develop, the commercial prospects for those product candidates may be harmed, and our ability to generate revenues will be materially impaired.

***Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following regulatory approval, if obtained.***

Undesirable side effects caused by any of our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities.

Certain side effects and potential drug-drug interactions have been observed in our product candidates to date. For example, in our Phase 1 clinical trial of MBX 2109, injection site adverse events were the most common treatment-related adverse event, and events of hypercalcemia were observed at the top doses in three subjects each in the single and multiple ascending dose cohort. Although these events were not serious adverse events and resolved without intervention, if we were unable to identify a dose with a tolerable side-effect profile, or were limited in our ability for our product candidates to be used with certain other drugs, the commercial success of our product candidates, if approved, could be limited. Injection site adverse events were observed in the single and multiple ascending dose cohorts of the Phase 1 clinical trial of MBX 1416 and we have added a drug interaction cohort to our Phase 1 clinical trial of MBX 1416 to evaluate interactions between MBX 1416 and certain other common drugs, which could be costly and time-consuming.

We may also observe additional safety or tolerability issues with our product candidates in ongoing or future clinical trials. Many compounds that initially showed promise in clinical or earlier-stage testing are later found to cause undesirable or unexpected side effects that prevented further development of the compound. Results of future clinical trials of our product candidates could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics, despite a favorable tolerability profile observed in earlier-stage testing.

If unacceptable side effects arise in the development of our product candidates, we, the FDA or comparable foreign regulatory authorities, the IRBs, or independent ethics committees at the institutions in which our trials are conducted, could suspend, limit or terminate our clinical trials, or the independent safety monitoring committee could recommend that we suspend, limit or terminate our trials, or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment-emergent side effects that are deemed to be drug-related could delay recruitment of clinical trial subjects or may cause subjects that enroll in our clinical trials to discontinue participation in our clinical trials. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We may need to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in harm to patients that are administered our product candidates. Any of these occurrences may adversely affect our business, financial condition and prospects significantly.

Moreover, clinical trials of our product candidates are conducted in carefully defined sets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects.

***If our clinical trials fail to replicate positive results from earlier preclinical studies or clinical trials conducted by us or third parties, we may be unable to successfully develop, obtain regulatory approval for or commercialize our product candidates.***

The results observed from preclinical studies or early-stage clinical trials of our product candidates may not necessarily be predictive of the results of later-stage clinical trials that we conduct. Similarly, positive results from such preclinical studies or early-stage clinical trials may not be replicated in our subsequent preclinical studies or clinical trials. Furthermore, our product candidates may not be able to demonstrate similar activity or adverse event profiles as other product candidates that we believe may have similar profiles. For example, our future preclinical or clinical trials for our existing and future product candidates may not continue to demonstrate the extended half lives and low peak-to-trough ratios that we have seen so far in our product candidates.

In addition, in our planned future clinical trials, we may utilize clinical trial designs or dosing regimens that have not been tested in prior clinical trials.

There can be no assurance that any of our clinical trials will ultimately be successful or support further clinical development of any of our product candidates. There is a high failure rate for drugs proceeding through clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events.

Additionally, we may utilize an “open-label” clinical trial design. An “open-label” clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a “patient bias” where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical trials may be subject to an “investigator bias” where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The results from an open-label trial may not be predictive of future clinical trial results of a product candidate when studied in a controlled environment with a placebo or active control.

Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA or comparable foreign regulatory authority approval.

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

From time to time, we may publish interim, topline or preliminary data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our reputation and business prospects.

***We may find it difficult to enroll patients in our future clinical trials given the limited number of patients who have the diseases some of our product candidates are intended to target. Additionally, we also compete for trial participants with other clinical trials for product candidates that are in the same areas as our product candidates. If we experience delays or difficulties in the enrollment of patients in clinical trials, our clinical development activities and our receipt of necessary regulatory approvals could be delayed or prevented.***

As we progress our programs, we may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or other comparable regulatory authorities outside the United States, or as needed to provide appropriate statistical power for a given trial. Enrollment may be particularly challenging for some of the rare diseases we are targeting in our programs such as MBX 2109 and MBX 1416. For instance, in our Phase 1 trial of MBX 2109, we added one new site to the trial following slow enrollment at the originally selected sites, in order to meet our enrollment requirements. Enrollment may also be challenging for product candidates targeting prevalent diseases, such as MBX 4291 or other product candidates in our obesity portfolio, due to the intense competition in

the field. In addition, if patients are unwilling to participate in our trials because of negative publicity from adverse events, competitive clinical trials for similar patient populations, clinical trials in competing product candidates or for other reasons, the timeline for recruiting patients, conducting studies and obtaining regulatory approval of our product candidates may be delayed. Moreover, some of our competitors may have ongoing clinical trials for product candidates that would treat the same indications as our product candidates, and patients who would otherwise be eligible for our future clinical trials may instead enroll in clinical trials of our competitors' product candidates.

Patient enrollment is also affected by other factors, some of which may include:

- severity of the disease under investigation;
- size of the patient population and process for identifying patients, including proximity and availability of clinical trial sites for prospective patients with conditions that have small patient pools;
- effects of global health crises, such as those related to COVID-19, on enrollment and/or completion of a trial;
- design of the trial protocol, including efforts to facilitate timely enrollment in clinical trials;
- availability and efficacy of approved medications for the disease under investigation;
- ability to monitor patients adequately during and after treatment;
- ability to obtain and maintain patient informed consent;
- risk that enrolled patients will drop out before completion of the trial;
- eligibility and exclusion criteria for the trial in question;
- perceived risks and benefits of the product candidate; and
- patient referral practices of physicians.

In addition, if we are unable to enroll a sufficient number of eligible patients in these trials in the United States, we may look to enroll in sites outside of the United States. Our ability to successfully initiate, enroll and complete a clinical trial in any foreign country is subject to numerous risks unique to conducting business in foreign countries, some of which may include:

- difficulty in establishing or managing relationships with CROs and physicians;
- different standards for the conduct of clinical trials;
- different standard-of-care for patients with a particular disease;
- difficulty in locating qualified local consultants, physicians and partners; and
- potential burden of complying with a variety of foreign laws, medical standards and regulatory requirements, including the regulation of pharmaceutical and biotechnology products.

Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing. If we or our collaborators have difficulty enrolling a sufficient number of patients to conduct our clinical trials, we may need to delay, limit or terminate ongoing or planned clinical trials or entire clinical programs, any of which would have an adverse effect on our business, financial condition, results of operations and prospects.

***The number of patients with the diseases and disorders for which we are developing our product candidates has not been established with precision. If the actual number of patients with the diseases or disorders we elect to pursue with our product candidates is smaller than we anticipate, we may have difficulties in enrolling patients in our clinical trials, which may delay or prevent development of our product candidates. Even if such product candidates are successfully developed and approved, the markets for our products may be smaller than we expect and our revenue potential and ability to achieve profitability may be materially adversely affected.***

Our pipeline includes product candidates for both endocrine and metabolic diseases, with our lead product candidates targeting chronic hypoparathyroidism ("HP"), post-bariatric hypoglycemia ("PBH"), and obesity. There is no precise method of establishing the actual number of patients with any of these disorders in any geography over any time period. With respect to many of the indications in which we have developed, are developing, or plan to develop our product candidates, we have estimates of the prevalence of the disease or disorder. The process we have used in developing an estimated incidence and prevalence for the indications we are targeting has involved collating limited data from multiple sources. Our estimates as to prevalence may not be accurate, and the actual

prevalence or addressable patient population for some or all of those indications, or any other indication that we elect to pursue, may be significantly smaller than our estimates. For example, the estimated patient population for HP, a rare endocrine disease, already tends to be small, and may be even smaller than our current estimates. Moreover, the patient population for PBH may decrease due to the development of novel treatments for obesity, reducing the potential need for bariatric surgery, and the patient population for obesity may decrease as novel treatments for obesity are introduced. In estimating the potential prevalence of indications we are pursuing, or may in the future pursue, including our estimates as to the prevalence of HP, PBH and obesity, we apply assumptions to available information that may not prove to be accurate. In each case, there is a range of estimates in the published literature and in marketing studies, which include estimates within the range that are lower than our estimates. The actual number of patients with these disease indications may, however, be significantly lower than we believe. Even if our prevalence estimates are correct, our product candidates may be developed for only a subset of patients with the relevant disease or disorder or our products, if approved, may be indicated for or used by only a subset. In the event the number of patients with the diseases and disorders we are studying is significantly lower than we expect, we may have difficulties in enrolling patients in our clinical trials, which may delay or prevent development of our product candidates. If any of our product candidates are approved and our prevalence estimates with respect to any indication or our other market assumptions are not accurate, the markets for our product candidates for these indications may be smaller than we anticipate, which could limit our revenues and our ability to achieve profitability or to meet our expectations with respect to revenues or profits.

***Even if any of our product candidates receives regulatory approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success, in which case we may not generate significant revenues or become profitable.***

We have never commercialized a product, and even if any of our product candidates is approved by the appropriate regulatory authorities for marketing and sale, it may nonetheless fail to achieve sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. Many of the indications for our product candidates have well-established standards of care that physicians, patients and payors are familiar with. Even if our product candidates are successful in registrational clinical trials, they may not be successful in displacing these current standards of care if we are unable to demonstrate superior efficacy, safety, ease of administration and/or cost-effectiveness. For example, physicians may be reluctant to take their patients off their current medications and switch their treatment regimen to our product candidates. Further, patients often acclimate to the treatment regimen that they are currently taking and do not want to switch unless their physicians recommend switching products or they are required to switch due to lack of coverage and adequate reimbursement. Even if we are able to demonstrate our product candidates' safety and efficacy to the FDA and other regulators, safety or efficacy concerns in the medical community may hinder market acceptance.

Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources, including management time and financial resources, and may not be successful. If any product candidate is approved but does not achieve an adequate level of market acceptance, we may not generate significant revenues and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of the product;
- the potential advantages of the product compared to competitive therapies;
- the prevalence and severity of any side effects;
- whether the product is designated under physician treatment guidelines as a first-, second- or third-line therapy;
- our ability, or the ability of any future collaborators, to offer the product for sale at competitive prices;
- the product's convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try, and of physicians to prescribe, the product;
- limitations or warnings, including interactions with other drugs or distribution or use restrictions contained in the product's approved labeling;
- the strength of sales, marketing and distribution support;
- changes in the standard of care for the targeted indications for the product; and
- availability and adequacy of coverage and reimbursement from government payors, managed care plans and other third-party payors.

Any failure by one or more of our product candidates that obtains regulatory approval to achieve market acceptance or commercial success would adversely affect our business prospects.

***We face significant competition in an environment of rapid change, and there is a possibility that our competitors may achieve regulatory approval before us or develop therapies that are safer or more advanced or effective than ours, or that we are unable to compete with existing entities that have made substantial investment into novel treatments for disease, which may harm our financial condition and our ability to successfully market or commercialize any product candidates we may develop.***

The development and commercialization of new drug products is highly competitive. We will face competition with respect to our product candidates and any product candidates that we may seek to develop or commercialize in the future from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent or other intellectual property protection and establish collaborative arrangements for research, development, manufacturing and commercialization. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the disease indications for which we have research programs. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, while others are based on entirely different approaches.

Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future that are approved to treat the same diseases for which we may obtain approval for any product candidates we may develop. This may include other types of therapies, such as small molecule, antibody and/or protein therapies.

Many of our current or potential competitors, either alone or with their collaboration partners, may have significantly greater financial resources and expertise in research and development, manufacturing, conducting preclinical studies and clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize product candidates that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any product candidates that we may develop or that would render any product candidates that we may develop obsolete or non-competitive. Our competitors also may obtain FDA or other regulatory approval for their product candidates more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, technologies developed by our competitors may render our product candidates uneconomical or obsolete, and we may not be successful in marketing any product candidates we may develop against competitors.

In addition, as a result of the expiration or successful challenge of our patent or other intellectual property rights, we could face risks relating to our ability to successfully prevent or delay launch of competitors' products. The availability of our competitors' products could limit the demand and the price we are able to charge for any product candidates that we may develop and commercialize.

***Due to the significant resources required for the development of our pipeline, and depending on our ability to access capital, we must prioritize the development of certain product candidates over others. Moreover, we may fail to expend our limited resources on product candidates or indications that may have been more profitable or for which there is a greater likelihood of success.***

We currently have three product candidates as well as several other programs at various stages of discovery and development. We seek to advance discovery and development for product candidates with an initial focus on both endocrine and metabolic disorders with high unmet need.

Due to the significant resources required for the development of our product candidates, we must decide which product candidates and indications to pursue and advance and the amount of resources to allocate to each. Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular product candidates, therapeutic areas or indications may not lead to the development of viable commercial products and may divert resources away from better opportunities. For instance, we have elected to evaluate MBX 1416 as a treatment for PBH, but there may be better indications for which to evaluate MBX 1416, and this decision may divert resources away from better opportunities for MBX 1416. If we make incorrect determinations regarding the viability or market potential of any of our product candidates or misread trends in the pharmaceutical industry, in particular for the rare diseases we are pursuing, our business, financial condition and results of operations

could be materially and adversely affected. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases and disease pathways that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to such product candidates through collaboration, licensing or royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain sole development and commercialization rights.

***We currently have no commercial marketing and sales organization and have no experience as a company in commercializing products, and we may have to invest significant resources to develop these capabilities. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our products, we may not be able to generate product revenue.***

We have no internal sales, marketing or distribution capabilities, nor have we commercialized a product. If any of our product candidates ultimately receives regulatory approval, we expect to establish a marketing and sales organization with technical expertise and supporting distribution capabilities to commercialize each such product in major markets, which will be expensive and time consuming. We have no prior experience as a company in the marketing, sale and distribution of pharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may also choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. We may not be able to enter into collaborations or hire consultants or external service providers to assist us in sales, marketing and distribution functions on acceptable financial terms, or at all. In addition, our product revenues and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute any products that we develop ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we are not successful in commercializing our products, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses.

***If we do not achieve our projected development and commercialization goals in the timeframes we announce and expect, the development and commercialization of our product candidates may be delayed, and our business and results of operations may be harmed.***

For planning purposes, we sometimes estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development objectives. These milestones may include our expectations regarding the commencement or completion of scientific studies and clinical trials, the submission of regulatory filings or commercialization objectives. From time to time, we may publicly announce the expected timing of some of these milestones, such as the completion of an ongoing clinical trial, the initiation of other clinical programs, receipt of marketing approval or a commercial launch of a product. The achievement of many of these milestones may be outside of our control. All of these milestones are based on a variety of assumptions which, if not realized as expected, may cause the timing of achievement of the milestones to vary considerably from our estimates, including:

- our available capital resources or capital constraints we experience;
- the rate of progress, costs and results of our clinical trials and research and development activities, including the extent of scheduling conflicts with participating clinicians and collaborators;
- our ability to identify and enroll patients who meet clinical trial eligibility criteria;
- our receipt of approvals by the FDA and other regulatory authorities and the timing thereof;
- other actions, decisions or rules issued by regulators;
- our ability to access sufficient, reliable and affordable supplies of materials used to manufacture our product candidates;
- the efforts of our collaborators with respect to the commercialization of our product candidates; and
- the securing of, costs related to, and timing issues associated with, product manufacturing as well as sales and marketing activities.

If we fail to achieve announced milestones in the timeframes we expect, the development and commercialization of our product candidates may be delayed, and our business and results of operations may be harmed.

**Risks related to regulatory, legal, and clinical trials**

***The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.***

We are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining regulatory approval from the FDA. Foreign regulatory authorities impose similar requirements. The time required to obtain approval by the FDA and comparable foreign authorities is inherently unpredictable, but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. Jurisdictions outside of the United States, such as the European Union or Japan, may have different requirements for regulatory approval, which may require us to conduct additional clinical, nonclinical or chemistry, manufacturing and control studies. To date, we have not submitted an NDA to the FDA or similar drug approval submissions to comparable foreign regulatory authorities for any product candidate. We must complete additional preclinical studies and clinical trials to demonstrate the safety and efficacy of our product candidates in humans before we will be able to obtain these approvals.

In addition, a product known as Yorvipath has received orphan medicine designation for hypoparathyroidism in the EU and was granted a marketing authorization in November 2023. In the EU, orphan medicines benefit from 10 years of market exclusivity once they receive a marketing authorization in the EU (which may be extended by two additional years when the results of specific studies are reflected in the summary of product characteristics ("SmPC") addressing the paediatric population and completed in accordance with a fully compliant paediatric investigation plan). This market exclusivity prevents the EMA and all EU Member States from accepting an application or granting a marketing authorization for a "similar medicinal product" for the same therapeutic indication as the authorized orphan medicine, subject to certain specific derogations. Regulation (EC) 847/2000 defines a "similar medicinal product" as one which contains a similar active substance or substances as contained in an authorized orphan medicinal product and which is intended for the same therapeutic indication. A "similar active substance" is defined in the same Regulation as an identical active substance, or an active substance with the same principal molecular structural features (but not necessarily all of the same molecular structural features) and which acts via the same mechanism. There are some limited derogations to the market exclusivity granted to orphan medicinal products in the EU. Specifically, a company may be able to market a similar medicinal product to an authorized orphan product if: (i) the marketing authorization holder for the authorized orphan product consents to the grant of a marketing authorization for the similar product; (ii) the marketing authorization holder for the authorized orphan product is unable to supply sufficient quantities of its product; or (iii) the later applicant can establish that its product, although similar to the authorized orphan product, is safer, more effective or otherwise clinically superior. Regulation (EC) 847/2000 provides details on what would constitute clinical superiority in this context, including that direct comparative clinical trials may be required to demonstrate greater efficacy or safety to the authorized orphan product. As a result, we may not be able to gain approval for MBX 2109 in the EU until expiry of the market exclusivity period for Yorvipath (which could run until 2035 at the latest), unless we can demonstrate that MBX 2109 is either not a similar medicinal product to Yorvipath (i.e. the active substance in MBX 2109, if not identical to Yorvipath, does not have the same principal molecular structural features and act via the same mechanism as Yorvipath) or, if it is, that MBX 2109 is safer, more effective or otherwise clinically superior. Any comparative studies required to demonstrate clinical superiority could be costly and time-consuming, and there is no certainty that we would succeed in adequately demonstrating that our product is clinically superior to Yorvipath.

Yorvipath is also approved in the United States for the treatment of HP in adults. In Phase 3 trials, palopegteriparatide treatment rendered the majority of patients independent of active vitamin D and calcium supplements (which reduced pill burden), reduced urinary calcium excretion and, by patient-reported-outcome assessments, improved quality of life.

Our current and future product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree as to the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from clinical trials or preclinical studies;

•the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA to the FDA or other submission or to obtain regulatory approval in the United States or elsewhere;

•the FDA or comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;

•the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval; and

•another company may benefit from market exclusivity for their product which prevents us from obtaining marketing authorization for our product in the same indication during such exclusivity period (as described above).

This lengthy approval process as well as the unpredictability of clinical trial results and market exclusivity issues described above may result in our failing to obtain regulatory approval to market any product candidate we develop, which would substantially harm our business, results of operations and prospects. The FDA and other comparable foreign authorities have substantial discretion in the approval process and determining when or whether regulatory approval will be granted for any product candidate that we develop. Even if we believe the data collected from future clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA or any other regulatory authority.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

***Our product candidates require specific shipping, storage, handling and administration, which in some cases, may require cold-chain logistics and subject our product candidates to risk of loss or damage if failures occur.***

Our product candidates are sensitive to temperature, storage and handling conditions. They must be stored at very low temperatures in specialized freezers or specialized shipping containers until immediately prior to use. The handling and administration of the therapy product, if approved, may need to be performed according to specific instructions and in some steps within specific time periods. Failure to correctly handle our product could negatively impact the efficacy and or safety of our product, or cause a loss of product. In addition, if approved, certain of our products may need to be frozen using specialized equipment and maintained following specific procedures in order to be stored without damage in a cost-efficient manner and without degradation. We will need to scale-up a cost-effective and reliable cold-chain distribution and logistics network, which we may be unable to accomplish. Failure to effectively scale-up our cold-chain supply logistics, by us or third parties, could in the future lead to additional manufacturing costs and delays in our ability to supply required quantities for commercial supply. For these and other reasons, we may not be able to manufacture our current or future product candidates at commercial scale or in a cost-effective manner. Even if we are able to manufacture and distribute the product candidates, if our products require specific procedures to maintain and use them, we may be limited in commercial opportunity.

***Any drug delivery device that we potentially use to deliver our product candidates may have its own regulatory, development, supply and other risks.***

We expect to deliver our product candidates via a drug delivery device, such as an injector or other delivery system. There may be unforeseen technical complications related to the development activities required to bring such a product to market, including primary container compatibility and/or dose volume requirements. Our product candidates may not be approved or may be substantially delayed in receiving approval if the devices that we choose to utilize or develop do not gain and/or maintain their own regulatory approvals or clearances, if required. Where approval of the drug product and device is sought under a single application, the increased complexity of the review process may delay approval. In addition, some drug delivery devices are provided by single-source unaffiliated third-party companies. We may be dependent on the sustained cooperation and effort of those third-party companies both to supply the devices and, in some cases, to conduct the studies required for approval or other regulatory clearance of the devices. Even if approval is obtained, we may also be dependent on those third-party companies continuing to maintain such approvals or clearances once they have been received. Failure of third-party companies to supply the devices, to successfully complete studies on the devices in a timely manner, or to obtain or maintain required approvals or clearances of the devices could result in increased development costs, delays in or failure to obtain regulatory approval and delays in product candidates reaching the market or in gaining approval or clearance for expanded labels for new indications.

***The FDA or comparable foreign regulatory authorities may disagree with our regulatory plan for our product candidates.***

The general approach for FDA approval of a new drug is dispositive data from two or more adequate and well-controlled clinical trials of the product candidate in the relevant patient population. Adequate and well-controlled clinical trials typically involve a large number of patients, have significant costs and take years to complete. The FDA or other regulatory authorities may disagree with us about whether a clinical trial is adequate and well-controlled or may request that we conduct additional clinical trials prior to regulatory approval. In addition, there is no assurance that the doses, endpoints and trial designs that we intend to use for our planned clinical trials, including those that we have developed based on feedback from regulatory agencies or those that have been used for the approval of similar drugs, will be acceptable for future approvals. For instance, if our ongoing Phase 1 trial of MBX 1416 is successful, we plan to run a combined Phase 2/3 to evaluate MBX 1416 in PBH. If the FDA disagrees with our approach, we may have to evaluate MBX 1416 in two separate trials, which would be costly and time-consuming.

Our clinical trial results may not support approval of our product candidates. In addition, our product candidates could fail to receive regulatory approval, or regulatory approval could be delayed, for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may not file or accept our NDA or marketing application for substantive review;
- the FDA or comparable foreign regulatory authorities may disagree with the dosing regimen, design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our product candidates are safe and effective for any of their proposed indications;
- the results of our clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that our product candidates' clinical and other benefits outweigh their safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from our preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of an NDA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

***We may in the future conduct clinical trials for drug candidates outside the United States, and the FDA and comparable foreign regulatory authorities may not accept data from such trials.***

We may in the future choose to conduct one or more additional clinical trials outside the United States, including, among other places, in the EU, South America, Australia and/or Asia. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for regulatory approval in the United States, the FDA will generally not approve the application based on foreign data alone unless: (i) the data is applicable to the U.S. population and U.S. medical practice; and (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in drug candidates that we may develop not receiving approval for commercialization in such jurisdiction.

***Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.***

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one

jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable foreign regulatory authorities must also approve the manufacturing and marketing of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries.

***While we may in the future seek designations for our product candidates with the FDA and comparable foreign regulatory authorities that are intended to confer benefits such as a faster development process, an accelerated regulatory pathway or regulatory exclusivity, there can be no assurance that we will successfully obtain such designations. In addition, even if one or more of our product candidates are granted such designations, we may not be able to realize the intended benefits of such designations.***

The FDA and comparable foreign regulatory authorities offer certain designations for product candidates that are designed to encourage the research and development of product candidates that are intended to address conditions with significant unmet medical need. These designations may confer benefits such as additional interaction with regulatory authorities, a potentially accelerated regulatory pathway and priority review. However, there can be no assurance that we will successfully obtain such designations for our product candidates. In addition, while such designations could expedite the development or approval process, they generally do not change the standards for approval. Even if we obtain such designations for our product candidates, there can be no assurance that we will realize their intended benefits.

For example, we may seek a Fast Track Designation for future product candidates we develop. If a product is intended for the treatment of a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address an unmet medical need for this condition, the product sponsor may apply for Fast Track Designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot be certain that the FDA would decide to grant it. Even if we do receive Fast Track Designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may rescind the Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development activities.

We may seek Breakthrough Therapy Designation for any product candidate that we develop. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA are also eligible for accelerated approval and priority review.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe a product candidate we develop meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of Breakthrough Therapy Designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if any product candidate we develop qualifies as a breakthrough therapy, the FDA may later decide that the drug no longer meets the conditions for qualification and rescind the designation.

Even in the absence of obtaining Fast Track and/or Breakthrough Therapy Designations, a sponsor can seek priority review at the time of submitting a marketing application. The FDA may designate a product for priority review if it is a product that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting adverse reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, or evidence of safety and effectiveness in a new subpopulation. A priority review designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from ten months to six months. Priority review designation may be rescinded if a product no longer meets the qualifying criteria.

***We may be unsuccessful in obtaining or may be unable to maintain the benefits associated with Orphan Drug Designation, including the potential for market exclusivity.***

Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the U.S., or a patient population greater than 200,000 in the U.S. where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the U.S. In the U.S., Orphan Drug Designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user fee waivers. In July 2022, the FDA granted MBX 2109 Orphan Drug Designation for the treatment of hypoparathyroidism.

Similarly, in the EU, the EC grants orphan medicinal product designation after receiving the opinion of the EMA's Committee for Orphan Medicinal Products on an orphan medicinal product designation application. Orphan medicinal product designation is intended to promote the development of medicinal products that are intended for the diagnosis, prevention or treatment of life threatening or chronically debilitating conditions affecting not more than five (5) in ten thousand (10,000) persons in the EU or for products intended for the diagnosis, prevention, or treatment of a life threatening, seriously debilitating or serious and chronic condition when, without incentives, it is unlikely that sales of the product in the EU would generate sufficient return to justify the necessary investment in developing the product. In each case, there must be no satisfactory method of diagnosis, prevention, or treatment authorized for marketing in the EU (or, if such a method exists, the product would be of significant benefit to those affected by the condition). In the EU, orphan medicinal product designation entitles a party to financial incentives such as reduction of fees or fee waivers.

Generally, if a drug with an Orphan Drug Designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the EC or the FDA from approving another marketing application for the same drug and indication for that time period, except in limited circumstances. The applicable period is seven years in the U.S. and ten years in the EU. The EU exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan medicinal product designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified.

Even if we obtain orphan drug exclusivity for a drug, that exclusivity may not effectively protect the designated drug from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

***Where appropriate, we plan to secure approval from the FDA or comparable foreign regulatory authorities through the use of expedited approval pathways, such as accelerated approval. If we are unable to obtain such approvals, we may be required to conduct additional preclinical studies or clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA or comparable regulatory authorities, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA or such other regulatory authorities may seek to withdraw the accelerated approval.***

Where possible, we plan to pursue accelerated development strategies in areas of high unmet need. We may seek an accelerated approval pathway for one or more of our therapeutic candidates from the FDA or comparable foreign regulatory authorities. Under the accelerated approval provisions in the Federal Food, Drug, and Cosmetic Act, and the FDA's implementing regulations, the FDA may grant accelerated approval to a therapeutic candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the therapeutic candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. Under the Food and Drug Omnibus Reform Act ("FDORA"), the FDA is permitted to require, as appropriate, that a post-approval confirmatory study or studies be underway prior to approval or within a specified time period after the date of approval for a product granted accelerated approval. FDORA also gives the FDA increased authority to withdraw approval of a drug or biologic granted accelerated approval on an expedited basis if the sponsor fails to conduct such studies in a timely manner, send status updates on such studies to the FDA every 180 days to be publicly posted by the agency, or if such post-approval studies fail to

verify the drug's predicted clinical benefit. The FDA is empowered to take action, such as issuing fines, against companies that fail to conduct with due diligence any post-approval confirmatory study or submit timely reports to the agency on their progress.

Prior to seeking accelerated approval, we would seek feedback from the FDA or comparable foreign regulatory authorities and would otherwise evaluate our ability to seek and receive such accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit an NDA or BLA for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent feedback from the FDA, or comparable foreign regulatory authorities, we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval, there can be no assurance that such application will be accepted or that any approval will be granted on a timely basis, or at all. The FDA or other comparable foreign regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type, including, for example, if other products are approved via the accelerated pathway and subsequently converted by FDA to full approval. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our therapeutic candidate would result in a longer time period to commercialization of such therapeutic candidate, could increase the cost of development of such therapeutic candidate and could harm our competitive position in the marketplace.

***Our relationships with healthcare providers and physicians and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.***

It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. Healthcare providers, physicians and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. Arrangements with third-party payors and customers can expose pharmaceutical manufacturers to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we conduct research and would sell, market and distribute our products. As a pharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, federal and state healthcare laws and regulations that may affect our ability to operate may apply. See the section titled, "Business–Government regulation–Other healthcare laws" included in our IPO Prospectus.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring business arrangements comply with applicable healthcare and privacy laws, as well as responding to possible investigations by government authorities, can be time and resource-consuming and can divert a company's attention from the business.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, the exclusion from participation in federal and state healthcare programs, individual imprisonment, reputational harm and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Further, defending against any such actions can be costly and time consuming, and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other providers or entities with whom we expect to do business is found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any of the above occur, our ability to operate our business and our results of operations could be adversely affected.

***Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, if approved, which could make it difficult for us to sell any product candidates profitably.***

The success of our product candidates, if approved, depends on the availability of coverage and adequate reimbursement from third-party payors. We cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential

revenue from, our product candidates or assure that coverage and reimbursement will be available for any product that we may develop. See the section titled, “Business–Government regulation–Coverage and reimbursement” included in our IPO Prospectus.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services ("CMS"). CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of product candidates, once approved. Patients are unlikely to use our product candidates, once approved, unless coverage is provided and reimbursement is adequate to cover a significant portion of their cost. There is significant uncertainty related to insurance coverage and reimbursement of newly approved products. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs. Payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives.

Moreover, increasing efforts by governmental and other third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals or clearances of our product candidates, if any, may be.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. A Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country

that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower.

***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 our IPO Prospectus.

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.

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.

***Off-label use or misuse of our product candidates may harm our reputation in the marketplace or result in injuries that lead to costly product liability suits.***

If our product candidates are approved by the FDA, we may only promote or market our product candidates in a manner consistent with their FDA-approved labeling. We will train our marketing and sales force against promoting our product candidates for uses outside of the approved indications for use, known as "off-label uses." We cannot, however, prevent a physician from using our product candidates off-label, when in the physician's independent professional medical judgment he or she deems it appropriate. Furthermore, the use of our product candidates for indications other than those approved by the FDA may not effectively treat such conditions. Any such off-label use of our product candidates could harm our reputation in the marketplace among physicians and patients. There may also be increased risk of injury to patients if physicians attempt to use our product candidates for these uses for

which they are not approved, which could lead to product liability suits that might require significant financial and management resources and that could harm our reputation.

***Inadequate funding for the FDA or other government agencies 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 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 agency have fluctuated in recent years as a result. In addition, government funding of other government agencies 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 or other government agencies 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 and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, 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, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

***Failure to access or a significant delay in accessing animal research models may materially adversely affect our ability to advance our preclinical programs and successfully develop any product candidates, which could result in significant harm to our business.***

Consistent with various rules, regulations and cGMP, our ability to advance our preclinical and clinical programs for our product candidates requires access to animal research models sufficient to assess safety and in some cases to establish the rationale for therapeutic use. Failure to access or a significant delay in accessing animal research models that meet our needs or that fulfill regulatory requirements may materially adversely affect our ability to advance our preclinical programs and successfully develop any product candidates and this could result in significant harm to our business. During the COVID-19 pandemic, researchers and CROs (including those engaged by us) experienced significant limitations in their access to animal research models, specifically including a sharp reduction in the availability of non-human primates ("NHPs") originating from breeding farms in Southeast Asia and limited access to the generation of genetically-modified rodent models used in efficacy evaluations. Prior to the pandemic, China was the leading exporter of NHPs employed in basic and applied research; however, early in 2020, China ceased exportation of cynomolgus monkeys, the species most commonly involved in pharmaceutical product development. This change in the world supply of a critical research model has resulted in increased demand from breeding farms principally located in Cambodia, Vietnam, and Mauritius Island, with a resultant marked increase in unit pricing. Consequently, this has further exacerbated an already constrained NHP supply for research purposes. If we are unable to obtain NHPs in sufficient quantities and in a timely manner to meet the needs of our preclinical research programs, if the price of NHPs that are available increases significantly, or if our suppliers are unable to ship the NHPs in their possession that are reserved for us, our ability to advance our preclinical programs and successfully develop any additional preclinical candidates we may identify may be materially adversely affected or significantly delayed.

***Even if we receive regulatory approval of any product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.***

If any of our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities. In addition, we will be subject to continued compliance with cGMP and GCP requirements for any clinical trials that we conduct post-approval.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations and applicable product tracking and tracing requirements. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA, other marketing application and previous responses to inspection observations. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly

post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. Certain endpoint data we hope to include in any approved product labeling also may not make it into such labeling, including exploratory or secondary endpoint data such as patient-reported outcome measures. The FDA may also require a risk evaluation and mitigation strategies, or REMS, program as a condition of approval of our product candidates, which could entail requirements for long-term patient follow-up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, we will have to comply with requirements including submissions of safety and other post-marketing information and reports and registration.

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

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or withdrawal of approvals;
- product seizure or detention or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

Additionally, under FDORA, sponsors of approved drugs and biologics must provide 6 months' notice to the FDA of any changes in marketing status, such as the withdrawal of a drug, and failure to do so could result in the FDA placing the product on a list of discontinued products, which would revoke the product's ability to be marketed. The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. The policies of the FDA and comparable foreign regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. In addition, the U.S. Supreme Court's July 2024 decision to overturn established case law giving deference to regulatory agencies' interpretations of ambiguous statutory language has introduced uncertainty regarding the extent to which the FDA's regulations, policies and decisions may become subject to increasing legal challenges, delays, and/or changes. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

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

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

***If we or any contract manufacturers and suppliers we engage fail to comply with environmental, health, and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.***

We and any contract manufacturers and suppliers we engage are subject to numerous federal, state, and local environmental, health, and safety laws, regulations, and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment, and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air, and water; and employee health and safety. We cannot eliminate the risk of contamination or injury from hazardous materials, including chemical and biological materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third-party facilities. We also could incur significant costs associated with civil or criminal fines and penalties.

In addition, we may incur substantial costs in order to comply with current or future environmental, health, and safety laws, regulations, and permitting requirements. These current or future laws, regulations, and permitting requirements may impair our research, development, or production efforts. Failure to comply with these laws, regulations, and permitting requirements also may result in substantial fines, penalties, or other sanctions or business disruption, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Any third-party contract manufacturers and suppliers we engage will also be subject to these and other environmental, health, and safety laws and regulations. Liabilities they incur pursuant to these laws and regulations could result in significant costs or an interruption in operations, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

***Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.***

We are exposed to the risk of fraud or other misconduct by our employees, consultants and commercial partners, and, if we commence clinical trials, our principal investigators. Misconduct by these parties could include intentional failures to comply with FDA regulations and other jurisdictions, provide accurate information to the FDA and other regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. We are also exposed to risks in connection with any insider trading violations by employees or others affiliated with us. We have adopted a code of conduct and an insider trading policy applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition, results of operations and prospects, including the imposition of significant fines or other sanctions.

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

We will face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell such product candidates. If we cannot successfully defend ourselves against claims that our product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any of our product candidates;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;

•loss of revenue; and

•the inability to commercialize any of our product candidates.

We anticipate that we will need to increase our insurance coverage when we begin clinical trials and if we successfully commercialize any product candidate. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

***Our internal computer and information technology systems, or those of our third-party vendors, collaborators, contractors, consultants or other third parties, may fail, become unavailable, or suffer security incidents, compromises, or data breaches, loss or leakage of data and other disruptions, which could result in a material disruption of our product development programs, compromise confidential, sensitive or personal information related to our business or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business.***

Our internal computer and information technology systems and those of our current and any future third-party vendors, collaborators, contractors, consultants or other third parties, are vulnerable to damage or interruption from, among other things, computer viruses, computer hackers, phishing attacks, ransomware, malware, social engineering, service interruptions, system malfunction, malicious code, employee theft, fraud, misconduct or misuse, denial-of-service attacks, sophisticated nation-state and nation-state-supported actors, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we seek to protect our information technology systems from system failure, accident and security breach, we have in the past and may in the future experience phishing and other security incidents which could result in a disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary, personal or confidential information or other disruptions. For example, the loss of clinical trial data from future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

While we have implemented cybersecurity measures designed to protect our information technology systems as well as the confidential and sensitive data in our possession, there can be no assurance that these measures will be adequate to detect, prevent, or adequately address any cybersecurity incident or data breach that we may face. Controls employed by our information technology department and other third parties could prove inadequate, and our ability to monitor such third parties' data security practices is limited. Due to applicable laws, rules, regulations and standards or contractual obligations, we may be held responsible for any information security failure or cybersecurity incident or compromise attributed to our third-party vendors as they relate to the information we share with them.

If we were to experience a cybersecurity incident, breach, compromise or other security event relating to our information systems or data, the costs, time and effort associated with the investigation, remediation and potential notification of the breach to counterparties, regulators and data subjects could be material. We may incur significant costs in an effort to detect and prevent security incidents or compromises, and we may face increased costs and requirements to expend substantial resources in the event of an actual or perceived security incident or compromise. In addition, techniques used to sabotage or to obtain unauthorized access to networks in which data is stored or through which data is transmitted change frequently, become more complex over time and generally are not recognized until launched against a target. The risk of a cybersecurity breach, incident, compromise or disruption, particularly through cyberattacks including supply chain attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. As a result, we and our third-party vendors may be unable to anticipate these techniques or implement adequate preventative measures quickly enough to prevent either an electronic intrusion into our systems or services or a compromise of critical information. We cannot guarantee that we will be able to detect or prevent any such incidents, and, our remediation efforts may not be successful or timely. Our efforts to improve our cybersecurity and protect data from compromise may also identify previously undiscovered instances of data breaches, compromises or other cybersecurity incidents. If we do not allocate and effectively manage the resources necessary to build and sustain the proper technology and cybersecurity infrastructure, we could suffer significant business disruption, including transaction errors, supply chain or manufacturing interruptions, processing inefficiencies, data loss or the loss of or damage to intellectual property or other proprietary, personal or confidential information. Although we currently maintain cybersecurity insurance, the insurance we maintain against the risk of this type of loss may not be sufficient to cover actual losses, or may not apply to the circumstances relating to any particular loss.

To the extent that any disruption or security breach were to result in a loss of, or damage to, our or our third-party vendors', collaborators', contractors', employees', consultants' or other third parties' data, including personal data, or applications or inappropriate disclosure, loss, destruction or alteration of, or access to, confidential, personal or proprietary information, we could incur significant liability including litigation exposure, substantial penalties and fines, we could become the subject of regulatory action, inquiry or investigation, our competitive position could be harmed, we could incur significant reputational damage and the

further development and commercialization of any product candidates we may develop could be delayed. Any of the above could have a material adverse effect on our business, financial condition, results of operations or prospects.

***Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing and selling certain product candidates we may identify outside of the United States and require us to develop and implement costly compliance programs.***

We will be subject to numerous laws and regulations in each jurisdiction outside the United States in which we operate in the future. The creation, implementation and maintenance of international business practices compliance programs is costly and such programs are difficult to enforce, particularly where reliance on third parties is required.

The FCPA prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. The anti-bribery provisions of the FCPA are enforced primarily by the Department of Justice. The SEC is involved with enforcement of the books and records provisions of the FCPA.

Similarly, the U.K. Bribery Act 2010 has extra-territorial effect for companies and individuals having a connection with the United Kingdom. The U.K. Bribery Act prohibits inducements both to public officials and private individuals and organizations. Compliance with the FCPA and the U.K. Bribery Act is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. Our expansion outside of the United States has required, and will continue to require, us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing or selling certain drugs and drug candidates outside of the United States, which could limit our growth potential and increase our development costs. The failure to comply with laws governing international business practices may result in substantial penalties, including suspension or debarment from government contracting. Violation of the FCPA can result in significant civil and criminal penalties. Indictment alone under the FCPA can lead to suspension of the right to do business with the U.S. government until the pending claims are resolved. Conviction of a violation of the FCPA can result in long-term disqualification as a government contractor. The termination of a government contract or relationship as a result of our failure to satisfy any of our obligations under laws governing international business practices would have a negative impact on our operations and harm our reputation and ability to procure government contracts. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

***We are subject to stringent and often unsettled laws, rules, regulations, policies, standards and contractual obligations related to data privacy and security and changes in such laws, rules, regulations, policies, standards and contractual obligations could adversely affect our business.***

We are subject to data privacy and protection laws, rules, regulations, policies, standards and contractual obligations that apply to the collection, transmission, storage, use, disclosure, transfer, maintenance and other processing of sensitive, personal and personally-identifying information, which, among other things, impose certain requirements relating to the privacy, security, transmission and other processing of personal information. The legislative and regulatory landscape for privacy and data protection continues to evolve in jurisdictions worldwide, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. However, our data privacy program is in its early stages and we have not yet assessed the applicability of and our compliance with data privacy-related laws, rules and regulations. As a result, we cannot guarantee that we are and have been in compliance with all applicable data privacy and protection laws, rules, regulations, policies and standards, and we may need to expend significant resources to implement privacy compliance measures. Additionally, we rely on certain third-party vendors to process certain confidential, sensitive or personal information on our behalf. Failure by us or our third-party vendors to comply with any of these laws, rules, regulations, contractual obligations or standards could result in notification obligations, enforcement actions, regulatory investigations or inquiries, significant fines, imprisonment of company officials and public censure, litigation and claims

for damages by affected individuals, customers or business partners, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

There are numerous U.S. federal and state laws, rules and regulations related to the privacy and security of personal information. In particular, regulations promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") establish privacy and security standards that limit the use and disclosure of individually identifiable health information, or protected health information, and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. The Genetic Information Nondiscrimination Act of 2008 ("GINA") clarified that genetic information is protected under HIPAA and restricts the use and disclosure of genetic information.

Additionally, laws in all 50 states require businesses to provide notice to customers whose personally identifiable information has been disclosed as a result of a cybersecurity incident or data breach. These laws are not consistent, and compliance in the event of a widespread cybersecurity incident or data breach is difficult and may be costly. Moreover, states have been frequently amending existing laws, requiring attention to changing regulatory requirements. We also may be contractually required to notify patients or other counterparties of a cybersecurity breach, incident, or compromise. Although we may have contractual protections with our service providers, any actual or perceived security breach, cybersecurity incident, or other information system compromise could harm our reputation and brand, expose us to potential liability or require us to expend significant resources on data security and in responding to any such actual or perceived breach, incident, or compromise. Any contractual protections we may have from our service providers may not be sufficient to adequately protect us from any such liabilities and losses, and we may be unable to enforce any such contractual protections. In addition to government regulation, privacy advocates and industry groups have and may in the future propose self-regulatory information technology system standards from time to time. These and other industry standards may legally or contractually apply to us, or we may elect to comply with such standards. Determining whether personal information has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and may be subject to changing interpretation.

If we are unable to properly protect the privacy and security of personal information, we could be alleged or actually found to have breached our contracts. Furthermore, if we fail to comply with applicable privacy laws, we could face significant administrative, civil and criminal penalties. We cannot be sure how these laws, rules and regulations will be interpreted, enforced or applied to our operations. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws, rules and regulations at the international, federal and state level may be costly and require ongoing modifications to our policies, procedures and systems.

We make public statements about our use, collection, disclosure and other processing of personal information through our privacy policies and information provided on our website. Although we endeavor to comply with our public statements and documentation, we may at times fail to do so or be alleged to have failed to do so. The publication of our privacy policies and other statements that provide promises and assurances about data privacy and security can subject us to potential government or legal action if they are found to be deceptive, unfair or misrepresentative of our actual practices.

Data privacy remains an evolving landscape at both the domestic and international level, with new laws, rules and regulations coming into effect and continued legal challenges. At the state level, numerous states have enacted or are in the process of enacting or considering comprehensive data privacy and security laws, rules and regulations while other states have focused on more narrow aspects of privacy.

For example, Washington state passed a health privacy law that will regulate the collection and sharing of health information, and the law also has a private right of action, which further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data. In addition, other states have proposed and/or passed legislation that regulates the privacy and/or security of certain specific types of information. For example, a number of states have passed laws that regulate biometric data specifically. These various privacy and security laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products. State laws are changing rapidly and there is discussion in the U.S. Congress of a new comprehensive federal data privacy law to which we may likely become subject, if enacted. The existence of different privacy laws in various jurisdictions in the country would make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance. Although many of the existing state privacy laws exempt clinical trial information and health information governed by HIPAA, future privacy and data protection laws may be broader in scope.

To the extent that these laws are or become applicable, all of these evolving compliance and operational requirements may impose significant costs, such as costs related to organizational changes, implementing additional protection technologies, training employees and engaging consultants and legal advisors, which are likely to increase over time. In addition, such requirements may

require us to modify our data processing practices and policies, utilize management's time and/or divert resources from other initiatives and projects. Our efforts to comply with these evolving data protection laws, rules and regulations may be unsuccessful. It is possible that these laws, rules and regulations may be interpreted and applied in a manner that is inconsistent with our practices and our efforts to comply with the evolving data protection rules may be unsuccessful. The laws are not consistent, and compliance in the event of a widespread cybersecurity incident or data breach is costly and time-consuming. States are also frequently amending existing laws, requiring attention to frequently changing regulatory requirements. We must devote significant resources to understanding and complying with this changing landscape.

Any failure or perceived failure by us or our third-party vendors to comply with laws, rules and regulations regarding data privacy and protection could result in damage to our reputation or expose us to risk of enforcement actions taken by data protection authorities and/or other third parties, including class action privacy litigation in certain jurisdictions, which carry the potential for significant penalties if we are found to be non-compliant. Similarly, failure to comply with federal and state laws, rules and regulations in the United States regarding privacy and security of personal information could expose us to penalties under such laws, rules and regulations. Any such failure, or perceived failure, by us or our third-party vendors to comply with data protection and privacy laws, rules and regulations could result in significant government-imposed fines or orders requiring that we change our practices, claims for damages or other liabilities, regulatory investigations and enforcement action, litigation and significant costs for remediation, any of which could adversely affect our business. Even if we are not determined to have violated these laws, rules or regulations, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our business, financial condition, results of operations or prospects. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

***The use of new and evolving technologies, such as artificial intelligence ("AI") in our operations may require us to expend material resources and may present risks and challenges that can impact our business including by posing security and other risks to our confidential information, proprietary information and personal information, any of which may result in reputational harm and liability, or otherwise adversely affect our business.***

We may choose to integrate AI into our operations, and this innovation presents risks and challenges that could affect its adoption, and therefore our business. There are significant risks involved in utilizing AI and no assurance can be provided that the usage of AI will enhance our business or assist our business in becoming more efficient or profitable. The use of certain AI technology can give rise to intellectual property risks, including compromises to proprietary intellectual property and intellectual property infringement and misappropriation. Other known risks of AI currently include inaccuracy, bias, toxicity, data privacy and cybersecurity issues, and data provenance disputes. In addition, AI may have errors or inadequacies that are not easily detectable. AI may also be subject to data herding and interconnectedness (i.e., multiple market participants utilizing the same data), which may adversely impact our business. If the data used to train AI or the content, analyses, or recommendations that AI applications assist in producing are or are alleged to be deficient, inaccurate, incomplete, overbroad or biased, our business, financial condition, and results of operations may be adversely affected. Additionally, we expect to see increasing government and supranational regulation and ethical concerns related to AI use which may also significantly increase the burden and cost of research, development and compliance in this area. For example, the EU's Artificial Intelligence Act ("AI Act") — the world's first comprehensive AI law — entered into force on August 1, 2024 and, with some exceptions, will become fully applicable 24 months thereafter. This legislation imposes significant obligations on providers and deployers of high risk AI systems, and encourages providers and deployers of AI systems to account for certain ethical principles in their design, development and use of these systems. The rapid evolution of AI will require the application of significant resources to design, develop, test and maintain our technology and products to help ensure that AI is implemented in accordance with applicable laws and regulations and in a socially responsible manner and to minimize any real or perceived unintended harmful impacts. The legal landscape and subsequent legal protection for the use of AI remains uncertain, and development of the law in this area could impact our ability to enforce our proprietary rights or protect against infringing uses. If we do not have sufficient rights to use the data on which AI relies or to the outputs produced by AI applications, we may incur liability through the violation of certain laws, third-party privacy or other rights or contracts to which we are a party. Our use of AI applications may also, in the future, result in cybersecurity incidents that implicate the personal data of customers or patients. Any such cybersecurity incidents related to our use of AI applications could adversely affect our reputation and results of operations.

Our vendors may also incorporate AI tools into their own offerings, and the providers of these AI tools may not meet existing or rapidly evolving regulatory or industry standards, including with respect to intellectual property, privacy and data security. Further, bad actors around the world use increasingly sophisticated methods, including the use of AI, to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business.

**Risks related to third-party relationships**

***We are reliant on a license agreement with Indiana University Research and Technology Corporation.***

We are reliant on a License Agreement (the "IURTC License Agreement") with Indiana University Research and Technology Corporation ("IURTC") 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. 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. Termination of our IURTC License Agreement or reduction or elimination of our licensed rights may require us to negotiate new or reinstated licenses with less favorable terms or to cease all development and commercialization of our current product candidates. In addition, delay in appointing or finding a suitable replacement provider, if one exists, could make it difficult for us to operate our business for that period. If any such events were to occur, they could have a material adverse effect on our business prospects, financial condition and results of operations. For more information, see “Business—License agreement”.

***We are dependent on third parties having accurately generated, collected, interpreted and reported data from certain preclinical studies and clinical trials that were previously conducted for our product candidates.***

We have relied on third parties, including Indiana University, to conduct certain preclinical studies and clinical trials. Therefore, we are dependent on these third parties having conducted their research and development in accordance with the applicable protocols, legal and regulatory requirements, and scientific standards; having accurately reported the results of all preclinical studies and clinical trials conducted with respect to such product candidates and having correctly collected and interpreted the data from these studies and trials. These risks also apply to any additional product candidates that we may acquire or in-license in the future. If these activities were not compliant, accurate or correct, the clinical development, regulatory approval or commercialization of our product candidates will be adversely affected.

***If conflicts arise between us and our collaborators or strategic partners, these parties may act in a manner adverse to us and could limit our ability to implement our strategies.***

If conflicts arise between our collaborators and corporate or strategic partners and us, the other party may act in a manner adverse to us and could limit our ability to implement our strategies. Some of our collaborators and strategic partners are conducting multiple product development efforts within each area that is the subject of the collaboration with us. Our collaborators or strategic partners, however, may develop, either alone or with others, products in related fields that are competitive with the product candidates we may develop that are the subject of these collaborations with us. Competing products, either developed by the collaborators or strategic partners or to which the collaborators or strategic partners have rights, may result in the withdrawal of partner support for any product candidates we may develop.

Additionally, some of our collaborators or strategic partners could also become our competitors in the future. Our collaborators or strategic partners could develop competing products, preclude us from entering into collaborations with their competitors, fail to obtain timely regulatory approvals, prevent us from obtaining timely regulatory approvals, terminate their agreements with us prematurely or fail to devote sufficient resources to the collaboration efforts, including development, delivery, manufacturing and commercialization of products. Any of these developments could harm our company and product development efforts.

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

The advancement of our product candidates and development programs and the potential commercialization of our current and future product candidates will require substantial additional cash to fund expenses. For some of our programs, we may decide to collaborate with other pharmaceutical and biotechnology companies with respect to development and potential commercialization. Likely collaborators may include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. In addition, if we are able to obtain regulatory approval for product candidates from foreign regulatory authorities, we may enter into collaborations with international biotechnology or pharmaceutical companies for the commercialization of such product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator’s resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator’s evaluation of a number of factors. Those factors may include the potential differentiation of our product candidate from competing product candidates, design or results of clinical trials, the likelihood of approval by the FDA or comparable foreign regulatory authorities and the regulatory pathway for any such approval, the

potential market for the product candidate, the costs and complexities of manufacturing and delivering the product to patients and the potential of competing products. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available for collaboration and whether such a collaboration could be more attractive than the one with us for our product candidate. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

Collaborations are complex and time-consuming to negotiate and document. Further, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Any collaboration agreements that we enter into in the future may contain restrictions on our ability to enter into potential collaborations or to otherwise develop specified product candidates. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense.

***We rely on third parties to assist in conducting our clinical trials. If they do not perform satisfactorily, we may not be able to obtain regulatory approval or commercialize our product candidates, or such approval or commercialization may be delayed, and our business could be substantially harmed.***

We have relied upon and plan to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct our clinical trials and expect to rely on these third parties to conduct clinical trials of any other product candidate that we develop. Our ability to complete clinical trials in a timely fashion depends on a number of key factors. These factors include protocol design, regulatory and IRB approval, patient enrollment rates and compliance with GCPs. We have opened clinical trial sites and may in the future enroll patients in a number of countries where our experience is limited. In most cases, we use the services of third parties, including CROs, to carry out our clinical trial-related activities and rely on such parties to accurately report their results. Our reliance on third parties for clinical development activities may impact or limit our control over the timing, conduct, expense and quality of our clinical trials. Moreover, the FDA requires us to comply with GCPs for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. The FDA enforces these GCPs through periodic inspections of clinical trial sponsors, principal investigators, clinical trial sites and IRBs. For certain commercial prescription drug products, manufacturers and other parties involved in the supply chain must also meet chain of distribution requirements and build electronic, interoperable systems for product tracking and tracing and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or other products that are otherwise unfit for distribution in the United States.

We remain responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards. Our failure or the failure of third parties to comply with the applicable protocol, legal and regulatory requirements and scientific standards can result in rejection of our clinical trial data or other sanctions. If we or our third-party clinical trial providers or third-party CROs do not successfully carry out these clinical activities, our clinical trials or the potential regulatory approval of a product candidate may be delayed or be unsuccessful. Additionally, if we or our third-party contractors fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our product candidates, which would delay the regulatory approval process. We cannot be certain that, upon inspection, the FDA will determine that any of our clinical trials comply with GCPs. We are also required to register certain clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Furthermore, the third parties conducting clinical trials on our behalf are not our employees, and except for remedies available to us under our agreements with such contractors, we cannot control whether or not they devote sufficient time, skill and resources to our ongoing development programs. Moreover, many CROs, including some of those that we have engaged to conduct our clinical trials, are experiencing enrollment challenges as a result of, among other things, high employee turnover driven by the post-COVID macroeconomic environment and the inexperience of new employees. Furthermore, at clinical trial sites, the availability of staff and trial participants has been limited due to a decrease in the number of clinical investigative sites across the globe. These contractors may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could impede their ability to devote appropriate time to our clinical programs. If these third parties, including clinical investigators, do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we may not be able to obtain, or may be delayed in obtaining, regulatory approvals for our product candidates. If that occurs, we will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. In such an event, our financial results and the commercial prospects for

any product candidates that we seek to develop could be harmed, our costs could increase and our ability to generate revenues could be delayed, impaired or foreclosed.

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

Any of the third-party organizations we utilize may terminate their engagements with us under certain circumstances. The replacement of an existing CRO or other third party may result in the delay of the affected trials or otherwise adversely affect our efforts to obtain regulatory approvals and commercialize our product candidates. For example, although we believe there are a number of other CROs we could engage, we may not be able to enter into alternative arrangements or do so on commercially reasonable terms. In addition, while we believe there may be suitable replacements for one or more of these service providers, there is a natural transition period when a new service provider begins work. As a result, delays may occur, which could negatively impact our ability to meet our expected clinical development timelines and harm our business, financial condition and prospects.

***Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.***

As product candidates proceed through preclinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as the vendors used to manufacture drug product or manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes. Such changes may also require additional testing, FDA notification or FDA approval. Moreover, if the formulation of our product candidates requires the use of delivery methods such as cold-chain distribution provided by third parties, whereby the product must be maintained between specified temperatures, we will be subject to reliance on our distribution partners to maintain the temperature of the formulation or else risk it being adulterated and rendered unusable. Any of the above could delay or prevent completion of clinical trials, require conducting bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay or prevent approval of our product candidates and jeopardize our ability to commence sales and generate revenue.

***Our use of third parties to manufacture our product candidates may increase the risk that we will not have sufficient quantities of our product candidates, raw materials, active pharmaceutical ingredients ("APIs"), or drug products when needed or at an acceptable cost.***

We do not own or operate manufacturing facilities for the production of clinical or commercial quantities of our product candidates, and we lack the resources and the capabilities to do so. Our current strategy is to outsource all manufacturing of our product candidates to third parties.

We currently rely on and engage third-party manufacturers to provide all of the API and the final drug product formulation of all of our product candidates that are being used in our clinical trials and preclinical studies. Although we believe that there are several potential alternative manufacturers who could manufacture our product candidates, we may incur added costs and delays in identifying and qualifying any such replacement. In addition, we typically order raw materials, API and drug product and services on a purchase order basis and do not enter into long-term dedicated capacity or minimum supply arrangements with any commercial manufacturer. We may not be able to timely secure needed supply arrangements on satisfactory terms, or at all. Our failure to secure these arrangements as needed could have a material adverse effect on our ability to complete the development of our product candidates or, to commercialize them, if approved. We may be unable to conclude agreements for commercial supply with third-party manufacturers or may be unable to do so on acceptable terms. There may be difficulties in scaling up to commercial quantities and formulation of our product candidates, and the costs of manufacturing could be prohibitive.

If our manufacturers have difficulty or suffer delays in successfully manufacturing material that meets our specifications, it may limit supply of our product candidates and could delay our clinical trials. Even if we are able to establish and maintain arrangements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the failure of the third-party manufacturer to comply with applicable regulatory requirements and reliance on third parties for manufacturing process development, regulatory compliance and quality assurance;
- manufacturing delays if our third-party manufacturers give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreement between us;
- limitations on supply availability resulting from capacity and scheduling constraints of third parties;

•the possible breach of manufacturing agreements by third parties because of factors beyond our control;

•the possible termination or non-renewal of the manufacturing agreements by the third party, at a time that is costly or inconvenient to us; and

•the possible misappropriation of our proprietary information, including our trade secrets and know-how.

If we do not maintain our key manufacturing relationships, we may fail to find replacement manufacturers or develop our own manufacturing capabilities, which could delay or impair our ability to obtain regulatory approval for our product candidates. If we do find replacement manufacturers, we may not be able to enter into agreements with them on terms and conditions favorable to us and there could be a substantial delay before new facilities could be qualified and registered with the FDA and other foreign regulatory authorities.

Additionally, if any third-party manufacturer with whom we contract fails to perform its obligations, we may be forced to manufacture the materials ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different manufacturer. In either scenario, our clinical trials supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change third-party manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. We may be unsuccessful in demonstrating the comparability of clinical supplies, which could require the conduct of additional clinical trials. The delays associated with the verification of a new third-party manufacturer could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a third-party manufacturer may possess technology related to the manufacture of our product candidate that such third party owns independently. This would increase our reliance on such third-party manufacturer or require us to obtain a license from such third-party manufacturer in order to have another third party manufacture our product candidates.

If any of our product candidates is approved by any regulatory agency, we intend to utilize arrangements with third-party contract manufacturers for the commercial production of those products. This process is difficult and time consuming and we may face competition for access to manufacturing facilities as there are a limited number of contract manufacturers operating under cGMPs that are capable of manufacturing our product candidates. Consequently, we may not be able to reach agreement with third-party manufacturers on satisfactory terms, which could delay our commercialization.

Some of our manufacturers may be located outside of the United States. There is currently significant uncertainty about the future relationship between the United States and various other countries, including China, with respect to trade policies, treaties, government regulations and tariffs. Increased tariffs could potentially disrupt our existing supply chains and impose additional costs on our business. Additionally, it is possible further tariffs may be imposed that could affect imports of APIs used in our product candidates, or our business may be adversely impacted by retaliatory trade measures taken by China or other countries, including restricted access to such raw materials used in our product candidates. Given the unpredictable regulatory environment in China and the United States and uncertainty regarding how the U.S. or foreign governments will act with respect to tariffs, international trade agreements and policies, further governmental action related to tariffs, additional taxes, regulatory changes or other retaliatory trade measures in the future could occur with a corresponding detrimental impact on our business and financial condition.

Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or voluntary recalls of product candidates, operating restrictions and criminal prosecutions, any of which could significantly affect supplies of our product candidates. The facilities used by our contract manufacturers to manufacture our product candidates must be evaluated by the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMPs. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, we may not be able to secure and/or maintain regulatory approval for our product candidates manufactured at these facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA finds deficiencies or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Contract manufacturers may face manufacturing or quality control problems causing drug substance production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP requirements. Any failure to comply with cGMP requirements or

other FDA and comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to develop our product candidates and market our products, if approved.

The FDA and other foreign regulatory authorities require manufacturers to register manufacturing facilities. The FDA and corresponding foreign regulators also inspect these facilities to confirm compliance with cGMPs.

Contract manufacturers may face manufacturing or quality control problems causing drug substance production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP requirements. Any failure to comply with cGMP requirements or other FDA and comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to develop our product candidates and market our products following approval, if obtained.

***If any third-party manufacturer of our product candidates is unable to increase the scale of its production of our product candidates or increase the product yield of its manufacturing, then our manufacturing costs may increase and commercialization may be delayed.***

In order to produce sufficient quantities to meet the demand for clinical trials and, if approved, subsequent commercialization of our product candidates, our third-party manufacturers will be required to increase their production and optimize their manufacturing processes while maintaining the quality of our product candidates. The transition to larger scale production could prove difficult. In addition, if our third-party manufacturers are not able to optimize their manufacturing processes to increase the product yield for our product candidates, or if they are unable to produce increased amounts of our product candidates while maintaining the same quality then we may not be able to meet the demands of clinical trials or market demands, which could decrease our ability to generate profits and have a material adverse impact on our business and results of operations.

***We may need to maintain licenses for APIs from third parties to develop and commercialize some of our product candidates, which could increase our development costs and delay our ability to commercialize those product candidates.***

Should we decide to use any APIs in any of our product candidates that are proprietary to one or more third parties, we would need to maintain licenses to those APIs from those third parties. If we are unable to gain or continue to access rights to these APIs prior to conducting preclinical toxicology studies intended to support clinical trials, we may need to develop alternate product candidates from these programs by either accessing or developing alternate APIs, resulting in increased development costs and delays in commercialization of these product candidates. If we are unable to gain or maintain continued access rights to the desired APIs on commercially reasonable terms or develop suitable alternate APIs, we may not be able to commercialize product candidates from these programs.

**Risks related to personnel, operations, and growth**

***We are dependent on the services of our management and other clinical and scientific personnel, and if we are not able to retain these individuals or recruit additional management or clinical and scientific personnel, our business will suffer.***

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. We are highly dependent upon our senior management, including our President and Chief Executive Officer, as well as our senior scientists and other members of our senior management team. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, initiation or completion of our planned clinical trials or the commercialization of our product candidates. Although we have executed employment agreements or offer letters with each member of our senior management team, these agreements are terminable at will with notice and, therefore, we may not be able to retain their services as expected. We do not currently maintain “key person” life insurance on the lives of our executives or any of our employees. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals.

***We will need to continue to significantly increase the size of our organization and we may have difficulties in managing our growth and expanding our operations successfully.***

As of September 30, 2024, we had 38 full-time employees. As we advance our products and product candidates through the development and commercialization process, we will need to expand managerial, operational, financial, sales and marketing and other resources to manage our operations, preclinical and clinical trials, research and development activities, regulatory filings, manufacturing and supply activities, and any marketing and commercialization activities or contract with other organizations to provide these capabilities for us. As operations expand, we expect that we will need to manage additional relationships with various suppliers and other organizations. Our ability to manage our operations and growth requires us to continue to improve our operational, financial and management controls, reporting systems and procedures across a global organization. Such growth could place a strain on our administrative and operational infrastructure.

Further, we may not be successful in maintaining our unique company culture and continuing to attract or retain qualified management and scientific and clinical personnel in the future due to the intense competition for qualified personnel among pharmaceutical, biotechnology and other businesses. Our industry has experienced a high rate of turnover of management personnel in recent years.

Additionally, we may not be able to make improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls. Our management, personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively execute our growth strategy requires that we either internally, together with collaboration partners or through third-party contractors, as applicable:

- expand our general and administrative functions;
- identify, recruit, screen, retain, incentivize and integrate additional employees;
- manage our internal development efforts effectively while carrying out our contractual obligations to third parties;
- establish and build a marketing and commercial organization; and
- continue to improve our operational, legal, financial, compliance and management controls, reporting systems and procedures.

If we are not able to attract, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

**Risks related to our intellectual property**

***Our commercial success depends on our ability to obtain, maintain, enforce, and otherwise protect our intellectual property and proprietary technology, and if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products and product candidates similar to ours and our ability to successfully develop and commercialize our product candidates may be adversely affected.***

Our commercial success depends, in large part, on our ability to obtain and maintain intellectual property rights protection through patents, trademarks, and trade secrets in the United States and other countries with respect to our technology and product candidates. If we do not adequately protect our intellectual property rights, competitors or other third parties may be able to erode, negate or preempt any competitive advantage we may have, which could harm our business and ability to achieve profitability. To protect our proprietary position, we have filed patent applications and may file other patent applications in the United States or abroad related to our product candidates that are important to our business; we also license and may purchase patents or patent applications filed by others. In particular, we are heavily reliant on patent rights we have exclusively in-licensed from IURTC pursuant to the IURTC License Agreement. The patent application process is expensive, time-consuming and complex. We may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. Our owned and in-licensed patent portfolio is generally at a very early stage. In particular, we do not currently own or in-license any issued patents relating to any of our product candidates and we also do not own or in-license any issued U.S. patents relating to our PEP technology or otherwise. Further, the only pending patent applications we currently own are two U.S. provisional patent applications relating to one of our product candidates.

We may not be able to obtain patents on certain inventions if those inventions are publicly disclosed prior to our filing a patent application covering them. We enter into nondisclosure and confidentiality agreements with parties who have access to confidential information, including confidential information regarding inventions not yet disclosed in patent applications. We cannot guarantee that any of these parties will not breach these confidentiality agreements and publicly disclose any of our inventions before a patent application is filed covering such inventions. If such confidential information is publicly disclosed, we may not be able to successfully patent it and consequently, we may not be able to prevent third parties from using such inventions.

Composition of matter patents for pharmaceutical and biological product candidates can provide a strong form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. We cannot be certain that the claims in our or our licensors' pending patent applications directed to the composition of matter of our product candidates will be considered patentable by the United States Patent and Trademark Office ("USPTO") or by patent offices in foreign countries, or that the claims in any of the issued patents we may own or license will be considered valid and enforceable by courts in the United States or foreign countries. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications,

physicians may prescribe such products “off-label.” Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

If the scope of the patent protection we obtain is not sufficiently broad, we may not be able to prevent others from developing and commercializing technology and products similar or identical to ours. The degree of patent protection we require to successfully compete in the marketplace may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We cannot provide any assurances that any of our in-licensed patents have, or that any of our owned or in-licensed pending patent applications that mature into issued patents will include claims with a scope sufficient to protect our product candidates or otherwise provide any competitive advantage. Other parties have developed or may develop technologies that may be related or competitive with our approach, and may have filed or may file patent applications and may have been issued or may be issued patents with claims that overlap or conflict with our patent portfolio, either by claiming the same compounds, formulations or methods or by claiming subject matter that could dominate our patent position. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Furthermore, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally twenty years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our patent portfolio may not provide us with adequate and continuing patent protection sufficient to exclude others from commercializing products similar or identical to ours.

Even if they are unchallenged, our owned and in-licensed patents and pending patent applications, if issued, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent our patent portfolio by developing similar or alternative product candidates in a non-infringing manner. For example, a third party may develop a product candidate that provides benefits similar to one of our product candidates but falls outside the scope of our patent protection or license rights. If the patent protection provided by the patent and patent applications we hold or pursue with respect to such product candidate is not sufficiently broad to impede such competition, our ability to successfully commercialize our product candidate could be negatively affected, which would harm our business.

We, or any future partners, collaborators, or licensees, may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position.

It is possible that defects of form in the preparation or filing of our patent portfolio may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If we or our partners, collaborators, or licensees whether current or future, fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our partners, collaborators, or licensees are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of our patent portfolio, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned or licensed patents and patent applications. We rely on our outside counsel or our licensing partners to pay these fees due to U.S. and non-U.S. patent agencies. The USPTO and various non-U.S. government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can, in many cases, be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliant events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

The patent position of biotechnology and pharmaceutical companies carries uncertainty. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are characterized by uncertainty.

Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Assuming the other requirements for patentability are met, currently, the first to file a patent application is generally entitled to the patent. However, prior to March 16, 2013, in the United States, the first to invent was entitled to the patent. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patent portfolio, or that we were the first

to file for patent protection of such inventions. If third parties have filed prior patent applications on inventions claimed in our patent portfolio that were filed on or before March 15, 2013, an interference proceeding in the United States can be initiated by such third parties to determine who was the first to invent any of the subject matter covered by our patent portfolio. If third parties have filed such prior applications after March 15, 2013, a derivation proceeding in the United States can be initiated by such third parties to determine whether our invention was derived from theirs.

Moreover, because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, any patents we may own or license may be challenged in the courts or patent offices in the United States and abroad. There is no assurance that all the potentially relevant prior art relating to our patent portfolio has been found. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or, in some cases, not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our patent portfolio, or that we were the first to file for patent protection of such inventions. If such prior art exists, it may be used to invalidate a patent, or may prevent a patent from issuing from a pending patent application. For example, such patent filings may be subject to a third-party submission of prior art to the USPTO, or to other patent offices around the world. Alternately or additionally, we may become involved in post-grant review procedures, oppositions, derivation proceedings, ex parte reexaminations, inter partes review, supplemental examinations, or interference proceedings or challenges before the USPTO or in district court in the United States, or similar proceedings in various foreign jurisdictions, including both national and regional, challenging patents or patent applications in which we have rights, including patents on which we rely to protect our business. An adverse determination in any such challenges may result in loss of the patent or claims in the patent portfolio being narrowed, invalidated or held unenforceable, in whole or in part, or in denial of the patent application or loss or reduction in the scope of one or more claims of the patent portfolio, any of which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products.

Our or our licensors' pending and future patent applications may not result in patents being issued that protect our business, in whole or in part, or which effectively prevent others from commercializing competitive products. For example, our or our licensors' provisional applications may never result in issued patents. A provisional patent application is not eligible to become an issued patent until, among other things, we or our licensors file a non-provisional patent application within 12 months of filing the related provisional patent application. If we or our licensors do not timely file non-provisional patent applications, we or our licensors may lose the priority dates with respect to such provisional patent applications and any patent protection on the inventions disclosed in such provisional patent applications. While we intend to timely file non-provisional patent applications relating to our current and future provisional patent applications, we cannot predict whether any of our or our licensors' patent applications for our technology and product candidates will result in the issuance of patents that effectively protect our technology and product candidates. Further, competitors may be able to design around our patents. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries also may diminish the value of our patents or narrow the scope of our patent protection. In addition, the laws of foreign countries may not protect our rights to the same extent or in the same manner as the laws of the United States. For example, patent laws in various jurisdictions, including jurisdiction covering significant commercial markets, such as the European Patent Office, China, and Japan, restrict the patentability of methods of treatment of the human body more than United States law does. If these developments were to occur, they could have a material adverse effect on our ability to generate revenue.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our future development partners will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance, whether intentional or not, can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case;
- patent applications may not result in any patents being issued;
- company-owned or in-licensed patents that have been issued or may be issued in the future may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- our competitors, many of whom have substantially greater resources and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use, and sell our product candidates, if approved;

•there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns;

•countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing products; and

•countries other than the U.S. may, under certain circumstances, force us to grant a license under our patents to a competitor, thus allowing the competitor to compete with us in that jurisdiction or forcing us to lower the price of our drug in that jurisdiction.

Issued patents that we may own or license may not provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. Our competitors may also seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend or assert our patents, or both, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid or unenforceable, or that our competitors do not infringe our patents. Thus, even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

We maintain certain information as company trade secrets. This information may relate to inventions that are not patentable or not optimally protected with patents. We use commercially acceptable practices to protect this information, including, for example, limiting access to the information and requiring passwords for our computers. Additionally, we execute confidentiality agreements with any third parties to whom we may provide access to the information and with our employees, consultants, scientific advisors, collaborators, vendors, contractors, and advisors. We cannot provide any assurances that all such agreements have been duly executed, and third parties may still obtain this information or may come upon this or similar information independently. It is possible that technology relevant to our business will be independently developed by a person who is not a party to such a confidentiality or invention assignment agreement. If any of our trade secrets were to be independently developed by a competitor or other third party, we would have no right to prevent such competitor or third party, or those to whom they communicate such independently developed information, from using that information to compete with us. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or trade secrets by contract manufacturers, consultants, collaborators, vendors, advisors, former employees and current employees. Monitoring unauthorized uses and disclosures is difficult and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Furthermore, if the parties to our confidentiality agreements breach or violate the terms of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a consequence of such breaches or violations. Our trade secrets could otherwise become known or be independently discovered by our competitors. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating our trade secrets. If any of these events occurs or if we otherwise lose protection for our trade secrets, our business, financial condition, results of operation and prospects may be materially and adversely harmed.

***If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our current and future licensors, we could lose license rights that are important to our business.***

We are heavily reliant upon the IURTC License Agreement pursuant to which we have been granted an exclusive, royalty-bearing license to certain patent rights that are important or necessary to the development of our proprietary technology and product candidates. Termination of the IURTC License Agreement or reduction or elimination of our licensed rights could lead to the loss of our ability to develop and commercialize our proprietary technology and product candidates. Further development of our proprietary technology and product candidates may require us to enter into additional license or collaboration agreements. Our future licenses may not provide us with exclusive rights to use the licensed intellectual property and technology, or may not provide us with exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our product candidates and proprietary technology in the future. Additionally, the IURTC License Agreement imposes, and future agreements may impose, various development, diligence, commercialization and other obligations on us and require us to meet development timelines, or to exercise commercially reasonable efforts to develop and commercialize licensed products, in order to maintain the licenses.

Disputes may arise between us and our current or future licensors regarding intellectual property subject to a license agreement, including:

•the scope of rights granted under the license agreement and other interpretation-related issues;

•our financial or other obligations under the license agreement;

•whether and the extent to which our technology and processes infringe, misappropriate or otherwise violate intellectual property of the licensor that is not subject to the licensing agreement;

•our right to sublicense patents and other rights to third parties;

•our diligence obligations under the license agreement and what activities satisfy those diligence obligations;

•our right to transfer or assign the license;

•the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our current or future licensors and us and our partners; and

•the priority of invention of patented technology.

In addition, the agreements under which we license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed, or license in the future, prevent or impair our ability to maintain our licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Despite our best efforts, our current or future licensors might conclude that we materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize products, if approved, and technology covered by these license agreements. As a result, we may be required to cease our development and commercialization of our product candidates and use of our proprietary technologies covered by the patent rights owned by the licensors. Furthermore, if the in-licensed patent rights fail to provide the intended exclusivity, competitors will have the freedom to seek regulatory approval of, and to market, products identical to ours. These events could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

***It is difficult and costly to protect our intellectual property and our proprietary technologies, and we may not be able to ensure their protection.***

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection for our product candidates, as well as on successfully defending these patents against potential third-party challenges. Our ability to protect our product candidates from unauthorized making, using, selling, offering to sell or importing by third parties is dependent on the extent to which we have rights under valid and enforceable patents that cover these activities.

The patent positions of pharmaceutical, biotechnology and other life sciences companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved and have in recent years been the subject of much litigation. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Over the past decade, U.S. federal courts have increasingly invalidated pharmaceutical and biotechnology patents during litigation often based on changing interpretations of patent law. Further, the determination that a patent application or patent claim meets all the requirements for patentability is a subjective determination based on the application of law and jurisprudence. The ultimate determination by the USPTO or by a court or other trier of fact in the United States, or corresponding foreign national patent offices or courts, on whether a claim meets all requirements of patentability cannot be assured. Although we have conducted searches for third-party publications, patents and other information that may affect the patentability of claims in our patent portfolio, we cannot be certain that all relevant information has been identified. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our own patent portfolio.

Although we exclusively in-license pending patent applications relating to our MBX 2109, MBX 1416, and MBX 4291 product candidates and we own two pending provisional patent applications relating to our MBX 2109 product candidate, we cannot provide assurances that any of our patent applications will be found to be patentable, including over our own prior art publications or patent literature, or will issue as patents. Neither can we make assurances as to the scope of any claims that may issue from our pending and

future patent applications nor to the outcome of any proceedings by any potential third parties that could challenge the patentability, validity or enforceability of our patent portfolio in the United States or foreign jurisdictions. Any such challenge, if successful, could limit patent protection for our product candidates and/or materially harm our business.

In addition to challenges during litigation, third parties can challenge the validity of our patents in the United States using post-grant review and inter partes review proceedings, which some third parties have been using to cause the cancellation of selected or all claims of issued patents of competitors. For a patent filed March 16, 2013 or later, a petition for post-grant review can be filed by a third party in a nine-month window from issuance of the patent. A petition for inter partes review can be filed immediately following the issuance of a patent if the patent has an effective filing date prior to March 16, 2013. A petition for inter partes review can be filed after the nine-month period for filing a post-grant review petition has expired for a patent with an effective filing date of March 16, 2013 or later. Post-grant review proceedings can be brought on any ground of invalidity, whereas inter partes review proceedings can only raise an invalidity challenge based on published prior art and patents. These adversarial actions at the USPTO review patent claims without the presumption of validity afforded to U.S. patents in lawsuits in U.S. federal courts and use a lower burden of proof than used in litigation in U.S. federal courts. Therefore, it is generally considered easier for a competitor or third party to have a U.S. patent invalidated in a USPTO post-grant review or inter partes review proceeding than invalidated in a litigation in a U.S. federal court. If any of our patents are challenged by a third party in such a USPTO proceeding, there is no guarantee that we will be successful in defending the patent, which may result in a loss of the challenged patent right to us.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- we may not be able to generate sufficient data to support full patent applications that protect the entire breadth of developments in one or more of our programs;
- it is possible that one or more of our pending patent applications will not become an issued patent or, if issued, that the patent claims will not have sufficient scope to protect our technology, provide us with commercially viable patent protection or provide us with any competitive advantages;
- if our pending applications issue as patents, they may be challenged by third parties as invalid or unenforceable under United States or foreign laws;
- we may not successfully commercialize our product candidates, if approved, before our relevant patents expire;
- we may not be the first to file patent applications for the inventions covered by our patent portfolio; or
- we may not develop additional proprietary technologies that are separately patentable.

In addition, to the extent that we are unable to obtain and maintain patent protection for our product candidates, or in the event that such patent protection expires, it may no longer be cost-effective to extend our portfolio by pursuing additional development of any of our product candidates for follow-on indications.

***Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time.***

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. The patent term of a U.S. patent may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the United States Patent and Trademark Office in granting a patent, or may be shortened if a patent is terminally disclaimed over another patent having an earlier expiration date.

Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized.

In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a Patent Term Extension, or PTE, of up to five years beyond the normal expiration of the patent to compensate patent owners for loss of enforceable patent term due to the lengthy regulatory approval process. A PTE grant cannot extend the remaining term of a patent beyond a total of 14 years from the date of the product approval. Further, PTE may only be applied once per product, and only with respect to an approved indication—in other words, only one patent (for example, covering the product itself, an approved use of said product, or a method of manufacturing said product) can be extended by PTE. Moreover, the scope of protection during the period of the PTE does not extend to the full scope of the claim, but instead only to the scope of the product as approved. We anticipate applying for PTE in the United States. Similar extensions may be available in other countries where we are prosecuting patents and we likewise anticipate applying for such extensions.

The granting of such patent term extensions is not guaranteed and is subject to numerous requirements. We might not be granted an extension because of, for example, failure to apply within applicable periods, failure to apply prior to the expiration of relevant patents, failure to exercise due diligence during the testing phase or regulatory review process or any other failure to satisfy any of the numerous applicable requirements. In addition, to the extent we wish to pursue patent term extension based on a patent that we in-license from a third party, we would need the cooperation of that third party. Moreover, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to obtain approval of competing products following our patent expiration by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. If this were to occur, it could have a material adverse effect on our ability to generate revenue.

***Changes in the interpretation of patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.***

The United States Congress is responsible for passing laws establishing patentability standards. As with any laws, implementation is left to federal agencies and the federal courts based on their interpretations of the laws. Interpretation of patent standards can vary significantly within the USPTO, and across the various federal courts, including the U.S. Supreme Court. Recently, the Supreme Court has ruled on several patent cases, generally limiting the types of inventions that can be patented. Further, there are open questions regarding interpretation of patentability standards that the Supreme Court has yet to decisively address. Absent clear guidance from the Supreme Court, the USPTO has become increasingly conservative in its interpretation of patent laws and standards.

In addition to increasing uncertainty with regard to our ability to obtain patents in the future, the legal landscape in the U.S. has created uncertainty with respect to the value of patents. Depending on any actions by Congress, and future decisions by the lower federal courts and the U.S. Supreme Court, along with interpretations by the USPTO, the laws and regulations governing patents could change in unpredictable ways and could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act (the "Leahy-Smith Act") signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our future issued patents. The Leahy-Smith Act included a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. Further, because of a lower evidentiary standard in these USPTO post-grant proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Thus, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our future issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

After March 16, 2013, under the Leahy-Smith Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether this inventor was the first to invent the claimed invention. As a result, a third party that files a patent application in the USPTO on or after March 16 2013, but before we file an application covering the same invention, could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing until publication or issuance, we cannot be certain that we or our licensors were the first to file any patent application related to our product candidates and other proprietary technologies we may develop. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing the claimed invention where the other party can show that they used the invention in commerce before our filing date. Accordingly, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our future issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new

patents or to enforce our existing patents and patents that we might obtain in the future. The U.S. Supreme Court has ruled on several patent cases in recent years; these cases often narrow the scope of patent protection available to inventions in the biotechnology and pharmaceutical spaces. For example, in Amgen Inc. v. Sanofi ("Amgen"), the U.S. Supreme Court held that certain of Amgen's patent claims defined a class of antibodies by their function of binding to a particular antigen. The U.S. Supreme Court further wrote that because the patent claims defined the claimed class of antibodies only by their function of binding to a particular antigen, a skilled artisan would have to use significant trial and error to identify and make all of the molecules in that class. The U.S. Supreme Court ultimately held that Amgen failed to properly enable its patent claims. In the 2013 case Assoc. for Molecular Pathology v. Myriad Genetics, Inc., the U.S. Supreme Court held that certain claims to DNA molecules are not patentable. While we do not believe that any of the patents owned or licensed by us will be found invalid based on this decision, we cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents. In 2023, the Federal Circuit issued a decision in In re Cellect, LLC involving the interaction of patent term adjustment ("PTA"), terminal disclaimers, and obviousness-type double patenting which may affect the patent term of any issued patents that rely on any PTA. In 2022, Congress passed the Inflation Reduction Act ("IRA"), which authorizes the Secretary of the Department of Health and Human Services ("HHS") to negotiate prices directly with participating manufacturers for selected medicines covered by Medicare even if these medicines are protected by an existing patent. For small molecule medicines, the process begins seven years after initial approval by the FDA. While we do not believe that the IRA or its effects will impact our ability to obtain patents in the near future, we cannot be certain that it will not affect our patent strategy in the long run.

Further, a new court system recently became operational in the European Union. The Unified Patent Court ("UPC") began accepting patent cases on June 1, 2023. The UPC is a common patent court with jurisdiction over patent infringement and revocation proceedings effective for multiple member states of the European Union. The broad geographic reach of the UPC could enable third parties to seek revocation of any of our European patents in a single proceeding at the UPC rather than through multiple proceedings in each of the individual European Union member states in which the European patent is validated. Under the UPC, a successful revocation proceeding for a European Patent under the UPC would result in loss of patent protection in those European Union countries. Accordingly, a single proceeding under the UPC could result in the partial or complete loss of patent protection in numerous European Union countries. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize our technology and product candidates and, resultantly, on our business, financial condition, prospects and results of operations. Moreover, the controlling laws and regulations of the UPC will develop over time and we cannot predict what the outcomes of cases tried before the UPC will be. The case law of the UPC may adversely affect our ability to enforce or defend the validity of our European patents. Patent owners have the option to opt-out their European Patents from the jurisdiction of the UPC, defaulting to pre-UPC enforcement mechanisms. We have decided to opt out certain European patents and patent applications from the UPC. However, if certain formalities and requirements are not met, our European patents could be subject to the jurisdiction of the UPC. We cannot be certain that our European patents will avoid falling under the jurisdiction of the UPC, if we decide to opt out of the UPC.

***We may not be able to seek or obtain patent protection throughout the world or enforce such patent protection once obtained.***

Filing, prosecuting, enforcing, and defending patents protecting our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. The requirements for patentability may differ in certain countries, particularly in developing countries; thus, even in countries where we do pursue patent protection, there can be no assurance that any patents will issue with claims that cover our products.

Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Additionally, laws of some countries outside of the United States and Europe do not afford intellectual property protection to the same extent as the laws of the United States and Europe. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in certain countries outside the United States and Europe or from selling or importing products made from our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop and market their own products and, further, may export otherwise infringing products to territories where we have patent protection, if our ability to enforce our patents to stop infringing activities is inadequate. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Proceedings to enforce our patent rights, whether successful or not, could result in substantial costs and divert our efforts and resources from other aspects of our business. Further, such proceedings could put our patents at risk of being invalidated, held unenforceable or interpreted narrowly; put our pending patent applications at risk of not issuing; and provoke third parties to assert

claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful.

Furthermore, while we intend to protect our intellectual property rights in major markets for our products, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products, if approved. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate.

Geopolitical actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors. For example, further to the United States and foreign government actions related to Russia's invasion of Ukraine, the Kremlin issued Decree 299 stating that Russian companies and individuals can use patented inventions without the owner's permission or compensation, if the patent is held by owners from "unfriendly countries," which include the United States. As a result, we would not be able to enforce our otherwise valid patent rights against an infringer in Russia.

Further, the standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. As such, we do not know the degree of future protection that we will have on our technologies, products and product candidates. While we will endeavor to try to protect our technologies, products and product candidates with intellectual property rights such as patents, as appropriate, the process of obtaining patents is time consuming, expensive and unpredictable.

***In order to protect our competitive position around our product candidates, we may become involved in lawsuits to enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful and which may result in our patents being found invalid or unenforceable.***

Competitors may seek to commercialize competitive products to our product candidates. In order to protect our competitive position, we may become involved in lawsuits asserting infringement of our patents, or misappropriation or other violations of other of our intellectual property rights. Litigation is expensive and time consuming and would likely divert the time and attention of our management and scientific personnel. There can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

If we file a patent infringement lawsuit against a perceived infringer, such a lawsuit could provoke the defendant to counterclaim that we infringe their patents and/or that our patents are invalid and/or unenforceable. In patent litigation in the United States, it is commonplace for a defendant to counterclaim alleging invalidity and/or unenforceability. In any patent litigation there is a risk that a court will decide that the asserted patents are invalid or unenforceable, in whole or in part, and that we do not have the right to stop the defendant from using the invention at issue. With respect to a counterclaim of invalidity, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. If any of our patents are found invalid or unenforceable, or construed narrowly, our ability to stop the other party from launching a competitive product would be materially impaired. Further, such adverse outcomes could limit our ability to assert those patents against future competitors. Loss of patent protection would have a material adverse impact on our business.

Even if we establish infringement of any of our patents by a competitive product, a court may decide not to grant an injunction against further infringing activity, thus allowing the competitive product to continue to be marketed by the competitor. It is difficult to obtain an injunction in U.S. litigation and a court could decide that the competitor should instead pay us a "reasonable royalty" as determined by the court, and/or other monetary damages. A reasonable royalty or other monetary damages may or may not be an adequate remedy. Loss of exclusivity and/or competition from a related product would have a material adverse impact on our business.

Litigation often involves significant amounts of public disclosures. Such disclosures could have a materially adverse impact on our competitive position or our stock prices. During U.S. litigation we would be required to produce voluminous records related to our patents and our research and development activities in a process called discovery. The discovery process may result in the disclosure of some of our confidential information. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could adversely affect the price of our common shares.

Litigation is inherently expensive, and the outcome is often uncertain. Any litigation likely would substantially increase our operating costs and reduce our resources available for development activities. Further, we may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. As a result, we may conclude that even if a competitor is infringing any of our patents, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our stockholders. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution.

If in the future, we in-license any patent rights, we may not have the right to file a lawsuit for infringement and may have to rely on a licensor to enforce these rights for us. If we are not able to directly assert our licensed patent rights against infringers or if a licensor does not vigorously prosecute any infringement claims on our behalf, we may have difficulty competing in certain markets where such potential infringers conduct their business, and our commercialization efforts may suffer as a result.

Concurrently with an infringement litigation, third parties may also be able to challenge the validity of our patents before administrative bodies in the United States or abroad. Such mechanisms include re-examination, post grant review and equivalent proceedings in foreign jurisdictions, e.g., opposition proceedings. Such proceedings could result in revocation or amendment of our patents in such a way that they no longer cover our products, potentially negatively impacting any concurrent litigation.

***If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates.***

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our product candidates without infringing, misappropriating or otherwise violating the intellectual property and other proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe, misappropriate or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Third parties may have U.S. and non-U.S. issued patents and pending patent applications relating to compounds, methods of manufacturing compounds and/or methods of use for the treatment of the disease indications for which we are developing our product candidates. If any third-party patents or patent applications are found to cover our product candidates, or their methods of use or manufacture, we may not be free to manufacture or market such product candidates as planned without obtaining a license, which may not be available on commercially reasonable terms, or at all.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our product candidates, including patent infringement lawsuits in the U.S. or abroad. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the composition, use or manufacture of our product candidates. Third parties may assert infringement claims against us based on existing patents that they own or in-license or patents that may grant to them (or which they may in-license) in the future, regardless of the merit of such patents or infringement claims. If our defenses to such assertions of infringement were unsuccessful, we could be liable for a court-determined reasonable royalty on our existing sales and further damages to the patent owner (or licensee), such as lost profits. Such royalties and damages could be significant. If we are found to have willfully infringed the claims of a third party's patent, the third party could be awarded treble damages and attorney's fees. Further, unless we obtain a license to such patent, we may be precluded from commercializing the infringing product candidate. Any of the aforementioned could have a material adverse effect on our business, financial condition, results of operations and prospects.

While we perform periodic searches for relevant patents and patent applications with respect to our product candidates, including MBX 2109, MBX 1416, and MBX 4291, we cannot guarantee the completeness or thoroughness of any of our patent searches or analyses including, but not limited to, the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, nor can we be certain that we have identified each and every patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of any of our product candidates in any jurisdiction. Patent applications in the United States and elsewhere are typically published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Certain U.S. applications that will not be filed outside the U.S. can remain confidential until patents issue. As a result, we may be unable to identify such patents or patent applications despite our best efforts. In addition, patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that any of our product candidates may be accused of infringing. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Accordingly, third parties may assert infringement claims against us based on intellectual property rights that exist now or arise in the future. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. The pharmaceutical and biotechnology industries have produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use or manufacture. The scope of protection

afforded by a patent is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that the relevant product or methods of using the product either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could significantly harm our business and operating results. In addition, parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources, and we may not have sufficient resources to bring these actions to a successful conclusion.

If we are found to infringe, misappropriate or otherwise violate a third party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product. If we were required to obtain a license to continue to manufacture or market the affected product, we may be required to pay substantial royalties or grant cross-licenses to our patents. Even if we were able to obtain a license, it could be nonexclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us. We cannot be certain that any such license will be available on acceptable terms, if at all. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations as a result of claims of patent infringement or violation of other intellectual property rights, Further, the outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of any adverse party. This is especially true in intellectual property cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree. Furthermore, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us; alternatively or additionally it could include terms that impede or destroy our ability to compete successfully in the commercial marketplace. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing a product or force us to cease some of our business operations, which could harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could adversely affect the price of our common shares. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

***Others may challenge inventorship or claim an ownership interest in our intellectual property which could expose it to litigation and have a significant adverse effect on its prospects.***

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors or the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent. Furthermore, ownership disputes may arise from alleged contributions of third parties involved in developing our product candidates and may result in joint ownership of our inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and/or ownership. Any disagreement over inventorship could result in our being forced to defend our determination of inventorship in a legal action which could result in substantial costs and be a distraction to our senior management and scientific personnel. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

While we typically require employees, consultants and contractors who may develop intellectual property on our behalf to execute agreements assigning such intellectual property to us, we may be unsuccessful in obtaining execution of assignment agreements with each party who in fact develops intellectual property that we regard as our own. Moreover, even when we obtain agreements assigning intellectual property to us, the assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached. In either case, we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Furthermore, individuals executing agreements with us may have preexisting or competing obligations to a third party, such as an academic institution, and thus

an agreement with us may be ineffective in perfecting ownership of inventions developed by that individual. If we are unsuccessful in obtaining assignment agreements from an employee, consultant or contractor who develops intellectual property on our behalf, the employee, consultant or contractor may later claim ownership of the invention. Any disagreement over ownership of intellectual property could result in our losing ownership, or exclusive ownership, of the contested intellectual property, paying monetary damages and/or being enjoined from clinical testing, manufacturing and marketing of the affected product candidate(s). Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our senior management and scientific personnel.

***We may be subject to claims that we have wrongfully hired an employee from a competitor or by third parties asserting that our employees or we have misappropriated their intellectual property or claiming ownership of what we regard as our own intellectual property.***

Many of our current and former employees and our licensors' current and former employees, including our senior management, were previously employed at universities or at other biotechnology or pharmaceutical companies, including some which may be competitors or potential competitors. Although we take commercially reasonable steps to ensure that our employees do not use the proprietary information, know-how or trade secrets of others in their work for us, including incorporating such intellectual property into our product candidates, we may be subject to claims that we or these employees have misappropriated the intellectual property of a third party.

If we or any of our employees are accused of misappropriating the proprietary information, know-how or trade secrets of a third party, we may be forced to defend such claims in litigation. If we are found to have misappropriated the intellectual property rights of a third party, we may be forced to pay monetary damages, sustain reputational damage, lose key personnel, or lose valuable intellectual property rights. Further, it may become necessary for us to obtain a license from such third party to commercialize any of our product candidates. Such a license may not be available on commercially reasonable terms or at all. Any of the aforementioned could materially affect the commercialization of any of our product candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

***We may rely on trade secrets and proprietary know-how which can be difficult to trace and enforce and, if we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.***

We consider proprietary trade secrets or confidential know-how and unpatented know-how to be important to our business. We may rely on trade secrets or confidential know-how to protect our technology, especially where patent protection is believed by us to be of limited value. We expect to rely on third parties for future manufacturing of our product candidates. We also expect to collaborate with third parties on the development of our product candidates and as a result must, at times, share trade secrets with our collaborators. We also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements.

Trade secrets or confidential know-how can be difficult to maintain as confidential. To protect this type of information against disclosure or appropriation by competitors, our policy is to require our employees, consultants, contractors and advisors to enter into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with us prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. However, current or former employees, consultants, contractors and advisers may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. The need to share trade secrets and other confidential information, including with future business partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations. Enforcing a claim that a third party obtained illegally and is using trade secrets or confidential know-how is expensive, time consuming and unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets and know-how. The enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators and we would have no right to prevent them from using that technology or information to compete with us. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

***We may need to acquire or license additional intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.***

A third party may hold intellectual property, including patent rights that are important or necessary to the development of our product candidates. It may be necessary for us to use the patented or proprietary technology of one or more third parties to commercialize our current and future product candidates.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development. If we are unable to acquire such intellectual property outright, or obtain licenses to such intellectual property from such third parties when needed or on commercially reasonable terms, our ability to commercialize our product candidates, if approved, would likely be delayed or we may have to abandon development of that product candidate and our business and financial condition could suffer.

If we in-license other product candidates in the future, we might become dependent on proprietary rights from third parties with respect to those product candidates. Any termination of such licenses could result in the loss of significant rights and would cause material adverse harm to our ability to develop and commercialize any product candidates subject to such licenses. Even if we are able to in-license any such necessary intellectual property, it could be on nonexclusive terms, including with respect to the use, field or territory of the licensed intellectual property, thereby giving our competitors and other third parties access to the same intellectual property licensed to us. In-licensing IP rights could require us to make substantial licensing and royalty payments. Patents licensed to us could be put at risk of being invalidated or interpreted narrowly in litigation filed by or against our licensors or another licensee or in administrative proceedings. If any in-licensed patents are invalidated or held unenforceable, we may not be able to prevent competitors or other third parties from developing and commercializing competitive products.

We may not have the right to control the prosecution, maintenance, enforcement or defense of patents and patent applications that we license from third parties. In such cases, we would be reliant on the licensor to take any necessary actions. We cannot be certain that such licensor would act with our best interests in mind, or in compliance with applicable laws and regulations, or that their actions would result in valid and enforceable patents. For example, it is possible that a licensor's actions in enforcing and/or defending a patent licensed by us may be less vigorous than had we conducted them ourselves. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our present or future licensors may have relied upon or may rely upon third-party consultants or collaborators or on funds from third parties such that our present or future licensors may not be the sole and exclusive owners of the patents we in-license. If other third parties have ownership rights to our present or future in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- our financial or other obligations under the license agreement;
- whether and the extent to which our technology and processes infringe intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of licensed technology in relation to our development and commercialization of our product candidates and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

The risks described elsewhere pertaining to our intellectual property rights also apply to the intellectual property rights that we may own or in-license now or in the future, and any failure by us or our licensors to obtain, maintain, defend and enforce these rights could have an adverse effect on our business. In some cases we may not have control over the prosecution, maintenance or

enforcement of the patents that we license, and may not have sufficient ability to provide input into the patent prosecution, maintenance and defense process with respect to such patents, and potential future licensors may fail to take the steps that we believe are necessary or desirable in order to obtain, maintain, defend and enforce the licensed patents.

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

We do not currently own any registered trademarks and we have not filed any trademark applications to date. While we may have common law protection for certain of our trademarks and trade names, it may be harder for us to rely on any such common law protection to prevent third parties from copying or using our trademarks or trade names without our permission. Our current or future trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. As a means to enforce our trademark rights and prevent infringement, we may be required to file trademark claims against third parties or initiate trademark opposition proceedings. This can be expensive and time-consuming, particularly for a company of our size. We may not be able to protect our rights to our trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. During trademark registration proceedings, we may receive rejections. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. Moreover, any name we propose to use for our products in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed product names, we may be required to expend significant additional resources in an effort to identify a usable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

***Intellectual property rights do not necessarily address all potential threats to our business.***

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

- others may be able to make products that are competitive to our product candidates or any of our future product candidates that are not covered by the claims of our patent rights;
- others may independently develop similar or alternative technologies or otherwise circumvent any of our technologies without infringing our patent portfolio;
- we or any of our collaborators might not have been the first to invent the inventions covered by our patent portfolio;
- we or any of our collaborators might not have been the first to file patent applications covering certain of the patents or patent applications that we or they own or have obtained a license, or will own or will have obtained a license;
- it is possible that our owned and in-licensed pending patent applications or those that we or our collaborators may file in the future will not lead to issued patents;
- others may have access to the same intellectual property rights licensed to us on a non-exclusive basis in the future;
- issued patents that we may own or in-license may not provide us with any competitive advantage, or may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights, or in countries where research and development safe harbor laws exist, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;

•we cannot predict the scope of protection of any patent issuing based on our owned or in-licensed patent applications, including whether the patent applications that we may own or in-license will result in issued patents with claims that are directed to our product candidates or uses thereof in the United States or in other foreign countries;

•the claims of any patent issuing based on our owned or in-licensed patent applications may not provide protection against competitors or any competitive advantages, or may be challenged by third parties;

•if enforced, a court may not hold that our owned or in-licensed patents are valid, enforceable and infringed;

•we may need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose;

•ownership of our patent portfolio may be challenged by third parties;

•the patents of third parties or pending or future applications of third parties, if issued, may have an adverse effect on our business;

•patent enforcement is expensive and time-consuming and difficult to predict; thus, we may not be able to enforce any of our patents against a competitor;

•the patents of others may have an adverse effect on our business, including if others obtain patents claiming subject matter similar to or improving that covered by our patents and patent applications; and

•we may choose not to file a patent application for certain inventions, instead choosing to rely on trade secret protection, and a third party may subsequently file a patent application covering such intellectual property.

Should any of these or similar events occur, they could significantly harm our business, results of operations and prospects.

**Risks Related to Ownership of Our Common Stock**

***The market price of our common stock may be volatile, which could result in substantial losses for our shareholders.***

The trading price of our common stock may be volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. The market price for our common stock may be influenced by those factors discussed in this “Risk Factors” section and many others, some of which may include:

•the success of existing or new competitive product candidates or technologies;

•the timing and results of preclinical studies and clinical trials for our current or future product candidates;

•failure or discontinuation of any of our development and research programs;

•results of any preclinical studies, clinical trials or regulatory approvals of product candidates of our competitors, or announcements about new research programs or product candidates of our competitors;

•commencement or termination of collaborations for our product development and research programs;

•regulatory or legal developments in the United States and other countries;

•developments or disputes concerning patent applications, issued patents or other intellectual property or proprietary rights;

•the recruitment or departure of key personnel;

•the results of efforts and level of expenses related to any of our research programs, clinical development programs or current or future product candidates;

•actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts, if any, that cover our stock;

•announcement or expectation of additional financing efforts;

•sales of our common stock by us, our insiders or other stockholders;

•expiration of market stand-off or lock-up agreements;

•variations in our financial results or those of companies that are perceived to be similar to us;

•changes in the structure of healthcare payment systems;

•market conditions in the pharmaceutical and biotechnology sectors;

•general economic, industry and market conditions, including the ongoing geopolitical conflict in Ukraine and the Israel-Hamas war, tensions in U.S.-China relations, rising interest rates and inflation; and

•the other factors described in this “Risk Factors” section.

In recent years, the stock market in general and the market for pharmaceutical and biotechnology companies in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. In particular, in relation to uncertainty around inflation and the U.S. Federal Reserve’s measures to slow inflation, the stock market has been exceptionally volatile. Market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance. Following periods of such volatility in the market price of a company’s securities, securities class action litigation has often been brought against that company. Because of the potential volatility of our stock price, we may become the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management’s attention and resources from our business.

***We incur significant costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.***

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002 ("SOX"), the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Global Select Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. We expect that we will need to hire additional accounting, finance and other personnel in connection with our becoming, and our efforts to comply with the requirements of being, a public company. Our management and other personnel need to devote a substantial amount of time towards maintaining compliance with these requirements. These requirements will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, the rules and regulations applicable to us as a public company make it more difficult and more expensive for us to obtain director and officer liability insurance, which make it more difficult for us to attract and retain qualified members of our board of directors. We continue to evaluate these rules and regulations and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to SOX Section 404, we will be required to furnish a report by our management on our internal control over financial reporting beginning with our second filing of an Annual Report on Form 10-K with the SEC after we become a public company. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with SOX Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants, adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by SOX Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

***An active trading market for our common stock may not be sustained.***

An active or liquid market in our common stock may not be sustained. The lack of an active market may impair the value of our stockholders’ shares, and our stockholders’ ability to sell their shares at the desired time and price. An inactive market may also impair our ability to raise capital by selling our common stock and our ability to enter into strategic collaborations or acquire other companies, products, or technologies by using our common stock as consideration.

***We may not be able to satisfy listing requirements of Nasdaq or obtain or maintain a listing of our common stock on Nasdaq.***

We must meet certain financial and liquidity criteria to maintain our Nasdaq listing. If we violate Nasdaq’s listing requirements, our common stock may be delisted. If we fail to meet any of Nasdaq’s listing standards, our common stock may be delisted. In

addition, our board of directors may determine that the cost of maintaining our listing on a national securities exchange outweighs the benefits of such listing. A delisting of our common stock from Nasdaq may materially impair our stockholders' ability to buy and sell our common stock and could have an adverse effect on the market price of, and the efficiency of the trading market for, our common stock. The delisting of our common stock could significantly impair our ability to raise capital and the value of your investment.

***If securities analysts do not continue to publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.***

The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us or our business. If one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. Similarly, if one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

***A significant portion of our total outstanding shares is restricted from immediate resale but may be sold into the market in the near future, which could cause the market price of our common stock to decline significantly, even if our business is doing well.***

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock. As of September 30, 2024, we have 33,376,058 shares of common stock outstanding. Of these shares, the 11,730,000 shares sold in our IPO may be resold in the public market immediately. The resale of 21,513,565 shares of our outstanding common stock is currently restricted under securities laws or as a result of lock-up or other agreements, but will be able to be sold after the expiration of the lock-up on March 12, 2025 and termination of restrictions under securities laws. Moreover, holders of an aggregate 20,336,599 shares of our common stock have rights, subject to conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We have also registered all shares of common stock that we may issue under our equity compensation plans or that are issuable upon exercise of outstanding options. These shares can be freely sold in the public market upon issuance and once vested, subject to volume limitations applicable to affiliates and lock-up agreements. If any of these additional shares are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

In addition, in the future, we may issue additional shares of common stock or other equity or debt securities convertible into common stock in connection with a financing, acquisition, litigation settlement, employee arrangements or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and could cause our stock price to decline.

***We are an "emerging growth company" and a "smaller reporting company," and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.***

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). We could be an emerging growth company until as late as December 31, 2029, although circumstances could cause us to lose that status earlier, including if we are deemed to be a "large accelerated filer," which occurs when the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30, or if we have total annual gross revenue of $1.235 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following December 31, or if we issue more than $1.0 billion in non-convertible debt during any three-year period before that time, in which case we would no longer be an emerging growth company immediately. For so long as we remain an emerging growth company, we are permitted and plan to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include not being required to comply with the auditor attestation requirements of SOX Section 404, not being required to comply with any requirement for a supplement to the auditor's report providing additional information about the audit and the financial statements, reduced disclosure obligations regarding executive compensation and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As a result, the information we provide stockholders will be different than the information that is available with respect to other public companies.

In addition, 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 are not subject to the 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 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 stock held by non-affiliates is less than $700 million and our annual revenue is 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 stock held by non-affiliates is less than $250 million or (ii) our annual revenue is less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates 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 Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

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

***Insiders own a significant percentage of our common stock and have the ability to exert significant control over matters subject to stockholder approval.***

Our directors and executive officers and their affiliates collectively own a significant percentage of our outstanding common stock. As a result, these stockholders, if they act together, will be able to influence our management and affairs and all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This concentration of ownership may have the effect of delaying or preventing a change in control of our company and might affect the market price of our common stock.

***We do not expect to pay any dividends for the foreseeable future. Investors may never obtain a return on their investment.***

You should not rely on an investment in our common stock to provide dividend income. We do not anticipate that we will pay any dividends to holders of our common stock in the foreseeable future. Instead, we plan to retain any earnings to maintain and expand our existing operations. In addition, any future credit facility may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any return on their investment. As a result, investors seeking cash dividends should not purchase our common stock.

***If we fail to establish and maintain proper and effective internal control over financial reporting, our operating results and our ability to operate our business could be harmed.***

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be re-evaluated frequently. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. We have begun the process of documenting, reviewing and improving our internal controls and procedures for compliance with SOX Section 404, which will require annual management assessment of the effectiveness of our internal control over financial reporting starting with our second filing of an Annual Report on Form 10-K.

Implementing any appropriate changes to our internal controls may distract our officers and employees, entail substantial costs to modify our existing processes and take significant time to complete. These changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy or consequent inability to produce accurate financial statements on a timely basis could increase our operating costs and harm our business. In addition, investors’ perceptions that our internal controls are inadequate or that we are unable to produce accurate financial statements on a timely basis cause investors to lose confidence in the accuracy and completeness of our financial reports and could cause the market price of our common stock to decline significantly.

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

We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and

communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

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

***Our amended and restated bylaws designate specific courts as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit stockholders' ability to obtain a favorable judicial forum for disputes with us.***

Pursuant to our amended and restated bylaws, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for any state law claims for (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of or based on a breach of a fiduciary duty owed by any director, officer or other employee of ours to us or our stockholders; (iii) any action asserting a claim pursuant to any provision of the Delaware General Corporation Law ("DGCL"), our fourth amended and restated certificate of incorporation or our amended and restated bylaws or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware; or (iv) any action asserting a claim governed by the internal affairs doctrine (the "Delaware Forum Provision"). The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act or the Securities Exchange Act of 1934, as amended, (the "Exchange Act"). Our amended and restated bylaws further provide that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, the Exchange Act, the respective rules and regulations promulgated thereunder or the Federal Forum Provision. In addition, our amended and restated bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock is deemed to have notice of and consented to the Delaware Forum Provision and the Federal Forum Provision; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

We recognize that the Delaware Forum Provision and the Federal Forum Provision in our amended and restated bylaws may impose additional litigation costs on stockholders in pursuing any such claims, particularly if the stockholders do not reside in or near the State of Delaware. Additionally, the forum selection clauses in our amended and restated bylaws may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage the filing of lawsuits against us and our directors, officers and employees, even though an action, if successful, might benefit our stockholders. In addition, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. While the Delaware Supreme Court and other state courts have upheld the validity of federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the federal district courts of the United States may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

***Provisions in our fourth amended and restated certificate of incorporation and Delaware law have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management.***

Our fourth amended and restated certificate of incorporation and restated bylaws and Delaware law contain provisions that may have the effect of discouraging, delaying or preventing a change in control of us or changes in our management that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. Our fourth amended and restated certificate of incorporation and our amended and restated bylaws include provisions that:

- authorize "blank check" preferred stock, which could be issued by our board of directors without stockholder approval and may contain voting, liquidation, dividend and other rights superior to our common stock;
- create a classified board of directors whose members serve staggered three-year terms;
- specify that special meetings of our stockholders can be called only by our board of directors;

•prohibit stockholder action by written consent;

•establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;

•provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;

•provide that our directors may be removed only for cause;

•specify that no stockholder is permitted to cumulate votes at any election of directors;

•expressly authorized our board of directors to make, alter, amend or repeal our amended and restated bylaws; and

•require supermajority votes of the holders of our common stock to amend specified provisions of our amended and restated certificate of incorporation and amended and restated bylaws.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock.

In addition, because we are incorporated in the State of Delaware, we are governed by the provisions of Section 203 of the DGCL, which prohibits a person who owns in excess of 15 percent of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15 percent of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Any provision of our fourth amended and restated certificate of incorporation, amended and restated bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock and could also affect the price that some investors are willing to pay for our common stock.

***Adverse developments affecting the financial services industry could adversely affect our current and projected business operations and our financial condition and results of operations.***

Adverse developments that affect financial institutions, such as events involving liquidity that are rumored or actual, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation as receiver. Although we assess our banking relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that us, the financial institutions with which we have credit agreements or arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry.

**General risks**

***We may become involved in securities class action litigation that could divert management's attention and harm our business, and insurance coverage may not be sufficient to cover all costs and damages.***

In the past, securities class action litigation has often followed certain significant business transactions, such as the sale of a company or announcement of any other strategic transaction, or the announcement of negative events, such as negative results from clinical trials. These events may also result in or be concurrent with investigations by the SEC. We may be exposed to such litigation or investigation even if no wrongdoing occurred. Litigation and investigations are usually expensive and divert management's attention and resources, which could adversely affect our business and cash resources and our ability to consummate a potential strategic transaction or the ultimate value our stockholders receive in any such transaction.

***Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.***

Our results of operations could be adversely affected by general conditions in the global economy, geopolitical tensions and in the global financial markets. A severe or prolonged economic downturn or additional global financial and political crises could result in a variety of risks to our business, including weakened demand for any product candidates we develop or our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers or other

third parties and create import and export issues, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

***We face risks related to health epidemics, pandemics and other widespread outbreaks of contagious diseases, which could significantly disrupt our operations, impact our financial results or otherwise adversely impact our business.***

Significant outbreaks of contagious diseases and other adverse public health developments could have a material impact on our business operations and operating results. For example, the spread of COVID-19 affected segments of the global economy and our operations. As a result of similar public health crises that may arise, we may experience disruptions that could adversely impact our operations, research and development, and as we continue developing, any preclinical studies, clinical trials and manufacturing activities we may conduct, some of which may include:

- delays or disruptions in research programs, preclinical studies, clinical trials or IND-enabling studies that we or our collaborators may conduct;
- interruption or delays in the operations of the FDA and comparable foreign regulatory agencies;
- interruption of, or delays in receiving and distributing, supplies of drug substance and drug product from our contract development manufacturing organizations ("CDMOs") to preclinical or clinical research sites or delays or disruptions in any preclinical studies or clinical trials performed by CROs;
- limitations imposed on our business operations by local, state or federal authorities to address a pandemic or similar public health crises; and
- business disruptions caused by potential workplace, laboratory and office closures and an increased reliance on employees working from home, disruptions to or delays in ongoing laboratory experiments and operations, staffing shortages, travel limitations, and cybersecurity and data accessibility or security issues.

In addition, the trading prices for biopharmaceutical companies have been highly volatile and we may face similar volatility in our stock price. We cannot predict the scope and severity of any economic recovery of health epidemics, pandemics and other widespread outbreaks of contagious diseases, including following any additional “waves” or other intensifying of a pandemic. If we or any of the third parties with whom we engage were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively affected, which could have a material adverse impact on our business, financial condition, our results of operations and prospects. Furthermore, such pandemics could exacerbate the other risks described in this section.

***We or the third parties upon whom we depend may be adversely affected by climate change, earthquakes, outbreak of disease, or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.***

Climate change, earthquakes, outbreak of disease, or other natural disasters, including extreme weather events and changing weather patterns such as storms, flooding, droughts, fires and temperature changes, which have become more common, could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, extreme weather risk, power outage, cybersecurity attack or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities of our third-party CDMOs, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. For example, we may experience delays in the supply of drug product for our clinical trials as a result of disruptions to the operations of the manufacturing facilities of some of our third-party CDMOs. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. In addition, cybersecurity liability insurance is difficult to obtain and may not cover any damages we would sustain based on any breach or compromise of our computer security protocols or other cybersecurity attack. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

***Our ability to effectively monitor and respond to the rapid and ongoing developments and expectations relating to environmental, social and governance matters, including related social expectations and concerns, may impose unexpected costs on us or result in reputational or other harm to us that could have a material adverse effect on our business, financial condition and results of operations.***

There is an increasing focus and rapid and ongoing developments and changing expectations from certain investors, customers, consumers, employees and other stakeholders concerning environmental, social and corporate governance ("ESG matters"). Additionally, public interest and legislative pressure related to public companies' ESG practices continue to grow, which may result in increased regulatory, social or other scrutiny on us.

A variety of organizations measure the performance of companies on ESG topics, and the results of these assessments are widely publicized. In addition, investment in funds that specialize in companies that perform well in such assessments are increasingly popular, and major institutional investors have publicly emphasized the importance of such ESG measures to their investment decisions. Topics taken into account in such assessments include, among others, the company's efforts and impacts on climate change and human rights, ethics and compliance with law, and the role of the company's board of directors in supervising various sustainability issues.

We may be required to make investments in matters related to ESG, which could be significant. Our failure or perceived failure to meet the standards set by various constituencies could damage our reputation and our relationships with investors, governments, customers, employees, third parties and the communities in which we operate and expose us to increased regulatory risk, put us at a commercial disadvantage relative to our peers and materially adversely affect our business, financial condition, results of operations, ability to participate in debt and equity markets and the value of our shares.

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

***(a) Recent Sales of Unregistered Equity Securities***

In the three years preceding the filing of this Quarterly Report, we have issued the following securities that were not registered under the Securities Act:

***Convertible note issuances***

In August 2022, we issued the 2022 Notes to certain accredited investors for gross in the aggregate principle amount of $10.0 million which included two options for conversion: (1) automatic conversion into shares of convertible preferred stock from the next qualified financing at 90% of the per share price of the convertible preferred stock sold in the qualified financing consummated on or prior to March 31, 2023, or 80% of the per share price of the convertible preferred stock sold in the qualified financing consummated after March 31, 2023 and (2) optional conversion into shares of convertible preferred stock from the next non-qualified financing at 90% of the per share price of the convertible preferred stock sold in the non-qualified financing consummated on or prior to March 31, 2023, or 80% of the per share price of the convertible preferred stock sold in the non-qualified financing consummated after March 31, 2023.

***Preferred stock issuances***

In November 2021, we issued an aggregate of 16,011,641 shares of our Series A preferred stock at a purchase price of $0.687 per share in connection with the achievement of a certain development milestone for gross proceeds of $11.0 million. In November 2022 and August 2023, we issued an aggregate of 129,240,032 shares of our Series B preferred stock as follows: (a) 40,545,552 shares of Series B preferred stock sold at a purchase price of $0.90 per share at the initial closing for gross proceeds of $36.5 million, (b) 12,573,381 shares of Series B preferred stock which were converted pursuant to the conversion of the 2022 Notes and (c) 76,121,099 shares of Series B preferred stock sold at a purchase price of $0.90 per share pursuant to the achievement of certain development milestones for gross proceeds of $68.5 million.

In August 2024, we issued an aggregate of 61,650,480 shares of our Series C preferred stock at a purchase price of $1.03 for gross proceeds of $63.5 million.

***Option issuances***

From January 1, 2021 through September 30, 2024, we have granted to our directors, officers, employees, consultants, and other key persons options to purchase an aggregate of 46,193,181 shares of common stock pursuant to the 2019 Plan.

***Common stock issuances***

From January 1, 2021 through September 30, 2024, we have sold to our directors, officers, employees, consultants, and other key persons an aggregate of 4,969,274 shares of common stock at a weighted-average exercise price of $0.21 per share pursuant to the 2019 Plan.

***Common stock repurchases***

From January 1, 2021 through September 30, 2024, we have repurchased 303,835 shares of our common stock from former employees at a weighted-average cash purchase price of $0.13 per share for an immaterial total fair value.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions, or any public offering. Unless otherwise specified above, the Registrant believes these transactions were exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act (and Regulation D or Regulation S promulgated thereunder) or Rule 701 promulgated under Section 3(b) of the Securities Act as transactions by an issuer not involving any public offering or under benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of the securities in each of these transactions represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were placed on the share certificates issued in these transactions. All recipients had adequate access, through their relationships with the Registrant, to information about the Registrant. The sales of these securities were made without any general solicitation or advertising.

***(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, pursuant to which we issued and sold an aggregate of 11,730,000 shares of common stock (inclusive of 1,530,000 shares of common stock sold pursuant to the underwriters' exercise of their option to purchase additional shares) at a public offering price of $16.00 per share for aggregate gross proceeds of $187.7 million and aggregate net cash proceeds of $170.5 million, after deducting approximately $13.1 million of underwriting discounts and commissions and approximately $4.1 million in other offering costs.

Our IPO closed on September 16, 2024. The underwriters of the offering were J.P. Morgan Securities LLC, Jefferies LLC, Stifel, Nicolaus & Company, Incorporated and Guggenheim Securities, LLC.

In connection with our IPO, no payments for such expenses were made directly or indirectly to (i) any of our officers or directors or their associates, (ii) any persons owning 10% or more of any class of our equity securities or (iii) any of our affiliates.

We are holding a significant portion of the balance of the net proceeds in a variety of capital preservation investments, including money market funds and U.S. government securities. As of September 30, 2024, there has been no material change in the planned proceeds from our IPO, as described in our final prospectus filed with the SEC on September 12, 2024 pursuant to Rule 424(b) under the Securities Act.

***(c) Issuer Repurchases of Securities***

We have not repurchased any of our registered equity securities since the date our final prospectus for IPO was filed with the SEC on September 12, 2024.

**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). |
| 10.1# | 2019 Stock Option and Grant Plan, as amended, and forms of award agreements thereunder (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-281764) filed with the SEC on September 9, 2024). |
| 10.2# | 2024 Stock Option and Incentive Plan and forms of award agreements thereunder (incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-281764) filed with the SEC on September 9, 2024). |
| 10.3# | 2024 Employee Stock Purchase Plan(incorporated by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-1 (File No. 333-281764) filed with the SEC on September 9, 2024). |
| 10.4# | Form of Officer Indemnification Agreement (incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1 (File No. 333-281764) filed with the SEC on September 9, 2024). |
| 10.5# | Form of Director Indemnification Agreement (incorporated by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1 (File No. 333-281764) filed with the SEC on September 9, 2024). |
| 10.6# | Senior Cash Incentive Bonus Plan (incorporated by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form S-1 (File No. 333-281764) filed with the SEC on September 9, 2024). |
| 10.7# | Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.7 to the Registrant's Registration Statement on Form S-1 (File No. 333-281764) filed with the SEC on September 9, 2024). |
| 10.8† | Exclusive License Agreement, dated as of June 10, 2020, between Indiana University Research and Technology Corporation and MBX Biosciences, Inc., as amended (incorporated by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form S-1 (File No. 333-281764) filed with the SEC on September 9, 2024). |
| 10.9# | Employment Agreement between the Registrant and P. Kent Hawryluk, President and Chief Executive Officer, to be in effect upon the closing of this offering (incorporated by reference to Exhibit 10.10 to the Registrant's Registration Statement on Form S-1 (File No. 333-281764) filed with the SEC on September 9, 2024). |
| 10.10# | Employment Agreement between the Registrant and Richard Bartram, Chief Financial Officer, to be in effect upon the closing of this offering (incorporated by reference to Exhibit 10.11 to the Registrant's Registration Statement on Form S-1 (File No. 333-281764) filed with the SEC on September 9, 2024). |
| 10.11# | Employment Agreement between the Registrant and Salomon Azoulay, Chief Medical Officer, to be in effect upon the closing of this offering (incorporated by reference to Exhibit 10.12 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.

# Indicates a management contract or any compensatory plan, contract or arrangement
† Portions of this exhibit (indicated by asterisks) will be omitted in accordance with the rules of the SEC because the Registrant has determined that information is both not material and is the type that the registrant treats as private or confidential.
+ 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 7, 2024

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

Date: November 7, 2024

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, 2024 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 7, 2024

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, 2024 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 7, 2024

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, 2024 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 7, 2024 By: /s/ P. Kent Hawryluk
**P. Kent Hawryluk**
**President and Chief Executive Officer**
**(Principal Executive Officer)**

Date: November 7, 2024 By: /s/ Richard Bartram
**Richard Bartram**
**Chief Financial Officer**
**(Principal Financial Officer and Principal Accounting Officer)**