UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2025

OR

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

For the transition period from to

Commission File Number: 001-42938

Evommune, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**85-0742575**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
1841 Page Mill Road, Suite 100 **Palo Alto, CA**	**94304**
(Address of principal executive offices)	(Zip Code)

(925) 247-4481

(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	EVMN	New York Stock Exchange

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 December 10, 2025, the registrant had 31,524,093 shares of common stock, $0.0001 par value per share, outstanding.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report contains express or implied forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These statements 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 on Form 10-Q include, but are not limited to, statements about:

- the success, cost and timing of our product development activities and clinical trials of our most-advanced product candidates, EVO756 and EVO301, and any future product candidates;
- the characteristics and potential advantages of our product candidates;
- our need to raise additional funding before we can expect to generate any revenues from product sales;
- our ability to obtain regulatory approval for our current or future product candidates that we may identify or develop;
- our ability to ensure adequate supply of our current or future product candidates;
- our ability to maintain third-party relationships necessary to conduct our business;
- our heavy dependence upon the success of our research to generate and advance additional product candidates;
- our ability to establish an adequate safety or efficacy profile for our current or future product candidates;
- the implementation of our strategic plans for our business, our current or future product candidates we may develop and our technology;
- our intellectual property position, including the scope of protection and contractual rights that we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- estimates of the number of patients with certain diseases, market sizes for certain diseases, conditions we intend to treat and the number of subjects that we intend to enroll in our clinical trials;
- our plans relating to the further development and manufacturing of our product candidates, including additional indications for which we may pursue;
- the rate and degree of clinical utility for our current or future product candidates and their acceptance by physicians, patients, third-party payors and others in the medical community;
- our estimates about the size of market opportunities relating to our product candidates;
- our expectations related to our capital requirements and our needs for additional financing;
- our ability to maintain and establish collaborations, licensing or other arrangements, including our ability to comply with our obligations pursuant to the terms of such agreements;
- our financial performance and liquidity;
- our ability to effectively manage our potential growth;
- developments relating to our competitors and our industry, including the impact of government regulation and policy;
- our ability to retain the continued service of our key professionals and consultants and to identify, hire and retain additional qualified professionals;
- our ability to maintain adequate internal controls over financial reporting and to manage the business of the Company in accordance with applicable laws and the highly regulated industry in which we participate; and
- other risks and uncertainties, including those listed under the section titled "Risk Factors."

In some cases, forward-looking statements can be identified 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. Investors 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 those implied or projected by forward-looking statements include, among other things, those listed under the section titled "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q. 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. Investors should read this Quarterly Report on Form 10-Q, the documents that we reference in this Quarterly Report on Form 10-Q and the other documents that we file with the Securities and Exchange Commission ("SEC"), with the understanding that our actual future results may be materially different from any future results expressed or implied by these forward-looking statements.

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. Investors 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 on Form 10-Q.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report on Form 10-Q, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

SPECIAL NOTE REGARDING COMPANY REFERENCES

Throughout this Quarterly Report on Form 10-Q, the "Company," "we," "us" and "our" refer to Evommune, Inc.

SPECIAL NOTE REGARDING TRADEMARKS

All trademarks, trade names and service marks appearing in this Quarterly Report on Form 10-Q are the property of their respective owners.

SUMMARY OF RISKS ASSOCIATED WITH OUR BUSINESS

Our business faces significant risks and uncertainties. If any of the following risks are realized, our business, financial condition and results of operations could be materially and adversely affected. You should carefully review and consider the full discussion of our risk factors in the section titled "Risk Factors" in Part II, Item 1A of this Quarterly Report on Form 10-Q. Some of the more significant risks include the following:

- We will need substantial additional funding in order to maintain our operations and advance the development and commercialization of our product candidates. Failure to obtain this necessary capital when needed, or on acceptable terms, may force us to delay, reduce or eliminate certain of our product development or research operations.
- Due to our limited resources and access to capital, we must, and have in the past decided to, prioritize development of certain product candidates over other potential product candidates. These decisions may prove to have been wrong and may adversely affect our ability to develop our own programs, our attractiveness as a commercial partner and may ultimately have an adverse impact on our commercial success.
- Preclinical and clinical drug development is a lengthy and expensive process, with uncertain timelines and outcomes. If preclinical studies or clinical trials of our product candidates are prolonged or delayed, we may be unable to obtain required regulatory approvals, and therefore be unable to commercialize our therapeutic candidates or any of our future therapeutic candidates on a timely basis or at all.
- Our clinical trials may fail to demonstrate substantial evidence of the safety and efficacy of our product candidates or any future product candidates, which would prevent or delay or limit the scope of regulatory approval and commercialization.
- Our product candidates may be associated with serious adverse, undesirable or unacceptable side effects or other properties or safety risks, which may delay or halt their clinical development, prevent their marketing approval, or lead to limited market demand, if approved. If such side effects are identified during the development of our product candidates or following approval, we may suspend or abandon our development of such product candidates, the commercial profile of any approved label may be limited, or we may be subject to other significant negative consequences following marketing approval.
- Our product candidates are subject to extensive regulatory and compliance obligations, which is costly and time-consuming and which may cause unanticipated delays or prevent the receipt of the required approvals to commercialize our product candidates.
- We currently have no marketing, sales or distribution capabilities, and we may need to invest significant resources to develop these capabilities. If we are unable to establish marketing, sales or distribution capabilities or enter into agreements with third parties to perform such activities, we may not be able to generate product revenue.
- We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.
- We rely on third-party manufacturers, contract research organizations ("CROs"), contract development and manufacturing organizations ("CDMOs") and suppliers to supply, develop and test components of our product candidates. The loss of our third-party manufacturers, CROs, CDMOs or suppliers, their failure to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, or at all, or changes in methods of product candidate manufacturing, development or formulation would materially and adversely affect our business.
- We are highly dependent on the services of our senior management team and if we are not able to retain members of our management team and recruit and retain additional management, clinical and scientific personnel, our business will be harmed.
- Our existing collaborations are, and our future collaborations may be, important to our business. If we are unable to enter into new collaborations, or, if our collaborations are not successful, our business could be adversely affected.
- We have licensed intellectual property rights from third parties and may do so in the future. Such licenses may be subject to early termination if we fail to comply with our obligations in our licenses with third parties, which could result in the loss of rights or technology that are material to our business.
- We may rely on one or more in-licenses from third parties. If we lose these rights, our business may be materially adversely affected, and if disputes arise with one or more licensors, we may be subject to future litigation as well as the potential loss of or limitations on our ability to develop and commercialize products and technologies covered by these license agreements.

PART I—FINANCIAL INFORMATION

EVOMMUNE, INC.
Condensed Consolidated Balance Sheets (unaudited)
(In thousands, except share and per share amounts)

	September 30, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 26,818	$ 16,255
Short-term investments	49,244	55,785
Prepaid expenses and other current assets	5,879	1,948
Total current assets	81,941	73,988
Operating lease right-of-use assets, net	160	472
Property and equipment, net	970	1,326
Restricted cash	1,412	208
Other non-current assets	61	61
Total assets	$ 84,544	$ 76,055
Liabilities, Convertible Preferred Stock, and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 3,576	$ 8,264
Accrued liabilities	6,309	6,729
Operating lease liability, current portion	160	487
Convertible preferred stock forward	—	8,928
Deferred revenue	—	3,000
Other current liabilities	371	573
Total current liabilities	10,416	27,981
Other non-current liabilities	261	535
Total liabilities	10,677	28,516
Commitments and contingencies (Note 6)		
Convertible preferred stock: $0.0001 par value — 157,657,729 shares authorized at September 30, 2025 and December 31, 2024, respectively, 157,657,729 and 116,716,142 shares issued and outstanding at September 30, 2025 and December 31, 2024, respectively (Liquidation preference $275,611 and $210,328 at September 30, 2025 and December 31, 2024, respectively)	257,004	191,776
Stockholders' deficit:		
Common stock, par value $0.0001 — 223,593,879 shares authorized at September 30, 2025 and December 31, 2024, respectively; 1,554,965 and 1,551,420 shares issued and outstanding at September 30, 2025 and December 31, 2024, respectively	—	—
Additional paid-in capital	9,679	7,982
Accumulated deficit	(192,816)	(152,219)
Total stockholders' deficit	(183,137)	(144,237)
Total liabilities, convertible preferred stock, and stockholders' deficit	$ 84,544	$ 76,055

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

EVOMMUNE, INC.
Condensed Consolidated Statements of Operations (unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Revenues:				
License revenue	$ 10,000	$ —	$ 13,000	$ 7,000
Operating expenses:				
Research and development	19,639	13,289	53,639	46,413
General and administrative	3,689	3,228	10,716	9,146
Total operating expenses	23,328	16,517	64,355	55,559
Loss from operations	(13,328)	(16,517)	(51,355)	(48,559)
Other income, net:				
Change in fair value of convertible preferred stock forward	—	—	8,928	—
Interest income	862	618	1,880	2,515
Other expense, net	(9)	(17)	(50)	(38)
Total other income, net	853	601	10,758	2,477
Net loss	(12,475)	(15,916)	(40,597)	(46,082)
Net loss attributable to common stockholders	(12,475)	(15,916)	(40,597)	(46,082)
Basic and diluted net loss per share of common stock	$ (8.07)	$ (10.47)	$ (26.36)	$ (30.69)
Weighted average basic and diluted shares of common stock outstanding	1,545,010	1,520,814	1,540,243	1,501,635

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

EVOMMUNE, INC.
Condensed Consolidated Statements of Convertible Preferred Stock and Stockholders' Deficit (unaudited)
(In thousands, except share amounts)

For the Three Months Ended September 30, 2025

	Convertible Preferred stock		Common stock		Additional paid-in	Accumulated	
	Shares	Amount	Shares	Amount	capital	Deficit	Total
Balance, July 1, 2025	157,657,729	$ 257,004	1,554,965	$ —	$ 9,108	$ (180,341)	$ (171,233)
Stock-based compensation	—	—	—	—	561	—	561
Vesting of early exercised options	—	—	—	—	10	—	10
Net loss	—	—	—	—	—	(12,475)	(12,475)
Balance, September 30, 2025	157,657,729	$ 257,004	1,554,965	$ —	$ 9,679	$ (192,816)	$ (183,137)

For the Three Months Ended September 30, 2024

	Convertible Preferred stock		Common stock		Additional paid-in	Accumulated	
	Shares	Amount	Shares	Amount	capital	Deficit	Total
Balance, June 30, 2024	85,222,619	$ 149,374	1,545,789	$ —	$ 7,052	$ (114,077)	$ (107,025)
Stock-based compensation	—	—	—	—	401	—	401
Vesting of early exercised options	—	—	—	—	12	—	12
Net loss	—	—	—	—	—	(15,916)	(15,916)
Balance, September 30, 2024	85,222,619	$ 149,374	1,545,789	$ —	$ 7,465	$ (129,993)	$ (122,528)

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

EVOMMUNE, INC.
Condensed Consolidated Statements of Convertible Preferred Stock and Stockholders' Deficit (unaudited)
(In thousands, except share amounts)

For the Nine Months Ended September 30, 2025

	Convertible Preferred stock		Common stock		Additional paid-in capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount			
Balance, January 1, 2025	116,716,142	$ 191,776	1,551,420	$ —	$ 7,982	$ (152,219)	$ (144,237)
Issuance of common stock on exercise of options	—	—	3,545	—	6	—	6
Issuance of Series C convertible preferred stock, net of transaction costs	40,941,587	65,228	—	—	—	—	—
Stock-based compensation	—	—	—	—	1,660	—	1,660
Vesting of early exercised options	—	—	—	—	31	—	31
Net loss	—	—	—	—	—	(40,597)	(40,597)
Balance, September 30, 2025	157,657,729	$ 257,004	1,554,965	$ —	$ 9,679	$ (192,816)	$ (183,137)

For the Nine Months Ended September 30, 2024

	Convertible Preferred stock		Common stock		Additional paid-in capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount			
Balance, January 1, 2024	85,222,619	$ 149,374	1,545,137	$ —	$ 6,197	$ (83,911)	$ (77,714)
Issuance of common stock on exercise of options	—	—	652	—	2	—	2
Stock-based compensation	—	—	—	—	1,228	—	1,228
Vesting of early exercised options	—	—	—	—	38	—	38
Net loss	—	—	—	—	—	(46,082)	(46,082)
Balance, September 30, 2024	85,222,619	$ 149,374	1,545,789	$ —	$ 7,465	$ (129,993)	$ (122,528)

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

EVOMMUNE, INC.
Condensed Consolidated Statements of Cash Flows (unaudited)
(In thousands)

	Nine Months Ended September 30,	
	2025	**2024**
Cash flows from operating activities:		
Net loss	$ (40,597)	$ (46,082)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	1,660	1,228
Accretion of discount on short-term investments	(1,184)	(1,374)
Depreciation and amortization	1,063	927
Change in fair value of convertible preferred stock forward	(8,928)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(1,998)	(311)
Accounts payable	(4,688)	3,652
Accrued liabilities	(1,479)	2,844
Operating lease liabilities	(591)	(567)
Deferred revenue	(3,000)	—
Net cash used in operating activities	(59,742)	(39,683)
Cash flows from investing activities:		
Purchases of short-term investments	(38,775)	(45,675)
Maturities of short-term investments	46,500	74,850
Purchase of property and equipment	(131)	(88)
Net cash provided by investing activities	7,594	29,087
Cash flows from financing activities:		
Proceeds from issuance of convertible preferred stock, net of issuance costs	65,228	—
Proceeds from exercise of stock options	6	2
Payment of deferred offering costs	(874)	—
Principal payments of finance lease liability	(287)	(124)
Principal payments of financing obligation	(158)	(160)
Net cash provided by (used in) financing activities	63,915	(282)
Net increase (decrease) in cash, cash equivalents and restricted cash	11,767	(10,878)
Cash, cash equivalents and restricted cash - beginning of period	16,463	29,232
Cash, cash equivalents and restricted cash - end of period	$ 28,230	$ 18,354
Reconciliation of cash, cash equivalents, and restricted cash to the amounts reports within the balance sheets		
Cash and cash equivalents	$ 26,818	$ 18,146
Restricted cash	1,412	208
Total cash, cash equivalents, and restricted cash	$ 28,230	$ 18,354
Supplemental cash flow disclosures:		
Cash paid for interest	$ 7	$ 28
Deferred offering costs in accrued expenses	$ 1,059	$ —
Non-cash investing and financing activities:		
Vesting of early exercised stock options	$ 31	$ 39
Assets acquired under finance leases	$ —	$ 1,032
Operating lease liabilities arising from obtaining right-of-use assets	$ 264	$ —

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

1. Organization and Description of the Business

Business and Organization

Evommune, Inc. and its subsidiaries ("Evommune" or the "Company") is a Delaware corporation headquartered in Palo Alto, California. Evommune is a clinical stage biotechnology company developing innovative therapies that target key drivers of chronic inflammatory diseases.

Liquidity

The Company has incurred significant operating losses since inception and has relied primarily on equity financing and license revenue to fund its operations. As of September 30, 2025, the Company had an accumulated deficit of $192.8 million. The Company expects to continue to incur substantial losses, and its ability to achieve and sustain profitability will depend on the successful development, approval, and commercialization of product candidates and on the achievement of sufficient revenue to support its cost structure. The Company may never achieve profitability and, unless and until it does, the Company will need to continue to raise additional capital.

As previously disclosed in the Company's consolidated financial statements for the year ended December 31, 2024, management identified conditions that raised substantial doubt about the Company's ability to continue as a going concern. During the nine months ended September 30, 2025, management implemented plans that alleviated the substantial doubt. The principal factor leading to this conclusion is additional capital raised through the issuance of preferred stock (Note 7), and the issuance of common stock in the Company's initial public offering ("IPO") in November 2025 (Note 11), through which the Company raised gross proceeds of $172.5 million. As of September 30, 2025, management expects that existing cash, cash equivalents and short-term investments will be sufficient to fund the Company's current operating plan for at least twelve months from the issuance date of these financial statements.

Significant Risks and Uncertainties

The Company operates in a dynamic and highly competitive industry and believes that changes in any of the following areas could have a material adverse effect on the Company's future financial position, results of operations, or cash flows: its ability to obtain future financing; its ability to continue research and development of its product candidates; payment obligations under license or collaboration agreements; advances and trends in new technologies and industry standards; results of clinical trials; regulatory approval and market acceptance of the Company's product candidates; development of sales, marketing and distribution infrastructure; competing therapies and marketing development; investment in or in-license other technologies; certain strategic relationships; competition from pharmaceutical or other biotechnology companies with greater financial resources or expertise; litigation or claims against its intellectual property portfolio, patent, product, regulatory, or other factors; operational, financial and management systems; and the Company's ability to attract and retain employees necessary to support its growth.

Products candidates being developed by the Company require approvals from the U.S. Food and Drug Administration ("FDA") or other international regulatory agencies prior to commercial sales. There can be no assurance that any product candidates will receive the necessary approvals. If the Company is denied approval, approval is delayed or the Company is unable to maintain approval, it could have a material adverse impact on the Company.

The Company has expended and expects to continue to expend substantial funds to complete the research, development and pre-clinical and clinical testing of product candidates. The Company also will be required to expend additional funds to establish commercial-scale manufacturing arrangements and to provide for the marketing and distribution of product candidates that may receive regulatory approval. If adequate funds are unavailable from operations or additional sources of financing, the Company may have to delay, reduce the scope of or eliminate one or more of its research or development programs which would materially and adversely affect its business, financial condition and results of operations.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP") as defined by the Financial Accounting Standards Board ("FASB") and with the rules and regulations of the Securities and Exchange Commission ("SEC"). Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, all adjustments, consistent of normal recurring adjustments, considered necessary for a fair statement have been included. Interim results are not necessarily indicative of results that may be expected for the fiscal year ending December 31, 2025 or other interim periods. The Condensed Consolidated Balance Sheet as of December 31, 2024 has been derived from the audited consolidated financial statements at that date but does not include all of the information required by GAAP for complete financial statements.

These unaudited condensed consolidated financial statements should be read in conjunction with the consolidated financial statements for the year ended December 31, 2024. Since the date of such consolidated financial statements, there have been no significant changes to the Company's significant accounting policies, other than as described below.

Reverse Stock Split

On October 17, 2025, the Company effected a 1-for-8.5180 reverse stock split of its common stock. Accordingly, all share and per share amounts for all periods presented in the accompanying consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect the reverse stock split. There was no effect on the number of shares of common stock or preferred stock authorized for issuance under the Company's certificate of incorporation or the par value of such securities. The shares of common stock underlying outstanding stock options and other equity instruments were proportionately reduced and the respective exercise prices, if applicable, were proportionately increased in accordance with the terms of the agreements governing such securities. In addition, the conversion ratios for each series of the Company's convertible preferred stock were proportionally adjusted (Note 7).

Segments

The Company operates in one segment considering the nature of the Company's products and services, class of customers, methods used to distribute the products and the regulatory environment in which the Company operates. The Company's chief operating decision maker ("CODM"), its Chief Executive Officer, manages and allocates resources to the operations of the company on a total company basis by assessing the overall level of resources available and how to best deploy these resources across functions and research and development projects that are in line with its long-term company-wide strategic goals. In making these decisions, the CODM uses consolidated financial information for purposes of evaluating performance and forecasting future period financial results. The CODM performs this assessment based on the Company's consolidated net loss. Through this analysis, the CODM assesses performance by comparing actual net loss versus the budget, and then decides how to allocate resources to invest in the Company's research and development programs. The following is a breakdown of net loss by category for the three and nine months ended September 30, 2025 and 2024 as managed by the CODM (in thousands).

	Three Months Ended		Nine Months Ended	
	September 30, 2025	September 30, 2024	September 30, 2025	September 30, 2024
License revenue	$ 10,000	$ —	$ 13,000	$ 7,000
Operating Expenses:				
EVO756	11,189	5,550	26,048	15,234
EVO301	1,087	2,412	5,489	17,418
Other research and development	4,547	2,804	14,059	6,701
Total external research and development	$ 16,823	$ 10,766	$ 45,596	$ 39,353
Research and development personnel costs	2,816	2,523	8,043	7,060
Total research and development operating expenses	$ 19,639	$ 13,289	$ 53,639	$ 46,413
General and administrative operating expenses	2,036	1,755	5,696	4,910
General and administrative personnel costs	1,653	1,473	5,020	4,236
Total general and administrative operating expenses	$ 3,689	$ 3,228	$ 10,716	$ 9,146
Total operating expenses	$ 23,328	$ 16,517	$ 64,355	$ 55,559
Other income, net	853	601	10,758	2,477
Net Loss	$ (12,475)	$ (15,916)	$ (40,597)	$ (46,082)

Other research and development consists of discovery research, pre-clinical programs and other early-stage development programs. The measure of segment assets, all of which are held in the United States, is reported on the condensed consolidated balance sheets as total assets. Additionally, segment depreciation expense is consistent with amounts reported within the consolidated statement of cash flows.

Revenue Recognition

The Company recognizes revenue in accordance with FASB ASC 606, Revenue from Contracts with Customers ("ASC 606"), the core principle of which is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled to receive in exchange for those goods or services. To achieve this core principle, five basic criteria must be met before revenue can be recognized: (1) identify the contract with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to performance obligations in the contract; and (5) recognize revenue when or as the Company satisfies a performance obligation. The Company only applies the five-step model to contracts when it determines that it is probable it will collect the consideration to which it is entitled in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Amounts received prior to satisfying the revenue recognition criteria are recognized as deferred revenue in the Company's consolidated balance sheets. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as current portion of deferred revenue. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue, non-current portion. Since inception, the Company's only revenues have been generated through license agreements.

License Revenue

The terms of the Company's license agreements typically may include payment to the Company of one or more of the following: nonrefundable, up-front license fees, research, development and commercial milestone payments; royalties and other contingent payments due based on the activities of the counterparty. Each of these types of revenue are recorded as license revenues in the Company's consolidated statements of operations. See Note 5 for additional details regarding the Company's license arrangements.

Transaction Price Allocated to Future Performance Obligations

ASC 606 requires that the Company disclose the aggregate amount of transaction price that is allocated to performance obligations that have not yet been satisfied as of September 30, 2025. The guidance provides certain practical expedients that limit this requirement. The Company has various contracts that meet the following practical expedients provided by ASC 606:

1. The performance obligation is part of a contract that has an original expected duration of one year or less.

2. Revenue is recognized from the satisfaction of the performance obligations in the amount billable to the customer.

3. The variable consideration is allocated entirely to a wholly unsatisfied performance obligation or to a wholly unsatisfied promise to transfer a distinct good or service that forms part of a single performance obligation.

Cash, Cash Equivalents and Short-term Investments

The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. As of September 30, 2025 and December 31, 2024, cash and cash equivalents consisted of cash and money market mutual funds. The Company has invested its excess cash in U.S. government securities, and intends and has the ability to hold these investments to maturity. All of the Company's investments in U.S. government securities are classified as held to maturity and are reported as short-term or long-term based on maturity dates at time of purchase. All of the Company's short-term investments had original maturity dates of less than 12 months. The fair values of held-to-maturity securities are measured using Level 2 inputs and approximate their amortized cost.

The following tables summarize the amortized cost of the Company's short-term investments as of September 30, 2025 and December 31, 2024:

	September 30, 2025			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Short-term investments:				
Held-to-maturity securities	$ 49,244	$ —	$ —	$ 49,244
Total short-term investments	$ 49,244	$ —	$ —	$ 49,244

	December 31, 2024			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Short-term investments:				
Held-to-maturity securities	$ 55,785	$ —	$ —	$ 55,785
Total short-term investments	$ 55,785	$ —	$ —	$ 55,785

Restricted Cash

Restricted cash is defined as cash and cash equivalents that cannot be withdrawn or used for general operating activities. As of September 30, 2025 and December 31, 2024, the Company's restricted cash was $1.4 million and $0.2 million, respectively, and was associated with letters of credit issued in connection with the Company's office leases.

Convertible Preferred Stock Forward

Certain provisions of the Series C Preferred Stock Purchase Agreement ("Series C SPA") obligated the Company to sell, and the investors to purchase, additional tranches of the Series C Convertible Preferred Stock ("Series C") at a future date and specified price (the "tranche closings forward") if certain clinical performance milestones were met. The tranche closings forward represented freestanding instruments as they are legally detachable and separately exercisable and, therefore, were accounted for separately from Series C as convertible preferred stock forwards (liability or asset). The tranche closings forward were settled in June 2025. See Note 7 for additional details regarding the Company's convertible preferred stock.

Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires deferred tax assets and liabilities to be recognized for the estimated future tax consequences attributable to differences between financial statement carrying amounts and respective tax bases of existing assets and liabilities, as well as for net operating loss carryforwards and research and development credits. Valuation allowances are provided if it is more likely than not that some portion or all of the deferred tax assets will not be realized. The impact of a change in the tax laws is recorded in the period in which the law is enacted.

Net Loss Per Share

Basic net loss per common share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding, without consideration of potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of shares of common stock and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, the convertible preferred stock, common stock subject to repurchase, stock options, restricted stock units ("RSUs"), and stock appreciation rights ("SARs") are considered to be potentially dilutive securities. Basic and diluted net loss per share is presented in conformity with the two-class method required for participating securities as the convertible preferred stock is considered a participating security. The Company's participating securities do not have a contractual obligation to share in the Company's losses. As such, the net loss is attributed entirely to common stockholders. Because the Company has reported a net loss for the reporting periods presented, the diluted net loss per common share is the same as basic net loss per common share for those periods.

The following table sets forth the computation of the basic and diluted net loss per share (in thousands, except share and per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Numerator:				
Net Loss	$ (12,475)	$ (15,916)	$ (40,597)	$ (46,082)
Denominator:				
Weighted-average common shares outstanding	1,554,965	1,545,789	1,553,497	1,545,710
Less: weighted-average unvested founder shares	—	—	—	(13,373)
Less: weighted-average unvested early-exercised options	(9,955)	(24,975)	(13,254)	(30,702)
Weighted-average common shares outstanding used to compute net loss per share, basic and diluted	1,545,010	1,520,814	1,540,243	1,501,635
Net loss per share, basic and diluted	$ (8.07)	$ (10.47)	$ (26.36)	$ (30.69)

The following outstanding shares of potentially dilutive securities were excluded from the computation of diluted net loss per share attributable to common stockholders for the periods presented because including them would have been antidilutive:

	Three and Nine Months Ended	
	2025	2024
Convertible preferred stock	19,147,559	10,643,818
Stock options outstanding	1,831,170	2,658,884
Restricted stock units outstanding	437,754	—
Stock appreciation rights outstanding	444,992	—
Common stock subject to repurchase	8,804	23,088
Total	21,870,279	13,325,790

The amounts above represent common stock equivalents, where applicable.

Deferred financing costs

The Company capitalizes costs that are directly associated with in-process equity and debt financings until such financings are consummated, at which time such costs are recorded against the gross proceeds from the applicable financing. If a financing is abandoned, deferred financing costs are expensed. As of September 30, 2025, the Company has incurred $2.1 million in fees associated with the IPO, $1.1 million of which has been paid as of September 30, 2025, which are recognized as a component of prepaid expenses and other current assets on the consolidated balance sheet.

Recent Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09 "Improvements to Income Tax Disclosures" ("ASU 2023-09"), which will require incremental income tax disclosures on an annual basis for all public entities. The amendments require that public business entities disclose specific categories in the rate reconciliation and provide additional information for reconciling items meeting a quantitative threshold. The amendments also require disclosure of income taxes paid to be disaggregated by jurisdiction, and disclosure of income tax expense disaggregated by federal, state and foreign. ASU 2023-09 is effective for annual reporting beginning with the fiscal year ending December 31, 2025. The Company does not expect this to have a material impact on its consolidated financial statements.

In November 2024, the FASB issued ASU 2024-03 "Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures" ("ASU 2024-03"), which will require additional expense disclosures for all public entities. The amendments require that at each interim and annual reporting period, an entity will disclose certain disaggregated expenses included in each relevant expense caption, as well as the total amount of selling expenses and, in annual periods, an entity's definition of selling expenses. ASU 2024-03 is effective for annual reporting periods beginning with the fiscal year ending December 31, 2027, and interim periods thereafter, with early adoption permitted. The Company is currently evaluating the incremental disclosures that will be required in its future consolidated financial statements.

3. Fair Value Measurements and Fair Value of Financial Instruments

The following table sets forth the Company's consolidated financial instruments that were measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands):

	Fair Value Measurements at September 30, 2025			
	Total	Level 1	Level 2	Level 3
Assets:				
Cash Equivalents				
Money market funds	$ 26,780	$ 26,780	$ —	$ —
Total fair value of assets	$ 26,780	$ 26,780	$ —	$ —

	Fair Value Measurements at December 31, 2024			
	Total	Level 1	Level 2	Level 3
Assets:				
Cash Equivalents				
Money market funds	$ 14,227	$ 14,227	$ —	$ —
Total fair value of assets	$ 14,227	$ 14,227	$ —	$ —
Liabilities:				
Convertible preferred stock forward	$ (8,928)	$ —	$ —	$ (8,928)
Total fair value of liabilities	$ (8,928)	$ —	$ —	$ (8,928)

Items classified as Level 1 within the valuation hierarchy consist of the Company's cash equivalents held in money market funds. The Company measures these investments at fair value determined based on Level 1 observable quoted price market inputs. The Company's money market funds are included in cash and cash equivalents in the consolidated balance sheets.

Items classified as Level 2 within the valuation hierarchy consist of the Company's excess cash invested in U.S. government securities, measured at fair value based on observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities or quoted prices in markets that are not active. The Company's U.S. government securities are included in short-term investments in the consolidated balance sheets.

Items classified as Level 3 within the valuation hierarchy consist of the Company's convertible preferred stock forward (Note 7). The fair value of the convertible preferred stock forward has been estimated at the date of inception, and re-measured at the end of each reporting period until the forwards expire. The Company used a standard forward pricing valuation model to estimate the fair value of the forward contracts with the following significant assumptions:

	June 26, 2025	December 31, 2024
Fair value per share of Series C Tranche II	$ 1.59	$ 0.22
Strike price	$ 1.59453	$ 1.59453
Expected term	0.003 years	0.58 years
Discount rate	4.11%	4.32%

The following table is a roll-forward of Level 3 assets for the periods indicated (in thousands) (Note 7):

	Series C Tranche Two Forward
Balance at January 1, 2024	$ —
Issuance of convertible preferred stock forward	(8,928)
Balance at December 31, 2024	(8,928)
Change in fair value of convertible preferred stock forward	8,928
Balance at September 30, 2025	$ —

In June 2025, the Company issued 40,941,587 shares of Series C and settled the convertible preferred stock forward.

4. Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	September 30, 2025	December 31, 2024
Accrued research and development	$ 1,949	$ 2,828
Accrued compensation	2,852	3,634
Deferred financing costs	1,059	53
Other	449	214
Total	$ 6,309	$ 6,729

5. Strategic Collaborations and License Agreements

The Company has entered into several license agreements for products currently under development. The Company's license agreements are disclosed in "Note 5. Strategic Collaborations and License Agreements" of the Company's annual audited consolidated financial statements for the year ended December 31, 2024. Since the date of such consolidated financial statements, there have been no significant changes to the Company's license agreements, other than the following.

Dermira

In December 2020, the Company entered into an exclusive license agreement with Dermira, Inc., a wholly owned subsidiary of Eli Lilly and Company ("Dermira"), to develop and commercialize EVO756 and two other development programs for the treatment of various inflammatory diseases (the "Dermira License Agreement").

The Dermira License Agreement remains in effect on a product-by-product and a country-by-country basis until the expiration of the royalty term for such product in such country. The Dermira License Agreement may be terminated by either party due to the other party's uncured material breach or bankruptcy.

Milestones and royalties are contingent upon future events and will be recorded when the milestones are achieved and when payments are due. For the nine months ended September 30, 2025, the Company has recorded $2.5 million as research and development expense upon achievement of a development milestone under the Dermira License Agreement. No other milestones were achieved under the Dermira License Agreement during the nine months ended September 30, 2025 and 2024.

Maruho Co., Ltd.

Maruho Japan Agreement

As of December 31, 2024, the Company had recorded short term deferred revenue of $3.0 million, attributable to the Company's on-going performance obligations. The Company recognized $3.0 million in license revenue for the nine months ended September 30, 2025 upon the satisfaction of the performance obligation. There was no deferred revenue recorded as of any other period and no outstanding performance obligations remain under the agreement. In addition, in July 2025, the Company received payment from Maruho of $10.0 million upon the achievement of a development milestone, which is recognized as license revenue for the three and nine months ended September 30, 2025. No other milestone or royalty revenues related to this agreement have been earned as of September 30, 2025.

AprilBio

In June 2024, the Company entered into a License, Development and Commercialization Agreement with AprilBio Co., Ltd. ("AprilBio") upon which AprilBio granted the Company an exclusive worldwide license to develop and commercialize an IL-18BP compound ("EVO301"). The Company is responsible for the payments of development milestones of up to $82.5 million, sales milestones of up to $377.5 million, and tiered royalty payments in the mid-to-high single digit percentage on covered product net worldwide sales. For the nine months ended September 30, 2025, the Company has recorded $1.5 million as research and development expense upon achievement of a development milestone under the AprilBio License, Development and Commercialization Agreement. No other milestones were achieved or recorded as research and development expenses for the nine months ended September 30, 2025 or 2024.

6. Commitments and Contingencies

Leases

The Company has operating leases for office space and equipment as well as finance leases of certain lab and office equipment. The Company's lab and office equipment leases have the original lease terms of three years each. Generally, the Company's leases are non-cancellable and do not have any residual value guarantees or any restrictions or covenants imposed by leases.

In July 2025, the Company executed a sixty-three-month lease agreement to lease office space in Palo Alto, California. The lease is expected to commence in January 2026 and includes annual lease payments during each of the first three years of approximately $1.5 million, with increases of approximately 3% each year thereafter for the remainder of the lease. The Palo Alto lease includes an option to terminate the lease after thirty-nine months, subject to a one-time termination fee equal to six months of base rent. The Palo Alto lease also includes a renewal option for one additional five-year period and does not have any residual value guarantees or any restrictions or covenants. The Company is not reasonably certain to exercise either the early-termination or renewal option, and therefore neither option is included in the measurement of the related right-of-use asset and lease liability.

In August 2025, the Company executed a sixty-month lease agreement to lease office space in New York, New York. The lease commenced in October 2025 and includes annual lease payments of approximately $0.4 million. The New York lease is non-cancellable and does not include a renewal option, any residual value guarantees or any restrictions or covenants.

As of September 30, 2025, future minimum lease payments included in the measurement of lease liabilities and financing obligations were as follows (in thousands):

	Operating lease	Finance lease	Financing obligation
2025	$ 162	$ 100	$ —
2026	—	400	—
2027	—	184	—
2028 and thereafter	—	—	—
Total undiscounted lease payments	162	684	—
Less: imputed interest	(2)	(79)	—
Total lease liability	160	605	—
Less: current portion	160	344	—
Operating and finance lease liability, net of current portion	$ —	$ 261	$ —

The following table contains a summary of the lease costs recognized under ASC 842 and other information pertaining to the Company's operating leases and finance leases (in thousands):

	Nine Months Ended September 30, 2025	Nine Months Ended September 30, 2024
Operating lease:		
Short-term lease cost	$ 834	$ 667
Variable lease cost	179	225
Operating lease cost	593	563
Total operating lease costs	1,606	1,455
Finance lease:		
Amortization of right-of-use assets	$ 287	$ 124
Interest on lease liabilities	60	37
Financing obligation:		
Interest expense	7	28
Total finance lease and financing obligation cost	354	189
Total lease cost	$ 1,960	$ 1,644

For the nine months ended September 30, 2025, cash payments were $0.4 million, $0.1 million and $0.3 million for operating leases, financing obligation and finance leases, respectively. For the nine months ended September 30, 2024, cash payments were $0.6 million, $0.2 million and $0.1 million for operating leases, financing obligation and finance leases, respectively. Interest expense is recorded within other expense in the Company's unaudited condensed consolidated statements of operations. The weighted average discount rate and remaining terms are as follows:

	Nine Months Ended September 30, 2025	Nine Months Ended September 30, 2024
Weighted-average remaining lease term (in years)		
Operating leases	0.3	0.8
Finance leases	1.8	2.7
Financing obligation	-	0.9
Weighted-average discount rate		
Operating leases	8.50%	8.00%
Finance leases	10.42%	10.68%
Financing obligation	12.70%	12.70%

Research and Development Agreements

The Company enters into contracts in the normal course of business with clinical research organizations, contract manufacturing organizations and other third-party vendors for clinical trials, manufacturing, testing and other research and development activities. These contracts generally provide for termination on notice, with varying termination fees, typically up to 50%, dependent on timing of notification in advance of planned activity timelines. As of September 30, 2025 and December 31, 2024, there were no amounts accrued related to termination and cancellation charges as these are not probable.

License Agreements

The Company has entered into various license agreements (Note 5), pursuant to which the Company is required to make payments contingent upon the occurrence of specified events. The Company is required to pay development and sales milestones and royalties on sales of products developed under these agreements. Except as disclosed in Note 5, no such milestone events occurred during the nine months ended September 30, 2025 and 2024.

Guarantees and Indemnifications

The Company accrues a liability for any contingent liabilities when it is probable that future expenditures will be made and that such expenditures can be reasonably estimated. Significant judgment is required to determine both probability and the estimated amount.

Legal proceedings

The Company was not subject to any material legal proceedings during the nine months ended September 30, 2025 and 2024, and no material legal proceedings are currently pending or threatened.

7. Convertible Preferred Stock

The Company's convertible preferred stock are disclosed in the financial statements included in "Note 7. Convertible Preferred Stock" for the year ended December 31, 2024. Since the date of such consolidated financial statements, there have been no significant changes to the Company's redeemable convertible preferred stock, other than the following.

On November 7, 2025 all of the Company's then-outstanding convertible preferred stock were automatically converted into shares of common stock. The Series Seed convertible preferred stock was converted at a ratio of 1-for-8.518, the Series A convertible preferred stock was converted at a ratio of 1-for-7.9557, the Series B convertible preferred stock was converted at a ratio of 1-for-7.8721 and the Series C convertible preferred stock was converted at a ratio of 1-for-8.518.

Series C Convertible Preferred Stock Tranche Closings Forward

The Company determined that its obligation to issue and the investors' obligation to buy additional shares of Series C in the Series C Tranche Two Closing at a fixed price represent freestanding instruments and forward contracts that are accounted for at fair value at the issuance date and re-measured at each reporting date until the expiration or the settlement of the obligation (the "Series C Tranche Two Forward"). At issuance and as of December 31, 2024, the Series C Tranche Two Forward liability's fair value was estimated as $8.9 million.

On May 20, 2025, the Company completed, and the board of directors approved, the achievement of the Series C milestone event and as a result, on June 27, 2025, the Company sold 40,941,587 shares of Series C redeemable convertible preferred stock at the original issuance price of $1.59453 when the total fair value of the Series C Tranche Two Forward was $0.0 million. The Company issued 40,941,587 shares of Series C and settled the related forward contracts in June 2025, and recognized a gain of $8.9 million for the nine months ended September 30, 2025. The Company received aggregate gross proceeds of $65.3 million as part of the Series C Tranche Two Closing.

The authorized, issued, and outstanding shares of the Company's convertible preferred stock and liquidation values as of September 30, 2025 and December 31, 2024 were as follows (in thousands, except for share amounts):

	As of September 30, 2025			
	Authorized Shares	Outstanding Shares	Liquidation Preference	Carrying Value
Series Seed	12,858,517	12,858,517	$ 12,462	$ 14,240
Series A	43,614,102	43,614,102	87,640	79,056
Series B	28,750,000	28,750,000	60,009	57,578
Series C	72,435,110	72,435,110	115,500	106,130
Total	157,657,729	157,657,729	$ 275,611	$ 257,004

	As of December 31, 2024			
	Authorized Shares	Outstanding Shares	Liquidation Preference	Carrying Value
Series Seed	12,858,517	12,858,517	$ 12,462	$ 14,240
Series A	43,614,102	43,614,102	87,640	79,056
Series B	28,750,000	28,750,000	60,009	57,578
Series C	72,435,110	31,493,523	50,217	40,902
Total	157,657,729	116,716,142	$ 210,328	$ 191,776

The significant rights and obligations of the Company's Series Seed Preferred Stock, Series A Preferred Stock, Series B Preferred Stock and Series C Preferred Stock (collectively "Convertible Preferred Stock") are disclosed in the Company's annual consolidated financial statements for the year ended December 31, 2024.

8. Common Stock

As of September 30, 2025, the Company is authorized to issue 223,593,879 shares of $0.0001 par value common stock. Each share of common stock is entitled to one vote. The holders of common stock are also entitled to receive dividends whenever funds are legally available and when declared by the board of directors, subject to prior rights of the preferred stockholders.

The Company had reserved common stock for future issuance as follows:

	September 30, 2025	December 31, 2024
Series Seed	1,509,545	1,509,545
Series A	5,482,142	5,482,142
Series B	3,652,131	3,652,131
Series C	8,503,741	3,697,272
Outstanding options under 2020 Stock Plan	3,737,440	3,715,207
Outstanding restricted stock units under 2020 Stock Plan	437,754	437,754
Options available for grants under the 2020 Stock Plan	121,686	147,462
Total	23,444,439	18,641,513

9. Stock Option Plan

Stock Options

In May 2020, the board of directors adopted the Evommune, Inc. 2020 Stock Plan (the "2020 Plan") under which officers, employees, outside directors and consultants may be eligible for the grant of equity awards. The 2020 Plan provides for the direct award or sale of shares, the grant of Incentive Stock Options ("ISO") and Nonstatutory Stock Options ("NSO") options to purchase shares and the grant of RSUs to acquire shares. The board of directors has authorized an aggregate number of 4,459,715 shares of the Company's common stock to be issued under the 2020 Plan. Options under the 2020 Plan may be granted for periods of up to 10 years at exercise prices no less than 100% of the fair market value of the Company's common stock on the date of grant with the exception of ISOs granted to a 10% holder which is no less than 110% of the fair market value of common stock on the date of grant. As of September 30, 2025, the Company had 121,686 shares available for issuance under the 2020 Plan.

The following table summarizes the Company's stock option activity from January 1, 2025 to September 30, 2025:

	Stock Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at January 1, 2025	3,715,207	$ 3.08	8.5	$ 585
Options granted	40,502	4.78		
Options exercised	(3,546)	1.71		5
Options cancelled or forfeited	(14,723)	3.84		
Outstanding at September 30, 2025	3,737,440	3.07	7.8	6,908
Exercisable at September 30, 2025	1,831,170	3.16	7.1	3,291
Vested and expected to vest at September 30, 2025	3,746,350	$ 3.07	7.8	$ 6,924

The weighted-average grant-date fair value of options granted during the nine months ended September 30, 2025 and 2024 was $3.58 and $1.37 per option, respectively. The aggregate intrinsic value of options exercised for both the nine months ended September 30, 2025 and 2024 was less than $0.1 million. Intrinsic values are calculated as the difference between the exercise price of the underlying options and the fair value of the common stock for the options that had exercise prices that were lower than the fair value per share of the common stock, multiplied by the related in the money options that would have been received by the option holders had they exercised their options at the end of the period.

As of September 30, 2025, the total unrecognized stock-based compensation expense for stock options was $4.0 million, which is expected to be recognized over a weighted-average period of 2.5 years. The total fair value of options vested for the nine months ended September 30, 2025 and 2024 was $1.3 million and $1.6 million, respectively.

The fair value of the stock options granted was estimated using the following assumptions:

	Nine Months Ended September 30,	
	2025	2024
Expected term	6.0 - 6.1 years	5.8 - 6.1 years
Expected volatility	87.65% - 89.12%	99.94% - 101.80%
Risk-free interest rate	3.68% - 4.07%	4.03% - 4.63%
Fair value of common stock	$2.30 - $3.75	$1.37
Dividend yield	0%	0%

Restricted Stock Units

In December 2024, certain employees were granted a total of 437,754 RSUs. The terms of the RSUs are disclosed in the Company's annual consolidated financial statements for the year ended December 31, 2024.

A summary of restricted stock activity during the nine months ended September 30, 2025, is as follows:

	Number of Units Outstanding	Grant Date Fair Value per Share
Unvested balance at January 1, 2025	437,754	$ 2.99
Granted	—	—
Vested	—	—
Unvested balance at September 30, 2025	437,754	$ 2.99

As of September 30, 2025, the total unrecognized stock-based compensation expense for unvested restricted stock was $1.3 million, which is expected to be recognized over a weighted-average period of 3.2 years. Prior to the completion of the Company's IPO on November 7, 2025, the performance condition associated with the RSUs was not considered probable, and accordingly, no stock compensation expense was recognized for the three and nine months ended September 30, 2025 and 2024. Upon completion of the IPO, the performance condition was met, and the Company began recognizing stock-based compensation expense for the RSUs over the remaining time-based vesting period.

Stock Appreciation Right

In December 2024, an employee was granted 444,992 SARs with a base price of $2.99 per unit. The terms of the SAR are disclosed in the Company' consolidated financial statements for the year ended December 31, 2024. Prior to the completion of the Company's IPO on November 7, 2025, the performance condition associated with the SARs was not considered probable, and accordingly, no stock-based compensation expense was recognized for the three and nine months ended September 30, 2025 and 2024. Upon completion of the IPO, the performance condition was met, and the Company began recognizing stock-based compensation expense for the SARs over the remaining measurement period, regardless of whether the market condition is met and the award does not begin to vest.

A summary of stock appreciation right activity during the nine months ended September 30, 2025 is as follows:

	Number of Units Outstanding	Grant Date Fair Value per Share
Unvested balance at January 1, 2025	444,992	$ 2.99
Granted	—	—
Vested	—	—
Unvested balance at September 30, 2025	444,992	$ 2.99

Stock-Based Compensation Expense

Stock compensation expense recorded for the three and nine months ended September 30, 2025 and 2024, consisted of expense for stock options. No stock compensation expense was recorded for RSUs or SARs for the three and nine months ended September 30, 2025 and 2024. The following table is a summary of stock compensation expense by function recognized for the periods indicated (in thousands):

	Three Months Ended September 30, 2025	Three Months Ended September 30, 2024	Nine Months Ended September 30, 2025	Nine Months Ended September 30, 2024
General Administrative	$ 341	$ 240	$ 1,015	$ 722
Research and development	220	161	645	506
	$ 561	$ 401	$ 1,660	$ 1,228

10. Income Taxes

The Company's interim income tax provision consists of U.S. federal and state income taxes based on the estimated annual effective tax rate that the Company expects for the full year together with the tax effect of discrete items. Each quarter the Company updates its estimate of the annual effective tax rate and records cumulative adjustments as necessary. As of September 30, 2025, and December 31, 2024, the Company was in a pre-tax loss position and is anticipated to remain so throughout the year. For the three and nine months ended September 30, 2025 and 2024, the Company did not record any tax benefit or expense. On July 4, 2025, the United States enacted tax legislation through the One Big Beautiful Bill Act ("OBBBA"). The Company is in the process of assessing the impact of this legislation on its financial statements. The current expectation is that OBBBA will not have a material impact on the Company's estimated annual effective tax rate in 2025 but will impact the split between current taxes payable and deferred taxes.

In assessing the realizability of deferred tax assets, management evaluates whether it is more likely than not that some portion or all of the deferred tax assets will be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income in those periods in which temporary differences become deductible and/or net operating losses can be utilized. Management assesses all positive and negative evidence when determining the amount of the net deferred tax assets that are more likely than not to be realized. This evidence includes, but is not limited to, prior earnings history, scheduled reversal of taxable temporary differences, tax planning strategies and projected future taxable income. Significant weight is given to positive and negative evidence that is objectively verifiable. Based on these factors, including cumulative losses in recent years, the Company continues to maintain a full valuation allowance against its net deferred tax assets as of September 30, 2025 and December 31, 2024.

11. Subsequent Events

Initial Public Offering

On November 7, 2025, the Company closed its IPO in which the Company sold 10,781,250 shares of its common stock at a public offering price of $16.00 per share, including 1,406,250 shares issued upon the exercise in full of the underwriters' over-allotment option to purchase additional shares. The Company received gross proceeds of $172.5 million. Net proceeds were $160.4 million, after deducting underwriting discounts and commissions. In addition, immediately prior to the closing of the IPO, all of the Company's then-outstanding convertible preferred stock were automatically converted into an aggregate of 19,147,559 shares of common stock.

On November 7, 2025 the Company filed an amended and restated certificate of incorporation, pursuant to which it increased the number of shares of common stock that the Company is authorized to issue to an aggregate of 500,000,000 and reduced the number of shares of preferred stock that the Company is authorized to issue to an aggregate of 10,000,000.

In October 2025, the Company's board of directors adopted the 2025 Equity Incentive Plan (the "2025 Plan") and the 2025 Employee Stock Purchase Plan (the "2025 ESPP"), which both became effective in connection with the IPO. The 2025 Plan provides for the grant of incentive stock options, nonstatutory stock options, SARs, RSU awards, performance awards, and other forms of awards to employees, non-employee directors and consultants. A total of 3,128,684 shares of the Company's common stock have been reserved for future issuance under the 2025 Plan in addition to shares underlying outstanding equity awards granted under the 2020 Stock Plan that expire, or are forfeited, cancelled, or reacquired, and any automatic increases in the number of shares of common stock reserved for future issuance under this plan. The 2025 ESPP reserves a total of 300,000 shares for future issuance of common stock pursuant to purchase rights granted to employees, in addition to any automatic increases in the number of shares of common stock reserved for future issuance under this plan.

In connection with the IPO, the Company granted options to purchase 1,780,638 shares of common stock to certain of our officers at an exercise price equal to the initial public offering price per share of $16.00 and a four-year vesting period. The Company also granted options to purchase 113,880 shares of common stock to certain of our directors at an exercise price equal to the initial public offering price per share of $16.00 and a three-year vesting period. The aggregate grant-date fair value of these awards was approximately $22.2 million, which the Company will recognize over the vesting periods.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited condensed financial statements and related notes appearing in this Quarterly Report on Form 10-Q and our audited financial statements and related notes included in our final prospectus for our initial public offering ("IPO") dated November 5, 2025, and filed with the Securities and Exchange Commission ("SEC") pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended (the "Securities Act") on November 6, 2025 (the "Prospectus"). This discussion and other parts of this Quarterly Report contain forward-looking statements based upon current beliefs, plans, and expectations related to future events and our future financial performance that involve risks, uncertainties and assumptions, such as statements of our plans, objectives, expectations, intentions, forecasts and projections. Our actual results and the timing of selected events could differ materially from those discussed in these forward-looking statements as a result of several factors including, but not limited to, those set forth under the section titled "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q. Our historical results are not necessarily indicative of the results that may be expected for any period in the future, and you should carefully read the section titled "Risk Factors" to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section titled "Special Note Regarding Forward-Looking Statements." 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 on Form 10-Q.

Overview

Evommune is a clinical-stage biotechnology company developing innovative therapies that target key drivers of chronic inflammatory diseases, with initial clinical development programs focusing on chronic spontaneous urticaria ("CSU"), atopic dermatitis ("AD") and ulcerative colitis ("UC"). Chronic inflammation is a significant healthcare problem in the world, substantially impacting patients' quality of life and leading to life-threatening conditions.

Our mission is to improve patients' daily lives and prevent the long-term effects of uncontrolled inflammation that are a consequence of the limitations of existing therapies. To achieve this, we are advancing a portfolio of differentiated product candidates that target key drivers of chronic inflammation.

Among our portfolio of programs, we currently have two product candidates, EVO756 and EVO301, in Phase 2 trials. We are initially developing EVO756 for the treatment of CSU and AD, and EVO301 for the treatment of AD and UC. We see broad expansion potential for both programs across additional chronic inflammatory diseases. We also intend to advance additional preclinical programs into clinical development.

We were incorporated under the laws of the State of Delaware in April 2020 under the name "Evommune, Inc." We have two wholly owned subsidiaries: Evommune Research, LLC and Evommune Biologics, LLC.

We have incurred significant operating losses in each year since our inception. As of September 30, 2025, we had an accumulated deficit of $192.8 million. We expect to continue to incur net losses for the foreseeable future, and we expect our research and development expenses, general and administrative expenses and capital expenditures will continue to increase. In particular, we expect our expenses to increase as we continue our development of, and seek regulatory approvals for, our product candidates, as well as hire additional personnel, pay fees to outside consultants, lawyers and accountants, and incur other increased costs associated with being a public company. In addition, if and when we seek and obtain regulatory approval to commercialize any product candidate, we will also incur increased expenses in connection with commercialization and marketing of any such product. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and our expenditures on other research and development activities.

We expect to continue to incur significant and increasing net operating losses for the next several years as we:

- continue the research and development of our clinical- and preclinical-stage product candidates and discovery-stage programs, including the continued development of our most advanced product candidates, EVO756 and EVO301;
- increase the amount of research and development activities to identify and develop product candidates;
- make milestone, royalty or other payments under in-license or collaboration agreements;
- maintain, expand and protect our intellectual property portfolio;

•expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development, manufacturing and commercialization efforts;

•establish sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval and intend to commercialize on our own or jointly with third parties;

•address any competing therapies and market developments;

•incur additional costs associated with operating as a public company;

•invest in or in-license other technologies; and

•experience any delays or encounter any issues with any of the above, including but not limited to failed studies or trials, complex results, manufacturing challenges, safety issues or other regulatory challenges.

As a result, we will require substantial additional funding to further develop our product candidates and support our continuing operations. To date, we have not had any products approved for sale and, therefore, have not generated any approved product-related revenue. We do not expect to generate any revenues from product sales unless and until we successfully complete development and obtain regulatory approval for one or more of our product candidates, which will not be for at least the next several years, if ever. If we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. As a result, until such time, if ever, that we can generate substantial product revenue, we expect to finance our cash requirements through equity offerings, debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed or on commercially acceptable terms, if at all. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies, including our research and development activities. If we are unable to raise capital, we will need to delay, reduce or terminate planned activities to reduce costs.

Strategic Collaborations and License Agreements

Dermira, Inc.

In December 2020, we entered into a License, Development and Commercialization Agreement with Dermira (the Dermira License Agreement") pursuant to which Dermira granted us an exclusive, worldwide license to develop and commercialize certain compounds, including the compound in development by us known as EVO756.

The Dermira License Agreement remains in effect on a product-by-product and a country-by-country basis until the expiration of the royalty term for such product in such country. The Dermira License Agreement may be terminated by either party due to the other party's uncured material breach or bankruptcy. Additionally, we may terminate the Dermira License Agreement for convenience upon a set number of days' prior notice.

In consideration for the licenses granted to us under the Dermira License Agreement, we paid to Dermira a $7.5 million upfront license fee. Additionally, in connection with our entry into the Dermira License Agreement, we issued to Dermira 3,227,805 shares of Series A Preferred Stock which was equal to approximately 5% of our fully diluted equity at the time of grant and was calculated by reference to the same per-share purchase price paid by the lead investor in the Series A Preferred Stock financing (as a completed qualified financing).

We are also obligated to pay to Dermira up to $45.0 million in development milestones for the development of EVO756 (or up to $135.0 million for the development of all licensed products), and up to $240.0 million in sales milestones for the development of EVO756 (or up to $720.0 million for the development of all licensed products) as well as tiered royalty payments in mid-single digit to low-tens percentages on worldwide sales of the licensed products.

As of September 30, 2025, we have paid a total of $11.0 million in upfront payments and development milestones under the Dermira License Agreement, which was recognized as research and development expense for the year in which they occurred. No milestones were achieved under the Dermira License Agreement during the year ended December 31, 2024. For the nine months ended September 30, 2025, we recorded $2.5 million as research and development expense upon achievement of a development milestone under the Dermira License Agreement. Milestones and royalties are contingent upon future events and will be recorded when the milestones are achieved and when payments are due.

Under the Dermira License Agreement, we may sublicense EVO756 to third parties. Dermira has consented to our sublicense of EVO756 to Maruho in Japan and certain Asian countries as described below.

Maruho Co., Ltd.

Maruho Japan Agreement

In September 2023, we entered into a strategic collaboration with Maruho and granted Maruho an exclusive license to develop and commercialize EVO756 in Japan (the "Maruho Japan Agreement"). Under the Maruho Japan Agreement, we are eligible to receive up to $60.0 million in upfront and customary milestone payments and royalty payments on future sales of EVO756 in Japan.

Maruho Greater Asia Agreement

In March 2024, we entered into a second strategic collaboration with Maruho (the "Maruho Greater Asia Agreement") and granted Maruho the exclusive license to develop and commercialize EVO756 in Greater China and certain other Asian countries. Under the Maruho Greater Asia Agreement, we are eligible to receive up to $62.0 million in upfront and customary milestone payments.

AprilBio Co., Ltd.

In June 2024, we entered into a license agreement with AprilBio (the "AprilBio License Agreement") under which AprilBio granted us an exclusive worldwide license to develop and commercialize EVO301. Under the AprilBio License Agreement, we paid an upfront payment of $15.0 million and may be required to pay milestone payments up to $460.0 million upon achievement of future milestones and royalties on future sales of EVO301. For the nine months ended September 30, 2025, we recorded $1.5 million as research and development expense upon achievement of a development milestone under the AprilBio License Agreement. No development milestones were recorded as research and development expenses for the nine months ended September 30, 2024. No other development or sales milestones have been achieved as of September 30, 2025.

Results of Operations

Three and nine months ended September 30, 2025 and 2024

The following sets forth our results of operations:

	Three Months Ended		Nine Months Ended	
	September 30, 2025	September 30, 2024	September 30, 2025	September 30, 2024
Revenue	$ 10,000	$ -	$ 13,000	$ 7,000
Operating expenses:				
Research and development	19,639	13,289	53,639	46,413
General and administrative	3,689	3,228	10,716	9,146
Total operating expenses	23,328	16,517	64,355	55,559
Loss from operations	(13,328)	(16,517)	(51,355)	(48,559)
Other income, net	853	601	10,758	2,477
Net loss	$ (12,475)	$ (15,916)	$ (40,597)	$ (46,082)

Revenue

For the nine months ended September 30, 2025 and 2024, we recognized $13.0 million and $7.0 million, respectively, in revenue through our license agreements. The increase was due to higher license revenue recognized under the Maruho Japan Agreement in 2025. License revenue of $3.0 million was recognized upon the satisfaction of the performance obligation and $10.0 million was recognized upon completion of development milestones under the Maruho Japan Agreement for the nine months ended September 30, 2025, compared to $7.0 million recognized under the Maruho Greater Asia Agreement for the nine months ended September 30, 2024.

For the three months ended September 30, 2025 and 2024, we recognized $10.0 million and $0.0 million, respectively, in revenue through our license agreements. The increase was due to higher license revenue recognized under the Maruho Japan Agreement in 2025. License revenue of $10.0 million was recognized upon completion of development milestones under the Maruho Japan Agreement for the three months ended September 30, 2025, compared to no development milestones achieved during the three months ended September 30, 2024.

Operating Expenses

Research and Development

The following table summarizes our research and development expenses for each of the periods indicated:

	Three Months Ended		Nine Months Ended	
	September 30, 2025	September 30, 2024	September 30, 2025	September 30, 2024
EVO756	$ 11,189	$ 5,550	$ 26,048	$ 15,234
EVO301	1,087	2,412	5,489	17,418
Discovery research	4,547	2,804	14,059	6,701
Personnel costs	2,816	2,523	8,043	7,060
Total research and development expenses	$ 19,639	$ 13,289	$ 53,639	$ 46,413

Research and development expenses were $53.6 million and $46.4 million for the nine months ended September 30, 2025 and 2024, respectively. The increase was primarily attributable to an increase in clinical trial expenses for EVO756 and additional preclinical research expenses for undisclosed discovery programs, which is classified as discovery research expense in the table above, partially offset by a decrease for EVO301, primarily related to our in-licensing which included an upfront license fee payment of $15.0 million, which was expensed as incurred in 2024.

Research and development expenses were $19.6 million and $13.3 million for the three months ended September 30, 2025 and 2024, respectively. The increase was primarily attributable to an increase in clinical trial expenses for EVO756 and additional preclinical research expenses for undisclosed discovery programs, which is classified as discovery research expense in the table above, partially offset by a decrease for EVO301.

General and Administrative

The following table summarizes our general and administrative expenses for each of the periods indicated:

	Three Months Ended		Nine Months Ended	
	September 30, 2025	September 30, 2024	September 30, 2025	September 30, 2024
Personnel costs	$ 1,653	$ 1,473	$ 5,020	$ 4,236
Stock-based compensation	341	240	1,015	722
Professional fees	728	604	1,905	1,767
Other general and administrative expenses	967	911	2,776	2,421
Total general and administrative expenses	$ 3,689	$ 3,228	$ 10,716	$ 9,146

General and administrative expenses were $10.7 million and $9.1 million for the nine months ended September 30, 2025 and 2024, respectively. The increase was primarily due to an increase in personnel costs due to increased headcount.

General and administrative expenses were $3.7 million and $3.2 million for the three months ended September 30, 2025 and 2024, respectively. The increase was primarily due to an increase in personnel costs and stock-based compensation due to increased headcount.

Other income, net

Other income, net was $10.8 million and $2.5 million for the nine months ended September 30, 2025 and 2024, respectively. The increase was primarily due to a decrease in the fair value of convertible preferred stock forward of $8.9 million upon settlement of the stock forward in June 2025, offset by a decrease in interest income of $0.6 million.

Other income, net was $0.9 million and $0.6 million for the three months ended September 30, 2025 and 2024, respectively. The increase was primarily due to an increase in interest income of $0.2 million.

Liquidity and Capital Resources

Sources of Liquidity

Our operations to date have been financed primarily by aggregate net proceeds from the issuance of convertible preferred stock and common stock. As of September 30, 2025, we maintained $76.1 million in cash, cash equivalents and short-term investments. In November 2025, we completed our IPO, pursuant to which we issued and sold an aggregate of 10,781,250 shares of common stock at a price to the public of $16.00 per share, including 1,406,250 shares issued upon the exercise in full of the underwriters' over-allotment option to purchase additional shares. We received aggregate net proceeds of $160.4 million after deducting underwriting discounts and commissions of $12.1 million. We expect that our cash, cash equivalents, and short-term investments as of September 30, 2025 together with the net proceeds from the IPO, will enable us to fund our operating expenses and capital expenditures requirements into the second half of 2028, based on our current business plan.

Cash Flows

The following table summarizes our cash flows for the periods indicated:

	Nine Months Ended	
	September 30, 2025	September 30, 2024
Net cash used in operating activities	$ (59,742)	$ (39,683)
Net cash provided by investing activities	7,594	29,087
Net cash provided by (used in) financing activities	63,915	(282)
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 11,767	$ (10,878)

Operating Activities

Cash used in operating activities of $59.7 million during the nine months ended September 30, 2025 was attributable to our net loss of $40.6 million, a net decrease of $11.7 million in our working capital, and non-cash income upon settlement of preferred stock forward of $8.9 million, partially offset by non-cash items, including stock-based compensation, accretion of discount on short-term investments and depreciation and amortization expense totaling $1.5 million.

Cash used in operating activities of $39.7 million during the nine months ended September 30, 2024 was attributable to our net loss of $46.1 million, partially offset by non-cash items, including stock-based compensation, accretion of discount on short-term investments and depreciation and amortization expense totaling $0.8 million, and a net increase of $5.6 million in our working capital.

Investing Activities

Cash provided by investing activities in the nine months ended September 30, 2025 comprised maturities of short-term investments of $46.5 million, partially offset by purchases of short-term investments of $38.8 million and property and equipment of $0.1 million.

Cash provided by investing activities in the nine months ended September 30, 2024 comprised maturities of short-term investments of $74.9 million, partially offset by purchases of short-term investments of $45.7 million and property and equipment of $0.1 million.

Financing Activities

Cash provided by financing activities for the nine months ended September 30, 2025 was $63.9 million, which comprised net proceeds from the sale and issuance of our Series C Preferred Stock, in June 2025 of $65.2 million, partially offset by payments of deferred offering costs of $0.9 million and principal payments on finance leases and financing obligations of $0.4 million.

Cash used in financing activities for the nine months ended September 30, 2024 was $0.3 million, which comprised principal payments on finance leases and financing obligations of $0.3 million.

Future Funding Requirements

Our primary uses of capital are, and we expect will continue to be, compensation and related expenses; costs related to third-party clinical research, manufacturing and development services; costs relating to the build-out of our headquarters and other offices, our laboratories and our manufacturing facility; license payments or milestone obligations that may arise; laboratory expenses and costs for related supplies; clinical costs; manufacturing costs; legal and other regulatory expenses and general overhead costs. We expect that our research and development expenses, general and administrative expenses and capital expenditures will continue to increase. Any product candidates we may develop may never achieve commercialization and we anticipate that we will continue to incur losses for the foreseeable future.

We will continue to require additional financing to advance our current product candidates through clinical development, to develop, acquire or in-license other potential product candidates and to fund operations for the foreseeable future. We will continue to seek funds, which may be through equity offerings, debt financings or other capital sources, including potential collaborations, out-licenses or dispositions and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. If we do raise additional capital through offerings of equity or equity-linked securities, the ownership interest of our existing stockholders may be diluted, and the terms of these securities may include liquidation or other preferences that may adversely affect our stockholders' rights. Debt and equity financings, 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 or declaring dividends. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies. If we are unable to raise capital, we will need to delay, reduce or terminate planned activities to reduce costs.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the progress, timing and completion of preclinical studies and clinical trials for our current or any future product candidates, as well as the associated costs, including any unforeseen costs we may incur as a result of preclinical study or clinical trial delays due to disease outbreaks, epidemics and pandemics or other causes;
- the timing and amount of milestone and royalty payments we are required to make or are eligible to receive under our license agreements with Dermira, Maruho, AprilBio and any future license or collaboration agreements;
- the number and characteristics of potential new product candidates we identify and decide to develop;
- the need for additional or expanded preclinical studies and clinical trials beyond those that we plan to conduct with respect to our current and future product candidates;
- the cost involved in growing the organization to the size needed to allow for the research, development and potential commercialization of our current or any future product candidates;
- the costs involved in filing patent applications, maintaining and enforcing patents or defending against infringement or other claims raised by third parties;
- the maintenance of our existing license and collaboration agreements and the entry into new license and collaboration agreements;
- the time and costs involved in obtaining regulatory approval for our product candidates and any delays we may encounter as a result of evolving regulatory requirements or adverse results with respect to any of our product candidates;
- the effect of competing technological and market developments;
- the cost and timing of completion of commercial-scale outsourced manufacturing activities;
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own;
- the cost associated with manufacturing and supply of our product candidates;
- the cost associated with operating as a public company;
- the amount of revenues, if any, we may derive either directly or in the form of royalty payments from future sales of our product candidates, if approved; and
- market acceptance of any approved product candidates.

A change in the outcome of any of these factors could mean a significant change in the costs and timing associated with the development of our current and future preclinical and clinical product candidates. Further, our operating plans may change, and we may need additional funds to meet operational needs and capital requirements for clinical trials and other research and development activities.

Contractual Obligations and Commitments

In July 2025 we executed a 63-month lease agreement to lease approximately 32,016 square feet of office space in Palo Alto, California. The lease is expected to commence in January 2026 and includes annual lease payments during each of the first three years of approximately $1.5 million, with increases of approximately 3% each year thereafter for the remainder of the lease. In August 2025, we executed a sixty-month lease agreement to lease approximately 4,686 square feet of office space in New York, New York. The lease commenced in October 2025 and includes annual lease payments of approximately $0.4 million.

We enter into contracts in the normal course of business with third-party service providers for clinical trials, preclinical research studies and testing, manufacturing and other services and products for operating purposes. We may also enter into additional research, manufacturing, supplier and other agreements in the future, which may require up-front payments and even long-term commitments of cash.

Critical Accounting Estimates

This 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") in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our financial statements. In accordance with GAAP, we evaluate our estimates and judgments on an ongoing basis, including those related to accrued research and development expenses, preferred stock warrant liabilities, and stock-based compensation. We base our estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

There have been no material changes to our critical accounting estimates from those described under in "Management's Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Estimates" included in the Prospectus.

Recently Adopted Accounting Pronouncements

Refer to Note 2, "Summary of Significant Accounting Policies," of the notes to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for a summary of recently issued and adopted accounting pronouncements.

Emerging Growth Company and Smaller Reporting Company Status

As an "emerging growth company" under the JOBS Act, we may delay the adoption of certain accounting standards until such time as those standards apply to private companies. Other exemptions and reduced reporting requirements under the JOBS Act for emerging growth companies include presentation of only two years of audited consolidated financial statements in a registration statement for an IPO, an exemption from the requirement to provide an auditor's report on internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act, an exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation and less extensive disclosure about our executive compensation arrangements.

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 provision allows an emerging growth company to delay the adoption of some accounting standards until those standards would otherwise apply to private companies. We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our consolidated financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

We may remain classified as an emerging growth company until the end of the fiscal year following the fifth anniversary of our IPO or such earlier time that we are no longer an emerging growth company. If the market value of our common stock that is held

by non-affiliates exceeds $700.0 million as of June 30 of any year, or if we have annual gross revenues of $1.235 billion or more in any fiscal year, we would cease to be an emerging growth company as of December 31 of the applicable year. We also would cease to be an emerging growth company if we issue more than $1.0 billion of non-convertible debt over a three-year period.
We are also a smaller reporting company as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures until the fiscal year following the determination that (i) our voting and non-voting common stock held by non-affiliates is at least $250.0 million measured on the last business day of our second fiscal quarter or (ii) our annual revenue is at least $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is at least $700.0 million measured on the last business day of our second fiscal quarter.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as defined in Rule 13a-15(e) and Rule 15d-15(e) under the Exchange Act that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2025. Based on the evaluation of our disclosure controls and procedures as of September 30, 2025, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no other changes to our internal control over financial reporting that occurred during the quarter ended September 30, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. We do not have any pending litigation that, separately or in the aggregate, would, in the opinion of management, have a material adverse effect on our results of operations, financial condition, or cash flows.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. Before deciding to invest in shares of our common stock, you 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, including our consolidated financial statements and their related notes included elsewhere herein and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations." If any of the following risks actually occurs, 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 also may materially and adversely affect our business, prospects, operating results and financial condition.

Risks Related to Our Limited Operating History, Financial Position and Capital Requirements

We have a limited operating history and no products approved for commercial sale, which may make it difficult to evaluate our current business and predict our future success and viability. We have incurred net losses in every year since our inception. We expect to continue to incur net losses in the future.

We are a clinical-stage biotechnology company with a limited operating history. Since our inception in 2020, we have invested most of our resources in developing our product candidates, building our intellectual property portfolio, conducting business planning, organizing and staffing our company, raising capital, conducting preclinical studies and, more recently, clinical trials and providing general and administrative support for these operations. Biopharmaceutical product development is a highly speculative undertaking, involving substantial upfront capital expenditure and significant risk. Any product candidate may fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval or become commercially viable, despite substantial investment on development or commercialization. To date, Evommune has not yet demonstrated its ability to successfully obtain regulatory approvals, manufacture a product on a commercial scale, or arrange for a third party to do so on its behalf, or conduct sales and marketing activities necessary for successful commercialization. Consequently, predictions about our future success or viability may not be as accurate as they could be if Evommune had a longer operating history or a history of successfully developing and commercializing biopharmaceutical products. We continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in each year since our inception. For the nine months ended September 30, 2025, we had a net loss of $40.6 million. As of September 30, 2025, we had an accumulated deficit of $192.8 million. We expect to continue to incur significant losses for the foreseeable future and expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our two clinical-stage product candidates, EVO756 and EVO301, along with any future product candidates we may develop.

We anticipate that our expenses will increase substantially if, and as, we:

- continue the research and development of our clinical- and preclinical-stage product candidates and discovery-stage programs, including the continued development of our most advanced product candidates, EVO756 and EVO301;
- increase the amount of research and development activities to identify and develop product candidates to advance into clinical trial development;
- make milestone, royalty or other payments under in-license or collaboration agreements;
- maintain, expand and protect our intellectual property portfolio;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development, manufacturing and commercialization efforts;
- establish sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval and intend to commercialize on our own or jointly with third parties;
- address any competing therapies and market developments;

- incur additional costs associated with operating as a public company;
- acquire or in-license other technologies; and
- experience any delays or encounter any issues with any of the above, including but not limited to failed studies or trials, complex results, manufacturing challenges, safety issues or other regulatory challenges.

To become and remain profitable, we and any potential future collaborators must develop and eventually commercialize products with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials, manufacturing our product candidates, either on our own or with contract development and manufacturing organizations ("CDMOs"), obtaining marketing approval for product candidates, marketing and selling any products for which we may obtain marketing approval and satisfying any post-marketing requirements. We may never succeed in any or all of these activities and, even if we do, we may never generate revenue that is significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability. Our failure to become and remain profitable would decrease the value of the company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations.

Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. Our future results of operations will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue.

We will need substantial additional funding in order to maintain our operations and advance the development and commercialization of our product candidates. Failure to obtain this necessary capital when needed, or on acceptable terms, may force us to delay, reduce or eliminate certain of our product development or research operations.

The development of biopharmaceutical product candidates, including conducting preclinical studies and clinical trials, is a time-consuming, capital-intensive and uncertain process. Our operations have consumed substantial amounts of cash since inception. To date, we have funded our operations primarily with proceeds from the sale of our convertible preferred stock. We expect our expenses to increase in connection with our ongoing activities, particularly as we advance our Phase 2 trials of EVO756 and EVO301, and continue to research, develop and initiate clinical trials of any other future product candidates. In addition, if we successfully develop and obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. 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 could be forced to delay, reduce or eliminate our product development programs or any future commercialization efforts.

As of September 30, 2025, we had cash, cash equivalents and short-term investments of approximately $76.1 million. Based on current operating assumptions, we expect that our existing cash, cash equivalents and short-term investments will enable us to fund our operating expenses and capital expenditure requirements into the second half of 2028. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect.

Future capital requirements for EVO756 and EVO301 or any of our other product development programs will depend on many factors, including:

- the progress, timing and completion of preclinical studies and clinical trials for our current or any future product candidates, as well as the associated costs, including any unforeseen costs we may incur as a result of preclinical study or clinical trial delays due to disease outbreaks, epidemics and pandemics or other causes;
- the timing and amount of milestone and royalty payments we are required to make or are eligible to receive under our license agreements with Dermira, Inc. ("Dermira"), Maruho Co., Ltd. ("Maruho"), AprilBio Co. Ltd. ("AprilBio") and any future license or collaboration agreements;
- the number and characteristics of potential new product candidates we identify and decide to develop;
- the need for additional or expanded preclinical studies and clinical trials beyond those that we plan to conduct with respect to our current and future product candidates;
- the cost involved in growing the organization to the size needed to allow for the research, development and potential commercialization of our current or any future product candidates;
- the costs involved in filing patent applications, maintaining and enforcing patents or defending against infringement or other claims raised by third parties;

- the maintenance of our existing license and collaboration agreements and the entry into new license and collaboration agreements;
- the time and costs involved in obtaining regulatory approval for our product candidates and any delays we may encounter as a result of evolving regulatory requirements or adverse results with respect to any of our product candidates;
- the effect of competing technological and market developments;
- the cost and timing of completion of commercial-scale outsourced manufacturing activities;
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own;
- the cost associated with manufacturing and supply of our product candidates;
- the cost associated with operating as a public company;
- the amount of revenues, if any, we may derive either directly or in the form of royalty payments from future sales of our product candidates, if approved; and
- market acceptance of any approved product candidates.

We do not have any committed external source of funds or other support for our development efforts and we cannot be certain that additional funding will be available on acceptable terms or at all. Until we can generate sufficient product or other revenue to finance our cash requirements, which we may never achieve, we expect to finance our future cash requirements through a combination of equity offerings, debt financings or other capital sources, including potential collaborations, out-licenses or dispositions and other similar arrangements.

Our ability to raise additional funds will depend on financial, economic and market conditions and other factors, over which we may have no or limited control. Market volatility resulting from geopolitical and economic instability, including as a result of trade policy, inflation and the wars between Russia and Ukraine and in the Middle East or other factors could also adversely impact our ability to access capital as and when needed. If adequate funds are not available on commercially acceptable terms when needed, we may be forced to delay, reduce or terminate the development or commercialization of all or part of our research programs or product candidates or we may be unable to take advantage of future business opportunities.

Raising additional capital may cause dilution to our stockholders and may restrict our operations or require us to relinquish rights to our product candidates.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including potential collaborations, out-licenses or dispositions and other similar arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders may be diluted, and the terms of these securities may include liquidation or other preferences that may adversely affect the rights of our stockholders. Debt and equity financings, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as redeeming shares, making investments, incurring additional debt, making capital expenditures, declaring dividends or placing limitations on our ability to acquire, sell or license intellectual property rights.

If we raise additional capital through future collaborations, strategic alliances or third-party licensing arrangements, we may have to relinquish certain valuable rights to our intellectual property, 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 capital when needed, we may be required to delay, limit, reduce or terminate our clinical development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Due to our limited resources and access to capital, we must, and have in the past decided to, prioritize development of certain product candidates over other potential product candidates. These decisions may prove to have been wrong and may adversely affect our ability to develop our own programs, our attractiveness as a commercial partner and may ultimately have an adverse impact on our commercial success.

Because we have limited resources and access to capital to fund our operations, we must decide which product candidates to pursue and the amount of resources to allocate to each. Our decisions concerning the allocation of research, collaboration, management and financial resources toward our product candidates or therapeutic areas may not lead to the development of viable commercial products and may divert resources away from better opportunities. Similarly, our decisions to delay, terminate or collaborate with third parties in respect of certain product development programs may also prove not to be optimal and could cause us to miss valuable opportunities. If we make incorrect determinations regarding the market potential of our product candidates or misread trends in the biotechnology industry, in particular for our most advanced product candidates, EVO756 and EVO301, our business, financial condition and results of operations could be materially adversely affected.

Risks Related to Discovery, Development and Regulatory Approval of Product Candidates

Preclinical and clinical drug development is a lengthy and expensive process, with uncertain timelines and outcomes. If preclinical studies or clinical trials of our product candidates are prolonged or delayed, we may be unable to obtain required regulatory approvals, and therefore be unable to commercialize our therapeutic candidates or any of our future therapeutic candidates on a timely basis or at all.

Successful development of pharmaceutical products involves a lengthy and expensive process, 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 or unexpected safety 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 marketing application preparation, discussions with the U.S. Food and Drug Administration ("FDA"), the European Medicines Agency ("EMA") or other comparable foreign regulatory authorities, including FDA, EMA or other comparable foreign regulatory authorities requesting additional preclinical or clinical data (such as long-term toxicology studies), or encountering unexpected safety or manufacturing issues;
- preclinical study results may show the product candidate to be less effective than desired or to have harmful on-target or off-target side effects; imposition of extensive 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.

Furthermore, 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 another 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. Even if we are able to obtain coverage and adequate reimbursement for our products once approved, there may be features or characteristics of our products, such as dose preparation requirements, that prevent our products from achieving market acceptance by the healthcare or patient communities.

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 Practice ("cGMPs") and Good Clinical Practice ("GCPs") for any clinical trials that we conduct post-approval. In addition, there is 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 ("AEs") 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.

Disruptions at the FDA and other government agencies caused by funding shortages or layoffs could hinder their ability to hire, retain or deploy key leadership and other personnel or otherwise prevent product candidates from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

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

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and approved by necessary government agencies, which would adversely affect our business. For example, over the last several years including on October 1, 2025, the U.S. government shut down several times and certain regulatory agencies, such as the FDA, furloughed or laid off critical employees and ceased critical activities. If a prolonged government shutdown or disruption occurs, it could significantly impact

the ability of the FDA and applicable foreign authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. In addition, such issues could also prevent the FDA or applicable foreign authorities from conducting their regular inspections, reviews or other regulatory activities, which in turn could significantly impact the ability of such authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Our clinical trials may fail to demonstrate substantial evidence of the safety and efficacy of our product candidates or any future product candidates, which would prevent or delay or limit the scope of regulatory approval and commercialization.

To obtain the requisite regulatory approvals to market and sell any of our product candidates, including EVO756, EVO301 and any other future product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe and effective for use in each targeted indication. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical development process. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization. We may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful, and a clinical trial can fail at any stage of testing. Further, the process of obtaining regulatory approval is expensive, often takes many years following the commencement of clinical trials and can vary substantially based upon the type, complexity and novelty of the product candidates involved, as well as the target indications, patient population and regulatory agency. Prior to obtaining approval to commercialize EVO756, EVO301 and any future product candidates in the United States or abroad, we or our potential future collaborators must demonstrate with substantial evidence from adequate and well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses.

Clinical trials that we conduct may not demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. If the results of our ongoing or future clinical trials are inconclusive with respect to the efficacy of our product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or, if there are safety concerns associated with our product candidates, we may be delayed in obtaining marketing approval, if at all. Additionally, any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications.

Even if the trials are completed to our satisfaction, clinical data are often susceptible to varying interpretations and analyses or may not provide a sufficient risk-benefit ratio, and we cannot guarantee that the FDA or comparable foreign regulatory authorities will interpret the results as we do or find a risk-benefit ratio for a proposed indication acceptable, and more trials could be required before we submit our product candidates for approval. We cannot guarantee that the FDA or comparable foreign regulatory authorities will view our product candidates as having efficacy even if we believe results observed in clinical trials are positive. Moreover, results acceptable to support approval in one jurisdiction may be deemed inadequate by another regulatory authority to support regulatory approval in that other jurisdiction. To the extent that the results of the trials are not satisfactory to the FDA or comparable foreign regulatory authorities for support of a marketing application, approval of EVO756, EVO301 and any future product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. Even if regulatory approval is secured for a product candidate, the terms of such approval may limit the scope and use of the specific product candidate, which may also limit our commercial potential.

The results of preclinical studies and early-stage clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials or results in other indications. Initial positive results in our clinical trials may not be indicative of results obtained when these trials are completed or in later-stage trials.

The results of preclinical studies and early-stage clinical trials may not be predictive of the results of later-stage clinical trials, and results in one indication may not predict results for the same product candidate in another indication. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Furthermore, 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 product candidates proceeding through clinical trials. Many companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development and any such setbacks in our clinical development could have a material adverse effect on our business and operating results. 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. 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 regulatory approval. Further, negative clinical trial results for a product candidate with respect to one indication may impact the potential or perceived potential of other indications. If our product candidates fail to demonstrate satisfactory characteristics in late-stage clinical trials, it could have a material adverse effect on our business, financial condition and results of operations.

Our product candidates may be associated with serious adverse, undesirable or unacceptable side effects or other properties or safety risks, which may delay or halt their clinical development, prevent their marketing approval or lead to limited market demand, if approved. If such side effects are identified during the development of our product candidates or following approval, we may suspend or abandon our development of such product candidates, the commercial profile of any approved label may be limited or we may be subject to other significant negative consequences following marketing approval.

Undesirable side effects that may be caused by 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. While our most advanced product candidates, EVO756 and EVO301, have generally been observed to be well tolerated in their preclinical studies and clinical trials to date, the results from future preclinical studies and clinical trials, including of our other product candidates, may identify safety concerns or other undesirable properties of our product candidates.

The results of our ongoing Phase 2 trials of EVO756 and EVO301 and future clinical trials of these and other product candidates may show that our product candidates cause undesirable or unacceptable side effects or even death. In such an event, our trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. Furthermore, we may be required to expend time and incur costs 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. Any of these occurrences may harm our business, financial condition and results of operations significantly.

Moreover, if our product candidates are associated with undesirable side effects in preclinical studies or clinical trials or have characteristics that are unexpected, we may elect to abandon their development or limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, which may limit the commercial expectations for the product candidate, if approved.

Additionally, adverse developments in clinical trials of pharmaceutical and biopharmaceutical products conducted by others may cause the FDA or other regulatory oversight bodies to suspend or terminate our clinical trials or to change the requirements for approval of any of our product candidates. For example, immunogenicity is a concern for all protein therapeutics in human clinical trials, and immunogenic reactions in patients in our trials may lead to adverse effects and impact exposure, which in turn may lead to protocol amendments, clinical holds or other actions that delay or significantly impact the prospects for our product candidates.

Additionally, if any of our product candidates receive marketing approval and we or others later identify undesirable or unacceptable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product and require us to take such approved product off the market;
- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- regulatory authorities may require a medication guide outlining the risks of such side effects for distribution to patients or that we implement a risk evaluation and mitigation strategy ("REMS") plan to ensure that the benefits of the product outweigh its risks;
- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we may be subject to limitations on how we may promote the product;
- we may suspend or abandon our development of the product;
- sales of the product may decrease significantly;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us or our potential future partners from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenue from the sale of our product candidates, if approved.

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

data. Data from our clinical trials reported as of a measurement date may not be predictive of the effect, if any, of our product candidates at any later measurement date.

From time to time, we may publish interim, top-line or preliminary data from our clinical trials. Preliminary and interim data from our clinical trials may change as more patient data become available. Preliminary or interim data from our clinical trials are not necessarily predictive of final results. Preliminary and interim data are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues, more patient data become available and we issue our final clinical trial report. Interim, top-line and preliminary 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, preliminary, top-line and interim data should be viewed with caution until the final data are available. Moreover, in connection with any data that is presented, caution should be exercised in drawing any conclusions from a comparison of data that does not come from head-to-head analysis. Material differences in the final data compared to the interim data could significantly harm our business prospects.

Additionally, data from a clinical trial as of any measurement date are only reflective of observations in such clinical trial at such date and should not be unduly used to predict any effect at a later measurement date. For example, in our Phase 2 trial of EVO756 in CIndU, we reported observations after four weeks of dosing. It is not possible to accurately predict what impact EVO756 would have had in this trial's subjects at any subsequent date.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could delay or prevent regulatory approval of, or limit commercial prospects for, the particular product candidate and harm our business prospects. In addition, the information we choose to publicly disclose regarding a particular preclinical study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine to include in our public disclosure. If the preliminary and interim data that we report differ from actual results or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control, which could adversely affect our business, operating results and prospects.

Patient enrollment and retention in clinical trials is a significant factor in the timing of clinical trials and depends on many factors, including the size and nature of the patient population, the eligibility criteria for the clinical trial, the nature of the trial protocol, the existing body of safety and efficacy data with respect to the study drug, the number, nature and duration of competing treatments and ongoing clinical trials of competing drugs for the same indication and the proximity of patients to clinical trial sites. As we progress our programs, we may not be able to initiate or continue clinical trials for any product candidates we identify or develop if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA, EMA or other comparable foreign authorities or as needed to provide appropriate statistical power for a given trial. Potential patients for any planned clinical trials may not be adequately diagnosed or identified with the diseases which we are targeting or may not meet the entry criteria for such trials. We also may encounter difficulties in identifying and enrolling patients with a stage of disease appropriate for our planned clinical trials and monitoring such patients adequately during and after treatment. Other pharmaceutical companies targeting these same diseases are recruiting clinical trial patients from these patient populations, which may make it more difficult to fully enroll our clinical trials.

In addition, we compete for trial participants with other clinical trials for product candidates that are in the same areas as our product candidates, which could reduce the number and types of participants available to us and could affect the timing and cost of our clinical trials. For example, some participants who might have opted to enroll in our clinical trials may instead opt to enroll in a clinical trial being conducted by one of our competitors or to use currently marketed therapies. Delay in recruiting clinical trial participants could adversely affect our ability to bring a product to market prior to our competitors and increase trial costs. Further, research and discoveries by others may result in breakthroughs that render our product candidates obsolete even before they begin to generate any revenue.

The eligibility criteria of our clinical trials, once established, may further limit the pool of available trial participants. If the actual number of patients that meet such criteria is smaller than we anticipate, we may encounter difficulties in enrolling patients in our clinical trials, thereby delaying or preventing development and approval of our product candidates. Even once enrolled we may be unable to retain a sufficient number of patients to complete any of our trials.

Furthermore, our efforts to build relationships with patient communities may not succeed, which could result in delays in patient enrollment in our clinical trials. In addition, any negative results we may report in clinical trials of a product candidate may make it difficult or impossible to recruit and retain patients in other clinical trials of that same product candidate or other product candidates. Delays or failures in planned patient enrollment or retention may result in increased costs, program delays or both, which could have a

harmful effect on our ability to develop our product candidates or could render further development impossible. Further, if patients drop out of our clinical trials, miss scheduled doses or follow-up visits or otherwise fail to follow clinical trial protocols, the integrity of data from our clinical trials may be compromised or not accepted by the FDA, EMA or other comparable foreign regulatory authorities, which would represent a significant setback for the applicable program. We have in the past and may in the future experience participant withdrawals or discontinuations from our clinical trials. Withdrawal of participants from our clinical trials may compromise the quality of our data. In addition, we may rely on contract research organizations ("CROs") and clinical trial sites to ensure proper and timely conduct of our future clinical trials and, while we intend to enter into agreements governing their services, we will be limited in our ability to compel their actual performance. Such delays or failures could adversely affect our business, operating results and prospects.

If we do not achieve our projected development goals in the time frames we announce and expect, the commercialization of our therapeutics may be delayed and, as a result, our stock price may decline.

From time to time, we estimate the timing of the anticipated accomplishment of various scientific, clinical, regulatory and other product development goals, which we sometimes refer to as milestones. These milestones may include our expectations regarding the commencement or completion of scientific studies and clinical trials and the submission of regulatory filings. 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 or the initiation of other clinical programs. All of these milestones are and will be based on numerous assumptions, 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, EMA and other comparable foreign 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 securing of, costs related to and timing issues associated with, product manufacturing as well as sales and marketing activities; and
- securing product reimbursement.

The actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control. If we do not meet these milestones as publicly announced, or at all, the commercialization of our product candidates may be delayed or never achieved and, as a result, our stock price may decline.

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

Obtaining and maintaining marketing approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain marketing approval in any other jurisdiction. For example, even if the FDA grants marketing approval of a product candidate, it does not mean that comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion and reimbursement of the product candidate in those countries. However, a failure or delay in obtaining marketing approval in one jurisdiction may negatively impact the marketing approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from 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.

Obtaining foreign marketing approvals and establishing and maintaining 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. If we or any future collaborator fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed, which would adversely affect our business, prospects, financial condition and results of operations.

Our product candidates are subject to extensive regulatory and compliance obligations, compliance with which is costly and time-consuming and which may cause unanticipated delays or prevent the receipt of the required approvals to commercialize our product candidates.

The research, clinical development, testing, quality control, safety, effectiveness, manufacturing, labeling, packaging, storage, record-keeping, advertising, promotion, marketing, import, export, distribution, post-approval monitoring and post-approval reporting of our product candidates are subject to extensive regulation by the FDA in the United States and by comparable foreign regulatory authorities in foreign markets. In the United States, neither we nor any future collaborators are permitted to market our product candidates until we receive regulatory approval from the FDA. The process of obtaining regulatory approval is expensive, often takes many years following the commencement of clinical trials and can vary substantially based upon the type, complexity and novelty of the product candidates involved, as well as the target indications and patient population. Approval policies or regulations may change, new relevant statutes or regulations may be enacted, and the FDA, EMA and other comparable foreign regulatory authorities have substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Despite the time and expense invested in clinical development of product candidates, regulatory approval is never guaranteed.

Prior to obtaining approval to commercialize a product candidate in the United States or abroad, we or our potential future collaborators must demonstrate with substantial evidence from adequate and well-controlled clinical trials, and to the satisfaction of the FDA, EMA or other comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses. Results from preclinical studies and clinical trials can be interpreted in different ways. Even if we believe the preclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA, EMA and other comparable foreign regulatory authorities, which could require us to delay or abandon clinical development plans.

In addition, regulatory authorities may require us to conduct further preclinical studies before evaluating our product candidate in a clinical trial. Once we initiate clinical trials, the FDA, EMA or other comparable foreign regulatory authorities may require additional clinical trials or suggest changes to our planned clinical trials, prior to and in support of the approval of a marketing application. Changes to data requirements by the FDA, EMA or other comparable foreign regulatory authorities during the development of our product candidates may cause the applicable regulatory authorities to require us to conduct additional preclinical studies or clinical trials for our product candidates either prior to or post-approval, or regulatory authorities may object to elements of our clinical development program.

The FDA, EMA or other comparable foreign regulatory authorities can delay, limit or deny approval of a product candidate for many reasons, including:

- such authorities may disagree with the design or implementation of our clinical trials;
- results from our clinical trials may not be sufficient for approval;
- serious and unexpected drug-related side effects may be experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- such authorities may not accept clinical data from trials which are conducted at clinical facilities or in countries where the standard of care is potentially different from that of the United States;
- we may be unable to demonstrate that a product candidate is safe and effective, and that a product candidate's clinical and other benefits outweigh its safety risks;
- such authorities may disagree with our interpretation or analysis of data from preclinical studies or clinical trials, such authorities may not agree that the data collected from clinical trials of our product candidates are acceptable or sufficient to support a submission to obtain regulatory approval in the United States or elsewhere, and such authorities may impose requirements for additional preclinical studies or clinical trials;
- such authorities may disagree regarding the formulation, labeling or the specifications of our product candidates;
- approval may be granted only for indications that are significantly more limited than what we apply for or with other significant restrictions on distribution and use;
- such authorities may find deficiencies in the manufacturing processes, approval policies or facilities of our third-party manufacturers with which we or any of our current or future collaborators contract for clinical and commercial supplies; or
- the approval policies or regulations of such authorities may significantly change in a manner rendering our or any of our potential future collaborators' clinical data insufficient for approval.

With respect to foreign markets, approval procedures vary among countries and, in addition to the foregoing risks, may involve additional product testing, administrative review periods and agreements with pricing authorities. In addition, events raising questions about the safety of certain marketed pharmaceuticals may result in increased cautiousness by the FDA, EMA and other comparable foreign regulatory authorities in reviewing new drugs based on safety, efficacy or other regulatory considerations and may result in significant delays in obtaining regulatory approvals. Any delay in obtaining, or inability to obtain, applicable regulatory approvals would prevent us or any of our potential future collaborators from commercializing our product candidates.

Of the large number of drugs in development, only a small percentage successfully complete the FDA, EMA or foreign regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, financial condition, results of operations and prospects.

We may develop our current or future product candidates in combination with other therapies, which would expose us to additional risks.

We may develop our current or potential future product candidates in combination with one or more currently approved therapies or therapies in development. Even if any of our current or future product candidates were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA, EMA or other comparable foreign regulatory authorities could revoke approval of the therapy used in combination with any of our product candidates, or safety, efficacy, manufacturing or supply issues could arise with these existing therapies. In addition, it is possible that existing therapies with which our product candidates are approved for use could themselves fall out of favor or be relegated to later lines of treatment. This could result in the need to identify other combination therapies for our product candidates or our own products being removed from the market or being less successful commercially.

We may also evaluate our current or future product candidates in combination with one or more other therapies that have not yet been approved for marketing by the FDA, EMA or other comparable foreign regulatory authorities. We will not be able to market and sell any product candidate in combination with any such unapproved therapies that do not ultimately obtain marketing approval.

Furthermore, we cannot be certain that we will be able to obtain a steady supply of such therapies for use in developing combinations with our product candidates on commercially reasonable terms or at all. Any failure to obtain such therapies for use in clinical development and the expense of purchasing therapies in the market may delay our development timelines, increase our costs and jeopardize our ability to develop our product candidates as commercially viable therapies. If the FDA, EMA or other comparable foreign regulatory authorities do not approve or withdraw their approval of these other therapies, or, if safety, efficacy, commercial adoption, manufacturing or supply issues arise with the therapies we choose to evaluate in combination with any of our current or future product candidates, we may be unable to obtain approval of or successfully market any one or all of the current or future product candidates we develop. Additionally, if the third-party providers of therapies or therapies in development used in combination with our current or future product candidates are unable to produce sufficient quantities for clinical trials or for commercialization of our current or future product candidates, or, if the cost of combination therapies are prohibitive, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

The FDA and any comparable foreign regulatory authorities may not accept data from trials conducted in locations outside of their jurisdiction.

Outside of the United States, we are presently conducting or plan to conduct clinical trials in Australia, New Zealand, Japan, Canada and the EU, and will likely choose to conduct additional international clinical trials in the future. The acceptance of trial data by the FDA or any comparable foreign regulatory authority from clinical trials conducted outside of their respective jurisdictions 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 marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice, (ii) the trials are performed by clinical investigators of recognized competence and pursuant to compliance with current GCP requirements and (iii) the FDA is able to validate the data through an on-site inspection or other appropriate means. Additionally, the FDA's clinical trial requirements, including the adequacy of the patient population studied and statistical powering, must be met. In addition, such foreign trials are 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 applicable foreign regulatory authority will accept data from trials conducted outside of its applicable jurisdiction. If the FDA or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our product candidates not receiving approval for commercialization in the applicable jurisdiction.

Conducting trials outside the United States also exposes us to additional risks, including risks associated with:

•additional foreign regulatory requirements;

•foreign exchange fluctuations;

•compliance with foreign manufacturing, customs, shipment and storage requirements;

•cultural differences in medical practice and clinical research;

•diminished protection of intellectual property in some countries; and

•interruptions or delays in our trials resulting from geopolitical events, such as war or terrorism.

Risks Related to Commercialization, Marketing and Competition of Our Product Candidates

We currently have no marketing, sales or distribution capabilities, and we may need to invest significant resources to develop these capabilities. If we are unable to establish marketing, sales or distribution capabilities or enter into agreements with third parties to perform such activities, we may not be able to generate product revenue.

We currently have no marketing, sales or distribution capabilities, nor has Evommune as a company commercialized a product, and we may need to invest significant resources to develop these capabilities. If we are unable to establish marketing, sales or distribution capabilities or enter into agreements with third parties to perform such activities, we may not be able to generate product revenue. If any of our product candidates ultimately receives marketing approval, we will be required to build a marketing and sales organization with technical expertise and supporting distribution capabilities to commercialize each such product in the markets that we target, which will be expensive and time-consuming, or 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. Evommune has 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. Furthermore, we are currently developing product candidates for multiple indications in different medical specialties, which will require us to build different sales and marketing capabilities that are tailored to a given product or medical specialty. 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 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 the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. 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 the market opportunities for any of our product candidates, if approved, are smaller than we estimate, our revenue may be adversely affected, and our business may suffer.

The precise incidence and prevalence for all the conditions we aim to address with our product candidates are unknown. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, third party reports, patient foundations and market research, and may prove to be incorrect. Further, new information may change the estimated incidence or prevalence of these diseases. The total addressable market across our product candidates will ultimately depend upon, among other things, the diagnosis criteria included in the final label for each of our product candidates approved for sale for these indications, the availability of alternative treatments and the safety, convenience, cost and efficacy of our product candidates relative to such alternative treatments, acceptance by the medical community and patient access, drug pricing and reimbursement. The number of patients in the United States and other major markets and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our product candidates or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business.

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The biotechnology and pharmaceutical industries are characterized by intense competition and rapid innovation. Our competitors may be able to develop other compounds or drugs that are able to achieve similar or better results. Our potential competitors include major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies and universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources,

such as larger research and development staff and experienced marketing and manufacturing organizations and well-established sales forces. Smaller or early-stage companies may also prove to be significant competitors, particularly as they develop novel approaches to treating disease indications that our product candidates are also focused on treating. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel therapeutics or to in-license novel therapeutics that could make the product candidates that we develop obsolete. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized or less costly than our product candidates or may develop proprietary technologies or secure patent protection that we may need for the development of our technologies and products. We believe the key competitive factors that will affect the development and commercial success of our product candidates are efficacy, safety, tolerability, reliability, convenience of use, price and reimbursement.

We anticipate that we will continue to face intense and increasing competition as new treatments enter the market and advanced technologies become available. There can be no assurance that our competitors are not currently developing, or will not in the future develop, products that are equally or more effective or are more economically attractive than any of our current or future product candidates. Competing products may gain faster or greater market acceptance than our products, if any, and medical advances or rapid technological development by competitors may result in our product candidates becoming non-competitive or obsolete before we are able to recover our research and development and commercialization expenses. If we or our product candidates do not compete effectively, we may suffer a material adverse effect on our business, financial condition and results of operations.

Even if a product candidate we develop receives marketing 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. The revenues that we generate from our sales may be limited, and we may never become profitable.

As a company, we have never commercialized a product. Even if our product candidates are approved by the appropriate regulatory authorities for marketing and sale, they may not gain acceptance among physicians, patients, third-party payors and others in the medical community. If any product candidates for which we obtain regulatory approval do not gain an adequate level of market acceptance, we could be prevented from, or significantly delayed in, achieving profitability. Market acceptance of our product candidates by the medical community, patients and third-party payors will depend on a number of factors, some of which are beyond our control. For example, physicians are often reluctant to switch their patients to new treatments and patients may be reluctant to switch from existing therapies even when new and potentially more effective or safer treatments enter the market.

Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may not be successful. If any of our product candidates are approved but do not achieve an adequate level of market acceptance, we could be prevented from or significantly delayed in achieving profitability. The degree of market acceptance of any product for which we receive marketing approval will depend on a number of factors, including:

- the clinical indications for which our product candidates are approved;
- physicians, hospitals and patients considering our product candidates as a safe and effective treatment;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or comparable foreign regulatory authorities, including any limitations or warnings;
- the timing of market introduction of our product candidates in relation to other potentially competitive products;
- the cost of our product candidates in relation to alternative treatments;
- the amount of upfront costs or training required for physicians to administer our product candidates;
- the availability of coverage and adequate reimbursement from third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of comprehensive coverage and reimbursement by third-party payors and government authorities;
- the relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies;
- the effectiveness of our sales and marketing efforts and distribution support; and
- the presence or perceived risk of potential product liability claims.

Even if we are able to commercialize any product candidate, the third-party payor coverage and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for our product candidates could limit our ability to market those products and decrease our ability to generate revenue.

The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors in the United States are essential for most patients to be able to afford treatments such as our products or product candidates, if approved. Our ability to achieve acceptable levels of coverage and reimbursement for drug treatments by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize our products and potentially attract additional collaboration partners to invest in the development of our product candidates. We cannot be sure that adequate coverage and reimbursement in the United States or elsewhere will be available for our products or any products that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for pharmaceutical products, medical devices and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug is available. It is possible that a third-party payor may consider our products or product candidates, if approved, and the generic or biosimilar parent drug as substitutable and only offer to reimburse patients for the generic drug. Even if we show improved efficacy or safety or improved convenience of administration with our products or product candidates, if approved, pricing of the existing parent drug may limit the amount we will be able to charge for such product. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our products or product candidates and may not be able to obtain a satisfactory financial return on products that we may develop.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs, biologics and medical devices will be covered. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs, biologics and medical devices. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our products or product candidates.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of our products and product candidates, if approved, and on related parent drugs. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Many countries, including the European Union ("EU") Member States, established complex and lengthy procedures to obtain price approvals, coverage and reimbursement. These procedures vary from country to country but are commonly initiated after grant of the related marketing authorization. More particularly, in the EU, potential reductions in prices and changes in reimbursement levels could be the result of different factors, including reference pricing systems. It could also result from the application of external reference pricing mechanisms, which consist of arbitrage between low-priced and high-priced countries. Reductions in the pricing of our medicinal products in one EU Member State could affect the price in other EU Member States and, thus, have a negative impact on our financial results. Other countries allow companies to fix their own prices for medical products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our products or product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits. As an example, many EU Member States review periodically their decisions concerning the pricing and reimbursement of medicinal products. The outcome of these reviews cannot be predicted and could have adverse effects on the pricing and reimbursement of our medicinal products in the EU Member States.

Moreover, increasing efforts by governmental and 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 new products approved and, as a result, they may not cover or provide adequate payment for our products or product candidates. We expect to experience pricing pressures in connection with the sale of our products and product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes or executive orders. The downward pressure on healthcare costs in general, particularly prescription drugs, medical devices and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

Even if we receive regulatory approval for any product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions on marketing or withdrawal from the market, and we may be subject to penalties

if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidates, when and if any of them are approved.

Even if we obtain any marketing approval for our current or any future product candidates, such approvals will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping and submission of safety and other post-market information. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as on-going compliance with cGMPs and GCPs, for any clinical trials that we may conduct post-approval. Any marketing approvals that we receive for our current or future product candidates may also be subject to a REMS, limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval or contain requirements for potentially costly post-marketing testing, including Phase 4 trials and surveillance to monitor the quality, safety and efficacy of the drug.

In addition, biopharmaceutical manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements and adherence to commitments made in the marketing application. If we or a regulatory authority discover previously unknown problems with a product, such as AEs of unanticipated severity or frequency, or problems with the facility where the product is manufactured or if a regulatory authority disagrees with the promotion, marketing or labeling of that product, a regulatory authority may impose restrictions relative to that product, the manufacturing facility or us, including requesting a recall or requiring withdrawal of the product from the market or suspension of manufacturing.

If we fail to comply with applicable regulatory requirements following approval of our current or future product candidates, a regulatory authority may, among other things:

- issue an untitled letter or warning letter asserting that we are in violation of the law;
- seek an injunction or impose administrative, civil or criminal penalties or monetary fines;
- suspend or withdraw marketing approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending marketing authorization application or supplement submitted by us or our strategic partners;
- restrict or suspend the marketing or manufacturing of the drug;
- seize or detain the drug or otherwise require the withdrawal of the drug from the market;
- refuse to permit the import or export of product candidates; or
- refuse to allow us to enter into supply contracts, including government contracts.

In addition, if any of our product candidates is approved, our product labeling, advertising and promotion will be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about drug products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The government has also required companies to enter into consent decrees and imposed permanent injunctions under which specified promotional conduct is changed or curtailed.

The FDA's policies, and those of equivalent foreign regulatory agencies, may change and additional government regulations may be enacted that could cause changes to or delays in the drug review process or suspend or restrict marketing 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. 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 be subject to enforcement action and we may not achieve or sustain profitability, which would harm our business, financial condition, results of operations and prospects.

Our future growth may depend, in part, on our ability to commercialize products in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future growth may depend, in part, on our ability to develop and commercialize our product candidates in foreign markets. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from applicable

regulatory authorities in foreign markets, and we may never receive such regulatory approvals for any of our product candidates. To obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements regarding safety and efficacy and governing, among other things, clinical trials, commercial sales, pricing and distribution of our product candidates. If we obtain regulatory approval of our product candidates and ultimately commercialize our products in foreign markets, we would be subject to additional risks and uncertainties, including:

- different regulatory requirements for approval of drugs in foreign countries;
- reduced protection for intellectual property rights;
- the existence of additional third-party patent rights of potential relevance to our business;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- foreign reimbursement, pricing and insurance regimes;
- workforce uncertainty in countries where labor unrest is common;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

Risks Related to Our Business and Operations, Employee Matters and Managing Growth

If our information technology systems or those of third parties with whom we work or our data, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions, litigation, fines and penalties, disruptions of our business operations, reputational harm, loss of revenue or profits and other adverse consequences.

In the ordinary course of our business, we and the third parties with whom we work process sensitive data, including personal data (such as health-related data). Cyber-attacks, malicious internet-based activity, online and offline fraud and other similar activities threaten the confidentiality, integrity and availability of our sensitive data and information technology systems and those of the third parties with whom we work. Such threats are prevalent and continue to rise, are increasingly difficult to detect and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states and nation-state-supported actors.

Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we, the third parties with whom we work, may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain and ability to produce, sell and distribute our goods and services.

We and the third parties with whom we work are subject to a variety of evolving threats, including social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, credential stuffing attacks, credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, attacks enhanced or facilitated by AI and other similar threats.

In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, inability to provide our products or services, loss of sensitive data and income, reputational harm and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

It may be difficult and costly to detect, investigate, mitigate, contain and remediate a security incident. Our efforts to do so may not be successful. Actions taken by us or the third parties with whom we work to detect, investigate, mitigate, contain and remediate a security incident could result in outages, data losses and disruptions of our business. Threat actors may also gain access to other networks and systems after a compromise of our networks and systems.

Remote work has increased risks to our information technology systems and data, as our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations.

Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

We rely on third parties to operate critical business systems to process sensitive data in a variety of contexts, including, without limitation, cloud-based infrastructure, data center facilities, encryption and authentication technology, employee email and other functions. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If the third parties with whom we work experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if the third parties with whom we work fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award.

In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or that of the third parties with whom we work have not been compromised.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps designed to detect, mitigate and remediate vulnerabilities in our information systems (such as our hardware and software, including that of third parties with whom we work). We have not and may not in the future, however, detect and remediate all such vulnerabilities including on a timely basis. Further, we have and may in the future experience delays in deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

Any of the previously identified or similar threats have in the past and may in the future cause a security incident or other interruption that have in the past and may in the future result in unauthorized, unlawful or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of or access to our sensitive data or our information technology systems or those of the third parties with whom we work. A security incident or other interruption could disrupt our ability (and that of third parties with whom we work) to provide our services.

We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Certain data privacy and security obligations have required us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and sensitive data.

Applicable data privacy and security obligations may require us, or we may voluntarily choose, to notify relevant stakeholders, including affected individuals, customers, regulators and investors, of security incidents or to take other actions, such as providing credit monitoring and identity theft protection services. Such disclosures and related actions can be costly, and the disclosure or the failure to comply with such applicable requirements could lead to adverse consequences.

If we (or a third party with whom we work) experience a security incident or are perceived to have experienced a security incident, we may experience material adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits and inspections), additional reporting requirements and oversight, restrictions on processing sensitive data (including personal data), litigation (including class claims), indemnification obligations, negative publicity, reputational harm, monetary fund diversions, diversion of management attention, interruptions in our operations (including availability of data), financial loss and other similar harms. Security incidents and attendant material consequences may prevent or cause customers to stop using our services, deter new customers from using our services and negatively impact our ability to grow and operate our business.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all or that such coverage will pay future claims.

In addition to experiencing a security incident, third parties may gather, collect or infer sensitive data about us from public sources, data brokers or other means that reveal competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Additionally, sensitive data of the Company could be leaked, disclosed or revealed as a result of or in connection with our employees', personnel's or vendors' use of generative AI technologies.

We and the third parties with whom we work are subject to stringent and evolving U.S. and foreign laws, regulations and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our (or the third parties with whom we work) actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions, litigation (including class claims) and mass arbitration demands, fines and penalties, disruptions of our business operations, reputational harm, loss of revenue or profits and other adverse business consequences.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit and share (collectively, "process") personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials and sensitive third-party data (collectively, "sensitive data").

Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements and other obligations relating to data privacy and security. In the United States, federal, state and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (for example, Section 5 of the Federal Trade Commission Act) and other similar laws (for example, wiretapping laws). For example, the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), imposes specific requirements relating to the privacy, security and transmission of individually identifiable protected health information by covered entities, business associates and their covered subcontractors.

Numerous U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct or delete certain personal data and to opt-out of certain data processing activities, such as targeted advertising, profiling and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive data, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018 ("CCPA") applies to personal data of consumers, business representatives and employees who are California residents and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for fines and allows private litigants affected by certain data breaches to recover significant statutory damages. The CCPA and other comprehensive U.S. state privacy laws exempt some data processed in the context of clinical trials, but these developments may further complicate compliance efforts, and increase legal risk and compliance costs for us, the third parties with whom we work. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future.

Outside the United States, an increasing number of laws, regulations and industry standards govern data privacy and security. For example, the European Union's General Data Protection Regulation ("EU GDPR"), the United Kingdom's GDPR ("UK GDPR") (collectively, "GDPR"), New Zealand's Privacy Act and Australia's Privacy Act impose strict requirements for processing personal data. For example, under the GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros under the EU GDPR, 17.5 million pounds sterling under the UK GDPR or, in each case, 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

Our employees and personnel may use generative artificial intelligence ("AI") or automated decision-making technologies to perform their work, and the disclosure and use of personal data in AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating AI and automated decision-making technologies. Our use of this technology could result in additional compliance costs, regulatory investigations and actions and lawsuits. If we are unable to use AI or automated decision-making technologies, it could make our business less efficient and result in competitive disadvantages.

Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area ("EEA") and the United Kingdom ("UK") have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt or have already adopted similarly stringent data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA standard contractual clauses, the UK's International Data Transfer Agreement / Addendum and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States or if the requirements for a legally compliant transfer are too

onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants and activist groups.

Additionally, the U.S. Department of Justice issued a rule entitled the Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons, which places additional restriction on certain data transactions involving countries of concern (for example, China, Russia and Iran) and covered individuals (individuals and entities located in or controlled by individuals or entities located in those jurisdictions) that may impact certain business activities such as vendor engagements, sale or sharing of data, employment of certain individuals and investor agreements. Violations of the rule could lead to significant civil and criminal fines and penalties. The rule applies regardless of whether data is anonymized, key-coded, pseudonymized, de-identified or encrypted, which presents particular challenges for companies like ours and may impact our ability to transfer data in connection with certain transactions or agreements.

We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. We also publish privacy policies, marketing materials and other statements concerning data privacy and security. Regulators in the United States are increasingly scrutinizing these statements, and if these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, misleading or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Obligations related to data privacy and security (and consumers' data privacy expectations) are quickly changing, becoming increasingly stringent and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources, which may necessitate changes to our services, information technologies, systems and practices and to those of any third parties that process personal data on our behalf.

We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties with whom we work may fail to comply with such obligations, which could negatively impact our business operations.

If we or the third parties with whom we work fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (for example, investigations, fines, penalties, audits, inspections and similar), litigation (including class-action claims) and mass arbitration demands, additional reporting requirements or oversight, bans or restrictions on processing personal data, orders to destroy or not use personal data and imprisonment of company officials.

In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations.

Any of these events could have a material adverse effect on our reputation, business or financial condition, including: loss of customers, interruptions or stoppages in our business operations (including, as relevant, clinical trials), inability to process personal data or to operate in certain jurisdictions, limited ability to develop or commercialize our products, expenditure of time and resources to defend any claim or inquiry, adverse publicity or substantial changes to our business model or operations.

We are highly dependent on the services of our senior management team and if we are not able to retain members of our management team and recruit and retain additional management, clinical and scientific personnel, our business will be harmed.

We are highly dependent on our senior management team. The employment agreements we have with these officers do not prevent such persons from terminating their employment with us at any time. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives. In addition, we will need to attract, retain and motivate highly qualified additional management, clinical and scientific personnel. If we are not able to retain our management and to attract, on terms acceptable to us, additional qualified personnel necessary for the continued development of our business, we may not be able to sustain our operations or grow.

We may not be able to attract or retain qualified personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. Many of the other pharmaceutical companies that we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer operating history in

the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates and consultants than what we have to offer. If we are unable to attract, retain and motivate high-quality personnel and consultants to accomplish our business objectives, the rate and success at which we can discover and develop product candidates and our business will be limited and we may experience constraints on our development objectives.

Failure to comply with health and data protection laws and regulations could lead to government enforcement actions, including civil or criminal penalties, private litigation and adverse publicity and could negatively affect our operating results and business.

We and any current and future collaborators may be subject to federal, state/provincial, municipal and foreign data protection laws and regulations, such as laws and regulations that address privacy and data security. In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws and federal and state consumer protection laws, including Section 5 of the Federal Trade Commission Act, that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations. In addition, we may obtain health information from third parties, including research institutions from which we obtain clinical trial data, that are subject to privacy and security requirements under HIPAA, as amended by HITECH. Depending on the facts and circumstances, we could be subject to civil, criminal and administrative penalties if we violate HIPAA.

Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data or, in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with these laws and regulations could result in government enforcement actions (which could include civil, criminal and administrative penalties), private litigation or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects, employees and other individuals about whom we or our current or future collaborators obtain personal information, as well as the providers who share this information with us, may limit our ability to collect, use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

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

As of December 31, 2024, we had U.S. federal net operating loss carryforwards of approximately $38.5 million. The amount of net operating loss carryforwards that we are permitted to deduct is limited to 80% of taxable income in each such taxable year to which the net operating loss carryforwards are applied. In addition, our U.S. federal net operating losses and tax credits may be subject to limitations under Sections 382 and 383 of the Internal Revenue Code of 1986 (the "Code"), if we have undergone or undergo an "ownership change," generally defined as a greater than 50 percentage point change (by value) in our equity ownership by certain stockholders over a rolling three-year period. We may have experienced such ownership changes in the past and may experience ownership changes in the future as a result of shifts in our stock ownership, some of which are outside our control. As a result, our ability to utilize our net operating loss carryforwards could be limited by an "ownership change," which could result in increased tax liability to us.

Legislation or other changes in U.S. tax law may have a material adverse effect on our business, cash flow, financial condition or results of operations.

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 ("IRS") and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many changes have been made to applicable tax laws and changes are likely to continue to occur in the future. On July 4, 2025, the One Big Beautiful Bill Act (the "Act") was enacted into law. The Act includes significant changes to the U.S. tax code, including restoration of immediate recognition of domestic research and development expenditures and reinstatement of 100% bonus depreciation for qualifying property. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations.

It cannot be predicted whether, when, in what form or with what effective dates, new tax laws may be enacted, or regulations and rulings may be enacted, promulgated or issued under existing or new tax laws, which could result in an increase in our or our stockholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law or in the interpretation thereof. Investors should consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in our common stock.

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

If earthquakes, fires, other natural disasters, terrorism and similar events beyond our control prevent us from using all or a significant portion of our headquarters or other facilities, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. We have a disaster recovery plan in place and are in the process of implementing a business continuity plan. We may incur substantial expenses as a result of the absence or limited nature of our internal or third-party service provider disaster recovery and business continuity plans, which could have a material adverse effect on our business. In addition, the long-term effects of climate change on general economic conditions and the pharmaceutical manufacturing and distribution industry in particular are unclear, and changes in the supply, demand or available sources of energy and the regulatory and other costs associated with energy production and delivery may affect the availability or cost of goods and services, including raw materials and other natural resources, necessary to run our business. If such an event were to affect our supply chain, it could have a material adverse effect on our ability to conduct our clinical trials, our development plans and business.

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

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

- decreased demand for any product candidate that we may develop;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- substantial monetary awards to trial participants or patients;
- significant time and costs to defend the related litigation;
- a diversion of management's time and our resources;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- the inability to commercialize any product candidate that we may develop;
- injury to our reputation and significant negative media attention; and
- a decline in our stock price.

We currently hold approximately $5.0 million in product liability insurance coverage in the aggregate. We may need to increase our insurance coverage as we expand our clinical trials and if we successfully commercialize any product candidate. Insurance coverage can be increasingly expensive. We may not be able to obtain or maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Although we will maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies will also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

We will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

As of July 31, 2025, we had 45 full-time employees. As we advance our research and development programs, we may need to further increase the number of our employees and the scope of our operations, particularly in the areas of clinical development, discovery biology, chemistry, manufacturing, general and administrative matters related to being a public company, regulatory affairs and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage any future growth, we must:

- identify, recruit, integrate, maintain and motivate additional qualified personnel;
- manage our development efforts effectively, including the initiation and conduct of clinical trials for our product candidates; and
- improve our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to develop, manufacture and commercialize our product candidates, if approved, will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert financial, other resources and a disproportionate amount of its attention away from day-to-day activities to managing these growth activities.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

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 or improper activities by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include insider trading, intentional failures to comply with FDA regulations or the regulations applicable in 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. 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 result in significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm and the curtailment or restructuring of our operations, any of which could have a negative impact on our business, financial condition, results of operations and prospects.

If we or any CDMOs 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 CDMOs 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 these 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 third-party facilities. We could also incur significant costs associated with civil or criminal fines and penalties.

Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research and product development efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

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 CDMOs 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.

International trade policies, including tariffs, sanctions and trade barriers may adversely affect our business, financial condition, results of operations and prospects.

We operate in a global economy, which includes utilizing third-party suppliers in several countries outside the United States. There is inherent risk, based on the complex relationships among the U.S. and the countries in which we conduct our business, that political, diplomatic and national security factors can lead to global trade restrictions and changes in trade policies and export regulations that may adversely affect our business and operations. The current international trade and regulatory environment is subject to significant ongoing uncertainty. The U.S. government has recently announced substantial new tariffs affecting a wide range of products and jurisdictions and has indicated an intention to continue developing new trade policies, including with respect to the pharmaceutical industry. In response, certain foreign governments have announced or implemented retaliatory tariffs and other protectionist measures. These developments have created a dynamic and unpredictable trade landscape, which may adversely impact our business, results of operations, financial condition and prospects.

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We currently rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for clinical testing, as well as for manufacture of any products that we may commercialize, if approved. Currently, several of our suppliers are located outside of the United States, including in China. We also rely on specialized laboratory equipment, supplies and materials, all or part of which we believe may be ultimately sourced from multiple countries outside the United States, to advance our research and development efforts.

Current or future tariffs could result in increased research and development expenses, including with respect to increased costs associated with active pharmaceutical ingredients, raw materials, laboratory equipment and research materials and components. In addition, such tariffs could increase our supply chain complexity and could also potentially disrupt our existing supply chain. Trade restrictions affecting the import of materials necessary for clinical trials could result in delays to our development timelines. Increased development costs and extended development timelines could place us at a competitive disadvantage compared to companies operating entirely domestically or in regions with more favorable trade relationships and could reduce investor confidence, negatively impacting our ability to secure additional financing on favorable terms or at all. In addition, as we advance toward commercialization in the future, tariffs and trade restrictions could hinder our ability to establish cost-effective production capabilities, negatively impacting our growth prospects.

The complexity of announced or future tariffs may also increase the risk that we or our customers or suppliers may be subject to civil or criminal enforcement actions in the United States or foreign jurisdictions related to compliance with trade regulations. Foreign governments may also adopt non-tariff measures, such as procurement preferences or informal disincentives to engage with, purchase from or invest in U.S. entities, which may limit our ability to compete internationally and attract non-U.S. investment, employees, customers and suppliers. Foreign governments may also take other retaliatory actions against U.S. entities, such as decreased intellectual property protection, increased enforcement actions or delays in regulatory approvals, which may result in heightened international legal and operational risks. In addition, the United States and other governments have imposed and may continue to impose additional sanctions, such as trade restrictions or trade barriers, which could restrict us from doing business directly or indirectly in or with certain countries or parties and may impose additional costs and complexity to our business.

Trade disputes, tariffs, restrictions and other political tensions between the United States and other countries may also exacerbate unfavorable macroeconomic conditions including inflationary pressures, foreign exchange volatility, financial market instability and economic recessions or downturns. The ultimate impact of current or future tariffs and trade restrictions remains uncertain and could materially and adversely affect our business, financial condition, results of operations and prospects. While we actively monitor these risks, any prolonged economic downturn, escalation in trade tensions or deterioration in international perception of U.S.-based companies could materially and adversely affect our business, ability to access the capital markets or other financing sources, results of operations, financial condition and prospects.

Risks Related to Government Regulatory and Legal Requirements

Our relationships with customers, physicians and third-party payors may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, other healthcare laws and regulations and health data privacy and security

laws and regulations, contractual obligations and self-regulatory schemes. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Healthcare providers and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors may subject us to various federal and state fraud and abuse laws and other healthcare laws, including, without limitation, the federal Anti-Kickback Statute, the federal civil and criminal false claims laws, the health care fraud provisions of HIPAA and the federal Physician Payments Sunshine Act and their implementing regulations. These laws will impact, among other things, our clinical research, as well as our proposed sales and marketing programs. In addition, we may be subject to health information privacy and security laws by the federal government, including HIPAA, as amended by HITECH, the states and other jurisdictions in which we may conduct our business.

Because of the breadth of these laws and the limited statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations.

Healthcare legislative reform measures may have a negative impact on our business and results of operations.

In the United States and foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives, including the 2010 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the "ACA"), which substantially changed the way healthcare is financed by both the government and private insurers and significantly impacts the U.S. pharmaceutical industry.

The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect:

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

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical and biologic products. In addition, 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.

In August 2022, the Inflation Reduction Act of 2022 ("IRA") was signed into law. The IRA includes several provisions that may impact our business, depending on how various aspects of the IRA are implemented. Provisions that may impact our business include a

$2,000 out-of-pocket cap for Medicare Part D beneficiaries, the imposition of new manufacturer financial liability on most drugs in Medicare Part D, permitting the U.S. government to negotiate Medicare Part B and Part D pricing for certain high-cost single-source drugs that have been on the market for at least seven years and biologics that have been on the market for at least 11 years covered under Medicare (the "Medicare Drug Price Negotiation Program") and requiring companies to pay rebates to Medicare for drug prices that increase faster than inflation. Further, under the IRA, orphan drugs are exempted from the Medicare Drug Price Negotiation Program, but only if they have one orphan designation and for which the only approved indication is for that disease or condition. If a product receives multiple orphan designations or has multiple approved indications, it may not qualify for the orphan drug exemption. The IRA permits the United States Department of Health and Human Services ("HHS") to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. These provisions began to take effect progressively starting in fiscal year 2023. On August 15, 2024, HHS announced the agreed-upon reimbursement price of the first ten drugs that were subject to price negotiations, although the Medicare Drug Price Negotiation Program is currently subject to legal challenges. On January 17, 2025, HHS selected fifteen additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program. In December 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework.

We cannot be sure whether additional legislative changes will be enacted, whether FDA regulations, guidance or interpretations will be changed or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. The current Trump administration is pursuing policies to reduce regulations and expenditures across government including at HHS, the FDA, the Centers for Medicare and Medicaid Services ("CMS") and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. These actions include, for example, (1) directives to reduce agency workforce program cuts, (2) rescinding a Biden administration executive order tasking the Center for Medicare and Medicaid Innovation to consider new payment and healthcare models to limit drug spending, (3) eliminating the Biden administration's executive order that directed HHS to establish an AI task force and develop a strategic plan, (4) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives, including by improving upon the Medicare Drug Price Negotiation Program and establishing Most-Favored-Nation pricing for pharmaceutical products, and (5) directing certain federal agencies to enforce existing law regarding hospital and plan price transparency and by standardizing prices across hospitals and health plans. Additionally, in its June 2024 decision in *Loper Bright Enterprises v. Raimondo*, the U.S. Supreme Court overturned the longstanding *Chevron* doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The *Loper Bright* decision could result in additional legal challenges to current regulations and guidance issued by federal agencies applicable to our operations, including those issued by the FDA. Congress may introduce and ultimately pass health care related legislation that could, among others, impact the drug approval process, modify the Medicare Drug Price Negotiation Program, expand the orphan drug exclusion under the IRA and reduce Medicaid enrollment and funding.

In addition, individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical 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 cannot predict what healthcare reform initiatives may be adopted in the future. We expect that these and other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and additional downward pressure on the price that we receive for any approved drug. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our drugs.

We may be exposed to liabilities under the U.S. Foreign Corrupt Practices Act (the "FCPA") and similar anti-corruption and anti-bribery laws, as well as trade sanctions, embargoes and anti-money laundering laws and regulations. Compliance with these legal standards could hinder our ability to compete in certain markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

Our operations are subject to U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations. The FCPA and these other laws generally prohibit us, our officers and our employees and intermediaries from, directly or indirectly, offering, authorizing or making improper payments to non-U.S. government officials for the purpose of obtaining or retaining business or other advantage. We engage third parties for clinical trials outside of the United States and may continue to do so in the future. We may also sell our products abroad if we enter a commercialization phase and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals for any product sales outside the United States. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. As our business expands, the applicability of the FCPA and other anti-bribery laws to our operations will increase. If our procedures and controls to monitor anti-bribery compliance fail to protect us from reckless or criminal acts committed by our employees or agents or if we, or our employees, agents, contractors or other collaborators, fail to comply with applicable anti-bribery laws, our reputation could be harmed and we could incur criminal or civil penalties, other sanctions and significant expenses, which could have a material adverse effect on our business, including our financial condition, results of operations, cash flows and prospects.

In addition, our products, if approved, may be subject to U.S. and foreign export controls, trade sanctions, embargoes and import laws and regulations. Governmental regulation of the import or export of our products or our failure to obtain any required import or export authorization for our products, when applicable, could harm our international or domestic sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments and persons targeted by U.S. sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations or in the countries, persons or products targeted by such regulations, could result in decreased use of our products by, or in our decreased ability to export our products to, existing or potential customers with international operations. Any decreased use of our products or limitation on our ability to export or sell our products would likely adversely affect our business.

There is substantial uncertainty regarding the new Administration's initiatives and how these might impact the FDA, its implementation of laws, regulations, policies and guidance and its personnel. Similar initiatives may also be directed toward other government agencies. These initiatives could prevent, limit or delay development and regulatory approval and impact commercialization, of our product candidates, which would impact our business.

FDA-regulated industries, such as ours, face substantial uncertainty regarding the regulatory environment we will face as we proceed with research and development, and possibly in future commercialization, efforts following the inauguration of President Trump in January 2025 (the "Administration"). Some of these efforts have manifested to date in the form of personnel measures that could impact the FDA's ability to hire and retain key personnel, which could result in delays in or limitations on our ability to obtain guidance from the FDA on our product candidates in development and obtain the requisite regulatory approvals in the future. Moreover, the Administration has proposed action to freeze or reduce the budget of the National Institutes of Health ("NIH") related to its funding for medical research, which could decrease the ability of facilities that rely on NIH funding to enroll and conduct clinical trials or increase the costs to us of conducting clinical trials. There remains general uncertainty regarding future activities. The Administration could issue or promulgate executive orders, regulations, policies or guidance that adversely affect us or create a more challenging or costly environment to pursue the development and sale of new therapeutic products. For example, on January 20, 2025, the Administration announced an executive order establishing the Department of Government Efficiency to maximize government efficiency and productivity. Pressures on and uncertainty surrounding the U.S. federal government's budget and potential changes in budgetary priorities could adversely affect the funding for existing programs and grants and increase the costs to us of conducting clinical trials. Alternatively, state governments may attempt to address or react to changes at the federal level with changes to their own regulatory frameworks in a manner that is adverse to our operations. If we or our collaborators become negatively impacted by future governmental orders, regulations, policies or guidance as a result of the Administration, there could be a material adverse effect on us and our business.

Risks Related to Third Party Relationships

We rely on third-party manufacturers, CROs, CDMOs and suppliers to supply, develop and test components of our product candidates. The loss of our third-party manufacturers, CROs, CDMOs or suppliers, their failure to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, or at all, or changes in methods of product candidate manufacturing, development or formulation would materially and adversely affect our business.

We do not own or operate facilities for drug manufacturing, storage, distribution or quality testing. We currently rely exclusively, and may continue to rely exclusively, on third-party contract manufacturers, to manufacture and test bulk drug substances, biologic and drug products, raw materials, samples, components or other materials and reports. Reliance on third-party manufacturers may expose us to different risks than if we were to manufacture product candidates ourselves. There can be no assurance that our preclinical and clinical development product supplies will not be limited, interrupted, terminated or of satisfactory quality or continue to be available at acceptable prices. In addition, any replacement of our manufacturer could require significant effort and expertise because there may be a limited number of qualified replacements.

The manufacturing process for a product candidate is subject to FDA, EMA and foreign regulatory authority review. In some cases, we, and our suppliers and manufacturers, some of which may be our sole source of supply, must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as cGMPs. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the FDA, EMA and other comparable foreign regulatory authorities. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, EMA and other comparable foreign regulatory authorities, we may not be able to rely on their manufacturing facilities for the manufacture of elements of our product candidates. Moreover, we do not control the manufacturing process at our contract manufacturers and are completely dependent on them for compliance with current regulatory requirements. In the event that any of our manufacturers fails to comply with such requirements or to perform its obligations in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to enter into an agreement with another third party, which we may not be able to do on reasonable terms, if at all, or the clinical development of our product candidates may be delayed. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such to another third party.

These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to enable us, or to have another third party, manufacture our product candidates. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines; and we may be required to repeat some of the development program. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget.

We expect to continue to rely on third-party manufacturers if we receive regulatory approval for any product candidate. We will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. Any manufacturing facilities used to produce our products will be subject to periodic review and inspection by the FDA and foreign regulatory authorities, including for continued compliance with cGMP requirements, quality control, quality assurance and corresponding maintenance of records and documents. If we are unable to obtain or maintain third-party manufacturing for product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully. Our or a third party's failure to execute on our manufacturing requirements, comply with cGMPs or maintain a compliance status acceptable to the FDA or foreign regulatory authorities could adversely affect our business in a number of ways, including:

- delay in the progress on certain research programs;
- an inability to initiate or continue clinical trials of product candidates under development;
- delay in submitting regulatory applications or receiving regulatory approvals, for product candidates;
- loss of the cooperation of existing or future collaborators;
- subjecting third-party manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease distribution or to recall batches of our product candidates; and
- in the event of approval to market and commercialize a product candidate, an inability to meet commercial demands for our therapeutics.

Additionally, our contract manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our contract manufacturers were to encounter any of these difficulties, our ability

to provide our product candidates to patients in preclinical and clinical trials, or to provide product for treatment of patients once approved, would be jeopardized.

In addition, we currently rely on foreign CROs and CDMOs, for manufacturing and development activities and will likely continue to rely on foreign CROs and CDMOs in the future. Foreign CDMOs may be subject to U.S. legislation, sanctions, trade restrictions and other foreign regulatory requirements which could increase the cost or reduce the supply of material available to us, delay the procurement or supply of such material or have an adverse effect on our ability to secure significant commitments from governments to purchase our potential therapies.

For example, if enacted, legislation pending in Congress known as the BIOSECURE Act would prohibit U.S. federal agencies from entering into or renewing a contract with any company that uses biotechnology equipment or services produced or provided by a "biotechnology company of concern" in the performance of that contract, which may impact one of our CDMOs. It would also prohibit loans or grant funding from U.S. federal agencies to entities that use any biotechnology equipment or services produced or provided by a "biotechnology company of concern" in the performance of the government grant or loan. The effects of this legislation, if enacted, is unknown; however, it could have the downstream effect of restricting the ability of pharmaceutical companies that enter into contracts with or receive funding from U.S. federal agencies from purchasing services or equipment from certain Chinese biotechnology companies, including those that are specifically named in the proposed BIOSECURE Act, as well as supply chain disruptions or delays. In addition to the BIOSECURE Act, any additional executive action, legislative action or potential sanctions with China could materially impact our work. U.S. executive agencies have the ability to designate entities and individuals on various governmental prohibited and restricted parties lists. Depending on the designation, potential consequences can range from a comprehensive prohibition on all transactions or dealings with designated parties or a limited prohibition on certain types of activities, such as exports and financing activities, with designated parties.

Furthermore, as product candidates progress through preclinical and clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield and manufacturing batch size, minimize costs and achieve consistent quality 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 current or future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commercialize our product candidates, if approved, and generate revenue.

We rely, and expect to continue to rely, on third parties, including independent clinical investigators, contracted laboratories and CROs, to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third parties, including independent clinical investigators, contracted laboratories and third-party CROs, to conduct our preclinical studies and clinical trials in accordance with applicable regulatory requirements, to validate our assays and to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third-party contractors and CROs are required to comply with good laboratory practices ("GLPs"), as applicable, and GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible, reproducible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Regulatory authorities enforce these GLPs and GCPs through periodic inspections of laboratories conducting GLP studies, trial sponsors, principal investigators and trial sites. If we, our investigators or any of our CROs or contracted laboratories fail to comply with applicable GLPs and GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional preclinical studies or clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our preclinical studies or clinical trials comply with applicable GLP or GCP regulations. In addition, our clinical trials must be conducted with product, including biologic product, produced in compliance with applicable cGMP regulations. Our failure to comply with these regulations may require us to repeat preclinical studies or clinical trials, which would delay the regulatory approval process.

Further, these laboratories, investigators and CROs are not our employees and we will not be able to control, other than by contract, the amount of resources, including time, which they devote to our product candidates and clinical trials. If independent laboratories, investigators or CROs fail to devote sufficient resources to the development of our product candidates, or if their performance is substandard, it may delay or compromise the prospects for approval and commercialization of any product candidates that we develop. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated.

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if we can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated.

There is a limited number of third-party service providers that specialize or have the expertise required to achieve our business objectives. If any of our relationships with these third-party laboratories, CROs or clinical investigators terminate, we may not be able to enter into arrangements with alternative laboratories, CROs or investigators or to do so in a timely manner or on commercially reasonable terms. If laboratories, CROs or clinical investigators do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our preclinical or clinical protocols, regulatory requirements or for other reasons, our preclinical or clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Switching or adding additional laboratories or CROs (or investigators) involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new laboratory or CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our contracted laboratories and CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and results of operations.

In addition, clinical investigators may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest or the FDA concludes that the financial relationship may have affected the interpretation of the preclinical study or clinical trial, the integrity of the data generated at the applicable preclinical study or clinical trial site may be questioned and the utility of the preclinical study or clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA. Any such delay or rejection could prevent us from commercializing our clinical-stage product candidate or any future product candidates.

The manufacturing of our product candidates is complex, and our third-party manufacturers may encounter difficulties in production. If we or any of our third-party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for clinical trials, our ability to obtain marketing approval or our ability to provide supply of our products for patients, if approved, could be delayed or stopped.

The process of manufacturing pharmaceuticals is complex, time-consuming, highly regulated and subject to multiple risks. Our contract manufacturers must comply with legal requirements, cGMPs and guidelines for the manufacturing of pharmaceuticals used in clinical trials and, if approved, marketed products. Our contract manufacturers may have limited experience in the manufacturing of cGMP batches.

Manufacturing pharmaceuticals is highly susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered at our third-party manufacturers' facilities, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely harm our business.

In addition, there are risks associated with large-scale manufacturing for clinical trials or commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, compliance with cGMPs, lot consistency and timely availability of raw materials. Even if we or our future collaborators obtain regulatory approval for any of our product candidates, there is no assurance that manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. If manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization, commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and prospects.

Scaling up a pharmaceutical manufacturing process is a difficult and uncertain task, and our third-party manufacturers may not have the necessary capabilities to complete the implementation, manufacturing and development process. If we are unable to adequately validate or scale-up the manufacturing process at our current manufacturers' facilities, we will need to transfer to another manufacturer and complete the manufacturing validation process, which can be lengthy. If we are able to adequately validate and scale-up the manufacturing process for our product candidates with a contract manufacturer, we will still need to negotiate with such contract manufacturer an agreement for commercial supply and it is not certain we will be able to come to agreement on terms acceptable to us.

We cannot assure that any stability or other issues relating to the manufacture of any of our current or future product candidates will not occur in the future. If our third-party manufacturers were to encounter any of these difficulties, our ability to provide any product candidates to patients in planned clinical trials and products to patients, once approved, would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of planned clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely. Any adverse developments affecting clinical or commercial manufacturing of our product candidates or products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls or other interruptions in the supply of our product candidates or products. We may also have to take inventory write-offs and incur other charges and expenses for product candidates or products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Accordingly, failures or difficulties faced at any level of our supply chain could adversely affect our business and delay or impede the development and commercialization of any of our product candidates or products, if approved, and could have an adverse effect on our business, prospects, financial condition and results of operations.

As part of our process development efforts, we also may make changes to the manufacturing processes at various points during development, for various reasons, such as controlling costs, achieving scale, decreasing processing time, increasing manufacturing success rate or other reasons. Such changes carry the risk that they will not achieve their intended objectives, and any of these changes could cause our current or future product candidates to perform differently and affect the results of our current or future clinical trials. In some circumstances, changes in the manufacturing process may require us to perform *ex vivo* comparability studies and to collect additional data from patients prior to undertaking more advanced clinical trials. For instance, changes in our process during the course of clinical development may require us to show the comparability of the product used in earlier clinical phases or at earlier portions of a trial to the product used in later clinical phases or later portions of the trial.

Our existing collaborations are, and our future collaborations may be, important to our business. If we are unable to enter into new collaborations, or if our collaborations are not successful, our business could be adversely affected.

A part of our strategy is to systematically evaluate and, as deemed appropriate, enter into strategic collaborations when strategically attractive, including potentially with major biotechnology or pharmaceutical companies. We have limited capabilities for product development and do not yet have any capability for commercialization. Accordingly, we have entered into, and may enter into, collaborations with other companies to provide us with important technologies and funding for our programs and technology. If we fail to enter into or maintain collaborations on reasonable terms or at all, our ability to develop our existing or future research programs and product candidates could be delayed, the commercial potential of our product candidates could change and our costs of development and commercialization could increase. Furthermore, we may find that our programs require the use of intellectual property rights held by third parties, and the growth of our business may depend in part on our ability to acquire or in-license these intellectual property rights.

Our existing collaborations and any future collaborations we may enter into may pose a number of risks, including, but not limited to, the following:

•collaborators have significant discretion in determining the efforts and resources that they will apply;

•collaborators may not perform their obligations as expected;

•collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs or license arrangements based on clinical trial results, changes in the collaborators' strategic focus or available funding or external factors, such as a strategic transaction that may divert resources or create competing priorities;

•collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;

•collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products, if approved, and product candidates if the collaborators believe that the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;

•product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;

•collaborators may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a product candidate or product;

•collaborators with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;

•disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or terminations of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates or might result in litigation or arbitration, any of which would be time-consuming and expensive;

•collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;

•collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;

•if a collaborator of ours is involved in a business combination, the collaborator might de-emphasize or terminate the development or commercialization of any product candidate licensed to it by us; and

•collaborations may be terminated by the collaborator, and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

If our future collaborations do not result in the successful discovery, development and commercialization of product candidates or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under such collaboration. Additionally, if one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our perception in the business and financial communities could be adversely affected.

We face significant competition in seeking appropriate collaborative partners. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon an 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 relating to our business. These factors may include the design or results of preclinical studies or clinical trials, the likelihood of regulatory approval, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of any uncertainty with respect to our ownership of technology (which can exist if there is a challenge to such ownership regardless of the merits of the challenge) and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us.

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, reduce the scope of any sales or marketing activities or increase our expenditures and undertake development or commercialization activities at our own expense. 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 product candidates or bring them to market and generate product revenue.

Reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Reliance on third parties to manufacture or commercialize our current or any future product candidates and on collaborations with additional third parties for the development of our current or any future product candidates, requires us to share trade secrets with these third parties. We may 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. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, services agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants 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. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information 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 could have an adverse effect on our business and results of operations.

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. 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 third-party collaborators. A competitor's discovery of our trade secrets could harm our business.

Risks Related to Intellectual Property

We have licensed intellectual property rights from third parties and may do so in the future. Such licenses may be subject to early termination if we fail to comply with our obligations in our licenses with third parties, which could result in the loss of rights or technology that are material to our business.

We are a party to licenses that give us rights to third-party intellectual property or technology that is necessary or useful for our business, and we may enter into additional licenses in the future. For example, we depend on licenses from Dermira and AprilBio for certain intellectual property relating to the development and commercialization of our clinical-stage product candidates, EVO756 and EVO301, respectively. Under these license agreements, we are or may become obligated to pay the licensor fees, which may include annual license fees, upstream license obligations, milestone payments, royalties, a percentage of revenues associated with the licensed technology and a percentage of sublicensing revenue. These fees may be significant, which could make it difficult for us to achieve or maintain profitability. In addition, under certain of such agreements, we are or may become required to diligently pursue the development of products using the licensed technology. If we fail to comply with these obligations, including due to our use of the intellectual property licensed to us in an unauthorized manner, and fail to cure our breach within a specified period of time, the licensor may have the right to terminate the applicable license, in which event we could lose valuable rights and technology that are material to our business, harming our ability to develop, manufacture and commercialize our product candidates.

In addition, the agreements under which we license intellectual property or technology to or from third-parties can be 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.

The licensing and acquisition of third-party intellectual property rights is a competitive practice, and companies that may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their larger size and cash resources or greater clinical development and commercialization capabilities. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire. The failure to obtain or in-license any compositions, methods of use, processes or other third-party intellectual property rights at a reasonable cost or on reasonable terms, could harm our business. If we fail to obtain licenses to necessary third-party intellectual property rights, we may need to cease use of the compositions or methods covered by such third-party intellectual property rights. Furthermore, we may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

Our success depends in part on our ability to protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.

Our commercial success will depend in large part on obtaining and maintaining patent, trademark and trade secret protection of our proprietary technologies and our product candidates, their respective components, formulations, combination therapies, and methods used to manufacture them and methods of treatment, as well as successfully defending these patents against third-party challenges. Our ability to stop unauthorized third parties from making, using, selling, offering to sell or importing our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents that cover these activities. If we are unable to secure and maintain patent protection for any product or technology we develop, or if the scope of the patent protection secured is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to commercialize any product candidates we may develop may be adversely affected. The patenting process is expensive and time-consuming, and we may not be able to file, prosecute and maintain or in-license, all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, we may not pursue, obtain or maintain patent protection in all relevant markets. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent

protection. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications or to maintain the patents, covering technology that we license from or license to third parties, and are reliant for such purposes on our licensors or licensees. In addition, we cannot guarantee that patent applications or patents that we initially believe to be owned by the company or a licensor will not be found to be encumbered by third party ownership or other third party rights that may not have been evident to us at the time of preparation, filing or in-licensing. For instance, such rights could arise from the intellectual contributions of company employees who were previously employed by third parties, such as universities or other biopharmaceutical or pharmaceutical companies, including our competitors or potential competitors, or from the intellectual contributions of company consultants, advisors or independent contractors with current or previous relationships with such third parties. Therefore, these patents and applications may not be prepared, filed, prosecuted or enforced in a manner consistent with the best interests of our business. Furthermore, licenses from such third parties may be required or desirable but may not be available on reasonable terms, or at all.

The strength of patents in the biotechnology field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries. Even if the patents are successfully issued, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around its claims. If the breadth or strength of protection provided by the patent applications we hold with respect to our product candidates is threatened, this could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our product candidates.

We may be required to disclaim part or all of the term of certain patents or all of the term of certain patent applications. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim, and we may be subject to a third-party submission of prior art to the United States Patent and Trademark Office ("USPTO") in connection with pending patent applications, and any analogous procedures outside the United States. There also may be prior art of which we are aware, but which we believe does not affect the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. No assurance can be given that if challenged, our patents would be found by a court to be valid or enforceable or that even if found valid and enforceable, a competitor's technology or product would be found by a court to infringe our patents. We may analyze patents or patent applications of our competitors that we believe are relevant to our activities and conclude that we are free to operate in relation to our product candidates, but our competitors may ultimately obtain issued claims, including in patents we consider to be unrelated, which block our efforts or may potentially result in our product candidates or our activities infringing such claims. The possibility exists that others will develop products which compete with our products on an independent basis which do not infringe our patents or other intellectual property rights or will design around the claims of patents to which we have rights that cover our products.

The United States has enacted and implemented wide-ranging patent reform legislation. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available or the availability of patent protection in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents that have already issued. Depending on actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future. For example, recent decisions raise questions regarding the award of patent term adjustment ("PTA") for patents in families where related patents have issued without PTA. Thus, it cannot be said with certainty how PTA will/will not be viewed in the future and whether patent expiration dates, or even patent validity, may be impacted. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. For example, the complexity and uncertainty of European patent laws have also increased in recent years. In Europe, a new unitary patent system took effect June 1, 2023, which has significantly impacted European patents, including those granted before June 1, 2023. Under the unitary patent system, European applications have the option, upon grant of a patent, of becoming a Unitary Patent which is subject to the jurisdiction of the Unitary Patent Court ("UPC"). Additionally, certain non-Unitary Patents that are European patents may also be subject to the jurisdiction of the UPC. As the UPC is a new court system, there is only a limited established body of substantive and procedural precedents, which increases the uncertainty of any litigation. Proprietors of certain European patents granted before the implementation of the UPC have the option of opting such patents out of the jurisdiction of the UPC and designating such patents as being subject to the jurisdiction of national courts. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of any potential changes.

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:

- others may be able to make or use compounds or proteins that are similar to our product candidates but that are not covered by the claims of patents to which we have rights;
- biologic drugs that are among our current product candidates may eventually become commercially available in biosimilar drug products. Patent protection for our products may not be available at all or may only be available with regard to the formulation of such products or methods of using such products, which are considered to provide limited protection;
- we or our licensors, as the case may be, may fail to meet our obligations to the U.S. government in regards to any in-licensed patents and patent applications funded by U.S. government grants, leading to the loss of patent rights and exclusivity;
- we or our licensors, as the case may be, might not have been the first to file patent applications for these inventions and, as a result, may be unable to obtain any patent protection for such inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that our pending patent applications will not result in issued patents;
- it is possible that there are prior public disclosures that could invalidate our or our licensors' patents, as the case may be, or parts of our patents or licensors' patents;
- it is possible that others may circumvent our owned or in-licensed patents without infringing them;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products or technology similar to our own;
- the laws of foreign countries may not protect ours or our licensors', as the case may be, proprietary rights to the same extent as the laws of the United States;
- the claims of our owned or in-licensed issued patents or patent applications, if and when issued, may not cover our product candidates;
- our owned or in-licensed issued patents may not provide us with any competitive advantages, may be narrowed in scope or be held invalid or unenforceable as a result of legal challenges by third parties;
- the inventors of our owned or in-licensed patents or patent applications may become involved with competitors, develop products or processes which design around our patents or become hostile to us or the patents or patent applications on which they are named as inventors;
- it is possible that our owned or in-licensed patents or patent applications omit individual(s) that should be listed as inventor(s) or include individual(s) that should not be listed as inventor(s), which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable;
- we have engaged in scientific collaborations in the past and will continue to do so in the future. Such collaborators may develop adjacent or competing products to ours that are outside the scope of our patents;
- we may not develop, or may not be able to develop, additional proprietary technologies for which we can obtain patent protection;
- it is possible that product candidates we develop may be covered by third parties' patents or other exclusive rights; and
- the patents of others may have an adverse effect on our business.

If we are unable to obtain and maintain sufficient intellectual property protection for our product candidates or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our products may be adversely affected.

We rely upon a combination of patents, trademarks, trade secret protection and confidentiality agreements to protect the intellectual property related to our product candidates and technologies and to prevent third parties from copying and further developing our inventions and intellectual property, thus eroding our competitive position in our markets. Our success depends in large part on our ability to obtain and maintain patent protection for our product candidates and their intended uses, maintain trade secret protection of our product candidates, as well as our ability to operate without infringing the proprietary rights of others. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel inventions and technologies that are important to our business or by in-licensing such patent rights. Our pending and future patent applications, including in-licensed patent applications, may not result in patents being issued or may not result in issued patents that will afford sufficient protection of our product candidates or their intended uses nor can there be any assurance that any patents that issue will be infringed, not designed around

and not invalidated by third parties, or that they will effectively prevent others from commercializing competitive technologies or products.

Obtaining and enforcing patents is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications or maintain or enforce patents that may issue based on our patent applications, or in-license any similar rights, at a reasonable cost or in a timely manner, including due to delays as a result of global pandemics impacting our or our licensors' operations. Further, we may decide to not pursue or seek patent protection in all relevant markets. It is also possible that we will fail to identify patentable aspects of our research and development results before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach these agreements and disclose such results before a patent application is filed, thereby jeopardizing our ability to seek and obtain patent protection. If we delay in filing a patent application, and a competitor files a patent application on the same or a similar technology before we do, we may face a limited ability to secure patent rights, or we may not be able to obtain a patent on such technology at all. Even if we are able to obtain a patent covering such technology, we may only be able to obtain a narrow scope of protection, and such narrow scope may be inadequate to protect our product candidates, or to block competitor products or product candidates that are similar to ours.

Composition of matter patents for pharmaceutical product candidates are considered to provide a strong form of intellectual property protection, because such patents provide protection for all uses of the product candidate. The claims in our pending patent applications, including in-licensed applications, that are directed to composition of matter coverage of our product candidates may not be found to be patentable by the USPTO or by patent offices in foreign countries. The courts in the United States or foreign countries may find that such patents are not valid and enforceable. 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 these products "off-label." Although products distributed pursuant to 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.

The patent position of biopharmaceutical companies generally is highly uncertain and involves complex legal and factual questions that are governed by laws and regulations that are subject to change. In recent years, patent rights have been the subject of much litigation, and such high rates of litigation may continue into the future. The issuance, scope, validity, enforceability and commercial value of our patent rights are subject to many factors including such litigation and, as a result, are subject to great uncertainty. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patent rights or narrow the scope of our patent protection. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, or vice versa.

We cannot ensure that patent rights relating to inventions described and claimed in our pending patent applications will issue or that patents based on our patent applications will not be challenged and rendered invalid or unenforceable.

The patent application process is subject to numerous risks and uncertainties, and we or any of our potential future collaborators may not be successful in protecting our product candidates by obtaining and successfully defending and enforcing patents. For example, we may not be aware of all third-party intellectual property rights potentially relating to our product candidates or their intended uses, and, as a result, the impact of such third-party intellectual property rights upon the patentability of our own patents and patent applications, including in-licensed patents and patent applications, as well as the impact of such third-party intellectual property upon our freedom to operate, is highly uncertain. Patent applications in the United States and other foreign 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 or our licensors were the first to make the inventions claimed in patents or pending patent applications to which we have rights or that we or our licensors were the first to file for patent protection of such inventions. As a result, the issuance, inventorship, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. We or any of our potential future collaborators may not be successful in protecting our product candidates by obtaining and defending patents. Although we have rights to U.S. and foreign patent applications, we cannot predict:

- if and when patents may issue based on our or our licensors' patent applications;
- the scope of protection of any patent issuing based on our or our licensors' patent applications;
- whether the claims of any patent issuing based on our or our licensors' patent applications will provide protection against competitors;
- whether or not third parties will find ways to invalidate or circumvent our patent rights;

- whether or not others will obtain patents claiming aspects similar to those covered by our or our licensors' patents and patent applications;
- whether we will need to initiate litigation or administrative proceedings to enforce or defend our patent rights which will be costly, time-consuming and require us to expend resources, whether we win or lose;
- whether the patent applications that we own or in-license will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries; and
- whether we may experience patent office interruption or delays to our ability to timely secure patent rights covering our product candidates.

The claims in our or our licensors' pending patent applications directed to our product candidates or technologies may not be considered patentable by the USPTO or by patent offices in foreign countries. Any such patent applications may not be issued as granted patents. One aspect of the determination of patentability of our inventions depends on the scope and content of the "prior art," which is information that was or is deemed available prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of our or our licensors' patent application claims or, if issued, affect the validity or enforceability of a patent claim. There may be disallowed double patenting among patents to which we have rights, which the patent examiner(s) fail to raise during prosecution. Even if the patents do issue based on our or our licensors' patent applications, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, patents in our portfolio (including in-licensed patents) may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. If the breadth or strength of our intellectual property position with respect to our product candidates is threatened, this could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates.

Our and our licensors' pending patent applications may be challenged in the USPTO or in patent offices in foreign countries. Also, because the issuance of a patent is not conclusive as to its scope, validity or enforceability, even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. For example, our and our licensors' pending patent applications may be subject to third-party pre-issuance submissions of prior art to the USPTO or patent offices in foreign countries, or our issued patents may be subject to post-grant review ("PGR") proceedings, oppositions, derivations, reexaminations or *inter partes* review ("IPR") proceedings, in the United States or elsewhere, challenging our patent rights. An adverse determination in any such challenges may result in loss of exclusivity or in our patent rights being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technologies and products or limit the duration of the patent protection of our technologies and product candidates. In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, only limited protection may be available and our patent rights may not provide us with sufficient rights or permit us to gain or keep any competitive advantage. Any failure to obtain or maintain patent protection with respect to our product candidates or their uses could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may rely on trade secret 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.

In addition to seeking patent protection for our product candidates and technologies, we may rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents or that may alternatively be covered by trade secret protection or through measures of confidentiality. Elements of our product candidates, including processes for their preparation and manufacture, may involve proprietary know-how, information or technology that is not covered by patents, or that is more advantageously protected by trade secrets or confidentiality, and thus for these aspects we may consider trade secrets and know-how to be our primary intellectual property. We may also rely on trade secret protection as temporary protection for concepts that may be included in a future patent filing. We expect to rely on CROs and third parties to generate chemical molecules and important research data. Any disclosure, either intentional or unintentional, by our employees or third-party consultants and vendors or CROs that we engage to perform research, clinical trials or manufacturing activities or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Because we rely on third parties in the development and manufacture of our product candidates, we must, at times, share trade secrets with them. Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

However, trade secret protection will not protect us from innovations that a competitor develops independently of our proprietary know-how. If a competitor independently develops a technology that we protect as a trade secret and files a patent application on that technology, then we may not be able to patent that technology in the future, may require a license from the competitor to use our own technology or know-how, and if the license is not available on commercially viable terms, then we may not be able to complete development of, or commercialize, our products. Although we require all of our employees, consultants, collaborators, CROs, contract manufacturers, advisors and any third parties who have access to our proprietary know-how, information or technologies to enter into confidentiality agreements, we cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes. We cannot be certain that our trade secrets and other confidential proprietary information may not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party unlawfully disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. Furthermore, the laws of some foreign countries do not protect proprietary rights, such as trade secrets rights, to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. We may need to share our proprietary information, including trade secrets, with future business partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, and this scenario could materially adversely affect our business, financial condition and results of operations.

Changes in U.S. patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our current and any future product candidates.

Changes in either the patent laws or interpretation of the patent laws in the United States and other foreign countries could increase uncertainties and costs and may diminish our ability to protect our inventions, obtain, maintain and enforce our intellectual property rights and, more generally, could affect the value of our patent rights or narrow the scope of our patent rights. The Leahy-Smith America Invents Act of 2011 (the "Leahy-Smith Act") included several significant changes to U.S. patent law that impacted how patent rights could be prosecuted, enforced and defended. 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 PGR, IPR 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 patent claim invalid even though the same evidence would be insufficient to invalidate the patent claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our or our licensors' 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 and our licensors' patent applications and the enforcement or defense of our or our licensors' issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, under the Leahy-Smith Act, the United States transitioned from a "first-to-invent" system to a "first-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 a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before we or our licensors file an application covering the same invention, could therefore be awarded a patent covering an invention to which we have rights even if we or our licensors made the invention before it was made by such third party. This will require us and our licensors to be cognizant 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 or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our product candidates and other proprietary technologies we may develop or (ii) invent any of the inventions claimed in our or our licensor's patents or patent applications. 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 or the other party benefits from a compulsory license.

These and future changes in patent law could increase the uncertainties and costs surrounding the prosecution of our and our licensors' patent applications and the enforcement or defense of our and our licensors' issued patents, all of which could have a negative effect on our business.

In addition, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our and our licensors' ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, already obtained. Depending on actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our and our licensors' ability to obtain new patents or to enforce patents that we have licensed or that we might obtain or license in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our and our licensors' ability to obtain new patents or to enforce patents that we have licensed or that we may obtain or license in the future.

We may be involved in lawsuits or proceedings to protect or enforce our patents or other intellectual property or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Competitors or other third parties may infringe or otherwise violate our patents, trademarks or other intellectual property or the patents of our licensors. To stop infringement or unauthorized use, we or our licensors may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one or more of our or licensors' patents is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our or our licensors' patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more patents to which we have rights at risk of being invalidated, held unenforceable or interpreted narrowly and could place patent applications to which we have rights under the risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business.

We may choose to challenge the patentability of claims in a third party's U.S. patent by requesting that the USPTO review the patent claims in an *ex-parte* re-exam, *inter partes* review or post-grant review proceedings. These proceedings are expensive and may consume our time or other resources. We may choose to challenge a third party's patent in patent opposition proceedings in the foreign patent offices. The costs of these opposition proceedings could be substantial and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO or other patent office then we may be exposed to litigation by a third party alleging that the patent is infringed by our product candidates or proprietary technologies.

In addition, because (i) some patent applications in the United States may be maintained in secrecy until the patents are issued, (ii) other patent applications in the United States and patent applications in many foreign jurisdictions are typically not published until 18 months after filing and (iii) publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our owned or in-licensed issued patents or our owned or in-licensed pending applications, or that we or, if applicable, a licensor, was the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering products or technology similar to ours before we or our licensors do so. Any such patent application may have priority over our owned and in-licensed patent applications or patents, which could require us to eventually seek to obtain rights to issued patents covering such technologies from third parties. If another party has filed a U.S. patent application on inventions similar to those owned by or in-licensed to us, we or, in the case of in-licensed technology, the licensor, may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the United States. We or our licensors may lose patent rights as a result. If we or one of our licensors is a party to an interference proceeding involving a U.S. patent application on inventions owned by or in-licensed to us, we may incur substantial costs, unduly occupy our management's time in connection with legal proceedings, divert management from its usual duties and substantially expend other resources, even if we are successful.

Interference proceedings provoked by third parties or brought by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could result in a loss of our or our licensors' current patent rights and could require us to cease using the related technology or to attempt to license rights to it from a prevailing third party or other third party. Our business could be harmed if the prevailing party or the other third party does not offer us a license on commercially reasonable terms or at all. Litigation or interference proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our proprietary or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during intellectual property litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.

Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing our or our licensors' issued patent, or any patents that may be issued as a result of our or our licensors' pending or future patent applications or other intellectual property rights, 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, or it may be otherwise impractical or undesirable to enforce our intellectual property. Our competitors or other third parties may be able to sustain the costs of complex patent litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. 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. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs, in- license needed technologies or other product candidates or enter into development partnerships that would help us bring our product candidates to market.

We may be subject to claims that our employees, consultants or advisors have wrongfully used or disclosed trade secrets or other confidential information of their current or former employers or claims asserting inventorship or ownership of what we regard as our own intellectual property.

Many of our employees, consultants and advisors are currently or were previously employed at universities or other healthcare, biotechnology or pharmaceutical companies, including our competitors or potential competitors and our licensors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer or client without authorization. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs, the expenditure of other resources and be a distraction to management.

We may be subject to claims that former employees, collaborators or other third parties have an interest in our or our licensors' 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 invalid or unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co-ownership of potential joint inventions. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. 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 rights 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, the expenditure of other resources and be a distraction to our management and other employees.

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

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and 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. Our in-licensed intellectual property is also subject to such risks. Any claims that we may be forced to defend against or that we assert could have a material adverse effect on our business, financial condition, results of operations and prospects.

Rights to improvements to our product candidates may be held by third parties.

In the course of testing our current or future product candidates, we may enter into agreements with third parties to conduct clinical testing, which may provide that improvements to our product candidates may be owned solely by a third party or jointly between the parties. If we determine that rights to such improvements owned solely by a third party are necessary to commercialize our product candidates or maintain our competitive advantage, we may need to obtain a license from such third party in order to use the improvements and continue developing, manufacturing or marketing the product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain such a license, it could be granted on non-exclusive terms, thereby potentially giving our competitors and other third parties access to the same technologies licensed to us. Failure to obtain a license on commercially reasonable terms or at all, or to obtain an exclusive license, could prevent us from commercializing our current or future product candidates or force us to cease some of our business operations, which could materially harm our business. If we determine that rights to improvements jointly owned between us and a third party are necessary to commercialize our product candidates or maintain our competitive advantage, we may need to obtain an exclusive license from such third party. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such improvements, such co-owners may be able to license their rights to other parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our intellectual property in order to enforce such intellectual property against other parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration date of a third-party patent, which might adversely affect our ability to develop and market our products.

We cannot guarantee that any patent searches or analyses that are performed, including the identification of relevant patents, the scope of patent claims or the expiration dates of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our current or future product candidates in any jurisdiction. The scope of a patent claim is determined by an interpretation of the law, the language of the claim, the written disclosure in the relevant patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our future products. We may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third-party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our future products.

We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.

Because our programs may in the future require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license or use these third-party proprietary rights. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary for our 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 or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

While we seek to obtain the right to control prosecution, maintenance and enforcement of the patents relating to our product candidates, there may be times when the filing and prosecution activities for patents and patent applications relating to our product candidates are controlled by our future licensors or collaboration partners. If any of our future licensors or collaboration partners fail to prosecute, maintain and enforce such patents and patent applications in a manner consistent with the best interests of our business, including by payment of all applicable fees for patents covering our product candidates, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. In addition, even where we have the right to control patent prosecution of patents and patent applications we have licensed to and from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensees, our future licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution.

We may enter into license agreements in the future with others to advance our existing or future research or allow commercialization of our current or future product candidates. These licenses may not provide 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 in the future.

In addition, subject to the terms of any such license agreements, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications covering the technology that we license from third parties. In such an event, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced and defended in a manner consistent with the best interests of our business. If our future licensors fail to prosecute, maintain, enforce and defend such patents or patent applications or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our current or future product candidates that are subject of such licensed rights could be adversely affected.

Our future licensors may rely on third-party consultants or collaborators or on funds from third parties such that our future licensors are not the sole and exclusive owners of the patents we in-license. If other third parties have ownership rights to our 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.

It is possible that we may be unable to obtain necessary licenses at a reasonable cost or on reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to redesign our technology, product candidates or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations and prospects significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current technology, manufacturing methods, product candidates or future methods or products resulting in either an injunction prohibiting our manufacture or future sales or, with respect to our future sales, an obligation on our part to pay royalties or other forms of compensation to third parties, which could be significant.

Disputes may arise between us and our 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;
- whether and the extent to which our technology and processes infringe on 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;
- when and under what conditions the license agreement may be terminated and the consequences thereof;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our 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 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 conditions, results of operations and prospects.

In spite of our best efforts, our 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 and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors might have the freedom to seek regulatory approval of, and to market, products identical to ours. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

From time to time, we may be required to license technologies relating to our programs from additional third parties to further develop or commercialize our current or future product candidates. Should we be required to obtain licenses to any third-party technology, including any such patents required to manufacture, use or sell our product candidates, such licenses may not be available to us on commercially reasonable terms, or at all. The inability to obtain any third-party license required to develop or commercialize any of our product candidates could cause us to abandon any related efforts, which could seriously harm our business and operations.

Third-party claims of intellectual property infringement may prevent or delay our product discovery, development and commercialization efforts.

Our commercial success depends in part on our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation, *inter partes* review, post grant review and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates and proprietary technologies infringe their intellectual property rights. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to our product candidates and programs. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our product candidates, technologies or methods.

If a third-party claims that we infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;
- substantial damages for infringement, which we may have to pay if a court decides that the product candidate or technology at issue infringes on or violates the third party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;
- a court prohibiting us from developing, manufacturing, marketing or selling our product candidates, or from using our proprietary technologies, unless the third party licenses its product rights to us, which it is not required to do;
- if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amounts or grant cross-licenses to intellectual property rights for its products; and
- redesigning our product candidates or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

Third parties may assert that we are employing their proprietary technology without authorization. Generally, conducting clinical trials and other development activities in the United States is protected under the Safe Harbor exemption as set forth in 35 U.S.C. § 271, and there are similar laws in some foreign jurisdictions. If any of our product candidates are approved by the FDA, that certain third party may then seek to enforce its patent by filing a patent infringement lawsuit against us. Even if we believe that any claims of such patent that could otherwise materially adversely affect commercialization of our product candidates, if approved, are valid and enforceable, we may be incorrect in this belief, or we may not be able to prove it in a litigation. In this regard, patents issued in the United States by law enjoy a presumption of validity that can be rebutted only with evidence that is "clear and convincing," a heightened standard of proof. There may be third-party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, constructs or molecules used in or formed during the manufacturing process, or any final product itself, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtained a license under the applicable patents or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent

were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business. Even if we obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign its infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Even if such a license is available, it may be non-exclusive, which could result in our competitors gaining access to the same intellectual property. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly.

Lastly, we may need to indemnify our customers and distributors against claims relating to the infringement of intellectual property rights of third parties related to our product candidates, including EVO756 and EVO301. Third parties may assert infringement claims against our customers or distributors. Our agreements with our customers or distributors may require us to initiate or defend protracted and costly litigation on behalf of our customers or distributors, regardless of the merits of these claims. If any of these claims succeed, we may be forced to pay damages on behalf of our customers, suppliers or distributors or may be required to obtain licenses for the product candidates or services they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our products or services.

Our intellectual property licensed from third parties may be subject to retained rights.

Our future licensors may retain certain rights under their agreements with us, including the right to use the underlying technology for noncommercial academic and research use, to publish general scientific findings from research related to the technology and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether our licensors limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse.

Government agencies may provide funding, facilities, personnel or other assistance in connection with the development of the intellectual property rights owned by or licensed to us. Such government agencies may have retained rights in such intellectual property. The United States federal government retains certain rights in inventions produced with its financial assistance under the Patent and Trademark Law Amendments Act (the "Bayh-Dole Act"), including the right to grant or require us to grant mandatory licenses or sublicenses to such intellectual property to third parties under certain specified circumstances, including if it is necessary to meet health and safety needs that we are not reasonably satisfying or if it is necessary to meet requirements for public use specified by federal regulations, or to manufacture products in the United States. Any exercise of such rights, including with respect to any such required sublicense of these licenses could result in the loss of significant rights and could harm our ability to commercialize licensed products. While we currently are not engaging with university partners, we cannot be sure that any co-developed intellectual property will be free from government rights pursuant to the Bayh-Dole Act. If, in the future, we co-own or license in technology which is critical to our business that is developed in whole or in part with federal funds subject to the Bayh-Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent offices in several stages over the lifetime of the patent. Certain foreign jurisdictions also require the payment of periodic annuity payments to maintain patent applications and avoid their abandonment. The USPTO and various foreign governmental patent agencies require compliance with a number of other procedural, documentary, fee payment and other provisions during the patent application process and following the issuance of a patent. 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 noncompliance 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. Noncompliance 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. In such an event, we or our licensors may fail to obtain patent protection, and our competitors might be able to enter the market, which would have a material adverse effect on our business.

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. The following examples are illustrative:

- others may be able to make compounds or formulations that are similar to our product candidates but that are not covered by the claims of any patents that we own or control;
- we or any strategic partners might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or control, which may cause such patents to be invalidated;
- we or our licensors might not have been the first to file patent applications covering certain of the inventions we own or control, which may prevent the patent applications from being granted or, if already granted, might cause them to be invalidated;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that noncompliance with the USPTO and foreign governmental agencies requirement for a number of procedural, documentary, fee payment and other provisions during the patent process or technology export can result in abandonment or lapse of a patent or patent application and partial or complete loss of patent rights in the relevant jurisdiction;
- pending patent applications that we own or control may not lead to issued patents;
- issued patents that we own or control may be held invalid or unenforceable as a result of legal challenges;
- our competitors might conduct research and development activities in the United States and other foreign countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights and then use the information learned from such activities to develop competitive product candidates for sale in our major commercial markets;
- we cannot predict the scope of protection of any patent issuing based on our patent applications, including whether the patent applications that we own or in-license will result in issued patents with claims directed to our product candidates or uses thereof in the United States or in other foreign countries;
- 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 health policy;
- countries other than the United States may have patent laws that are less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates;
- the claims of any patent issuing based on our patent applications may not provide protection against competitors or any competitive advantages or may be challenged by third parties;
- if enforced, a court may find that our patents are invalid, unenforceable or not infringed;
- we may not develop additional proprietary technologies that are patentable; and
- 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.

We may not be able to protect our intellectual property rights throughout the world, which could negatively impact our business.

Filing, prosecuting and defending patents covering our current and any future product candidates throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can have a different scope and strength than do those in the United States. Consequently, we may not be able to prevent third parties from practicing our or our licensors' inventions in all countries outside the United States or from selling or importing products made using our or our licensors' inventions in and into the United States or other countries. Competitors may use our or our licensors' technologies in jurisdictions where we have not obtained patent protection to develop their own product candidates and, further, may export otherwise infringing product candidates to territories where we or our licensors may obtain patent protection, but where patent enforcement is not as strong as that in the United States. These product candidates may compete with our product candidates in jurisdictions where we and our licensors do not have any issued or licensed patents, and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property, particularly those relating to biopharmaceutical products, which could make it difficult in those jurisdictions for us to stop the infringement or misappropriation of our patent rights or other intellectual property rights, or the marketing of competing products in violation of our proprietary rights. Proceedings to enforce our patent and other intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Furthermore, such proceedings could put our patent rights at risk of being invalidated, held unenforceable or interpreted narrowly, could put our or our licensors' patent applications at risk of not issuing and could provoke third parties to assert claims of infringement or misappropriation 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. Similarly, if our trade secrets are disclosed in a foreign jurisdiction, competitors worldwide could have access to our proprietary information and we may be without satisfactory recourse.

Such disclosure could have a material adverse effect on our business. Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. In addition, certain developing countries, including China and India, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. In addition, many countries limit the enforceability of patents against government agencies or government contractors. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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

Our current or future trademarks or trade names may be challenged, opposed, infringed, circumvented, invalidated, cancelled, declared generic, determined to be not entitled to registration or determined to be infringing on other marks. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in foreign jurisdictions. 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. Any trademark litigation could be expensive. In addition, we could be found liable for significant monetary damages, including treble damages, disgorgement of profits and attorneys' fees, if we are found to have willfully infringed a trademark. We may not be able to protect our exclusive right to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential collaborators or customers in our markets of interest. 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. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

Moreover, any name we propose to use with our product candidates 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 and other jurisdictions. 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 proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable 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. Trademark-related risks similar to those present in the United States may also be present in foreign jurisdictions.

We may seek additional in-licenses from third parties. If we are unable to acquire these rights, our business may be materially adversely affected, and if disputes arise with future licensors, we may be subject to future litigation as well as the potential loss of or limitations on our ability to develop and commercialize products and technologies covered by these license agreements.

The growth of our business may depend in part on our ability to acquire or in-license additional proprietary rights. We may be unable to acquire or in-license any relevant third-party intellectual property rights that we identify as necessary or important to our business operations at a reasonable cost or on reasonable terms, if at all, which would adversely affect our business. We may need to cease use of the technology covered by such third-party intellectual property rights and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license under such intellectual property rights, any such license may be non-exclusive and may allow our competitors access to the same technologies licensed to us. The licensing and acquisition of third-party intellectual property rights is a competitive practice, and companies that may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive for commercializing our product candidates. More established companies may have a competitive advantage over us due to their larger size and cash resources or greater clinical development and commercialization capabilities. We may not be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates and technology that we may seek to acquire.

Even if we successfully enter into license agreements with third parties under which we receive rights to intellectual property that are important to our business, our continued rights to use the technology we license would be subject to the continuation of and compliance with the terms of those agreements. These intellectual property license agreements may require of us various development, regulatory or commercial diligence obligations, payment of milestones or royalties and other obligations. If we fail to comply with our obligations under these agreements, we use the licensed intellectual property in an unauthorized manner or we are subject to bankruptcy-related proceedings, the terms of the license agreements may be materially modified, such as by rendering currently exclusive licenses non-exclusive, or it may give our licensors the right to terminate their respective agreement with us, which could limit our ability to implement our current business plan and materially adversely affect our business, financial condition, results of operations and prospects.

We may also in the future enter into license agreements with third parties under which we are a sublicensee. If our sublicensor fails to comply with its obligations under its upstream license agreement with its licensor, the licensor may have the right to terminate the upstream license, which may terminate our sublicense. If this were to occur, we would no longer have rights to the applicable intellectual property unless we are able to secure our own direct license with the owner of the relevant rights, which we may not be able to do on reasonable terms, or at all, which may impact our ability to continue to develop and commercialize our product candidates incorporating the relevant intellectual property.

In some cases, we may not control the prosecution, maintenance or filing of the patents to which we hold licenses, or the enforcement of those patents against third parties. Hence, our success will depend in part on the ability of our licensors to obtain, maintain and enforce patent protection for our licensed intellectual property, in particular, those patents to which we have secured exclusive rights. Our licensors may not successfully prosecute the patent applications to which we are licensed in a manner consistent with the best interests of our business. Even if patents are issued in respect of these patent applications, our licensors may fail to maintain these patents, may determine not to pursue litigation against other companies that are infringing these patents or may pursue such litigation less aggressively than we would. Without protection for the intellectual property we license, other companies might be able to offer substantially identical products for sale, which could adversely affect our competitive business position and harm our business prospects. Further, we may have limited control over these activities or any other intellectual property that may be in-licensed. For example, we cannot be certain that such activities by licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We may have limited control over the manner in which our licensors initiate an infringement proceeding against a third-party infringer of the intellectual property rights or defend certain of the intellectual property that is licensed to us. It is possible that the licensors' infringement proceeding or defense activities may be less vigorous than had we conducted them ourselves. In the event our licensors fail to adequately pursue and maintain patent protection for patents and applications they control and to timely cede control of such prosecution to us, our competitors might be able to enter the market, which would have a material adverse effect on our business.

Moreover, disputes may arise with respect to our licensing or other upstream agreements, including:

- the scope of rights granted under the agreements and other interpretation-related issues;
- whether and the extent to which our systems and consumables, technologies and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under any collaborative development relationships;
- our diligence obligations under the license and sub-license agreements and what activities satisfy those diligence obligations;

- our right to transfer or assign the sublicense;
- when and under what conditions the sublicense agreement may be terminated and the consequences thereof;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our upstream licensors and us and our partners; and
- the priority of invention of patented technology.

In spite of our efforts to comply with our obligations under our in-license agreements, our licensors might conclude that we have materially breached our obligations under our license agreements and might therefore terminate the relevant license agreement, thereby removing or limiting our ability to develop and commercialize products and technology covered by these license agreements. If any such in-license is terminated, or if the licensed patents fail to provide the intended exclusivity, competitors or other third parties might have the freedom to market or develop products similar to ours. In addition, absent the rights granted to us under such license agreements, we may infringe the intellectual property rights that are the subject of those agreements, we may be subject to litigation by the licensor, and, if such litigation by the licensor is successful, we may be required to pay damages to such licensor, or we may be required to cease our development and commercialization activities which are deemed infringing, and, in such event, we may ultimately need to modify our activities or products to design around such infringement, which may be time- and resource-consuming, and which may not be ultimately successful. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, certain of our future agreements with third parties may limit or delay our ability to consummate certain transactions, may impact the value of those transactions or may limit our ability to pursue certain activities. For example, we may in the future enter into license agreements that are not assignable or transferable or that require the licensor's express consent in order for an assignment or transfer to take place.

Risks Related to Ownership of Our Common Stock

We do not know whether an active, liquid and orderly trading market will be sustained for our common stock or what the market price of our common stock will be, and, as a result, it may be difficult for you to sell your shares of our common stock.

Prior to our IPO in November 2025, there was no public trading market for our common stock. If a liquid market for our common stock is not sustained, it may be difficult for you to sell your shares of our common stock at an attractive price or at all. We cannot predict the prices at which our common stock will trade. It is possible that in one or more future periods our results of operations may be below the expectations of public market analysts and investors, and, as a result of these and other factors, the price of our common stock may fall. An inactive market may also impair our ability to raise capital by selling our common stock and our ability to acquire other companies, products or technologies by using our common stock as consideration.

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

The stock market in general, and the market for pharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. 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:

- results of clinical trials and preclinical studies of our product candidates or those of our competitors or existing or future collaborators;
- failure to meet or exceed financial and development projections we may provide to the public;
- failure to meet or exceed the financial and development projections of the investment community;
- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors;
- actions taken by regulatory agencies with respect to our product candidates, clinical studies, manufacturing process or sales and marketing terms;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key personnel;
- significant lawsuits, including patent or stockholder litigation;

- if securities or industry analysts do not publish research or reports about our business or if they issue adverse or misleading opinions regarding our business and stock;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions or market conditions in the pharmaceutical and biotechnology sectors;
- sales of our securities by us or other securityholders in the future;
- if we fail to raise an adequate amount of capital to fund our operations or continued development of our product candidates;
- trading volume of our common stock;
- announcements by competitors of new commercial products, clinical progress or lack thereof, significant contracts, commercial relationships or capital commitments;
- the introduction of technological innovations or new therapies that compete with our product candidates;
- period-to-period fluctuations in our financial results; and
- the other factors described in this "Risk Factors" section.

In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources.

Our executive officers, directors and principal stockholders have the ability to control or significantly influence all matters submitted to our stockholders for approval.

As of September 30, 2025, our executive officers, directors and stockholders beneficially owning 5% or greater of our common stock, in the aggregate, beneficially owned a significant percentage of our outstanding shares of common stock. As a result, if these stockholders were to choose to act together, they would be able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these stockholders, if they choose to act together, would control or significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire.

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

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.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock may be influenced by the research and reports that equity research analysts publish about us and our business. Equity research analysts may elect not to provide research coverage of our common stock and such lack of research coverage may adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our common stock could decline if one or more equity research analysts downgrade our stock or issue unfavorable commentary or research. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our common stock could decrease, which in turn could cause our stock price or trading volume to decline.

Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws and Delaware law may 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 amended and restated certificate of incorporation and amended 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. The provisions of our amended and restated certificate of incorporation and amended and restated bylaws:

- 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;
- do not permit stockholders to cumulate votes at any election of directors;
- expressly authorize our board of directors to make, alter, amend or repeal our amended and restated bylaws; and
- require majority votes of all 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 Delaware General Corporation Law (the "DGCL"), which prohibits a person who owns in excess of 15% 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% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Any provision of our 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.

Our amended and restated certificate of incorporation contain exclusive forum provisions, which may limit a stockholder's ability to bring a claim in a judicial forum it finds favorable and may discourage lawsuits with respect to such claims.

Our amended and restated certificate of incorporation provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware) will be the sole and exclusive forum for (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of breach of or based on a fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders; (3) any action asserting a claim against us or any of our current or former directors, officers, employees or stockholders arising pursuant to any provision of the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws; or (4) any action asserting a claim governed by the internal affairs doctrine. In addition, our amended and restated certificate of incorporation designate the federal district courts of the United States as the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act; however, such exclusive forum provision does not apply to claims brought to enforce a duty or liability created by the Securities Exchange Act of 1934, as amended (the "Exchange Act"). The validity and enforceability of such provision is uncertain in a number of courts other than Delaware Supreme Court and certain other state courts.

We recognize that these provisions 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, these forum selection clauses in our amended and restated certificate of incorporation 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 such lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. Section 22 of the Securities Act creates a concurrent jurisdiction for state and federal courts over all suits brought concerning a duty or liability created by the securities laws, 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 selection provision. The federal selection provision may also impose additional litigation costs on stockholders who assert the provision is unenforceable, and, if the provision is found to be unenforceable, we may incur additional costs with resolving such matters. The Court of Chancery of the State of Delaware 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.

General Risk Factors

We will incur significantly increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Exchange Act, which require, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), as well as rules subsequently adopted by the SEC and NYSE to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, the Dodd-Frank Wall Street Reform and Consumer Protection Act includes significant corporate governance and executive compensation related provisions that require the SEC to adopt additional rules and regulations in these areas, such as "say on pay" and proxy access. Emerging growth companies ("EGCs") and smaller reporting companies are exempted from certain of these requirements, but we may be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Shareholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. The increased costs will decrease our net income or increase our net loss and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

We are an EGC and a smaller reporting company, and the reduced reporting requirements applicable to EGCs 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"). For as long as we continue to be an EGC, we may take advantage of certain exemptions from various public company reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to have our internal control over financial reporting audited by our independent registered public accounting firm under Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, being required to provide only two years of audited financial statements and two years of selected financial data, exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We may take advantage of these exemptions until the last day of the fiscal year ending after the fifth anniversary of our IPO or until we are no longer an emerging growth company, whichever is earlier. We will cease to be an EGC prior to the end of such five-year period if certain earlier events occur, including if we become a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, our annual gross revenues equal or exceed $1.235 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period prior to such time. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock.

In addition, the JOBS Act provides that an EGC can take advantage of an extended transition period for complying with certain new or revised accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards, and therefore we will not be subject to the same requirements to adopt new or revised accounting standards as other public companies that are not emerging growth companies.

We are also a "smaller reporting company" as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

If we experience material weaknesses in our internal control over financial reporting in the future or otherwise fail to maintain an effective system of internal control over financial reporting in the future, we may not be able to accurately or timely report our

financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

We may in the future discover material weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

We, and our independent registered public accounting firm, were not required to perform an evaluation of our internal control over financial reporting as of December 31, 2024 in accordance with the provisions of the Sarbanes-Oxley Act. Accordingly, we cannot assure you that we will not in the future identify material weaknesses. Material weaknesses may exist when we become required to report on the effectiveness of our internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls over financial reporting, we may not be able to produce timely and accurate financial statements. If that were to happen, our investors could lose confidence in our reported financial information, the market price of our stock could decline, and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC or other regulatory authorities.

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

These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make any related person transaction disclosures. 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.

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

If, after listing, we fail to satisfy NYSE's continued listing requirements, such as the corporate governance requirements or the minimum closing bid price requirement, the NYSE may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our common stock to become listed again on the NYSE or any other securities exchange, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the NYSE minimum bid price requirement or prevent future non-compliance with NYSE's listing requirements.

Our insurance policies are expensive and only protect us from some business risks, which will leave us exposed to significant uninsured liabilities.

While we maintain commercial insurance at a level we believe is appropriate against certain risks commonly insured in the industry in which we operate, there is no guarantee that our insurer will cover costs or that we will be able to obtain the desired level of coverage on acceptable terms in the future. Some of the policies we currently maintain include general liability, crime insurance, products liability, workers' compensation, cyber, directors' and officers', employment practices and fiduciary liability insurance. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. Changes in the market conditions and our business operations may necessitate the addition of new insurance policies or change of our existing insurance policies. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our financial position and results of operations.

We also expect that operating as a U.S. public company will make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, on our board committees or as executive officers. We do not know, however, if we will be able to maintain existing insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would negatively affect our business, financial condition and results of operations.

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

From time to time we may be subject to litigation claims through the ordinary course of our business operations regarding, but not limited to, securities litigation, employment matters, security of patient and employee personal data, contractual relations with collaborators and licensors and intellectual property rights. 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.

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

Set forth below is information regarding shares of equity securities sold, and options granted, by us during the three months ended September 30, 2025 that were not registered under the Securities Act.

(a) Unregistered Sales of Equity Securities

During the three months ended September 30, 2025, we granted stock options to purchase an aggregate of 19,955 shares of our common stock at a weighted-average exercise price of $4.95 per share, to certain of our employees, pursuant to our 2020 Stock Plan (the "2020 Plan").

The issuances of the securities under the 2020 Plan described above were deemed to be exempt from registration under Rule 701 promulgated under the Securities Act as transactions under compensatory benefit plans and contracts relating to compensation, or under Section 4(a)(2) of the Securities Act as a transaction by an issuer not involving a public offering. The recipients of such securities were our employees and received the securities under our equity incentive plans. Appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions had adequate access, through employment, business or other relationships, to information about us.

On November 7, 2025, we filed a registration statement on Form S-8 under the Securities Act to register all of the shares of our common stock subject to outstanding options and all shares of our common stock otherwise issuable pursuant to our equity compensation plans.

(b) Use of Proceeds From Initial Public Offering

On November 5, 2025, our registration statement on Form S-1 became effective for our IPO. At the closing of our IPO on November 7, 2025, we sold 10,781,250 shares of common stock, which included the exercise in full by Morgan Stanley & Co. LLC, Leerink Partners LLC, Evercore Group L.L.C. and Cantor Fitzgerald & Co. of their over-allotment option to purchase 1,406,250 additional shares, at an initial public offering price of $16.00 per share and received gross proceeds of $172.5 million, which resulted in aggregate net proceeds to us of approximately $160.4 million, after deducting underwriting discounts and commissions. There has been no material change in the planned use of proceeds from that described in the final prospectus for our IPO filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act.

Item 3. Defaults Upon Senior Securities.

Not Applicable

Item 4. Mine Safety Disclosures.

Not Applicable

Item 5. Other Information.

(c) Rule 10b5-1 Trading Plans

During the three months ended September 30, 2025, no director or officer of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in item 408(a) of Regulation S-K.

Item 6. Exhibits.

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, which is incorporated herein by reference

		Incorporated by Reference			
Exhibit Number	**Description**	**From**	**File No.**	**Exhibit**	**Filing Date**

3.1	Amended and Restated Certificate of Incorporation of the Registrant.	8-K	001-42938	3.1	November 7, 2025
3.2	Amended and Restated Bylaws of the Registrant.	S-1	333-290793	3.4	October 9, 2025
4.1	Form of Common Stock of the Registrant.	S-1	333-290793	4.1	October 9, 2025
4.2	Third Amended and Restated Investors' Rights Agreement, dated October 30, 2024, by and among the Registrant and the investors party thereto.	S-1	333-290793	4.2	October 9, 2025
10.1	Evommune, Inc. 2025 Equity Incentive Plan.	S-8	333-291386	99.3	November 7, 2025
10.2	Forms of Stock Option Grant Notice, Option Agreement, Notice of Exercise, Restricted Stock Unit Agreement and Restricted Stock Unit Grant Notice under the 2025 Plan.	S-1/A	333-290793	10.3(b)	October 17, 2025
10.3	Evommune, Inc. 2025 Employee Stock Purchase Plan.	S-1/A	333-290793	10.4	October 17, 2025
10.5	Amendment to Employment Agreement, dated September 22, 2025, by and between the Registrant and Eugene A. Bauer.	S-1	333-290793	10.7	October 9, 2025
31.1+	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, 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.

* These certifications are being furnished solely to accompany this quarterly report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and are not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

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.

Evommune, Inc.

Date: December 11, 2025 By: /s/ Luis Peña
Luis Peña
President and Chief Executive Officer
(Principal Executive Officer)

Date: December 11, 2025 By: /s/ Kyle Carver
Kyle Carver, CPA, MBA
Chief Financial Officer
(Principal Financial and Accounting Officer)