UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended September 30, 2026
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: 001-43436

Latigo Biotherapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**83-2625838**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

1300 Rancho Conejo Boulevard
Suite 305
Thousand Oaks, California 91320
(805) 716-2927
(Address including zip code, and telephone number including area code, of registrant's principal executive offices)

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	**LTGO**	**The Nasdaq Global Select Market**

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports); and (2) has been subject to such filing requirements for the past 90 days. Yes ☐ No ☒

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

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 Act). Yes ☐ No ☒

As of November 2, 2026, the registrant had 66,299,347 shares of common stock outstanding.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q (this Quarterly Report) contains forward-looking statements about us and our industry that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this Quarterly Report, including statements regarding future events, our business strategy, and the plans and objectives of management for future operations, are forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections. In some cases, you can identify forward-looking statements because they contain words such as "aim," "anticipate," "assume," "believe," "can," "contemplate," "continue," "could," "design," "due," "estimate," "expect," "goal," "intend," "may," "might," "objective," "plan," "positioned," "potential," "predict," "project," "seek," "shall," "should," "target," "will," "would" or the negative of these words or other similar terms or expressions.

These statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- the initiation, timing, progress and results of our research and development programs, preclinical studies and clinical trials;
- the timing of and costs involved in obtaining and maintaining regulatory approval of onzotrigine, LTG-321, LTG-418 and any future product candidates that we may identify or develop;
- the beneficial characteristics, including potential safety, efficacy and therapeutic effects of onzotrigine, LTG-321 and LTG-418;
- our ability to efficiently and cost-effectively conduct our current and future preclinical studies and clinical trials;
- our ability to obtain funding for our operations necessary to complete further development and, if approved, commercialization of onzotrigine, LTG-321 and LTG-418;
- our ability to identify and develop onzotrigine, LTG-321 and LTG-418 for treatment of additional indications;
- the performance of our third-party service providers, including our suppliers and manufacturers;
- the rate and degree of market acceptance and clinical utility for onzotrigine, LTG-321, LTG-418 and any other product candidates we may develop;
- the effects of competition with respect to onzotrigine, LTG-321 and LTG-418 or any other product candidates we may develop, as well as innovations by competitors in our industry;
- our estimates regarding the potential market opportunities and the number of patients for onzotrigine, LTG-321, LTG-418 and any future product candidates, if approved for commercial use;
- the implementation of our strategic plans for our business, onzotrigine, LTG-321, LTG-418 and any future product candidates we may develop;
- our intellectual property position, including the scope of protection we are able to establish, maintain, defend and enforce for intellectual property rights covering onzotrigine, LTG-321, LTG-418 and any future product candidates we may develop;
- our ability to attract and retain key scientific or management personnel;
- regulatory and legal developments in the United States;
- our ability to attract and retain employees and collaborators with development, regulatory and commercialization expertise;
- the accuracy of our estimates regarding future expenses, future revenue, capital requirements and need for additional financing;
- the period over which we estimate our existing cash and cash equivalents will be sufficient to fund our future operating expenses and capital expenditure requirements;
- our expectations regarding the impact of global health pandemics, geopolitical conflicts and economic uncertainty, including interest rate changes and inflation on our business and operations, including clinical trials, collaborators, CROs and employees; and
- our expectations regarding the period during which we qualify as an emerging growth company under the JOBS Act.

These forward-looking statements reflect our management's beliefs and views with respect to future events and are based on estimates and assumptions as of the date of this Quarterly Report and are subject to risks and uncertainties. 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, 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. We discuss many of the risks associated with the forward-looking statements in greater detail under the heading "Risk Factors" and elsewhere in this Quarterly Report. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we undertake no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in any forward-looking statements, whether as a result of new information, future events or otherwise.

We may use our website as a means of disclosing material non-public information and for complying with our disclosure obligations under Regulation Fair Disclosure promulgated by the U.S. Securities and Exchange Commission (SEC). These disclosures will be included on our website under the "Investors" section.

SUMMARY OF RISKS RELATED TO OUR BUSINESS

Our business is subject to a number of risks of which you should be aware before making a decision to invest in our common stock. These risks are more fully described in Part II, Item 1A. “Risk Factors” in this Quarterly Report, including the following:

- We are a clinical-stage biopharmaceutical company with a limited operating history. We have no history of commercializing products, which may make it difficult to evaluate our approach to the discovery and development of our product candidates and the prospects for our future viability.
- We have incurred substantial losses since our inception. As of September 30, 2026 our accumulated deficit was approximately $312.8 million. We anticipate incurring substantial and increasing losses for the foreseeable future and may never achieve or maintain profitability.
- We will require substantial additional financing to achieve our goals, which may cause dilution to our stockholders, and failure to obtain additional capital when needed, or on acceptable terms to us, could cause us to delay, limit, reduce, or terminate our product development or future commercialization efforts.
- We only have two product candidates, onzotrigine and LTG-321, in clinical development. If we are unable to continue to advance our product candidates in clinical development, obtain regulatory approval and ultimately commercialize our product candidates or experience significant delays in doing so, our business will be materially harmed.
- Preclinical and clinical development involves a lengthy and expensive process, with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial or real-world results. Our product candidates may not have favorable results in clinical trials or preclinical studies or receive regulatory approval on a timely basis, if at all.
- We will need to grow our organization, and we may experience difficulties in managing our growth and expanding our operations, which could adversely affect our business.
- We are dependent on the services of our management and other clinical and scientific personnel, and if we are not able to retain these individuals or recruit additional management or clinical and scientific personnel, our business will suffer.
- Our projections regarding the market opportunities for our product candidates may not be accurate and the actual market for our products may be smaller than we estimate.
- If we are unable to obtain, maintain and protect sufficient patent and other intellectual property rights for our product candidates and technology, or if the scope of patent and other intellectual property rights obtained is not sufficiently broad, we may not be able to compete effectively in our market.
- We rely on certain in-licensed patents and other intellectual property rights in connection with our development of our product candidates and may be required to acquire or license additional patents or other intellectual property rights to continue to develop and commercialize our product candidates.
- We rely on third parties to conduct our preclinical studies and clinical trials. If these third parties that we rely on to execute our preclinical studies or clinical trials do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates.
- We rely on third-party manufacturers and suppliers to supply our product candidates. The loss of our third-party manufacturers or suppliers, or their failure to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, within acceptable timeframes, or at all, would materially and adversely affect our business.
- We may form or seek collaborations or strategic alliances, enter into licensing arrangements or other business transactions in the future, and we may not realize the benefits of such transactions.
- Competitive products may reduce or eliminate the commercial opportunity for our product candidates for our current or future indications. If our competitors develop technologies or product candidates more rapidly than we do, or their technologies are more effective or safer than ours, our ability to develop and successfully commercialize our product candidates may be adversely affected.
- Even if our product candidates receive regulatory approval, they may fail to achieve the degree of market acceptance by physicians, patients and others in the medical community necessary for commercial success, in which case we may not generate significant revenues or become profitable.

- We currently have no marketing and sales organization and have no experience as a company in commercializing products, and we may have to invest significant resources to develop these capabilities. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our products, we may not be able to generate product revenue.
- Ongoing healthcare legislative and regulatory reform measures may adversely affect our business, results of operations and financial condition.
- A significant portion of our total outstanding shares are eligible to be sold into the market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is doing well.
- We identified a material weakness in our internal control over financial reporting. If we fail to remediate this material weakness, or if we identify additional material weaknesses in the future or otherwise fail to maintain effective 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.

Part I - Financial Information

Item 1. Financial Statements

LATIGO BIOTHERAPEUTICS, INC.
Condensed Balance Sheets
(in thousands, except share and per share amounts)
(Unaudited)

	September 30, 2026	December 31, 2025
ASSETS		
Current assets:		
Cash and cash equivalents	$ 401,241	$ 69,437
Restricted cash	168	192
Prepaid expenses and other current assets	5,033	4,200
Total current assets	406,442	73,829
Operating lease right-of-use assets	1,141	625
Property and equipment, net	440	446
Other assets	433	616
Total assets	$ 408,456	$ 75,516
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 5,085	$ 5,015
Accrued expenses and other current liabilities	8,174	12,868
Operating lease liabilities, current	705	563
Total current liabilities	13,964	18,446
Operating lease liabilities, non-current	483	127
Other long-term liabilities	35	35
Total liabilities	14,482	18,608
Commitments and contingencies (Note 6)		
Redeemable convertible preferred stock: $0.0001 par value per share, none and 264,397,134 shares authorized at September 30, 2026 and December 31, 2025, respectively; none and 41,155,082 shares issued and outstanding with aggregate liquidation preference of none and $287,899 at September 30, 2026 and December 31, 2025, respectively	—	288,582
Stockholders' equity (deficit):		
Preferred stock: $0.0001 par value per share, 10,000,000 shares authorized at September 30, 2026 and none authorized at December 31, 2025; no shares issued and outstanding at September 30, 2026 and December 31, 2025	—	—
Common stock: $0.0001 par value per share, 999,999,999 shares and 342,000,000 shares authorized at September 30, 2026 and December 31, 2025, respectively; 66,299,347 shares and 878,521 shares issued and outstanding at September 30, 2026 and December 31, 2025, respectively	7	—
Additional paid-in capital	706,805	11,457
Accumulated deficit	(312,838)	(243,131)
Total stockholders' equity (deficit)	393,974	(231,674)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 408,456	$ 75,516

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

LATIGO BIOTHERAPEUTICS, INC.
Condensed Statements of Operations and Comprehensive Loss
(in thousands, except per share amounts)
(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2026	**2025**	**2026**	**2025**
Operating expenses:				
Research and development	$ 17,502	$ 22,097	$ 56,361	$ 63,709
General and administrative	5,427	2,626	15,812	8,271
Total operating expenses	22,929	24,723	72,173	71,980
Loss from operations	(22,929)	(24,723)	(72,173)	(71,980)
Interest income	(2,126)	(728)	(2,864)	(2,113)
Interest expense	699	—	950	—
Change in fair value of preferred stock tranche liability	—	795	—	1,674
Change in fair value of derivative liability	(5,148)	—	(5,148)	—
Loss on extinguishment of debt	4,581	—	4,581	—
Other expense, net	14	6	15	42
Total other (income) expense, net	(1,980)	73	(2,466)	(397)
Net loss and comprehensive loss	$ (20,949)	$ (24,796)	$ (69,707)	$ (71,583)
Net loss and comprehensive loss per share — basic and diluted	$ (0.55)	$ (29.50)	$ (5.22)	$ (95.16)
Weighted-average number of shares used in computing net loss per share — basic and diluted	37,838	840	13,363	752

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

LATIGO BIOTHERAPEUTICS, INC.
Condensed Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
(in thousands, except for share data)
(Unaudited)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Capital	Deficit	(Deficit)
Balance at December 31, 2025	41,155,082	$ 288,582	878,521	$ —	$ 11,457	$ (243,131)	$ (231,674)
Issuance of common stock upon exercise of stock options	—	—	46,672	—	78	—	78
Stock-based compensation expense	—	—	—	—	1,978	—	1,978
Net loss	—	—	—	—	—	(22,961)	(22,961)
Balance at March 31, 2026	41,155,082	$ 288,582	925,193	$ —	$ 13,513	$ (266,092)	$ (252,579)
Issuance of common stock upon exercise of stock options	—	—	63,043	—	153	—	153
Stock-based compensation expense	—	—	—	—	2,143	—	2,143
Net loss	—	—	—	—	—	(25,797)	(25,797)
Balance at June 30, 2026	41,155,082	$ 288,582	988,236	$ —	$ 15,809	$ (291,889)	$ (276,080)
Conversion of redeemable convertible preferred stock to common stock upon IPO	(41,155,082)	$ (288,582)	41,155,082	4	288,578	—	288,582
Issuance of common stock upon IPO, net of underwriting discounts, commissions and offering costs	—	—	22,080,000	2	364,378	—	364,380
Conversion of convertible notes to common stock upon IPO	—	—	1,957,755	1	35,239	—	35,240
Issuance of common stock upon exercise of stock options	—	—	118,274	—	265	—	265
Stock-based compensation expense	—	—	—	—	2,536	—	2,536
Net loss	—	—	—	—	—	(20,949)	(20,949)
Balance at September 30, 2026	—	$ —	66,299,347	$ 7	$ 706,805	$ (312,838)	$ 393,974

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balance at December 31, 2024	26,311,071	$ 137,529	821,921	$ —	$ 4,365	$ (133,964)	$ (129,599)
Issuance of Series B redeemable convertible preferred stock, net of preferred stock tranche liability of $458K and issuance costs of $566K	9,896,006	98,976	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	1,475	—	1,475
Net loss	—	—	—	—	—	(20,952)	(20,952)
Balance at March 31, 2025	36,207,077	$ 236,505	821,921	$ —	$ 5,840	$ (154,916)	$ (149,076)
Stock-based compensation expense	—	—	—	—	1,677	—	1,677
Net loss	—	—	—	—	—	(25,835)	(25,835)
Balance at June 30, 2025	36,207,077	$ 236,505	821,921	$ —	$ 7,517	$ (180,751)	$ (173,234)
Issuance of Series B redeemable convertible preferred stock upon settlement of preferred stock tranche liability, net of issuance costs of $53	4,948,005	$ 52,077	—	—	—	—	—
Issuance of common stock upon exercise of stock options	—	—	48,817	—	107	—	107
Early exercise liability settlement	—	—	—	—	250	—	250
Stock-based compensation expense	—	—	—	—	1,825	—	1,825
Net loss	—	—	—	—	—	(24,796)	(24,796)
Balance at September 30, 2025	41,155,082	$ 288,582	870,738	$ —	$ 9,699	$ (205,547)	$ (195,848)

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

LATIGO BIOTHERAPEUTICS, INC.
Condensed Statements of Cash Flows
(in thousands)
(Unaudited)

	Nine months ended September 30,	
	2026	**2025**
Cash flows from operating activities:		
Net loss	$ (69,707)	$ (71,583)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash lease expense	442	323
Depreciation	152	200
Stock-based compensation expense	6,657	4,977
Change in fair value of preferred stock tranche liability	—	1,674
Change in fair value of derivative liability	(5,148)	
Amortization of debt discount and issuance costs and non-cash interest expense	975	—
Loss on extinguishment of debt	4,581	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(833)	(1,775)
Other assets	92	266
Accounts payable	70	(246)
Accrued expenses and other current liabilities	(4,694)	3,848
Operating lease liabilities	(461)	(314)
Net cash used in operating activities	(67,874)	(62,630)
Cash flows from investing activities:		
Purchases of property and equipment	(146)	(135)
Net cash used in investing activities	(146)	(135)
Cash flows from financing activities:		
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs paid	—	149,379
Proceeds from issuance of convertible notes, net of issuance costs paid	34,832	—
Proceeds from issuance of common stock upon exercise of stock options	496	108
Proceeds from IPO, net of underwriting discounts, commissions and offering costs paid	364,380	—
Net cash provided by financing activities	399,708	149,487
Net increase in cash, cash equivalents and restricted cash	331,688	86,722
Cash, cash equivalents and restricted cash, beginning of period	69,721	17,918
Cash, cash equivalents and restricted cash, end of period	$ 401,409	$ 104,640
Supplemental cash flow information:		
Right-of-use assets obtained in exchange for operating lease liabilities	$ 959	$ 310
Supplemental disclosure for non-cash investing and financing activities:		
Settlement of Series B redeemable convertible preferred stock tranche liability	$ —	$ 2,132
Conversion of redeemable convertible preferred stock to common stock upon IPO	$ 288,582	$ —
Conversion of convertible notes to common stock upon IPO	$ 35,240	$ —
Reclassification from liability to equity upon vesting of early exercised stock options	$ —	$ 250

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

LATIGO BIOTHERAPEUTICS, INC.
Notes to the Condensed Financial Statements
(Unaudited)

1. Organization

Description of Business

Latigo Biotherapeutics, Inc. (the Company) is a clinical-stage biopharmaceutical company committed to developing innovative non-opioid pain medicines designed to rapidly and effectively stop the transmission of pain without the risk of addiction.

The Company was incorporated in Delaware in November 2018, under the name Desmond, Inc. In December 2019, the Company changed its name to Latigo Biotherapeutics, Inc. The Company is headquartered in Thousand Oaks, California.

Liquidity

The accompanying unaudited condensed financial statements have been prepared assuming the Company will continue as a going concern, which assumes that the Company will realize its assets and satisfy its liabilities in the normal course of business. The Company is subject to risks inherent in operating an early-stage biotechnology and pharmaceutical business. These risks include, but are not limited to, dependence on the development of marketable products, the ability to attract, retain, and motivate qualified personnel, rapid technological changes and the rapidly evolving nature of the biopharmaceutical industry.

As of September 30, 2026, the Company had cash and cash equivalents of $401.2 million which includes net proceeds of $364.4 million from its initial public offering (“IPO”) completed in August 2026. The Company has incurred net losses of $69.7 million and $71.6 million for the nine months ended September 30, 2026 and 2025, respectively. The net cash used in operating activities was $67.9 million and $62.6 million for the nine months ended September 30, 2026 and 2025, respectively.

The Company has incurred significant losses and negative cash flows from operations since its inception and expects to continue to incur substantial losses for the foreseeable future, and its ability to achieve and sustain profitability will depend on the successful development, approval, and commercialization of any product candidates it may develop, and on the achievement of sufficient revenue to support its cost structure. The Company may never achieve profitability and, unless and until it does, it will need to continue to raise additional capital.

The Company historically financed its operations primarily through the issuances of convertible promissory notes, demand notes and redeemable convertible preferred stock, and most recently, through sale of its common stock in its IPO.

The Company completed its IPO in August 2026, receiving net proceeds of approximately $364.4 million after deducting underwriting discounts, commissions, and offering expenses. As a result, the Company's existing cash and cash equivalents are sufficient to fund the Company's operating plans for at least the 12-month period following the date that these unaudited condensed financial statements and accompanying notes were issued. Accordingly, the prior substantial doubt about the Company's ability to continue as a going concern has been alleviated.

2. Summary of Significant Accounting Policies

Reverse Stock Split

On July 28, 2026 the Company amended its amended and restated certificate of incorporation to effect a 1-for-6.42441 reverse stock split of the Company’s common stock and redeemable convertible preferred stock (the Reverse Stock Split). The par value and authorized shares of the common stock and redeemable convertible preferred stock were not adjusted as a result of the Reverse Stock Split. All issued and outstanding common stock, redeemable convertible preferred stock, options to purchase common stock, and per share amounts contained in the financial statements have been retroactively adjusted to give effect to the Reverse Stock Split for all periods presented.

Initial Public Offering

In August 2026, the Company completed its IPO, pursuant to which the Company issued and sold 22,080,000 shares of its common stock at a public offering price of $18.00 per share (the IPO Price), including 2,880,000 additional shares of its common stock pursuant to the exercise in full by the underwriters of their option to purchase shares of common stock from the Company at the IPO Price. As a result, the Company received net proceeds of approximately $364.4 million, after deducting underwriting discounts, commissions and other offering expenses of approximately $33.1 million. Immediately prior to the closing of the IPO, the Company’s outstanding redeemable convertible preferred stock automatically converted into 41,155,082 shares of common stock.

Following the closing of the IPO, no shares of redeemable convertible preferred stock were authorized or outstanding. In connection with the completion of the IPO, on August 10, 2026, the Company's certificate of incorporation was amended and restated to (i) authorize 999,999,999 shares of common stock, par value $0.0001 per share, which eliminates all references to the previously existing series of redeemable convertible preferred stock; and (ii) authorize 10.0 million shares of undesignated preferred stock, par value $0.0001 per share, that may be issued from time to time by the Company's board of directors (Board of Directors) in one or more series.

Basis of Presentation

The accompanying unaudited interim condensed financial statements have been prepared in conformity with U.S. generally accepted accounting principles (U.S. GAAP). Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. GAAP as found in the Accounting Standards Codification (ASC) and Accounting Standards Updates (ASUs) of the Financial Accounting Standards Board (FASB). Certain prior period amounts have been reclassified to conform the prior period presentation to the current period.

Unaudited Interim Condensed Financial Information

The condensed balance sheet as of December 31, 2025 was derived from the Company's audited financial statements but does not contain all of the footnote disclosures from the annual financial statements. The accompanying unaudited interim condensed financial statements as of September 30, 2026 and for the three and nine months ended September 30, 2026 and 2025, have been prepared by the Company, pursuant to the rules and regulations of the SEC for interim financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to such rules and regulations. Accordingly, these unaudited interim condensed financial statements should be read in conjunction with the audited financial statements as of and for the years ended December 31, 2025 and 2024, included in the Company's prospectus filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended (Securities Act) on August 7, 2026. In the opinion of management, all adjustments, consisting only of normal recurring adjustments necessary for a fair statement of the Company's condensed financial position as of September 30, 2026 and condensed results of operations and comprehensive loss, condensed statements of redeemable convertible preferred stock and stockholders' equity (deficit) and condensed cash flows for the three and nine months ended September 30, 2026 and 2025 have been made. The results of operations for the three and nine months ended September 30, 2026 are not necessarily indicative of the results of operations that may be expected for the full fiscal year.

Use of Estimates

The preparation of unaudited interim condensed financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts and disclosures reported in the unaudited interim condensed financial statements and accompanying notes. These estimates form the basis for judgments the Company makes about the carrying values of assets and liabilities that are not readily apparent from other sources. Management bases its estimates on historical experience and various other relevant assumptions believed to be reasonable under the circumstances. Significant estimates and assumptions reflected within these unaudited interim condensed financial statements include, but are not limited to, useful lives of property and equipment, the rate used in determining the present value of lease payments, fair value of assets and liabilities, research and development accruals, the valuation of the Company's common stock and stock-based awards granted under the Company's stock-based compensation plan, the valuation of the preferred stock tranche liability and the fair value of the change of control derivative liability associated with convertible notes, uncertain tax positions and the valuation allowance for deferred income tax assets. Actual results may differ from these estimates and assumptions.

Segment Information

The Company operates and manages its business as one reportable and operating segment. Operating segments are defined as components of an enterprise where separate financial information is evaluated regularly by the chief operating decision maker (CODM) in deciding how to allocate resources and assess performance. The Company's CODM is the Chief Executive Officer, who reviews financial information on a company-wide basis for purposes of allocating resources and assessing financial performance.

Concentration of Credit Risks

The Company is exposed to credit risk in the event of default by the financial institutions holding its cash and cash equivalents to the extent recorded in the balance sheet. Financial instruments, which potentially subject the Company to a concentration of credit risk, consist primarily of cash and cash equivalents. The Company invests its cash equivalents in money market funds. Cash and cash equivalents may be held in financial institutions in amounts that exceed federally insured limits, and the Company has not experienced any losses on such accounts and does not believe it is exposed to any unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

Risks and Uncertainties

The Company is subject to risks and uncertainties common to early-stage companies in the pharmaceutical and biotechnology industry, including, but not limited to, the outcome of clinical trials, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technologies, compliance with government regulations, ability to secure additional capital to fund operations, and potential delays associated with the Company's anticipated and planned trials. The Company is subject to a number of risks similar to other clinical stage biopharmaceutical companies, including, but not limited to, changes in any of the following areas that the Company believes could have a material adverse effect on its future financial position or results of operations: risks related to the successful discovery and development of its product candidates, ability to raise additional capital, development of new technological innovations by its competitors and delay or inability to obtain drug substance and finished drug product from the Company's third-party contract manufacturers necessary for the Company's product candidates, protection of intellectual property rights, litigation or claims against the Company based on intellectual property rights and regulatory clearance and market acceptance for any of the Company's product candidates for which the Company receives marketing approval.

Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval prior to commercialization of a product. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance-reporting capabilities. Even if the Company's development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

Moreover, the Company is subject to risks and uncertainties as a result of global business, political and macroeconomic events and conditions, including increasing financial market volatility and uncertainty, inflation, interest rate fluctuations, uncertainty with respect to the federal budget and debt ceiling and potential government shutdowns related thereto, potential instability in the global banking system, cybersecurity events, the impact of war or military conflict, including regional conflicts around the world, and public health pandemics. The extent to which business, political and macroeconomic factors, including increasing financial market volatility and uncertainty, will impact the Company's business will depend on future developments that are highly uncertain and cannot be predicted at this time.

The preparation of unaudited interim condensed financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the unaudited interim condensed financial statements and accompanying notes. The extent to which the increasing financial market volatility and uncertainty may directly or indirectly impact the unaudited interim condensed financial statements is highly uncertain and subject to change.

Cash, Cash Equivalents and Restricted Cash

The Company considers all highly liquid investments with original maturities of three months or less from the date of purchase to be cash equivalents. Cash equivalents are reported at fair value. At September 30, 2026 and December 31, 2025, the Company's cash equivalents are in money market funds.

A reconciliation of cash, cash equivalents, and restricted cash reported in the Company's balance sheets to the amount reported within its statements of cash flows was as follows (in thousands):

	September 30, 2026	December 31, 2025
Cash and cash equivalents	$ 401,241	$ 69,437
Restricted cash, current	168	192
Restricted cash, non-current ("Other assets")	—	92
Total cash, cash equivalents and restricted cash	$ 401,409	$ 69,721

Restricted cash is comprised of cash that is restricted as to withdrawal or use under the terms of certain contractual agreements. Restricted cash as of September 30, 2026 and December 31, 2025 consists of $0.2 million and $0.3 million, respectively, related to the Company's lease of office space in San Francisco, California. Restricted cash balances are classified as current or non-current based on the expected duration of the restriction.

Property and Equipment, Net

Property and equipment is recorded at cost, less accumulated depreciation. Depreciation and amortization are computed using the straight-line method over the shorter of estimated useful lives of the assets or the respective lease term. The estimated useful life of each asset category is as follows:

Fixed Assets Category	Estimated Useful Life
Laboratory equipment and furniture	3 – 5 years
Leasehold improvements	Shorter of remaining lease term or estimated useful life

Depreciation begins at the time the asset is placed in service. Maintenance and repairs are expensed as incurred. Upon sale or retirement of assets, the cost and related accumulated depreciation is removed from the balance sheet and the resulting gains and losses are reflected in the statements of operations and comprehensive loss.

Impairment of Long-Lived Assets

The Company evaluates its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying value of these assets may not be recoverable. Recoverability of these assets is measured by comparing the carrying amount of each asset to the future undiscounted cash flows the asset is expected to generate over its remaining life. If the asset is considered to be impaired, the amount of any impairment is measured as the difference between the carrying value and the fair value of the impaired asset. There have been no impairments of the Company's long-lived assets in the periods presented.

Operating Leases

At inception of a contract, the Company determines whether an arrangement is or contains a lease. For each lease, the Company determines the classification as either an operating lease or a financing lease. Lease recognition occurs at the lease commencement date and lease liability amounts are determined based on the present value of lease payments over the lease term. The lease term may include options to extend or terminate the lease only when it is reasonably certain that the Company will exercise that option.

The Company uses its incremental borrowing rate based on the information available at lease commencement date in determining the present value of lease payments if the Company's leases do not provide an implicit rate. The Company determines its incremental borrowing rate based on the rate of interest that the Company would have to pay to borrow on a collateralized basis over a similar term, an amount equal to the lease payments in a similar economic environment. Right-of-use (ROU) assets represent the Company's right to use underlying assets for the lease term and operating lease liabilities represent the Company's obligation to make lease payments under the lease. ROU assets are measured as the lease liability plus initial direct costs and prepaid lease payments, less lease incentives granted by the lessor.

The Company elected to apply the practical expedient of combining lease and non-lease components for the real estate lease asset class. Fixed lease payments on operating leases are recognized as lease expense over the expected term of the lease on a straight-line basis. Variable lease expenses that are not considered fixed are recognized as incurred.

In addition, the Company elected the short-term lease practical expedient that allows the lessee to not record a lease liability and ROU asset for all leases with a term of 12 months or less.

As of September 30, 2026 and December 31, 2025, the Company did not have any material finance leases.

Redeemable Convertible Preferred Stock

Prior to its IPO, the Company recorded all shares of redeemable convertible preferred stock at their respective fair values on the dates of issuance, less issuance costs and, if applicable, net of preferred stock tranche liabilities. In the event of a deemed liquidation event, the holders of shares of redeemable convertible preferred stock then outstanding shall be entitled to be paid a certain liquidation preference out of the assets of the Company available for distribution to its stockholders. Redeemable convertible preferred stock was classified outside of stockholders' equity (deficit) on the balance sheet as certain deemed liquidation events are not solely within the Company's control.

Upon the closing of the Company's IPO, all shares of convertible preferred stock then outstanding automatically converted into an aggregate of 41,155,082 shares of common stock. Refer to Note 8 for additional information.

Preferred Stock Tranche Liability

The purchase agreements for the Company's Series B redeemable convertible preferred stock provide the Company an obligation to issue additional shares of Series B redeemable convertible preferred stock in subsequent closings.

The Company's obligation to issue additional shares of Series B redeemable convertible preferred stock at a future date was determined to be a freestanding instrument that should be accounted for as a liability. At initial recognition, the Company recorded the preferred stock tranche liability on the balance sheet at fair value. The preferred stock tranche liability is subject to remeasurement at each subsequent reporting date until settled, with changes in fair value recognized as a component of other expense (income) in the statements of operations and comprehensive loss.

Immediately prior to the settlement of the preferred stock tranche liability in September 2025 the Company remeasured the preferred stock tranche liability. The preferred stock tranche liability was then settled and the Series B redeemable convertible preferred stock was recorded at fair value, less issuance costs.

Change of Control Derivative Liability

Prior to their conversion upon the IPO, the Series 2026A unsecured convertible promissory notes (the Convertible Notes) contained a change of control repayment premium that is required to be bifurcated from the debt host and accounted for separately as a derivative liability under ASC 815, Derivatives and Hedging. The change of control repayment premium required the Company to repay the noteholders in cash an amount equal to outstanding principal, unpaid accrued interest, and an additional premium equal to 100% of outstanding principal upon a change of control event. This feature was not clearly and closely related to the debt host because it provides for a repayment amount substantially in excess of par plus accrued interest and is contingently exercisable upon the occurrence of a corporate transaction event. The derivative liability was initially recognized at fair value, with an offsetting debt discount recorded as a reduction of the carrying amount of the Convertible Notes. See Note 7 for further discussion.

The fair value of the derivative liability was estimated using a scenario-based with-and-without analysis that compares the probability-weighted present value of the Convertible Notes including the change of control repayment premium with the probability-weighted present value of the Convertible Notes excluding that feature. The analysis considered multiple potential settlement scenarios, including an initial public offering, a qualified financing, a change of control, repayment at maturity and dissolution. Expected cash flows under each scenario are discounted using rates appropriate for the nature and risk of the applicable settlement scenario.

Prior to the Company's IPO, the derivative liability was remeasured to fair value at each reporting period and the related change was reflected as a change in fair value of derivative liability on the condensed statements of operations and comprehensive loss. Immediately prior to the settlement of the Convertible Notes in connection with the IPO in August 2026, the derivative liability was remeasured to zero and derecognized.

Research and Development

Research and development costs are expensed as incurred. Research and development expenses consist primarily of costs related to research, design, development, clinical trials, regulatory activities, medical affairs activities, salaries and benefits of research and development personnel, and allocated facility-related expenses. Payments made prior to the receipt of goods and services to be used in research and development are deferred and recognized as expense in the period in which the related goods are received or services are rendered.

The Company has entered into various agreements with outsourced contract manufacturing and development vendors. The Company estimates accrued research and development expenses as of each balance sheet date based on facts and circumstances known at that time. At each balance sheet date, the Company confirms the accuracy of its estimates with internal personnel and external service providers, and makes adjustments, if necessary. Research and development accruals are estimated based on the level of services performed, progress of the studies, including the phase or completion of events, and contracted costs. The estimated costs of research and development services provided, but not yet invoiced, are included in accrued expenses on the balance sheets. If the actual timing of the performance of services or the level of effort varies from the original estimates, the Company will adjust the accrual accordingly. Payments made under these arrangements in advance of the performance of the related services are recorded as prepaid expenses and other current assets until the services are rendered. To date, there have been no material adjustments to the Company's estimates of accrued research and development expenses.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and benefits, including stock-based compensation expense; professional fees for legal, accounting, auditing, tax and consulting services; travel expenses; and facility-related expenses, which include expenses for rent and maintenance of facilities and other operating costs. The Company expenses all general and administrative expenses as incurred.

Stock-Based Compensation

The Company accounts for share-based payments at fair value. The grant date fair value of options granted is measured using the Black-Scholes option pricing model. Option awards vest based on the satisfaction of a service requirement and stock-based compensation expense is recorded on a straight-line basis over the applicable service period, which is generally four years. For performance-based stock options, the Company will assess the probability of performance conditions being achieved in each reporting period. The amount of stock-based compensation expense recognized in any one period related to performance-based stock options can vary based on the achievement or anticipated achievement of the performance conditions. Forfeitures are recognized in the period in which the forfeiture occurs.

The Company permits certain employees to exercise stock options prior to vesting. Shares issued upon early exercise are subject to a repurchase right that lapses as the underlying options vest. Proceeds received from early exercise of unvested options are recorded as a liability until the underlying shares vest, at which time the liability is reclassified to additional paid-in capital. The early exercise of options does not accelerate recognition of stock-based compensation expense.

Income Taxes

The Company utilizes the asset and liability approach to account for income taxes. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and income tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Deferred tax assets are reduced by a valuation allowance if it is more likely than not that these assets may not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which the temporary differences representing net future deductible amounts become deductible.

The Company recognizes uncertain tax positions taken or expected to be taken on a tax return. Tax positions are initially recognized when it is more likely than not that the position will be sustained upon examination by the tax authorities. Such tax positions are initially and subsequently measured as the largest amount of tax benefit that is more likely than not of being realized upon ultimate settlement with the tax authority, assuming full knowledge of the position and relevant facts. Judgment is required to evaluate uncertain tax positions. The evaluations are based on a number of factors, including changes in facts and circumstances, changes in tax law, correspondence with tax authorities during the course of the audit, and effective settlement of audit issues.

The Company’s policy is to include penalties and interest expense related to income taxes as a component of income tax expense, as necessary.

Comprehensive Loss

Comprehensive loss represents all changes in stockholders’ equity (deficit) except those resulting from distributions to stockholders. There was no difference between net loss and comprehensive loss for the three and nine months ended September 30, 2026 and 2025.

Net Loss Per Share Attributable to Common Stockholders

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period, without consideration of potentially dilutive securities. Diluted net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common stock and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, redeemable convertible preferred stock, stock options, and common stock subject to repurchase related to unvested early exercise of stock options are considered potentially dilutive securities.

Basic and diluted net loss attributable to common stockholders per share is presented in conformity with the two-class method required for participating securities as the redeemable convertible preferred stock is considered a participating security because it participates in dividends with common stock. The Company also considers the shares issued upon the early exercise of stock options subject to repurchase to be participating securities because holders of such shares have non-forfeitable dividend rights in the event a dividend is paid on common stock. The holders of all series of redeemable convertible preferred stock and the holders of early exercised shares subject to repurchase do not have a contractual obligation to share in the Company's losses. As such, the net loss was attributed entirely to common stockholders. Because the Company has reported a net loss for all periods presented, diluted net loss per share is the same as basic net loss per share for those periods because the impact of potentially dilutive securities would be anti-dilutive.

Deferred Offering Costs

The Company's deferred offering costs consist of legal, accounting and other general and administrative costs directly attributable to the Company's IPO. In connection with the Company's IPO in August 2026, offering costs of $5.2 million, including $3.3 million previously deferred, were charged against the IPO proceeds in additional paid-in capital in stockholders' equity. As of September 30, 2026 and December 31, 2025, there were no deferred offering costs, and all offering costs incurred in connection with the IPO had been paid in full as of September 30, 2026.

Accounting Pronouncements Not Yet Adopted

The Company is an "emerging growth company," as defined in the Securities Act. Under the Jumpstart Our Business Startups Act of 2012, an emerging growth company has the option to adopt new or revised accounting guidance either (i) within the same periods as otherwise applicable to public business entities, or (ii) within the same time periods as non-public business entities, including early adoption when permissible. With the exception of accounting guidance the Company elected to early adopt, when permissible, the Company has elected to adopt new or revised accounting guidance within the same time periods as non-public business entities.

In November 2024, the FASB issued ASU No. 2024-03, Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40), which requires that a public entity disclose the amounts of (a) purchases of inventory, (b) employee compensation, (c) depreciation and (d) intangible asset amortization included in each relevant expense caption presented on the face of the income statement. The standard also requires an entity to disclose a qualitative description of the amounts remaining in relevant expense captions that are not separately disaggregated quantitatively as well as disclose the total amount of selling expenses and, annually, the entity's definition of selling expenses. ASU 2024-03 will be effective for annual periods beginning after December 15, 2026 and interim periods within fiscal years beginning after December 15, 2027, with either retrospective or prospective application. The standard allows for early adoption of these requirements; the Company is currently evaluating the disclosure impacts of its adoption.

3. Fair Value Measurements

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability, or an exit price, in the principal or most advantageous market for that asset or liability in an orderly transaction between market participants on the measurement date. In accordance with the authoritative guidance on fair value measurements and disclosures under U.S. GAAP, the Company discloses and recognizes the fair value of its assets and liabilities using a hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to valuations based upon unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to valuations based upon unobservable inputs that are significant to the valuation (Level 3 measurements). Financial instruments include cash and cash equivalents, accounts payable and accrued expenses that approximate fair value due to their relatively short maturities.

The authoritative guidance on fair value measurements establishes a three-tier fair value hierarchy for disclosure of fair value measurements as follows:

Level 1—Inputs are unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date;

Level 2—Inputs are observable, unadjusted quoted prices in active markets for similar assets or liabilities, unadjusted quoted prices for identical or similar assets or liabilities in markets that are not active or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities; and

Level 3—Unobservable inputs that are significant to the measurement of the fair value of the assets or liabilities that are supported by little or no market data.

The carrying amounts of the Company's financial instruments for the periods ended September 30, 2026 and December 31, 2025 approximate fair value due to their relatively short maturities. The change of control derivative liability was remeasured to zero and derecognized in August 2026 upon IPO.

Fair Value of Financial Assets

The following tables set forth the fair value of the Company's financial assets, which consist of cash equivalents, that were measured on a recurring basis (in thousands):

	September 30, 2026				
	Fair Value Hierarchy Level	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Assets					
Money market funds	Level 1	$ 397,271	$ —	$ —	$ 397,271

	December 31, 2025				
	Fair Value Hierarchy Level	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Assets					
Money market funds	Level 1	$ 67,478	$ —	$ —	$ 67,478

There has been no transfer between levels of the fair value measurement hierarchy during the periods presented.

Change of Control Derivative Liability

The fair value of the change of control derivative liability was estimated using a scenario-based analysis comparing the probability-weighted present value of the Convertible Notes with and without the bifurcated change of control premium feature. The Company employed a probability-weighted approach that evaluated multiple settlement scenarios, including automatic conversion upon an initial public offering, automatic conversion upon a qualified financing, contingent cash repayment upon a change of control event, repayment at maturity, and dissolution. For each scenario, the Company estimated the applicable settlement amount, discounted the expected settlement amount to the valuation date and applied a probability weighting. The fair value of the embedded derivative was determined as the difference between the probability-weighted value of the Convertible Notes with and without the change of control repayment premium.

The significant unobservable input used in the fair value measurement of the change of control derivative liability was the probability assigned to a change of control event occurring while the Convertible Notes remained outstanding, which was estimated at 15% as of the issuance date and as of June 30, 2026. As the IPO became imminent during the three months ended September 30, 2026, the probability of a change of control event was reassessed at 0%, because the IPO was virtually certain to occur before maturity and an IPO was excluded from the definition of a change of control. Accordingly, the fair value of the derivative liability immediately prior to the closing of the IPO was zero. Changes in this probability would have the most direct impact on the fair value of the derivative liability; an increase in the probability of a change of control would increase the fair value of the liability, while a decrease would reduce it.

The following provides a roll forward of the fair value of the change of control derivative liability measured at fair value on a recurring basis using Level 3 significant unobservable inputs (in thousands):

	2026
Beginning balance, January 1	$ —
Recognition in connection with convertible notes offering	5,148
Change in fair value	(5,148)
Ending balance, September 30	$ —

Preferred Stock Tranche Liability

The fair value of the preferred stock tranche liability was based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy.

The preferred stock tranche liability was valued as a forward contract. The value was determined using a probability-weighted present value calculation. In determining the fair value of the preferred stock tranche liability obligation, estimates and assumptions impacting the fair value included the per share estimated fair value of the Company's Series B redeemable convertible preferred stock, discount rates, estimated time to tranche closing, and probability of the second tranche closing.

Upon settlement of the preferred stock tranche liability in September 2025, the fair value of a share of Series B redeemable convertible preferred stock was $10.54.

The following provides a roll forward of the fair value of the preferred stock tranche liability measured at fair value on a recurring basis using Level 3 significant unobservable inputs (in thousands):

	2025
Beginning balance, January 1	$ —
Issuance	458
Change in fair value	1,674
Settlement	(2,132)
Ending balance, September 30	$ —

4. Balance Sheet Components

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

	September 30, 2026	December 31, 2025
Prepaid Clinical Research Organizations (CRO) expenses	$ 1,807	$ 1,434
Clinical deposits	1,262	2,016
Prepaid insurance	1,226	—
Other prepaid expenses	738	750
Total prepaid expenses and other current assets	$ 5,033	$ 4,200

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

	September 30, 2026	December 31, 2025
Laboratory equipment	$ 1,290	$ 1,200
Office furniture and fixtures	126	100
Construction-in-progress	30	—
Total property and equipment, at cost	1,446	1,300
Less: Accumulated depreciation	(1,006)	(854)
Total property and equipment, net	$ 440	$ 446

Depreciation expense was $0.1 million and $0.2 million for the three and nine months ended September 30, 2026, respectively. Depreciation expense was $0.1 million and $0.2 million for the three and nine months ended September 30, 2025, respectively.

Accrued expenses and other current liabilities consisted of the following (in thousands):

	September 30, 2026	December 31, 2025
Accrued research and development expenses	$ 4,374	$ 8,364
Accrued bonus expense	2,846	3,892
Accrued consulting and professional services	294	301
Accrued compensation and benefits expenses	660	311
Total accrued expenses and other current liabilities	$ 8,174	$ 12,868

5. Leases

Operating Leases

In June 2021, the Company entered into an operating lease for 7,638 square feet of office and research and development space in Thousand Oaks, California. The lease term is for approximately 5.3 years, with no renewal option.

In June 2025, the Company entered into a lease for 2,375 square feet of office space in San Francisco, California, that is set to expire on July 31, 2027.

On March 25, 2026, the Company entered into a First Amendment to the lease (the "Lease Amendment") to expand its existing leased office and laboratory space located in Thousand Oaks, California. Pursuant to the Lease Amendment, the Company expanded the leased premises to include an additional approximately 3,700 rentable square feet. The lease term for the expansion premises commenced on April 1, 2026, and the Lease Amendment extends the lease term to June 30, 2028. The Company remeasured the lease liability and right-of-use asset as of April 1, 2026, using an incremental borrowing rate of 12.62%, reflecting the increase in future lease payments resulting from the Lease Amendment. The remeasurement resulted in an increase of $1.0 million to the lease liability and a corresponding increase to the right-of-use asset.

6. Commitments and Contingencies

The Company enters into contracts in the normal course of business with various third parties for clinical trials, preclinical research studies and testing, manufacturing and other services and products for operating purposes. These contracts generally provide for termination upon notice. Payments due upon cancellation consist of payments for services provided or expenses incurred up to the date of cancellation and may include termination penalties or non-cancelable fees. Under such agreements, the exact amounts owed by the Company in the event of termination will be based on the timing of the termination and the exact terms of the agreement. If cancelled, these contracts are not anticipated to have a material effect on the Company’s financial condition, results of operations, or cash flows.

License Agreement with Lieber Institute, Inc.

In July 2020, the Company entered into a License Agreement with Lieber Institute, Inc. (d/b/a: Lieber Institute for Brain Development), or LIBD, which was subsequently amended in August 2020 and January 2022. Pursuant to the license agreement, LIBD granted to the Company a worldwide, exclusive, sub-licensable and royalty-bearing license, under certain patent and other intellectual property rights owned or controlled by LIBD, including patents claiming compounds for inhibiting $Na_v1.8$, to make, use, sell, offer to sell, import, research, develop, and commercialize products that contain any compound that is disclosed or claimed in any of the licensed patents or is developed by LIBD and is directed to or interacting with $Na_v1.8$, provided that such products are claimed by the licensed patents (Licensed Products) for any and all uses and applications, including all diagnostic, prophylactic and therapeutic uses. The Company has the right, subject to certain time limitations, to elect to expand its exclusive license to include LIBD’s patents and other intellectual property rights for new compounds discovered by LIBD that were not disclosed or claimed in the licensed patents as of July 2020 and that target or interact with $Na_v1.8$. Pursuant to the terms of the license agreement, the Company must use commercially reasonable efforts to develop a Licensed Product and commercialize such Licensed Product in each jurisdiction in which regulatory approval is obtained.

As consideration for the license and other rights granted to the Company by LIBD, on September 23, 2020 the Company issued 434,840 shares of Series A redeemable convertible preferred stock equal to a mid-single digit percentage of the Company’s equity capital, on a fully diluted basis, following the Company’s initial closing of the Series A redeemable convertible preferred stock financing.

The Company’s milestone and royalty payment obligations under the license vary depending upon whether the Licensed Product is covered by at least one valid claim of a licensed patent that is solely owned by LIBD, or a Sole Product, or the Licensed Product is only covered by valid claims of licensed patents that the Company jointly owns with LIBD, or a Joint Product. The Company has concluded its development candidate known as onzotrigine is a Joint Product. The Company has concluded it is not currently developing any Licensed Products that are Sole Products, and the Company does not have any current intentions to develop any Licensed Products that are Sole Products.

The Company has agreed to pay LIBD up to an aggregate of $48.5 million upon the achievement of pre-specified development and regulatory milestones with respect to the first Sole Product, up to an aggregate of $23.75 million for each subsequent Sole Product, and up to an aggregate of $95.0 million upon the achievement of pre-specified sales milestones with respect to all Sole Products.

For the first Joint Product, the Company has agreed to pay LIBD up to an aggregate of $4.0 million upon the achievement of pre-specified regulatory milestones, and up to an aggregate of $9.5 million upon the achievement of pre-specified sales milestones; the Company does not have any milestone payment obligations for subsequent Joint Products. No milestones have been achieved to date under this license agreement for any Licensed Product.

The Company must also pay LIBD royalties on the net sales of Licensed Products. The royalty rates for Sole Products are tiered and range from low- to mid-single-digit percentages, and the royalty rate for Joint Products is a low-single-digit percentage. The royalty payments are subject to reduction if, on a Licensed Product-by-Licensed Product and country-by-country basis, there are no valid patent claims covering the Licensed Product in such country or if the Company makes certain payments to third parties for intellectual property licenses, all subject to a customary royalty floor. The royalty term will terminate on a Licensed Product-by-Licensed Product and country-by-country basis on the latest of (i) a specified number of years after first commercial sale of such Licensed Product in such country, (ii) the expiration of the last valid claim of a licensed patent that covers such Licensed Product in such country and (iii) the earlier of expiration of regulatory exclusivity or the first commercial sale of a generic product referencing such Licensed Product in such country. If the Company sublicenses its rights to Sole Products or licensed patents solely owned by LIBD, then it must pay LIBD a low double-digit percentage of non-royalty sublicensing revenue received from sublicensees for rights to Sole Products and a low single-digit percentage of non-royalty sublicensing revenue from sublicensees for rights to Joint Products or jointly-owned patents.

The license agreement shall expire on a country-by-country and Licensed Product-by-Licensed Product basis upon the expiration of the royalty term for such Licensed Product in such country. Upon expiration of the royalty term with respect to a Licensed Product in a country, the Company will have a fully paid-up, irrevocable, perpetual license with respect to such Licensed Product in such country.

Either party may terminate the license agreement if the other party commits a material breach of the agreement and fails to cure that breach within the applicable specified period. The Company may terminate the license agreement in its entirety or on a country-by-country basis upon a specified prior notice period. LIBD may terminate the license agreement if the Company or its affiliate or sublicensee initiates an action challenging the validity or enforceability of any licensed patents or if the Company fails to use commercially reasonable efforts to develop or commercialize a Licensed Product for a specified period, does not submit a written diligence plan to LIBD for its approval and does not initiate such LIBD-approved plan to cure the failure within a specified period. Upon termination, all rights and licenses granted to the Company shall terminate and revert back to LIBD, and under certain circumstances LIBD will have an exclusive, time-limited right to negotiate the terms of a license to certain of the Company's intellectual property, data and regulatory approvals for the Licensed Products.

As the Company determined that the acquired licensed technology had no alternative future use, no intangible asset was recognized on the balance sheet.

Legal Proceedings

In the ordinary course of business, the Company may be subject to legal proceedings, claims and litigation, as the Company operates in an industry susceptible to patent legal claims. The Company accounts for estimated losses with respect to legal proceedings and claims when such losses are probable and estimable. Legal fees are expensed in the period in which they are incurred. As of September 30, 2026, the Company was not a party to any material legal proceedings or claims and no liabilities were recorded for loss contingencies.

Indemnifications

In the ordinary course of business, the Company enters into agreements that may include indemnification provisions. As permitted under Delaware law and in accordance with its bylaws, the Company indemnifies its officers and directors for certain events or occurrences while the officer or director is or was serving in such capacity. The Company is also party to indemnification agreements with its officers and directors. In some cases, the indemnification will continue after the termination of the agreement.

The maximum potential amount of future payments that the Company could be required to make under these provisions is not determinable. The Company is not currently aware of any indemnification claims. Accordingly, the Company has not recorded any liabilities for these indemnification rights and agreements in these unaudited interim condensed financial statements.

7. Convertible Notes

In June 2026, the Company issued Convertible Notes to various holders in the aggregate principal amount of $35.0 million. The Company received gross cash proceeds of $35.0 million and incurred approximately $0.2 million of debt issuance costs.

The Convertible Notes were due and payable in full in June 2027, which is twelve months from the issuance date. The Convertible Notes accrued interest at the rate of 5.0% per annum, daily from the issuance date through the date of their settlement upon the Company's IPO.

Upon completion of the Company's IPO in August 2026, $35.2 million of the outstanding principal and unpaid accrued interest under the Convertible Notes automatically converted into 1,957,755 shares of the Company's common stock at the IPO price of $18.00 per share.

Prior to their conversion upon the Company's IPO, the Convertible Notes contained a change of control repayment premium that qualified as an embedded derivative under ASC 815, Derivatives and Hedging, and was bifurcated and accounted for separately. The issuance date estimated fair value of the derivative liability was $5.1 million, with an offsetting debt discount recorded as a reduction of the carrying amount of the Convertible Notes. The derivative liability was remeasured to fair value at June 30, 2026 and through the date of its conversion to common stock upon the Company's IPO. There was no change in the estimated fair value of the derivative liability from the issuance date through June 30, 2026. As the IPO became imminent during the three months ended September 30, 2026, the probability of a change of control occurring while the Convertible Notes remained outstanding was reassessed at 0%, and immediately prior to the closing of the IPO the fair value of the derivative liability was remeasured to zero. The Company recognized a gain of $5.1 million, presented as "Change in fair value of derivative liability" in the condensed statements of operations and comprehensive loss for the three and nine months ended September 30, 2026, and the derivative liability was derecognized.

The debt discount and debt issuance costs allocated to the debt were presented as direct deductions from the principal amount of the Convertible Notes and were amortized to interest expense over the expected term of the Convertible Notes using the effective interest method. Interest expense on the Convertible Notes was $0.7 million and $0.9 million for the three and nine months ended September 30, 2026, respectively, consisting of contractual interest of $0.2 million in each period and amortization of debt discount and issuance costs of $0.5 million and $0.7 million, respectively. The contractual interest was settled in shares upon the IPO and is reflected as accrued interest in the table below. The amount presented in the statement of cash flows for the nine months ended September 30, 2026 as "Amortization of debt discount and issuance costs and non-cash interest expense" consists of the interest expense described above and debt issuance costs of less than $0.1 million allocated to the derivative liability. These issuance costs were expensed as incurred and are not included in interest expense, and the related cash payment is presented within financing activities.

Because the settlement required delivery of a variable number of shares with a value equal to a fixed monetary amount, the Company accounted for the settlement as an extinguishment of debt rather than a conversion. The Company recognized a loss on extinguishment of debt of $4.6 million in the three and nine months ended September 30, 2026, calculated as follows (in thousands):

Principal	$	35,000
Accrued interest		240
Unamortized debt discount		(4,457)
Unamortized debt issuance cost		(124)
Net carrying amount of the Convertible Notes		30,659
Reacquisition price: fair value of 1,957,755 shares at $18.00 plus cash in lieu of fractional shares		35,240
Loss on extinguishment of debt	$	4,581

No Convertible Notes were outstanding as of September 30, 2026.

8. Redeemable Convertible Preferred Stock

Immediately prior to the closing of the Company's IPO in August 2026, the Company's outstanding redeemable convertible preferred stock automatically converted into 41,155,082 shares of common stock. Following the closing of the IPO, no shares of redeemable convertible preferred stock were authorized or outstanding.

The Company's redeemable convertible preferred stock consisted of the following as of December 31, 2025 (in thousands, except share and per share amounts):

	December 31, 2025				
	Shares Authorized	Shares Issued and Outstanding	Original Issue Price	Liquidation Preference	Carrying Value
Series Seed	6,032,384	938,979	$ 2.28	$ 2,140	$ 2,123
Series A	51,727,645	8,051,735	4.45	35,759	35,634
Series A-2	111,273,075	17,320,357	5.78	100,000	99,772
Series B	95,364,030	14,844,011	10.11	150,000	151,053
	264,397,134	41,155,082		$ 287,899	$ 288,582

In January 2025, the Company entered into a Series B redeemable convertible preferred stock purchase agreement (the Series B Purchase Agreement), pursuant to which it issued a total of 9,896,006 shares of Series B redeemable convertible preferred stock at a price of $10.1050 per share for gross cash proceeds of $100.0 million and incurred aggregate issuance costs of $0.6 million in two closings in January and March 2025 (initial closing).

The Series B Purchase Agreement provided the Company an obligation to issue an additional 4,948,005 shares of Series B redeemable convertible preferred stock (preferred stock tranche liability) at a price of $10.1050 per share in a subsequent closing on or before September 30, 2025. Upon the initial closing of the Series B redeemable convertible preferred stock, the Company recorded a preferred stock tranche liability of $0.4 million. The fair value of the preferred stock tranche liability was allocated from the gross cash proceeds of $100.0 million of the Series B redeemable convertible preferred stock issuance, and the residual value was then allocated to the Series B redeemable convertible preferred stock.

In September 2025, pursuant to the terms outlined in the Series B Purchase Agreement and upon approval by the Board of Directors, the Company settled the preferred stock tranche liability, issuing 4,948,005 shares of Series B redeemable convertible preferred stock at a price of $10.1050 per share for gross cash proceeds of $50.0 million and incurred issuance costs of $0.1 million. As a result of this issuance, the preferred stock tranche liability of $2.1 million was settled and the Series B redeemable convertible preferred stock was recorded at its fair value of $52.1 million.

9. Common Stock

As of September 30, 2026 and December 31, 2025, the Company was authorized to issue 999,999,999 shares and 342,000,000 shares, respectively, of $0.0001 par value common stock. Common stockholders are entitled to one vote per share on all matters to be voted on by the stockholders of the Company and are entitled to dividends, if and when declared by the Board of Directors. Prior to the IPO, such rights were subject to the priority rights of holders of the redeemable convertible preferred stock. As of September 30, 2026 and December 31, 2025, no dividends were declared by the Company.

In August 2026, the Company completed its IPO. In connection with the Company's IPO, the Company issued and sold 22,080,000 shares of its common stock at the IPO Price, including 2,880,000 additional shares of its common stock pursuant to the exercise in full by the underwriters of their option to purchase shares of common stock from the Company at the IPO Price. As a result, the Company received approximately $364.4 million in net proceeds, after deducting underwriting discounts and commissions and other offering costs of approximately $33.1 million.

Immediately prior to the closing of the IPO, all outstanding shares of redeemable convertible preferred stock converted into 41,155,082 shares of common stock, and the Convertible Notes converted into 1,957,755 shares of common stock.

Common stock reserved for future issuance, on an as-converted to common stock basis, as of September 30, 2026 and December 31, 2025, consisted of the following:

	September 30, 2026	December 31, 2025
Redeemable convertible preferred stock	—	41,155,082
Stock options, issued and outstanding	10,283,831	9,179,303
Equity awards, authorized for future issuance	3,950,734	1,558,349
Total	14,234,565	51,892,734

10. Stock-Based Compensation

2019 Stock Plan

In 2019, the Company adopted the Latigo Biotherapeutics, Inc., 2019 Stock Plan (the 2019 Plan), which authorizes the Company to grant incentive stock options (ISOs), non-qualified stock options (NSOs) and the direct award or sale of shares to employees, directors and consultants of the Company. ISOs can only be granted to employees. The 2019 Plan is administered by the Board of Directors, or the Board of Directors may appoint a committee to which it delegates such administration.

The 2019 Plan shall terminate automatically ten years after the date when the Board of Directors approved the most recent increase in the number of shares reserved under the 2019 Plan. As of December 31, 2025, 1.6 million shares of common stock were available for future issuance pursuant to the 2019 Plan. No shares remained available for future issuance under the 2019 Plan as of September 30, 2026, as the 2019 Plan was replaced by the 2026 Equity Incentive Plan (the 2026 Plan), which is further discussed below. However, the 2019 Plan will continue to govern outstanding equity awards granted thereunder. The shares of common stock underlying any awards under the 2026 Plan and the 2019 Plan that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by the Company prior to vesting, satisfied without the issuance of stock, expire or are otherwise terminated (other than by exercise) will be added to the shares of the Company's common stock available for issuance under the 2026 Plan.

Option awards generally vest over a four-year period, with either 25% vesting on the first anniversary of the grant date and monthly thereafter or with monthly vesting over the four-year period. The exercise price of stock options granted under the 2019 Plan must be at least equal to the fair market value of the common stock on the date of grant. The term of option awards is determined by the Board of Directors and shall not exceed 10 years from grant date, or in the case of ISOs granted to a ten percent stockholder, the term is no more than 5 years from the grant date.

2026 Plan

In June 2026, the Board of Directors adopted the 2026 Equity Incentive Plan (the 2026 Plan), which was subsequently adopted by the Stockholders in July 2026. No awards were permitted to be granted under the 2026 Plan until the Company’s Registration Statement on Form S-1 was declared effective by the SEC on August 6, 2026 in connection with the Company’s IPO. The 2026 Plan allows for the issuance of equity-based and cash-based incentive awards to the Company's officers, employees, directors and consultants. The 2026 Plan is administered by the Board of Directors or a committee thereof (the Plan Administrator). The exercise prices, vesting and other restrictions are determined at the discretion of the Plan Administrator, subject to the provisions of the 2026 Plan.

The maximum number of shares of common stock that may be issued under the 2026 Plan is 14,611,431 shares, which is the sum of: (i) 3,764,069 new shares, plus (ii) 1,004,213 shares available for issuance under the 2019 Plan, plus (iii) up to 9,843,149 returning shares as such shares become available from time to time. The 2026 Plan provides that the number of shares reserved and available for issuance under the 2026 Plan will automatically increase on January 1st of each year, commencing on January 1, 2027 and ending on (and including) January 1, 2036, by an amount equal to the lesser of (i) 5% of the total number of shares of Fully Diluted Capital Stock (as defined in the 2026 Plan) outstanding on December 31st of the preceding calendar year, or (ii) such smaller number of shares of Common Stock as the Board of Directors may designate prior to the applicable January 1st, subject to adjustment as provided in the 2026 Plan. As of September 30, 2026, 3,323,389 shares of common stock remained available for future issuance under the 2026 Plan.

2026 ESPP

In June 2026, the Board of Directors adopted the 2026 Employee Stock Purchase Plan (the 2026 ESPP), which was subsequently approved by the Company’s stockholders in July 2026 and became effective on August 5, 2026, the date immediately prior to the date the SEC declared the Company’s Registration Statement on Form S-1 effective. The 2026 ESPP initially reserved and authorized the issuance of up to a total of 627,345 shares of the Company’s common stock to participating employees. The 2026 ESPP provides that the number of shares reserved and available for issuance will be automatically increased on January 1st of each year, commencing on January 1, 2027 and ending on (and including) January 1, 2036, in an amount equal to the lesser of (i) 1.0% of the total number of shares of Fully Diluted Capital Stock (as defined in the 2026 ESPP) outstanding on December 31st of the preceding calendar year, (ii) 1,882,035 shares of Common Stock or (iii) such smaller number of shares of Common Stock as the Board of Directors may designate prior to the applicable January 1st. As of September 30, 2026, no shares were issued or sold under the 2026 ESPP.

The following tables summarize the Company's option activity for the 2019 Plan and 2026 Plan for the nine months ended September 30, 2026 and 2025:

	Shares Subject to Options Outstanding	Weighted-Average Exercise Price per share	Weighted-Average Remaining Contractual Life (in years)	Aggregate intrinsic value (in thousands)
Outstanding as of December 31, 2025	9,179,303	$ 3.17	8.27	$ 25,755
Vested and expected to vest as of December 31, 2025	9,179,303	3.17	8.27	$ 25,755
Granted	1,886,019	9.79		
Exercised	(227,989)	2.18		1,292
Cancelled or forfeited	(532,852)	3.44		
Expired	(20,650)	2.23		
Outstanding as of September 30, 2026	10,283,831	$ 4.40	7.66	$ 127,219
Vested and exercisable as of September 30, 2026	4,809,089	$ 2.80	6.68	$ 66,865
Vested and expected to vest as of September 30, 2026	10,283,831	$ 4.40	7.66	$ 127,219

	Shares Subject to Outstanding Options and Common Shares Subject to Repurchase	Weighted-Average Exercise Price per share	Weighted-Average Remaining Contractual Life (in years)	Aggregate intrinsic value (in thousands)
Outstanding as of December 31, 2024	6,525,632	$ 1.79	8.82	$ 18,643
Vested and expected to vest options as of December 31, 2024	6,640,085	$ 1.79	8.83	$ 18,951
Granted	3,296,212	5.53		
Exercised	(48,817)	2.19		163
Cancelled or forfeited	(562,234)	3.95		
Expired	(23,120)	2.19		
Outstanding as of September 30, 2025	9,187,673	$ 3.17	7.71	$ 25,748
Vested and exercisable as of September 30, 2025	2,616,475	$ 1.82	6.78	$ 10,882
Vested and expected to vest options as of September 30, 2025	9,187,673	$ 3.17	7.71	$ 25,748

The weighted average grant-date fair value of options granted during the three and nine months ended September 30, 2026, was $12.60 per share and $7.70 per share, respectively. The total fair value of options granted during the three and nine months ended September 30, 2026 were $6.7 million and $14.5 million, respectively. The total fair value of options vested during the three and nine months ended September 30, 2026, was $1.9 million and $7.2 million, respectively.

The weighted average grant-date fair value of options granted during the three and nine months ended September 30, 2025, was $3.81 per share and $3.92 per share, respectively. The total fair value of options granted during the three and nine months ended September 30, 2025 were $0.9 million and $12.9 million, respectively. The total fair value of options vested during the three and nine months ended September 30, 2025, was $3.1 million and $4.4 million, respectively.

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock options and the fair value of the Company's common stock for stock options that were in-the-money at each reporting period. The aggregate intrinsic value of stock options exercised for the three and nine months ended September 30, 2026, was $0.7 million and $1.3 million, respectively. The aggregate intrinsic value of stock options exercised for the three and nine months ended September 30, 2025 was $0.2 million.

Executive Officer and Director Grants

In February 2024, the Board of Directors approved the grant of a stock option award for approximately 0.1 million shares to a director, with vesting subject to the achievement of a performance condition related to the consummation of a deemed liquidation event. Subsequently, in January 2025, the Company determined that the performance condition was not achieved, and the stock option award was cancelled. Accordingly, no stock-based compensation expense was recognized in connection with this award.

In July and August 2024, the Board of Directors approved the grants of stock option awards for a total of approximately 2.8 million shares to three executive officers joining the Company, including the Chief Executive Officer, Chief Medical Officer and Chief Financial Officer. The Chief Executive Officer's grant allows for early exercise of the stock options. In August 2024, the Board of Directors approved the early exercise of stock option awards for approximately 0.1 million shares related to the Chief Executive Officer's grant. The cash proceeds received from the early exercise of $0.3 million were recorded as an early exercise liability in accrued expenses and other current liabilities until July 2025, when the underlying shares issued pursuant to early exercise of stock options fully vested and the related early exercise liability was reclassified in its entirety to additional paid-in capital, resulting in no further remaining liability balance.

In April 2025, the Board of Directors approved a total of 461,612 stock option awards to certain executive officers and a member of the Board of Directors. The stock option awards include vesting criteria subject to the achievement of performance-based conditions related to the second tranche closing of the Series B redeemable convertible preferred stock financing in addition to service conditions. The Company assessed the probability that the performance criteria would be met as of the grant date. The grant date fair value of the awards was $3.92 per share. In the three and nine months ended September 30, 2026, the Company recognized expense for the stock options of $0.1 million and $0.3 million, respectively. In the three and nine months ended September 30, 2025, the Company recognized expense for the stock options of $0.1 million and $0.2 million, respectively. As of September 30, 2026, there was $1.0 million of unamortized stock-based compensation related to the portion of stock options, which is expected to be recognized over a weighted average period of 2.34 years.

Stock Option Valuation

In determining the fair value of the options granted, the Company uses the Black-Scholes option-pricing model and assumptions discussed below. Each of these inputs is subjective and generally requires significant judgment to determine.

Fair Value of Common Stock

The fair value of the shares of common stock underlying stock options has historically been determined by the Board of Directors. Prior to the IPO, in the absence of a public market for the Company's common stock, the Board of Directors determined the fair value of the common stock at the time of grant of the option by considering a number of objective and subjective factors including important developments in the Company's operations, valuations performed by independent third parties, sales of redeemable convertible preferred stock, actual operating results and financial performance, the conditions in the pharmaceutical and biotechnology industry and the economy in general, the stock price performance and volatility of comparable public companies and the lack of liquidity of the Company's common stock, among other factors. Prior to the IPO, the Company considered the stay private scenario, mergers and acquisitions (M&A) scenario and IPO exit scenario. In the stay-private scenario, the subject company transaction method was used, which examines prior transactions in the same or related equity of the Company. Probability-weighted expected return method was utilized to capture the value attributable to the IPO outcomes and M&A outcome. A hybrid method was used to allocate equity value to common stock under the stay private, IPO and M&A scenarios. Subsequent to the IPO, the fair value of the Company's common stock is determined based on the closing market price of the Company's common stock on Nasdaq on the date of grant.

Expected Term

The expected term represents the period that the Company's options granted are expected to be outstanding and is determined using the simplified method (based on the midpoint between the vesting date and the end of the contractual term). The Company has very limited historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior for its stock option grants. The Company will continue to apply this process until a sufficient amount of historical information regarding exercise patterns and post-vesting employment termination behavior becomes available.

Volatility

As the Company was not publicly traded prior to the IPO and does not have sufficient trading history after the IPO, the expected volatility for the Company's stock options was determined by using an average of historical volatilities of selected industry peers deemed to be comparable to the Company's business corresponding to the expected term of the awards.

Expected Dividends

The expected dividend assumption is based on the Company's history and expectation of dividend payouts. The expected dividend yield is 0% as the Company has not paid and does not anticipate paying dividends on its common stock.

Risk-Free Rate

The risk-free rate assumption is based on the U.S. Treasury yield curve whose term is consistent with the expected term of the stock options.

The fair value of options granted during the three and nine months ended September 30, 2026 and 2025 was estimated using the following assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Expected dividend yield	– %	– %	– %	– %
Risk-free interest rate	4.42%	3.68%	3.81% – 4.42%	3.68% – 4.29%
Expected volatility	77.58%	76.36% – 76.44%	73.49% – 77.58%	76.36% – 80.05%
Expected term (in years)	5.98	6.01 – 6.02	5.98 – 6.08	5.95 – 6.08

The following table summarizes the components of stock-based compensation expense recognized in the Company's statements of operations and comprehensive loss (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Research and development	$ 1,199	$ 811	$ 3,076	$ 2,219
General and administrative	1,337	1,014	3,581	2,758
Total stock-based compensation expense	$ 2,536	$ 1,825	$ 6,657	$ 4,977

As of September 30, 2026, the total stock-based compensation expense related to stock options not yet recognized was $24.4 million, which is expected to be recognized over a weighted average period of 2.79 years.

11. Income Taxes

The Company's tax provision for interim periods is determined using an estimate of its annual effective tax rate, adjusted for discrete items, if any, that arise during the period. Each quarter, the Company updates its estimate of the annual effective tax rate and, if the estimated annual effective tax rate changes, the Company makes a cumulative adjustment in such period. No such adjustment was made as of September 30, 2026. The Company's effective federal and state tax rate for the three and nine months ended September 30, 2026 and 2025 was 0%, and the Company did not record any income tax expense or benefit during the three and nine months ended September 30, 2026 and 2025, primarily as a result of estimated net operating losses for the fiscal year to date offset by the increase in the valuation allowance against its deferred tax asset. All losses before income taxes arose in the United States.

12. Net Loss Per Share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows (in thousands, except share and per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Numerator:				
Net loss	$ (20,949)	$ (24,796)	$ (69,707)	$ (71,583)
Net loss attributable to common stockholders	(20,949)	(24,796)	(69,707)	(71,583)
Denominator:				
Weighted-average common shares outstanding	37,837,870	859,064	13,362,930	834,438
Less: Weighted-average common shares subject to repurchase	—	(18,661)	—	(82,171)
Weighted-average common shares outstanding used to calculate net loss per share attributable to common stockholders, basic and diluted	37,837,870	840,403	13,362,930	752,267
Net loss per share attributable to common stockholders, basic and diluted	$ (0.55)	$ (29.50)	$ (5.22)	$ (95.16)

The Company's potentially dilutive securities, which include redeemable convertible preferred stock and stock options, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted-average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The Company excluded the following shares from the computation of diluted net loss per share attributable to common stockholders as of September 30, 2026 and 2025, because including them would have had an anti-dilutive effect:

	Nine Months Ended September 30,	
	2026	2025
Series Seed redeemable convertible preferred stock	—	938,979
Series A redeemable convertible preferred stock	—	8,051,735
Series A-2 redeemable convertible preferred stock	—	17,320,357
Series B redeemable convertible preferred stock	—	14,844,011
Common stock options issued and outstanding	10,283,831	9,187,673
Total anti-dilutive securities	10,283,831	50,342,755

13. Segment Reporting

The accounting policies of the segment are the same as those described in Note 2. Summary of Significant Accounting Policies.

The Company operates as one operating and reportable segment. The Company's CODM reviews and evaluates net loss to monitor budget versus actual results and to analyze cash flows for purposes of allocating resources and assessing financial performance. Segment assets provided to the CODM are consistent with those reported on the unaudited interim condensed balance sheets.

In addition to the significant expense categories included within net loss presented in the Company's statements of operations and comprehensive loss, disaggregated expenses were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Research and development expenses:				
Direct Program Costs Onzotrigine	$ 4,944	$ 11,097	$ 20,200	$ 28,232
Other clinical and non-clinical programs	5,147	5,141	15,352	19,638
Personnel-related R&D expenses	6,111	4,298	16,599	11,995
Other R&D expenses	1,300	1,561	4,210	3,844
Total research and development expenses	17,502	22,097	56,361	63,709
General and administrative expenses	5,427	2,626	15,812	8,271
Other segment items - total other (income) expense, net	(1,980)	73	(2,466)	(397)
Net loss	$ 20,949	$ 24,796	$ 69,707	$ 71,583

14. Related Party Transactions

The Company’s Chief Medical Officer ("CMO") owns an approximate 7.5% economic interest in Emerge Holdco, LLC, the ultimate parent entity of Lotus Clinical Research ("Lotus").

In August 2026, the Company entered into a Master Clinical Research Organization Agreement ("CRO Agreement") with Lotus in which Lotus agreed to provide clinical research and development services for one of the Company’s clinical studies.

Within the nine months ended September 30, 2026, the Company recognized $0.5 million in research and development expenses in connection with the CRO Agreement.

The Company’s prepaid expenses, accounts payable and accrued expenses as of September 30, 2026, related to the agreement are immaterial. The Company did not incur similar costs during the corresponding period in the prior year.

15. Subsequent Events

On November 3, 2026 ("Effective Date"), the Company's Board of Directors ("Board") appointed Todd N. Smith as President and Chief Executive Officer, succeeding Nima Farzan. Mr. Farzan resigned from the Board on the Effective Date.

In connection with the transition, the Company entered into a transition and separation agreement with Mr. Farzan ("Transition Agreement").

Under the Transition Agreement, Mr. Farzan will remain an employee of the Company through January 1, 2027, unless his employment is terminated earlier. Following the termination of his employment, the Company will retain Mr. Farzan as an independent consultant to provide transitional and advisory services through December 31, 2027 (the "Consulting Period"), unless the consulting arrangement is terminated earlier.

The Transition Agreement provides for certain severance and continuation of benefits. Mr. Farzan's outstanding equity awards will continue to vest during the remaining period of his employment and the time of the Consulting Period. The Company is currently evaluating the accounting treatment of the Transition Agreement and an estimate of the financial effect cannot be made.

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

The following discussion and analysis of our financial condition and results of operations and the unaudited interim condensed financial statements and related notes included in this Quarterly Report should be read in conjunction with the financial statements and related notes thereto as of and for the year ended December 31, 2025 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in the prospectus filed on August 7, 2026, pursuant to Rule 424(b) under the Securities Act of 1933, as amended (the Securities Act), with the Securities and Exchange Commission (the SEC), or the Prospectus. This discussion and analysis and other parts of this Quarterly Report contain forward-looking statements based upon our current plans and expectations that involve risks, uncertainties and assumptions, such as statements regarding our plans, objectives, expectations, intentions and beliefs. 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 sections of this Quarterly Report titled "Special Note Regarding Forward-Looking Statements", "Risk Factors" and elsewhere in this Quarterly Report. You should carefully read the section of this Quarterly Report titled "Risk Factors" to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements.

Overview

We are a clinical-stage biopharmaceutical company committed to developing innovative non-opioid pain medicines designed to rapidly and effectively stop the transmission of pain without the risk of addiction. Pain represents one of the largest and most pervasive therapeutic markets in the United States, driving an estimated 250 million prescriptions annually across acute and chronic settings; however, a continued reliance on opioids has contributed to a persistent public health crisis with significant societal and economic costs. Our two most advanced candidates, onzotrigine and LTG-321, are oral $Na_v1.8$ inhibitors designed to inhibit the transmission of pain. We are also advancing additional $Na_v1.8$ candidates that can address alternative formulation and delivery approaches. Beyond $Na_v1.8$, we plan to explore other ion channel targets involved in pain transmission that offer complementary mechanisms of action, enabling potential use in multi-modal treatment to enhance pain relief or address diverse pain etiologies. Pain is heterogeneous and can be experienced in a chronic or acute manner, within both musculoskeletal and neuropathic pain. Our initial development efforts are focused on musculoskeletal pain, where we believe there is significant unmet need and an opportunity for differentiated clinical benefit utilizing a $Na_v1.8$ mechanism. We aim to build one of the broadest pipelines of pain therapeutics, which we believe, combined with our management team's deep expertise in pain biology, clinical translation and trial execution, positions us to deliver meaningful patient benefit and to change the current treatment paradigm of pain medicines.

Our lead product candidate onzotrigine is an oral $Na_v1.8$ inhibitor designed to provide fast-acting, opioid-sparing relief for the treatment of acute pain. We believe onzotrigine will address a critical unmet need in a high-volume market where opioids remain the standard of care due to a lack of effective, non-addictive alternatives with rapid onset. The 2025 U.S. Food and Drug Administration (FDA) approval of the first $Na_v1.8$ inhibitor, suzetrigine (Journavx) provides a clear development and regulatory precedent for this therapeutic class. We recently received positive data for onzotrigine in our randomized, placebo and comparator-controlled trial in 343 patients undergoing abdominoplasty. This large-scale efficacy trial was designed and conducted to be pivotal and met its primary endpoint and key secondary endpoints with high statistical significance. Key highlights include:

- ***Met primary endpoint and achieved ~50% greater analgesic effect than opioid comparator:*** High dose onzotrigine (450mg loading followed by 300mg every 12 hours) met its primary endpoint of Summed Pain Intensity Difference from 0 to 48 hours (SPID48) versus placebo, achieving a 62.1-point ($p<0.001$) improvement versus placebo and exceeding hydrocodone bitartrate/acetaminophen (HB/APAP), which is commonly known as Vicodin, the opioid comparator's SPID48 of 40.9 ($p=0.001$).
- ***Achieved rapid onset of meaningful pain relief:*** Median time to a 2-point reduction in NPRS score was 52 minutes with high dose onzotrigine, and 83 minutes for HB/APAP, the opioid comparator in the trial.
- ***Demonstrated opioid sparing:*** 52.3% of patients receiving high dose onzotrigine remained opioid-free during the 48-hour treatment period ($p<0.001$). Pain experienced by these patients was sufficiently managed by onzotrigine alone and required no rescue medicine. In the placebo group, only 22.1% remained opioid-free.
- ***Dose response observed:*** Low dose onzotrigine (300mg loading followed by 150mg every 12 hours) also demonstrated statistically significant improvement versus placebo (SPID48 of 37.8; $p=0.003$), roughly comparable to the effect of HB/APAP, the opioid comparator in the trial.

Onzotrigine has been generally well-tolerated and has generated favorable clinical pharmacology data characterized by limited DDI potential and balanced renal and hepatic clearance in preclinical studies.

Based on our discussions with the FDA, we believe our proposed CMC manufacturing and stability plan for the commercial material for onzotrigine is reasonable for supporting regulatory approval.

In order to submit a New Drug Application (NDA) seeking FDA approval of onzotrigine as a potential treatment for moderate to severe acute pain, including postoperative pain, we are also required to conduct an open-label safety trial to attain a certain number of safety exposures at the intended commercial dose and to demonstrate safety across a mix of demographics and surgical settings to more adequately match the real-world setting.

We plan to initiate a placebo-controlled Phase 3 trial in participants undergoing bunionectomy and an open-label Phase 3 safety trial exploring onzotrigine within a broader population of patients with moderate to severe acute pain across a variety of post-surgical and non-surgical settings with topline results expected in the second half of 2027.

In November, we announced the addition of an opioid active comparator arm to the planned Phase 3 trial in participants with moderate to severe acute pain undergoing bunionectomy. Patients in this study arm will receive a combination of oxycodone and acetaminophen, commonly known as Percocet. The randomized, double-blind, placebo and comparator-controlled trial is expected to enroll approximately 480 patients overall, with participants randomized to receive either onzotrigine (450 mg loading dose followed by 300 mg every 12 hours; approximately 200 patients), oxycodone/acetaminophen (oxycodone 5mg/ acetaminophen 325mg every 6 hours; 80 patients), or placebo (approximately 200 patients). The primary endpoint is SPID48. Secondary endpoints include opioid-sparing assessments (% of opioid-free patients, total opioid rescue consumption, and incidence of vomiting and/or rescue antiemetic use) and time to meaningful pain relief (time to 2-point reduction in NPRS vs. baseline). Rescue medication (oxycodone 5mg orally Q4H as needed) will be permitted for patients whose pain is inadequately controlled by study treatment, similar to the abdominoplasty trial.

In addition to oral dosing, onzotrigine is also being advanced as a potential intravenous (IV) formulation to support use in hospital settings and enable transition from inpatient postoperative care to outpatient pain management.

LTG-321 is our next-generation candidate for the inhibition of $Na_v1.8$, initially being developed for the treatment of chronic musculoskeletal pain, starting with OA. LTG-321 is structurally distinct from onzotrigine. LTG-321's differentiated profile may enable a lower effective dose and once-daily dosing, characteristics we believe are particularly important for a chronic-use setting. In the Phase 1 trial, data as of May 15, 2026 showed that LTG-321 demonstrated robust pharmacodynamic (PD) activity as measured by an increased pain tolerance threshold, with continued activity at 24 hours after a single dose in the CPT. We have refined the CPT methodology and it has provided a quantifiable and repeatable clinical endpoint that has translated into clinical trial outcomes for our lead product candidate. We have initiated a Phase 2 proof-of-concept trial investigating LTG-321 in patients with OA of the knee.

The trial is designed as a randomized, double-blind, placebo controlled within subject crossover trial in approximately 120 patients with WOMAC pain as the primary endpoint to establish clinical proof-of-concept in chronic musculoskeletal pain and inform subsequent pivotal trial design. We expect to report topline results in the second half of 2027.

Our earlier stage pipeline consists of LTG-418, a next-generation $Na_v1.8$ inhibitor being developed for the treatment of acute and chronic pain. LTG-418 is structurally distinct from onzotrigine and LTG-321 and is predicted to have a dose which will be substantially lower than the expected doses for onzotrigine and LTG-321. We believe the predicted lower dose with LTG-418 is one of the features that may enable additional opportunities for other formulations and routes of administration including gels, patches, eye drops, inhalers and injectables, expanding our reach within the pain market and offering patients therapeutic options beyond oral and IV delivery. Suitable tolerability was demonstrated in completed 14-day non-GLP toxicology studies in both rats and non-human primates.

We are also conducting discovery research on additional ion channel modulators involved in peripheral transmission of pain that represent potential complementary mechanisms of action to $Na_v1.8$ inhibition for additional pain relief including in other pain etiologies like neuropathic pain.

Our differentiated approach to addressing the shortcomings of current pain management and drug development is built on overcoming challenges in developing novel pain medicines through development of preclinical tools including electrophysiology in human DRG neurons and NHP microneurography to measure the effect of compounds on pain target engagement, optimization of CPT as a reliable biomarker that allows rapid in-human evaluation of analgesic effect with minimal investment and deep expertise in clinical trial design and execution.

We have incurred significant operating losses and negative cash flows since our inception, consistent with our operating plan. Our net losses were $69.7 million and $71.6 million for the nine months ended September 30, 2026 and 2025, respectively. As of September 30, 2026, we had an accumulated deficit of $312.8 million and cash and cash equivalents of $401.2 million.

Since our inception, we have financed our operations primarily through the sale of shares of our redeemable convertible preferred stock and convertible notes. In June 2026, the Company issued unsecured convertible promissory notes (the Convertible Notes) to various holders in the aggregate principal amount of $35.0 million. Additionally, in August 2026, we closed our initial public offering (IPO) pursuant to which we issued and sold 22,080,000 shares of our common stock at a public offering price of $18.00 per share (IPO Price), including 2,880,000 additional shares of our common stock pursuant to the exercise in full by the underwriters of their option to purchase shares of common stock from us at the IPO Price. As a result, we received net proceeds of approximately $364.4 million, after deducting underwriting discounts, commissions and other offering expenses of approximately $33.1 million. Immediately prior to the closing of our IPO, the Convertible Notes automatically converted into 1,957,755 shares of common stock. Based on our current operating plans, we estimate that our cash and cash equivalents will be sufficient to fund our projected operating expenses and capital expenditure requirements into 2029.

We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we expect. Our existing cash and cash equivalents will not be sufficient for us to fund our product candidates through clinical trials, regulatory approval and commercialization, and we will need to raise substantial additional capital in order to do so. We plan to monitor expenses and may raise additional capital opportunistically through the sale of public or private equity, debt financings or other capital sources, which may include our existing and any future licensing or collaboration arrangements, strategic collaborations and other strategic arrangements with third parties. Our ability to access capital when needed is not assured, and if capital is not available to us when, and in the amounts, needed, and on acceptable terms, we may need to delay, scale back or abandon some or all of our development programs and other operations, which could materially affect our business, financial condition, and results of operations.

Components of Results of Operations

Operating Expenses

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

Research and Development Expenses

Our research and development expenses consist primarily of external and internal costs related to the development of our product candidates.

External costs include:

- expenses incurred in connection with conducting clinical trials including investigator grants and site payments for time and pass-through expenses and expenses incurred under agreements with CROs, other vendors or central laboratories and service providers engaged to conduct our trials;
- the cost of manufacturing our product candidates for clinical supply, including costs for laboratory supplies, research materials and reagents;
- expenses incurred in connection with research, laboratory consumables and preclinical studies.

Internal costs include:

- personnel-related expenses, including salaries and related benefits and stock-based compensation expense for personnel engaged in research and development functions; and
- facilities, depreciation, and other expenses, which include allocated expenses for rent and maintenance of facilities, insurance and supplies.

We track direct external research and development expenses by stage of program, clinical or preclinical. We track outsourced development, outsourced personnel costs and other external research and development costs of specific programs. Our internal research and development expenses are deployed across multiple programs and, as such, are not separately tracked. Significant judgment and estimates are made in determining the accrued or prepaid expense balances at the end of any reporting period.

Research and development activities are central to our business model. We cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the preclinical and clinical development of any of our product candidates. Certain factors, among others, that contribute to this uncertainty include future trial designs and regulatory requirements, which cannot be determined with accuracy at this time based on our stage of development. Additionally, product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. As a result, we expect that our research and development expenses will increase substantially in connection with our planned preclinical and clinical development activities.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel-related expenses, including salaries and related benefits and stock-based compensation expense, professional fees for legal, accounting, audit, tax and consulting services, travel expenses and facility-related expenses, which include expenses for rent and maintenance of facilities and other operating costs. We expense all general and administrative expenses as incurred. We expect our general and administrative expenses to increase for the foreseeable future as we continue to improve our infrastructure and operate as a public company. This may include expenses related to compliance with the rules and regulations of the SEC and listing standards applicable to companies listed on a national securities exchange, additional insurance, investor relations activities and other administrative and professional services.

Other (Income) Expense, Net

Other (income) expense, net consists of interest earned on our cash and cash equivalents. Interest expense consists of contractual interest and the amortization of debt discount and issuance costs on the Convertible Notes issued in June 2026, which converted into common stock in connection with our IPO in August 2026. We expect interest income to vary each reporting period depending on our average money market fund balance during the period and market interest rates.

Change in Fair Value of Preferred Stock Tranche Liability

Our redeemable convertible preferred stock tranche liability is accounted for at fair value at inception, with changes in the fair value recorded as a component of other (income) expense, net in the statements of operations and comprehensive loss at each reporting period through settlement. Refer to Note 3 to our unaudited interim condensed financial statements included elsewhere in this *Quarterly Report* for further discussion of the preferred stock tranche liability.

Change in Fair Value of Derivative Liability

Change in fair value of derivative liability reflects the remeasurement of the change of control repayment premium embedded in the Convertible Notes.

Loss on Extinguishment of Debt

Loss on extinguishment of debt reflects the settlement of the Convertible Notes in shares of common stock upon the closing of our IPO.

Results of Operations

Comparison of the three and nine months ended September 30, 2026 and 2025

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2026	2025	Change	2026	2025	Change
Operating expenses:						
Research and development	$ 17,502	$ 22,097	$ (4,595)	$ 56,361	$ 63,709	$ (7,348)
General and administrative	5,427	2,626	2,801	15,812	8,271	7,541
Total operating expenses	22,929	24,723	(1,794)	72,173	71,980	193
Loss from operations	(22,929)	(24,723)	1,794	(72,173)	(71,980)	(193)
Interest income	(2,126)	(728)	(1,398)	(2,864)	(2,113)	(751)
Interest expense	699	—	699	950	—	950
Change in fair value of preferred stock tranche liability	—	795	(795)	—	1,674	(1,674)
Change in fair value of derivative liability	(5,148)	-	(5,148)	(5,148)	—	(5,148)
Loss on extinguishment of debt	4,581	-	4,581	4,581	—	4,581
Other expense, net	14	6	8	15	42	(27)
Total other (income) expense, net	(1,980)	73	(2,053)	(2,466)	(397)	(2,069)
Net loss and comprehensive loss	$ (20,949)	$ (24,796)	$ 3,847	$ (69,707)	$ (71,583)	$ 1,876

Research and Development

The following table summarizes our external and internal costs for the periods presented (in thousands):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2026	2025	Change	2026	2025	Change
Direct Program Costs Onzotrigine	$ 4,944	$ 11,097	$ (6,153)	$ 20,200	$ 28,232	$ (8,032)
Other clinical and non-clinical programs	5,147	5,141	6	15,352	19,638	(4,286)
Personnel-related R&D expenses	6,111	4,298	1,813	16,599	11,995	4,604
Other R&D expenses	1,300	1,561	(261)	4,210	3,844	366
Total research and development expenses	$ 17,502	$ 22,097	$ (4,595)	$ 56,361	$ 63,709	$ (7,348)

Research and development expenses were $17.5 million for the three months ended September 30, 2026 compared to $22.1 million for the three months ended September 30, 2025. The net decrease of $4.6 million was primarily due to a $6.2 million decrease in direct costs related to clinical and non-clinical development of onzotrigine and a $0.3 million decrease in other R&D expenses, partially offset by a $1.8 million increase in personnel-related expenses due to increased headcount to support our development activities, including stock-based compensation. Direct program costs for other clinical programs were flat compared to the prior-year period.

The $6.2 million net decrease in direct costs related to clinical and non-clinical development of onzotrigine was primarily due to a $6.7 million decrease in expenses for clinical trials and a $0.3 million decrease in clinical manufacturing related expenses, offset by a $0.8 million increase in discovery and non-clinical related activities for onzotrigine and a $0.1 million increase in general R&D related expenses for onzotrigine.

Direct program costs for other clinical programs were $5.1 million for each of the three months ended September 30, 2026 and 2025. A $1.1 million increase in discovery and non-clinical expenses and a $0.1 million increase in clinical trial expenses were partially offset by a $1.0 million decrease in clinical manufacturing expenses and a $0.1 million decrease in general research and development expenses.

The $1.1 million net increase in discovery and non-clinical expenses for other clinical programs was mainly driven by a $0.8 million increase related to LTG-321, our next-generation candidate for the inhibition of Nav1.8, a $0.4 million increase related to next generation Nav1.8 inhibitor molecules due to timing of such research activities and a $0.2 million increase related to LTG-418, partially offset by a $0.3 million decrease related to a clinical program which has since been terminated.

Clinical trial expenses for other clinical programs increased by $0.1 million due to a $0.6 million increase in clinical trial expenses related to LTG-321, offset by a $0.5 million decrease related to a clinical program which has since been terminated.

Other R&D expenses decreased by $0.3 million, as $0.5 million lower consulting and professional fees were partially offset by $0.2 million higher IT, facility, and travel costs.

Research and development expenses were $56.4 million for the nine months ended September 30, 2026 compared to $63.7 million for the nine months ended September 30, 2025. The net decrease of $7.3 million was primarily due to a decrease of $8.0 million of direct costs related to clinical and non-clinical development of onzotrigine and a $4.3 million decrease in direct program costs for other clinical programs, offset by an increase of $4.6 million in personnel-related expenses due to increased headcount to support our development activities, including stock-based compensation, and an increase of $0.4 million in other R&D expenses.

The $8.0 million net decrease in direct costs related to clinical and non-clinical development of onzotrigine was primarily due to a $7.9 million decrease in expenses for clinical trials and a $1.8 million decrease in clinical manufacturing related expenses, offset by a $1.3 million increase in discovery and non-clinical related activities for onzotrigine and a $0.4 million increase in general R&D related expenses for onzotrigine.

The $4.3 million net decrease related to other clinical programs was mainly comprised of a $2.5 million decrease in clinical trial expenses, a $1.7 million decrease in clinical manufacturing expenses and a $0.6 million decrease in general research and development expenses, offset by a $0.5 million increase in discovery and non-clinical expenses.

The $0.5 million net increase in discovery and non-clinical expenses for other clinical programs was mainly driven by a $2.1 million increase related to next generation Nav1.8 inhibitor molecules due to timing of such research activities, a $0.6 million increase related to LTG-321, our next generation candidate for the inhibition of Nav1.8, and a $0.2 million increase related to LTG-418, offset by a $2.4 million net decrease related to a clinical program which has since been terminated.

The $2.5 million net decrease in clinical expenses for other clinical programs was driven by a $4.1 million decrease related to a clinical program which has since been terminated, offset by a $1.7 million increase in clinical trial expenses related to LTG-321.

The $1.7 million net decrease in clinical manufacturing expenses was driven by a $2.1 million decrease related to a clinical program which has since been terminated and a $0.6 million decrease related to LTG-321, offset by a $0.8 million increase related to LTG-418 and a $0.2 million increase related to next generation Nav1.8 inhibitor molecules due to timing of such research activities.

The $0.4 million net increase in other R&D expenses was primarily driven by a $0.8 million increase in IT, facilities, office and other expenses, including a $0.3 million increase in IT and facility allocations, a $0.2 million increase in travel and entertainment expenses, a $0.2 million increase in shipping expense and a $0.1 million increase in R&D related software and subscription expenses, partially offset by a $0.3 million decrease in consulting and professional fees.

General and Administrative

The following table summarizes our general and administrative expenses for the periods presented (in thousands):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2026	2025	Change	2026	2025	Change
Employee-related, including stock-based compensation	$ 2,674	$ 1,966	$ 708	$ 7,910	$ 5,354	$ 2,556
Legal and professional services	1,086	163	923	3,538	1,337	2,201
Consulting and contractor	706	89	617	1,529	355	1,174
IT, facilities, office, and other	961	408	553	2,835	1,225	1,610
Total general and administrative expenses	$ 5,427	$ 2,626	$ 2,801	$ 15,812	$ 8,271	$ 7,541

General and administrative expenses were $5.4 million for the three months ended September 30, 2026, compared to $2.6 million for the three months ended September 30, 2025. The $2.8 million increase was primarily attributable to a $0.7 million increase in personnel-related costs, including stock-based compensation, a $0.9 million increase in legal and professional fees, a $0.6 million increase in consulting and external contractor-related expenses and a $0.6 million increase in IT and facilities-related expenses.

General and administrative expenses were $15.8 million for the nine months ended September 30, 2026, compared to $8.3 million for the nine months ended September 30, 2025. The $7.5 million increase was primarily attributable to a $2.6 million increase in personnel-related costs, including stock-based compensation, a $2.2 million increase in legal and professional fees, a $1.6 million increase in IT and facilities-related expenses and a $1.2 million increase in consulting and external contractor-related expenses.

Other (Income) Expense, Net

Total other (income) expense, net was income of $2.0 million for the three months ended September 30, 2026 compared to expense of $0.1 million for the three months ended September 30, 2025. The $2.1 million change was primarily due to a $5.1 million gain from the change in fair value of the derivative liability through the conversion date of the Convertible Notes in connection with our IPO, a $1.4 million increase in interest income as a result of higher average cash and cash equivalents balances following the IPO, and a $0.8 million decrease in expense from the change in fair value of the preferred stock tranche liability, which was settled in September 2025, partially offset by a $4.6 million loss on extinguishment of debt upon the conversion of the Convertible Notes and a $0.7 million increase in interest expense on the Convertible Notes.

Total other income, net was $2.5 million for the nine months ended September 30, 2026 compared to $0.4 million for the nine months ended September 30, 2025. The $2.1 million increase was primarily due to a $5.1 million gain from the change in fair value of the derivative liability, a $1.7 million decrease in expense from the change in fair value of the preferred stock tranche liability and a $0.8 million increase in interest income, partially offset by a $4.6 million loss on extinguishment of debt and a $0.9 million increase in interest expense on the Convertible Notes.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have primarily funded our operations through the sale of shares of our redeemable convertible preferred stock and convertible notes. We have not generated any revenue from product sales and have incurred significant annual operating losses and negative cash flows from our operations. In June 2026, we raised $35.0 million in gross proceeds from the sale of Convertible Notes. In addition, in August 2026, we closed our IPO, through which we received net proceeds of approximately $364.4 million. As of September 30, 2026, we had cash and cash equivalents of $401.2 million. Based on our current operating plans, we estimate that our cash and cash equivalents will be sufficient to fund our projected operating expenses and capital expenditure requirements into 2029. Our total future capital requirements will depend on many factors and are subject to the risks and uncertainties set forth in the section titled “Risk Factors.”

Future Funding Requirements

To date, we have not generated any revenue. We do not expect to generate any meaningful revenue unless and until we obtain regulatory approval of and commercialize any of our product candidates, and we do not know when, or if, that will occur. We will continue to require substantial additional capital to develop our product candidates and fund operations for the foreseeable future. Moreover, we expect our expenses to increase in connection with our ongoing activities, particularly as we continue the development of and seek regulatory approvals for our product candidates. Further, we are subject to all the risks associated with the development of new biopharmaceutical products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may harm our business. Our expenses will increase if, and as, we:

- advance our product candidates through preclinical and clinical development;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- seek to discover and develop additional product candidates;
- establish a sales, marketing, medical affairs and distribution infrastructure to commercialize any product candidates for which we may obtain marketing approval and intend to commercialize on our own or jointly;
- expand our operational, financial and management systems and increase personnel, including personnel to support our development, manufacturing and commercialization efforts and our operations as a public company;
- maintain, expand, protect and enforce our intellectual property portfolio; and

- acquire or in-license other product candidates and technologies.

In order to complete the development of our product candidates and to build the sales, marketing and distribution infrastructure that we believe will be necessary to commercialize our product candidates, if approved, we will require substantial additional funding. Until we can generate a sufficient amount of revenue from the commercialization of our product candidates, we may seek to raise any necessary additional capital through the sale of public or private equity, debt financings or other capital sources, which may include our existing and any future licensing or collaboration arrangements, strategic collaborations and other strategic arrangements with third parties. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, including restricting our operations and limiting our ability to incur liens, issue additional debt, pay dividends, repurchase our common stock, make certain investments or engage in merger, consolidation, licensing or asset sale transactions. If we raise funds through collaborations, strategic partnerships and other similar arrangements with third parties, we may be required to grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. We may be unable to raise additional funds or to enter into such agreements or arrangements on favorable terms, or at all. If we are unable to raise additional funds when needed, we may be required to delay, reduce or eliminate our product development or future commercialization efforts.

We have based our projections of operating capital requirements on our current operating plans, which are based on several assumptions that may prove to be incorrect, and we may use all of our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research, development and commercialization of product candidates, we are unable to estimate the exact amount and timing of our working capital requirements. Our future funding requirements will depend on many factors, including:

- the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical studies and clinical trials;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs of future activities, including product sales, medical affairs, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- the costs of manufacturing commercial-grade products and sufficient inventory to support commercial launch;
- the revenue, if any, received from the commercial sale of our products, should any of our product candidates receive marketing approval;
- the cost and timing of hiring new employees to support our continued growth;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the ability to establish and maintain collaborations on favorable terms, if at all;
- the extent to which we acquire or in-license other product candidates and technologies; and
- the timing, receipt and amount of sales of, or milestone payments related to or royalties on, our current or future product candidates, if any.

A change in the outcome of any of these or other factors with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. Furthermore, our operating plan may change in the future, and we may need additional funds to meet operational needs and capital requirements associated with such operating plan.

Cash Flows

Comparison of the Nine Months Ended September 30, 2026 and 2025

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

	Nine Months Ended September 30,		
	2026	2025	Change
Cash used in operating activities	$ (67,874)	$ (62,630)	$ (5,244)
Cash used in investing activities	(146)	(135)	(11)
Cash provided by financing activities	399,708	149,487	250,221
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 331,688	$ 86,722	$ 244,966

Operating Activities

Cash used in operating activities for the nine months ended September 30, 2026, was mainly comprised of our net loss of $69.7 million, and the change in net operating assets and liabilities of $5.8 million, offset by non-cash charges of $7.7 million. The non-cash charges were primarily related to stock-based compensation expense, change in fair value of derivative liability and loss on extinguishment of debt.

Cash used in operating activities for the nine months ended September 30, 2025, was mainly comprised of our net loss of $71.6 million, offset by a $1.8 million change in net operating assets and liabilities and non-cash charges of $7.2 million. The non-cash charges were primarily related to stock-based compensation expense and change in fair value of preferred stock tranche liability.

Investing Activities

Cash used in investing activities during the nine months ended September 30, 2026 and 2025, reflects our investment in property and equipment during the period.

Financing Activities

Cash provided by financing activities during the nine months ended September 30, 2026, was comprised of $364.4 million in net proceeds from our IPO, $34.8 million of proceeds from issuance of convertible promissory notes and $0.5 million of proceeds from issuance of common stock upon exercise of stock options.

Cash provided by financing activities during the nine months ended September 30, 2025, was comprised of $149.4 million in net proceeds from issuance of Series B redeemable convertible preferred stock, net of issuance costs.

Contractual Obligations and Commitments

In addition to ongoing capital needs to fund our ongoing operations, our material cash requirements include the following contractual and other obligations.

Operating Leases

We lease office and laboratory space in Thousand Oaks, California under a non-cancelable operating lease that expires in June 2028 and office space in San Francisco, California under a non-cancelable operating lease that expires in July 2027.

These commitments are also recognized as operating lease liabilities on our balance sheet as of September 30, 2026. See Note 5 to our unaudited interim condensed financial statements included elsewhere in this *Quarterly Report* for more information on our lease obligations.

License Agreement

In July 2020, we entered into a license agreement with Lieber Institute, Inc. (LIBD), which was subsequently amended in August 2020 and January 2022 (License Agreement), under which LIBD granted us a worldwide, exclusive, sub-licensable and royalty-bearing license, under certain patent and other intellectual property rights owned or controlled by LIBD. Under the License Agreement, we have agreed to pay LIBD up to an aggregate of $48.5 million upon the achievement of pre-specified development and regulatory milestones with respect to the first sole product, up to an aggregate of $23.75 million for each subsequent sole product, and up to an aggregate of $95.0 million upon the achievement of pre-specified sales milestones with respect to all sole products. We have concluded we are not currently developing any licensed products that are sole products, and we do not have any current intentions to develop any licensed products that are sole products. For the first joint product, we have agreed to pay LIBD up to an aggregate of $4.0 million upon the achievement of pre-specified regulatory milestones, and up to an aggregate of $9.5 million upon the achievement of pre-specified sales milestones; we do not have any milestone payment obligations for subsequent joint products. No milestones have been achieved to date under this license agreement for any licensed product. We must also pay LIBD royalties on the net sales of licensed products. The royalty rates for sole products are tiered and range from low-single digit to mid-single digit percentages and the royalty rate for joint products is a low-single digit percentage. The royalty payments are subject to reduction if, on a licensed product-by-licensed product and country-by-country basis, there are no valid patent claims covering the licensed product in such country or if we make certain payments to third parties for intellectual property licenses, all subject to a customary royalty floor. If we sublicense our rights to sole products or licensed patents solely owned by LIBD, then we must pay LIBD a low double-digit percentage of non-royalty sublicensing revenue received from sublicensees for rights to sole products and a low single-digit percentage of non-royalty sublicensing revenue from sublicensees for rights to joint products or jointly-owned patents.

Purchase and Other Obligations

In addition, we have entered into contracts in the normal course of business with CROs, contract manufacturing organizations (CMOs) and other third parties for preclinical research studies and testing, clinical trials and manufacturing services. These contracts do not contain any minimum purchase commitments and are cancelable by us upon prior notice. Cancellation payments may include amounts for services performed, expenses incurred, non-cancelable commitments and applicable termination fees. We have entered into agreements with certain vendors for the provision of goods and services, which includes manufacturing services with CMOs and development services with CROs. These agreements may include certain provisions for purchase obligations and termination obligations that could require payments for the cancellation of committed purchase obligations or for early termination of the agreements. The amount of the cancellation or termination payments varies and are based on the timing of the cancellation or termination and the specific terms of the agreement.

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

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our unaudited interim condensed financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of our unaudited interim condensed financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, costs and expenses and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ materially from these estimates under different assumptions or conditions.

There have been no significant changes to our critical accounting estimates from those described in Management's Discussion and Analysis of Financial Condition and Results of Operations - Critical Accounting Policies and Significant Estimates and Judgments and our audited financial statements as of and for the year ended December 31, 2025 as included in our prospectus dated August 7, 2026 related to our IPO filed pursuant to Rule 424(b)(4) under the Securities Act.

Emerging Growth Company and Smaller Reporting Company Status

We are an "emerging growth company" as defined in the JOBS Act, and we may remain an emerging growth company for up to five years following the closing of the IPO which occurred in August 2026. For so long as we remain an emerging growth company, we are permitted and intend to rely on certain exemptions from various public company reporting requirements, including not being required to have our internal control over financial reporting audited by our independent registered public accounting firm pursuant to Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and any golden parachute payments not previously approved. 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 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 take advantage of the benefits of this extended transition period and, therefore, we are not subject to the same requirements to adopt new or revised accounting standards as other public companies that are not emerging growth companies; however, we may adopt certain new or revised accounting standards early. We would cease to be an emerging growth company upon the earliest to occur of: (i) the last day of the fiscal year following the fifth anniversary of the completion of our IPO; (ii) the last day of the fiscal year in which we have $1.235 billion or more in annual revenue; (iii) the date on which we first qualify as a large accelerated filer under the rules of the SEC; and (iv) the date on which we have, in any three-year period, issued more than $1.0 billion in non-convertible debt securities.

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 the market value of our voting and non-voting 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 the market value of our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

As a "smaller reporting company" as defined by Item 10(f)(1) of Regulation S-K, we are not required to provide the information required by this item.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As of September 30, 2026, management, with the participation and supervision of our Chief Executive Officer and our Chief Financial Officer, has evaluated our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act). Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that, as a result of the material weakness in our internal control over financial reporting described below, as of September 30, 2026, our disclosure controls and procedures were not effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Material weakness in internal control over financial reporting

In connection with the preparation of our financial statements for the years ended December 31, 2024 and 2025, we identified a material weakness in our internal control over financial reporting.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements would not be prevented or detected on a timely basis.

We did not design and maintain effective controls related to the period-end financial reporting process to ensure adequate segregation of duties, including controls related to account reconciliations and journal entries. Specifically, certain personnel have incompatible duties including the ability to (i) create and post manual journal entries without an independent review and (ii) prepare and review account reconciliations.

The material weakness did not result in a misstatement to our financial statements. However, this material weakness could result in a misstatement of substantially all of our accounts or disclosures that would result in a material misstatement of our annual or interim financial statements that would not be prevented or detected.

Management's Plan to Remediate the Material Weakness

To remediate the material weakness, we have designed and started to implement control activities in response to the risks posed as a result of the lack of segregation of duties in the period-end financial reporting process, including control activities related to journal entries and account reconciliations, and control activities related to journal entries in the information systems.

The material weakness will not be considered remediated until management completes the design and implementation of the measures described above and the controls operate for a sufficient period of time and management has concluded, through testing, that these controls are effective.

Changes in Internal Control over Financial Reporting

There are no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the quarter ended September 30, 2026, 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. There are currently no claims or actions pending against us, the ultimate disposition of which we believe could have a material adverse effect on our results of operations. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 1A. Risk Factors

You should carefully consider the risks described below, as well as all of the other information contained in this Quarterly Report and in our other public filings, including in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations," and in our condensed unaudited financial statements and the related notes appearing elsewhere in this Quarterly Report and in our other public filings, which could materially affect our business, financial condition or future results. While we believe that the risks and uncertainties described below are the material risks currently facing us, additional risks that we do not yet know of or that we currently think are immaterial may also arise and materially affect our business, financial condition, results of operations and prospects. If any of the following risks materialize, our business, financial condition, results of operations and prospects could be materially and adversely affected. In that case, the trading price of our common stock could decline, and you may lose some or all of your investment.

We may disclose changes to risk factors or additional risk factors from time to time in our future filings with the SEC.

Risks Related to Our Limited Operating History, Financial Position and Need for Additional Capital

We are a clinical-stage biopharmaceutical company with a limited operating history. We have no history of commercializing products, which may make it difficult to evaluate our approach to the discovery and development of our product candidates and the prospects for our future viability.

We are a clinical-stage biopharmaceutical company with a limited operating history. We were formed in November 2018, and our operations to date have been limited to organizing, staffing, and financing our company, business planning, conducting research and development activities, conducting preclinical studies and clinical trials for our product candidates, and establishing our intellectual property portfolio.

Onzotrigine and LTG-321 are in clinical development, and LTG-418 and our other product candidates and programs are in preclinical development or discovery stages. We have not yet demonstrated an ability to successfully obtain regulatory approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, conduct sales and marketing activities necessary for successful product commercialization or generate revenues. We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies in clinical development, especially clinical-stage pharmaceutical and biotechnology companies such as ours. Any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products.

We have incurred substantial losses since our inception. As of September 30, 2026, our accumulated deficit was approximately $312.8 million. We anticipate incurring substantial and increasing losses for the foreseeable future and may never achieve or maintain profitability.

Investment in pharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval and become commercially viable. Our net loss was $20.9 million and $24.8 million for the three months ended September 30, 2026 and 2025, respectively, and $69.7 million and $71.6 million for the nine months ended September 30, 2026 and 2025, respectively. As of September 30, 2026, we had an accumulated deficit of approximately $312.8 million. Substantially all of our losses have resulted from expenses incurred in connection with research and development, preclinical study and clinical trial costs, and from general and administrative costs associated with our operations.

We expect to continue to incur significant expenses and additional operating losses for the foreseeable future as we seek to advance our product candidates through preclinical and clinical development, expand our research and development activities, develop new product candidates, complete clinical trials, seek regulatory approval and prepare to, and if we receive regulatory approval, commercialize our products. Furthermore, the costs of advancing product candidates into each succeeding clinical phase tend to increase substantially over time. The total costs to advance any of our product candidates to regulatory approval in even a single jurisdiction would be substantial.

Because of the numerous risks and uncertainties associated with product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to generate any revenue from the commercialization of any approved products or achieve or maintain profitability. Our expenses will also increase substantially as we operate as a public company and add clinical, scientific, operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts.

We have no product candidates approved for commercial sale and have not generated any revenue from the sale of products. Our ability to become and remain profitable depends on our ability to generate revenue. We do not expect to generate significant revenue, if any, unless and until we, either alone or with a collaborator, are able to obtain regulatory approval for, and successfully commercialize, our product candidates for their initial and potential additional indications, or any other product candidates we may develop in the future.

Successful commercialization will require achievement of many key milestones, including demonstrating each product candidate's safety and efficacy in clinical trials, obtaining regulatory approval for these product candidates, manufacturing, marketing and selling those products for which we, or any of our future collaborators, may obtain regulatory approval, satisfying any post-marketing requirements and obtaining reimbursement for our products from private insurance or government payors. Because of the uncertainties and risks associated with these activities, we are unable to accurately and precisely predict the timing and amount of expenses or when, or if, we will be able to generate any revenue, the extent of any further losses, or if or when we might achieve profitability. We and any future collaborators may never succeed in these activities and, even if we do, or any future collaborators do, we may never generate revenues that are large enough for us to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Additionally, our expenses could increase if we are required by the FDA, or any comparable foreign regulatory authority, to perform clinical trials in addition to those currently expected, or if there are any delays in completing our clinical trials or in the non-clinical or manufacturing-related activities associated with the development of our product candidates. Even if we succeed in obtaining regulatory approvals for and commercializing onzotrigine, LTG-321 or LTG-418, we expect to incur substantial development costs and other expenditures to develop and market additional product candidates.

We may also encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue or raise additional capital. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and our working capital. Our failure to become and remain profitable may depress the market price of our common stock and could impair our ability to raise capital, expand our business, build out our pipeline or continue our operations. If we continue to suffer losses as we have in the past, you may not receive any return on your investment and may lose your entire investment.

We will require substantial additional financing to achieve our goals, which may cause dilution to our stockholders, and failure to obtain additional capital when needed, or on acceptable terms to us, could cause us to delay, limit, reduce or terminate our product development or future commercialization efforts.

The development of pharmaceutical product candidates is capital-intensive. We expect to continue to spend substantial amounts of cash to conduct further research and development, preclinical studies, and clinical trials of our current and any future product candidates, to seek regulatory approvals for our product candidates and to prepare for and launch and commercialize any products if we receive regulatory approval.

Our operations have consumed substantial amounts of cash since our inception. As of September 30, 2026, we had $401.2 million of cash and cash equivalents.

Based on our current operating plan, we estimate that our existing cash and cash equivalents will be sufficient to fund our projected operating expenses and capital expenditure requirements into 2029. Our future capital requirements and the period for which our existing resources will support our operations may vary significantly from what we expect, and we will in any event require additional capital in order to complete clinical development of our current programs. Our monthly spending levels will vary based on new and ongoing development and corporate activities. Because the length of time and activities associated with development of our product candidates and programs is highly uncertain, we are unable to estimate the actual funds we will require for development and any approved marketing and future commercialization activities, if any. Our future capital requirements will depend on many factors, including:

- the scope, timing, progress, costs and results of discovery, preclinical development and clinical trials for our current or future product candidates;
- the number of clinical trials required for regulatory approval of our current or future product candidates, which may differ

between the United States and other countries or regions;

- the costs, timing and outcome of regulatory review of any of our current or future product candidates;
- the costs associated with acquiring or licensing additional product candidates, technologies or assets, including the timing and amount of any milestones, royalties or other payments due in connection with our acquisitions and licenses;
- the cost of manufacturing clinical and commercial supplies of our current or future product candidates;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims, including any claims by third parties that we are infringing upon their intellectual property rights;
- our ability to maintain existing, and establish new, strategic collaborations or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales and distribution, for any product candidate for which we receive regulatory approval;
- the revenue, if any, received from commercial sales of the product candidate(s) for which we receive regulatory approval;
- expenses to attract, hire and retain skilled personnel;
- the costs of operating as a public company;
- our ability to establish a commercially viable pricing structure and obtain approval for coverage and adequate reimbursement from third-party and government payors for any products that receive regulatory approval;
- our ability to mitigate the impact of adverse macroeconomic conditions or geopolitical events and conflicts, including any health epidemics and their residual effects, bank failures or inflation and increased interest rates, on our preclinical and clinical development or operations;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in businesses, products and technologies.

We will require substantial additional capital to achieve our business objectives, which we may raise through public or private equity offerings, debt financings or other capital sources, including strategic collaborations, licenses and other similar arrangements to enable us to complete the development and potential commercialization of our product candidates.

Additional funds may not be available on a timely basis, on favorable terms or at all, and such funds, if raised, may not be sufficient to enable us to continue to implement our long-term business strategy.

Additionally, if we raise additional funds through future collaborations, licenses and other similar arrangements, we may have to relinquish valuable rights to our future revenue streams or product candidates or grant licenses on terms that may not be favorable to us and/or that may reduce the value of our common stock. Market volatility resulting from potential negative global economic conditions and disruptions in the United States and international credit and financial markets including due to geopolitical conflicts, tariffs, other fiscal and trade policy changes, bank failures, supply chain and labor disruptions, the effects of a health epidemic or pandemic or other factors may further adversely impact our ability to access capital as and when needed. Our failure to raise capital as and when needed would have a negative effect on our financial condition and our ability to pursue our business strategy. In addition, attempting to secure additional financing may divert the time and attention of our management from day-to-day activities and harm our development efforts.

In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of our common stock. Any future debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, selling or licensing our assets, making capital expenditures, declaring dividends or encumbering our assets to secure future indebtedness. Such restrictions could adversely impact our ability to conduct our operations and execute our business plan. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed or on terms acceptable to us, we would be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

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

If we are unable to successfully develop, obtain approval and commercialize treatments for acute and chronic pain, our business could be materially harmed.

We currently have two product candidates in clinical development. Onzotrigine is being developed for the treatment of moderate to severe acute pain, including postoperative pain, with an intended use, as needed, for up to 30 days, and LTG-321 is being developed initially for the treatment of chronic musculoskeletal pain. We have completed a clinical trial for onzotrigine for the treatment of moderate to severe acute pain in patients undergoing abdominoplasty, which, based on our discussions with the FDA, may serve as one of the two pivotal adequate well-controlled trials required to demonstrate efficacy to support approval of onzotrigine for the treatment of moderate to severe acute pain, including postoperative pain. We plan to conduct a placebo-controlled Phase 3 trial in patients undergoing bunionectomy and an open-label Phase 3 safety trial exploring onzotrigine within a broader population of patients with moderate to severe acute pain across a variety of post-surgical and non-surgical settings to meet FDA requirements for patient exposures. We have also completed Phase 1 clinical trials for LTG-321 for the treatment of chronic pain and have initiated a Phase 2 clinical trial investigating LTG-321 in participants with chronic pain associated with osteoarthritis of the knee. We also have a product candidate in preclinical development, LTG-418, which is being developed for the treatment of acute and chronic pain. If we do not obtain approval of onzotrigine, LTG-321 or LTG-418 or any of our future product candidates, our business may be materially harmed. Even if we receive regulatory approval for onzotrigine, LTG-321 or LTG-418 or any of our future product candidates, they may not gain or maintain market acceptance among physicians and patients or other members of the medical community. In addition to the risks normally associated with launching a new branded product, onzotrigine, LTG-321 and LTG-418 will need to compete in a mature pain market that includes low-cost generic drugs, including opioids, non-steroidal anti-inflammatory drugs, acetaminophen and local anesthetics. If we are not able to successfully develop, obtain approval for and commercialize treatments for acute and chronic pain, our future net product revenues and cash flows will be adversely affected and our business could be materially harmed.

We only have two product candidates, onzotrigine and LTG-321, in clinical development. If we are unable to continue to advance our product candidates in clinical development, obtain regulatory approval and ultimately commercialize our product candidates or experience significant delays in doing so, our business will be materially harmed.

We are substantially dependent on the success of our product candidates, onzotrigine and LTG-321, which are in clinical development. We also have a product candidate in preclinical development, LTG-418. We will need to continue to progress onzotrigine, LTG-321 and LTG-418 through our ongoing and planned clinical trials and progress any future development program through preclinical studies and submit INDs to the FDA or comparable foreign regulatory applications to applicable foreign regulatory authorities prior to initiating their clinical development.

Our ability to generate product revenues, which we do not expect will occur for a number of years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates. The success of our product candidates will depend on several factors, including the following:

- completion of preclinical studies with favorable results, including certain studies required to be in compliance with good laboratory practice (GLP) requirements;
- successful enrollment in, and completion of, clinical trials in accordance with good clinical practice (GCP) requirements and other applicable rules and regulations and with favorable results;
- completion of toxicology and clinical pharmacology with favorable results, which are necessary to advance our product candidates into subsequent phases of clinical trials or for approval;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- allowance to proceed with clinical trials under INDs by the FDA or under similar regulatory submissions by applicable foreign regulatory authorities for the conduct of clinical trials of our product candidates and our proposed design of future clinical trials;
- maintaining and establishing relationships with contract research organizations (CROs) and clinical sites for the clinical development of our product candidates;
- demonstrating the safety and efficacy of our product candidates to the satisfaction of the FDA and other applicable foreign regulatory authorities;
- the sufficiency of our abdominoplasty trial to serve as one of the two adequate well-controlled trials required to demonstrate efficacy to support approval of onzotrigine for the treatment of moderate to severe acute pain, including postoperative pain;
- receipt of regulatory approvals from applicable regulatory authorities, including new drug applications (NDAs) from the

FDA and approvals from comparable foreign regulatory authorities and maintaining such approvals;

- making arrangements with third-party manufacturers to manufacture sufficient quantities of product candidates for clinical and commercial use;
- establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- acceptance of any products we develop and their benefits and uses, if and when approved, by patients, the medical community and third-party payors;
- establishing and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates;
- effectively competing with other therapies;
- obtaining and maintaining healthcare coverage and adequate reimbursement from third-party payors;
- maintaining an acceptable safety profile of our products following approval; and
- building and maintaining an organization of people who can successfully develop our product candidates.

We have not yet succeeded and may not succeed in demonstrating efficacy and safety for any product candidates in clinical trials to support obtaining regulatory approval. Given our stage of development, it may take multiple years before we can demonstrate the safety and efficacy of a product candidate sufficient to warrant approval for commercialization, if we can do so at all. If we are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize our product candidates, we may not be able to generate sufficient revenue to continue our business.

Our approach to the development of product candidates is unproven, and we do not know whether we will be able to develop any products of commercial value, or if competing technological approaches will limit the commercial value of our product candidates.

Our success depends on our ability to identify, develop and obtain regulatory approval for and commercialize our product candidates. While we have had favorable preclinical study and early clinical trial results, we may not succeed in demonstrating efficacy and safety for any product candidates in subsequent clinical trials or in obtaining regulatory approval thereafter.

Our approach focuses on $Na_v1.8$ inhibition, which addresses peripheral pain signaling. Certain pain states involve central sensitization and brain-based pain processing mechanisms that are not directly targeted by $Na_v1.8$ inhibition. If central pain components are significant drivers of pain in the patient populations we target, the efficacy of onzotrigine, LTG-321, LTG-418 and any of our future product candidates may be limited or less durable than anticipated. In addition, there is uncertainty regarding whether repeated or chronic dosing of $Na_v1.8$ inhibitors may lead to compensatory mechanisms or tolerance, reducing therapeutic effect over time. If tolerance develops or central pain mechanisms limit efficacy, our product candidates may fail to demonstrate sufficient clinical benefit to support regulatory approval or commercial success.

We may also be unsuccessful in using our approach to identify additional product candidates, and any of our product candidates may be shown to have harmful side effects or may have other characteristics that may necessitate additional clinical testing or make the product candidates unmarketable or unlikely to receive or maintain regulatory approval. In particular, any failure of one of our development programs, or a competitor's product or development program that is pursuing a similar approach, could create a perception that our other programs are less likely to succeed or that our approach is not viable.

In addition, the pharmaceutical industry is characterized by rapidly advancing technologies. Our future success will depend in part on our ability to maintain a competitive position with our approach. If we fail to stay at the forefront of technological change in using our approach to create and develop product candidates, we may be unable to compete effectively. Our competitors may render our approach obsolete or limit the commercial value of our product candidates through advances in existing technological approaches or the development of new or different approaches. By contrast, adverse developments with respect to other companies that attempt to use a similar approach to our approach may adversely impact the actual or perceived value of our approach and potential of our product candidates.

If any of these events occur, our ability to successfully discover, develop and commercialize any product candidates may be impaired and the value of our company could decline significantly.

Preclinical and clinical development involves a lengthy and expensive process, with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial or real-world results. Our product candidates may not have favorable results in clinical trials or preclinical studies or receive regulatory approval on a timely basis, if at all.

Onzotrigine and LTG-321 are in clinical development and LTG-418 is in preclinical development. The risk of failure of our product candidates is high. It is impossible to predict when or if our product candidates will receive regulatory approval. To obtain the requisite regulatory approvals to commercialize our product candidates, we must demonstrate through lengthy, complex and expensive clinical trials that our product candidates are safe and effective in patient populations for the intended indication(s) for use. Preclinical studies and clinical trials can take many years to complete, and their outcomes are inherently uncertain. Failure can occur at any time during the preclinical study or clinical trial process, despite promising preclinical or clinical results. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials, and results in one indication may not be predictive of results to be expected for the same product candidates in another indication. Specifically, results from any single acute pain model may not be predictive of results in other acute pain models or indications within musculoskeletal pain. For example, results from studies in an abdominoplasty model may not predict results in a bunionectomy model or other musculoskeletal indications. Additionally, results from our previously conducted dental pain study, which showed no active treatment separated from placebo with statistical significance, were not replicated in our abdominoplasty trial. We cannot ensure that results obtained in any completed or ongoing study will be replicated in future studies across different indications or patient populations, including in any proposed chronic pain indications. Results observed in acute pain studies may not be predictive of efficacy or safety in chronic pain settings, which involve fundamentally different patient populations, dosing regimens and disease mechanisms.

Additionally, differences in trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unfavorable safety profiles, notwithstanding promising results in earlier trials. Such setbacks have occurred and may occur for many reasons, including, but not limited to: clinical sites and investigators may deviate from clinical trial protocols, whether due to lack of training or otherwise, and we may fail to detect any such deviations in a timely manner; patients may fail to adhere to any required clinical trial procedures; our product candidates may fail to demonstrate effectiveness or safety in certain patient subpopulations, which has not been observed in earlier trials due to limited sample size, lack of analysis or otherwise; or our clinical trials may not adequately represent the patient populations we intend to treat, whether due to limitations in our trial designs or otherwise, such as where one patient subgroup is overrepresented in the clinical trial. We may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates achieved promising results have nonetheless failed to obtain regulatory approval of such product candidates or, upon commercialization, achieve or maintain positive real-world results. More specifically, the FDA's regulatory expectations for non-opioid pain therapies continue to evolve, and we cannot predict how changing agency priorities, review standards or guidance documents applicable to this therapeutic class may affect the regulatory pathway for onzotrigine, LTG-321, LTG-418 and any of our future product candidates. The FDA may impose novel requirements, including additional or expanded clinical trials, different primary endpoints or heightened safety data thresholds, that are specific to non-opioid analgesics and that were not contemplated at the time we designed our clinical program. Any such changes could significantly delay approval, if any, increase development costs, or require us to substantially modify our development plans.

Most product candidates that commence clinical trials are never approved as commercial products and there can be no assurance that any of our current or future clinical trials will ultimately be successful or support the approval of our current or any future product candidates.

We may experience delays in initiating or completing clinical trials or reporting data readouts for such trials, due to unforeseen events or otherwise, that could delay or prevent our ability to receive regulatory approval or commercialize our current and any future product candidates, including:

- regulators, such as the FDA or comparable foreign regulatory authorities, Institutional Review Boards (IRBs) or ethics committees may impose additional requirements before permitting us to initiate a clinical trial, may not authorize us or our investigators to commence or conduct a clinical trial at a prospective trial site, may not allow us to amend trial protocols or regulators may disagree as to the design or implementation of our clinical trials and require that we modify or amend our clinical trial protocols or statistical analysis plans;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with CROs or with individual clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among trial sites;
- delays in identifying, recruiting and training suitable clinical investigators;
- IRBs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional participants or withdrawing their approval of the trial;

- changes or amendments to the clinical trial protocol;
- clinical trial sites may deviate from the trial protocol, fail to ensure the integrity of the data being collected at the site or drop out of a trial;
- failure by any of our third-party contractors to perform in accordance with GCP requirements or applicable regulatory rules and guidelines in other countries;
- the number of participants required for clinical trials may be larger than we anticipate, we may experience difficulty in finding and enrolling sufficient qualified patients for our trials, enrollment in clinical trials may be slower than we anticipate or participants may drop out or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- participants may fail to enroll or remain in our trials at the rate we expect, or fail to return for post-treatment follow-up, including participants failing to remain in our trials due to movement;
- patients choosing an alternative product for the indications for which we are developing our product candidates, or participating in competing clinical trials;
- the quality or quantity of data relating to our product candidates or other materials necessary to conduct our clinical trials may be inadequate to initiate or complete a given clinical trial;
- we may experience difficulties in manufacturing, or fail to manufacture, sufficient quantities of our product candidates for use in clinical trials;
- participants experiencing severe or serious unexpected drug-related adverse effects;
- reports from clinical testing conducted by other companies of other therapies in the same class of agents that could be considered similar to our product candidates may raise safety, tolerability or efficacy concerns about our product candidates;
- the cost of clinical trials may be greater than we anticipate, and we may lack adequate funding to initiate or continue one or more of our clinical trials;
- a facility manufacturing our product candidates or any of their components being ordered by the FDA or comparable foreign regulatory authorities to temporarily or permanently suspend production due to violations of current Good Manufacturing Practice (cGMP) regulations or other applicable requirements or cross-contaminations of product candidates in the manufacturing process;
- changes to our manufacturing processes may be necessary or desired;
- third-party contractors being unwilling or unable to satisfy their contractual obligations to us in a timely or accurate manner;
- third-party contractors could become debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our planned marketing applications; and
- clinical trials of our product candidates may fail to show appropriate safety, tolerability or efficacy, may produce negative or inconclusive results or may otherwise fail to improve on the existing standard of care, and we may decide, or regulators may require us, to conduct additional clinical trials or we may decide to abandon product development programs.

Clinical trials must be conducted in accordance with the FDA and other applicable regulatory authorities' legal requirements, regulations and guidelines, and remain subject to oversight by these governmental agencies as well as ethics committees or IRBs responsible for overseeing the conduct of clinical trials and ensuring the welfare of the research participants. We could encounter delays if a clinical trial is suspended or terminated by us, the IRBs of the institutions in which such trials are being conducted, the FDA or comparable foreign regulatory authorities or the Data Safety Monitoring Board for such trial. A suspension or termination may be imposed due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical trial protocols, adverse findings from inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities, unforeseen safety issues or adverse side effects, failure to establish or achieve clinically meaningful trial endpoints, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. For example, the FDA placed our IND for onzotrigine on a clinical hold from May 2024 to November 2024 due to insufficient non-clinical data to support the initial submission of our abdominoplasty pain trial in April 2024. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to regulators or to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial. Clinical trials may also be delayed or terminated as a result of ambiguous or negative interim results.

Additionally, we have in the past and may in the future create synthetic molecules for comparative purposes. For example, we have created a synthetic version of suzetrigine for use in preclinical studies. We believe the results of these studies help us understand how the therapeutic index of our product candidates compare to competitor products. However, we cannot be certain that any synthetic molecule that we create is the same as the molecule we are attempting to recreate, and the results of the studies comparing any such synthetic molecule to any other product candidate may be different than the actual results of a head-to-head study of any such product candidate against a competitor molecule. Additional preclinical and clinical testing will be needed to evaluate the therapeutic index of our product candidates, and to understand their therapeutic potential relative to approved drugs and other product candidates in development.

Further, conducting clinical trials in foreign countries, as we are doing for our product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled subjects in foreign countries to adhere to clinical protocols as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, and political and economic risks, including war, relevant to such foreign countries.

Many of the factors that cause, or lead to, a delay in the commencement or completion of, or the termination or suspension of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Further, the FDA may disagree with our interpretation of data from clinical trials or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials.

We may, in the future, conduct preclinical and clinical research in collaboration with other academic, pharmaceutical or biotechnology entities in which we combine our development efforts with those of our collaborators. Such collaborations may be subject to additional delays because of the management of the trials, contract negotiations and the need to obtain agreement from multiple parties, which may increase our future costs and expenses.

Our product development costs will increase if we experience delays in clinical testing or in seeking regulatory approvals. We do not know whether any of our clinical trials will begin as planned, will need to be redesigned or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates and may allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates, if approved. Any delays or increase in costs in our clinical development programs may harm our business, financial condition, results of operations and prospects.

We may find it difficult to enroll patients in our clinical trials. If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

Patient enrollment is a significant factor in the timing of clinical trials, and the timing of our clinical trials depends, in part, on the speed at which we can recruit and enroll patients to participate in our trials, as well as completion of required follow-up periods. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to identify and enroll a sufficient number of eligible patients to participate in these trials to such trial's conclusion as required by the FDA or comparable foreign regulatory authorities.

Patient enrollment is affected by many factors including the size and nature of the patient population, competing clinical trials in the same or similar indications or at the same trial site, the severity of the condition under investigation, the availability and efficacy of approved drugs and diagnostics for the condition under investigation, the number and location of clinical sites, the proximity of patients to clinical sites, willingness of patients to participate in a decentralized clinical trial that may involve remote monitoring technologies, the inclusion and exclusion criteria for the trial, perceived risks and benefits of the product candidate under study, the design of the clinical trial, continued enrollment of prospective patients by clinical trial sites, the risk that enrolled patients will not complete a clinical trial, our ability to recruit clinical trial investigators with the appropriate competencies and experience, efforts to facilitate timely enrollment in clinical trials, patient referral practices of physicians, the ability to monitor patients adequately during and after treatment, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new products that may be approved for, or any product candidates under investigation for, the indications we are investigating. Clinical trial recruitment and enrollment activities may also be delayed as a result of macro-factors such as public health emergencies or pandemics, natural disasters and acts of terror or war.

Even if we are able to enroll a sufficient number of patients in our clinical trials, we may have difficulty maintaining enrollment of such patients, and delays in enrollment may result in increased costs or may affect the timing or outcome of our clinical trials. Any of these conditions may negatively impact our ability to complete such trials or include results from such trials in regulatory submissions, which could adversely affect our ability to advance the development of our product candidates.

Further, other pharmaceutical or biotechnology companies targeting these same conditions may be recruiting clinical trial patients from similar patient populations, which may make it more difficult in the future to fully enroll any clinical trials. Our inability to enroll a sufficient number of patients for any of our future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. In addition, we expect to rely on 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 have limited influence over their actual performance.

We cannot assure you that our assumptions used in determining expected clinical trial timelines are correct or that we will not experience delays in enrollment, which would result in the delay of completion of such trials beyond our expected timelines.

Use of our product candidates could be associated with adverse side effects, adverse events or other safety risks, which could delay or preclude the candidate's approval, cause us to suspend or discontinue clinical trials, cause us to abandon the product candidates, limit the commercial profile of any future approved product or result in other significant negative consequences that could severely harm our business, prospects, operating results and financial condition.

Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics related to our product candidates. Undesirable side effects caused by our product candidates could cause us, the IRB or regulatory authorities to interrupt, delay or halt clinical trials or cause the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities, or, if such product candidate is approved, result in a more restrictive label, including an inability to include an opioid-free label claim, and other post-approval requirements. Any treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or could result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

If our product candidates are associated with undesirable side effects or have unexpected characteristics in clinical trials, we may need to interrupt, delay or abandon their development or limit 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.

Because our initial clinical programs target acute pain in otherwise generally healthy patient populations, such as patients undergoing elective surgical procedures, even modest safety or tolerability signals may be viewed as unacceptable by the FDA, the IRB, clinical investigators or prescribers. Regulators and prescribers may apply a stricter risk-benefit standard to a product candidate intended for use in healthy individuals than they would for therapies targeting serious or life-threatening conditions. The full safety and tolerability profile of onzotrigine, LTG-321 and LTG-418 cannot be assessed until substantially larger and longer studies have been completed, and unexpected findings in later trials could result in clinical holds, restrictive labeling, Risk Evaluation and Mitigation Strategy (REMS) requirements or reduced market acceptance.

Patients in our ongoing and planned clinical trials may in the future suffer significant adverse events or other side effects not observed in our preclinical studies or previous clinical trials. Even if such side effects do not preclude the product candidates from obtaining or maintaining regulatory approval, undesirable side effects may not support an opioid-free label claim or inhibit market acceptance due to tolerability concerns as compared to other available therapies. Any of these developments could materially harm our business, financial condition and prospects.

Additionally, if our product candidates receive regulatory approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result. For example, the FDA could require us to adopt a REMS to ensure that the benefits of treatment with such product candidates outweigh the risks for each potential patient, which may include, among other things, a communication plan to health care practitioners, patient education, extensive patient monitoring or distribution systems and processes that are highly controlled, restrictive and more costly than what is typical for the industry. Other potentially significant negative consequences associated with post-marketing identification of adverse events or other safety risks include:

- we may be required to suspend marketing of a product, or we may decide to remove such product from the marketplace;
- regulatory authorities may withdraw or modify their approvals of a product;
- regulatory authorities may require additional warnings or new contraindications on the label, or may limit access of a product to selective specialized centers with additional safety reporting and with requirements that patients be geographically close to these centers for all or part of their treatment;
- we may be required to create a medication guide outlining the risks of a product for patients, or to conduct post-marketing studies;
- we may be required to change the way a product is distributed or administered;
- we could be subject to fines, injunctions or the imposition of criminal or civil penalties, or be sued and held liable for harm caused to participants or patients; and
- a product may become less competitive, and our reputation may suffer.

Any of these events could diminish the usage or otherwise limit the commercial success of our product candidates and prevent us from achieving or maintaining market acceptance of our product candidates, if approved by the FDA or other regulatory authorities.

We may expend our limited resources to pursue a particular product candidate or a particular indication and fail to capitalize on product candidates or indications that may present a greater commercial opportunity or for which there is a greater likelihood of success.

Because we have limited resources, we must choose to pursue and fund the development of specific product candidates. Our resource allocation and other decisions may cause us to fail to identify and capitalize on viable potential product candidates or additional indications or other profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular indication or product candidate, we may relinquish valuable rights to that product candidate through collaborations, licenses and other similar arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidates.

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

From time to time, we may publicly disclose preliminary or topline data from our preclinical studies and clinical trials, which are based on preliminary analyses of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular preclinical study or clinical trial. We also make assumptions, estimations, calculations and conclusions as part of our data analyses, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline or preliminary results that we report may differ from future results of the same studies or trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the topline or preliminary data we previously published. As a result, topline and preliminary data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments for their condition. Adverse differences between interim data and final data could significantly harm our business prospects.

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 impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and could adversely affect the success of our business. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If the interim, topline or preliminary 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, financial condition, results of operations and prospects. Further, disclosure of interim, topline or preliminary data by us or by our competitors could result in volatility in the price of our common stock.

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

Any product candidates we may develop and the activities associated with their development and commercialization, including their design, testing, manufacture, record-keeping, labeling, storage, approval, advertising, promotion, import, export, marketing and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities in the United States and by comparable foreign regulatory authorities. Failure to obtain regulatory approval for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction. We have not received approval to market any product candidates from regulatory authorities in any jurisdiction and it is possible that none of the product candidates we may seek to develop in the future will ever obtain regulatory approval. We have no experience in filing and supporting the applications necessary to gain regulatory approvals. Although we believe that we have the capabilities to conduct preclinical studies and clinical trials and to eventually submit regulatory approval applications using our internal resources, we selectively employ and may in the future rely on CROs or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority.

The process of obtaining regulatory approvals, both in the United States and abroad, is expensive, often takes many years following the commencement of clinical trials, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved, as well as the target indications and patient populations. Changes in regulatory approval policies during the development period, changes in or the enactment of additional statutes or regulations or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Prior to obtaining approval to commercialize a product candidate in the United States or abroad, we 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. Despite the time and expense invested in clinical development of product candidates, regulatory approval of a product candidate is never guaranteed. Of the large number of drugs in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized.

The FDA or 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 execution of our clinical trials;
- negative or ambiguous results from our clinical trials or results may not meet the level of statistical significance or persuasiveness required by the FDA or comparable foreign regulatory agencies for approval;
- serious and unexpected drug-related side effects may be experienced by patients 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 that are conducted at clinical facilities or in countries where the standard of care is potentially different from that of their own country;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- such authorities may disagree with our interpretation 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 the submission of an NDA or other submission or 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 with us regarding the formulation, labeling and/or the product specifications of our product candidates;
- approval may be granted only for indications that are significantly more limited than those sought by us, and/or may include significant restrictions on distribution and use;
- such authorities may find deficiencies in the manufacturing processes or facilities of the third-party manufacturers with which we contract for clinical and commercial supplies; or
- such authorities may not accept a submission due to, among other reasons, the content or formatting of the submission.

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.

Even if we eventually complete clinical trials and receive approval of an NDA or comparable foreign marketing application for our product candidates, the FDA or comparable foreign regulatory authority may grant approval contingent on the performance of costly additional clinical trials and/or the implementation of a REMS, which may be required because the FDA believes it is necessary to ensure safe use of the product after approval.

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

We are conducting and plan to conduct additional clinical trials for our product candidates outside the United States and the FDA may not accept data from such trials.

We are conducting and plan to conduct additional clinical trials outside the United States. For example, we have completed Phase 1 trials for onzotrigine and LTG-321 in New Zealand. The acceptance of study data from clinical trials conducted outside the U.S. or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all.

Where data from foreign clinical trials are intended to serve as the sole basis for regulatory approval in the United States, the FDA will not approve the application on the basis of foreign data alone unless those data are applicable to the U.S. population and U.S. medical practice, the clinical trials were performed by clinical investigators of recognized competence and the data are considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, if the study was not otherwise subject to an IND, the FDA will not accept the data as support for an application for regulatory approval unless the study is well-designed and well-conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar requirements for clinical data gathered outside of their respective jurisdictions. In addition, such clinical trials would be subject to the applicable local laws of the foreign jurisdictions where the clinical trials are conducted. There can be no assurance the FDA will accept data from clinical trials conducted outside of the United States. If the FDA does not accept any such data, it would likely result in the need for additional clinical trials, which would be costly and time-consuming and delay aspects of our development plan.

In addition, the conduct of clinical trials outside the United States could have a significant impact on us. Risks inherent in conducting international clinical trials include:

- foreign regulatory requirements that could burden or limit our ability to conduct our clinical trials;
- difficulties staffing and managing foreign operations;
- compliance with legal requirements applicable to privacy, data protection, information security and other matters;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including value-added tax, withholding and payroll taxes;
- administrative burdens of conducting clinical trials under multiple foreign regulatory schema;

- foreign exchange fluctuations;
- manufacturing, customs, shipment and storage requirements;
- impact of geopolitical events or a public health crisis on our ability to produce our product candidates and conduct clinical trials in foreign countries;
- potential liability under the Foreign Corrupt Practices Act of 1977, as amended (FCPA), or comparable foreign regulations;
- cultural differences in medical practice and clinical research; and
- diminished protection of intellectual property in some countries.

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

We may seek regulatory approval for our product candidates outside the United States. Foreign regulatory authorities have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants regulatory approval of a product candidate, comparable regulatory authorities in foreign jurisdictions also must approve the manufacturing, marketing and promotion of the product candidate in those jurisdictions. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In addition, in some 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 also is subject to approval.

Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with the regulatory requirements in international markets and/or receive and maintain applicable regulatory approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed, which could adversely affect our business, results of operations and financial condition.

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

As product candidates progress through clinical trials to regulatory 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 safety, efficacy, stability, purity, 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 and/or may lead to delays and additional costs. Additionally, any changes we may make to our product candidates may cause such candidates to perform differently than in prior clinical trials or could negatively affect our ability to utilize or interpret our existing data. Such changes could delay initiation or completion of clinical trials, lead to negative trial results, require the conduct of bridging studies or clinical trials or the repetition of one or more studies or clinical trials, increase development costs, delay potential regulatory approval and jeopardize our ability to commercialize our product candidates or generate revenue.

We have received Fast Track Designation for onzotrigine for the treatment of acute pain; however, there is no guarantee that a Fast Track Designation will lead to a faster development, regulatory review or approval process, nor does it increase the likelihood that our product candidates will receive regulatory approval.

On February 18, 2025, the FDA granted Fast Track Designation for onzotrigine for the treatment of acute pain. Depending on the data from our preclinical studies and clinical trials, we may decide to seek Fast Track Designation for some or all of our other product candidates.

The Fast Track program is intended to expedite or facilitate the process for reviewing product candidates that meet certain criteria. Specifically, drugs are eligible for Fast Track designation if they are intended, alone or in combination with one or more drugs or biologics, to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast Track designation applies to the combination of the product candidate and the specific indication for which it is being studied. The sponsor of a Fast Track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once an NDA is submitted, the application may be eligible for priority review. An NDA submitted for a Fast Track product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application.

The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive Fast Track Designation for our product candidate, it may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may also withdraw the Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program. Furthermore, such a designation does not increase the likelihood that the product candidate will receive regulatory approval in the United States. Many product candidates that have received Fast Track Designation have ultimately failed to obtain approval.

Risks Related to Our Business and Operations

We will need to grow our organization, and we may experience difficulties in managing our growth and expanding our operations, which could adversely affect our business.

As of September 30, 2026, we had 71 full-time employees. As we continue development and pursue the potential commercialization of our product candidates, and as we continue to operate as a public company, we expect to expand our employee base for managerial, development, regulatory, financial, information technology, marketing and sales capabilities, or contract with third parties to provide these capabilities for us. In the future, we expect to have to manage additional relationships with collaborators or partners, suppliers and other organizations. Our ability to manage our operations and future growth will require us to continue to improve our operational, financial, and management controls, reporting systems and procedures, which may lead to significant costs and may divert management attention. We may not be able to implement improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls. Our inability to successfully manage our growth and expand our operations could adversely affect our business, financial condition, results of operations and prospects.

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

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. Pain therapeutics is a specialized field with a limited pool of scientists, clinicians and drug developers with deep domain expertise. We are highly dependent upon our Chief Executive Officer, Chief Medical Officer and other members of our management team. The loss of services of any of these individuals could delay or prevent the successful development and commercialization of our product candidates. In November 2026, we announced a management transition that involved a change in our Chief Executive Officer. While the transition was intended to position the Company for longer-term success as we mature, in the short to intermediate term, the transition may create uncertainty, divert management's attention and resources, and it may not align with the expectations of employees, vendor partners, or other external stakeholders. As a result, the transition could negatively affect our operations, strategic initiatives, employee engagement and retention.

Although we have executed employment agreements or offer letters with each member of our senior management team, these agreements are terminable at will with or without notice and, therefore, we may not be able to retain their services as expected. Additionally, we do not currently maintain "key person" life insurance on the lives of our executives or any of our employees.

We will need to expand and effectively manage our managerial, operational, financial and other resources in order to successfully pursue our clinical development and commercialization efforts. We may not be successful in maintaining our company culture and continuing to attract or retain qualified management and scientific and clinical personnel in the future due to the intense competition for qualified personnel among pharmaceutical, biotechnology and other businesses. If we are not able to attract, integrate, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

Our employees, independent contractors, consultants, commercial partners, and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other illegal activity by our current and any future employees, independent contractors, consultants, commercial partners, CROs, third-party manufacturers and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to comply with FDA or other regulations, provide true, complete and accurate information to the FDA and other comparable foreign regulatory authorities, comply with manufacturing standards we may establish, comply with healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. If we obtain FDA approval of our product candidates and begin commercializing the product in the United States, our potential exposure under these laws will increase significantly, and our costs associated with compliance with these laws are likely to increase. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. 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 governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material and adverse effect on our business, financial condition, results of operations and prospects, including the imposition of significant civil, criminal, and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of our operations, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, integrity oversight and reporting obligations or reputational harm.

Our projections regarding the market opportunities for our product candidates may not be accurate and the actual market for our products may be smaller than we estimate.

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 conditions, as well as the subset of people with these conditions 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 sales of our competitors, scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect in general, or as to their applicability to our company. Further, new trials may change the estimated incidence or prevalence of these conditions. The total addressable market of our product candidates, if approved, will ultimately depend upon, among other things, the diagnosis criteria included in the final label for our product candidates approved for sale for these indications, if any, the ability of our product candidates to improve on the safety, convenience, cost and efficacy of competing therapies or therapies in development, acceptance by the medical community and patients, 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, if approved, and our product candidates or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our business, financial condition, results of operations and prospects.

Our business entails a significant risk of product liability and our ability to obtain sufficient insurance coverage could adversely affect our business, financial condition, results of operations and prospects.

As we conduct clinical trials of our current or future product candidates, we are exposed to significant product liability risks inherent in the development, testing, manufacturing and marketing of new treatments. Product liability claims could delay or prevent completion of our development programs. If we succeed in obtaining approval for, and marketing, products, such claims or certain adverse event trends could result in an investigation by the FDA, comparable foreign regulatory authorities or other regulators into the safety and efficacy of our future approved products, our manufacturing processes and facilities or our marketing programs and potentially a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used, or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our future approved products, termination of clinical trial sites or entire trial programs, withdrawal of clinical trial participants, injury to our reputation and significant negative media attention, significant costs to defend the related litigation, a diversion of management's time and our resources from our business operations, substantial monetary awards to trial participants or patients, loss of revenue, the inability to commercialize any products that we may develop and a decline in our stock price. We may need to obtain higher levels of product liability insurance for later stages of clinical development or marketing our product candidates. Any insurance we may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could adversely affect our business, financial condition, results of operations and prospects.

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include property, general liability, clinical trials, and directors' and officers' liability insurance. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our business, financial condition, results of operations and prospects.

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 upon which we rely process sensitive data, and, as a result, we and the third parties upon which we rely face a variety of evolving threats, including but not limited to ransomware attacks, which could cause security incidents. 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 and 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 services.

We and the third parties with whom we work are subject to a variety of evolving threats, including but not limited to 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, ability 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/or 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. For example, threat actors may use an initial compromise of one part of our environment to gain access to other parts of our environment or leverage a compromise of our networks or systems to gain access to the networks or systems of third parties with whom we work, such as through phishing or supply chain attacks. 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.

In addition, our reliance on third parties could introduce cybersecurity risks and vulnerabilities and other threats to our business operations. We rely significantly on third parties to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, cloud-based infrastructure, data center facilities, encryption and authentication technology, employee email, content delivery to customers, information technology and security, and other functions. We also rely on third parties to provide other products, services, parts or otherwise to operate our business, including with respect to our cybersecurity infrastructure. 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, through our third-party information security vendors, have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be complied with or effective.

We take steps designed to detect, mitigate and remediate vulnerabilities in our information systems (such as our hardware and/or 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 developing and 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 information or our information technology systems, or those of the third parties with whom we work. For example, in February 2026, our third-party information technology and security vendors alerted us to a business email compromise involving one of our employees. While our vendors were able to quickly identify the incident, reset the impacted employee's credentials, and take other remedial actions, we have been, and expect to continue to be, the target of unsuccessful and successful phishing attacks and related business email compromise. While our vendors did not identify any material loss from the February 2026 incident, we rely significantly on these third parties to identify, investigate, eradicate, and remediate security incidents, and we cannot guarantee that future occurrences will be addressed similarly. A security incident or other interruption could disrupt our ability (and that of third parties with whom we work) to operate our business.

We may expend significant resources or modify our business 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 information.

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/or oversight; restrictions on processing sensitive information (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 negatively impact our ability to grow and operate our business.

Our customer 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. Additionally, our vendor contracts, including those with vendors responsible for our information technology or security functions, may contain limitations of liability that may not cover our liabilities, damages or claims against those third parties.

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 information about us from public sources, data brokers or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position.

The adoption and deployment of AI and machine learning technologies in our operations, and in particular our R&D efforts, may not be effective and may expose us to risk.

We use AI and machine learning (collectively, AI Technologies) in our business.

As with many technological innovations, there are significant risks involved in developing, maintaining and deploying these technologies and there can be no assurance that the usage of or any future investments in such technologies will always enhance our products or services or be beneficial to our business, including our efficiency or profitability, if at all.

The development and use of AI Technologies also present various privacy and security risks that may impact our business. For example, AI Technologies are subject to rapidly evolving privacy and data security laws, as well as increasing regulation and scrutiny. Several jurisdictions around the globe, including the European Union (EU) and certain U.S. states, have proposed, enacted, or are considering laws governing the development and use of AI Technologies, such as the EU's AI Act and the Colorado Artificial Intelligence Act. For example, the EU AI Act sets out a risk-based framework, subjecting certain AI Technologies to numerous compliance obligations, including transparency, conformity and risk assessment, monitoring and human oversight requirements. Under the EU AI Act, non-compliant companies may be subject to administrative fines of up to 35 million Euros or 7% of a company's total worldwide annual turnover for the preceding financial year, whichever is the higher.

Certain of our activities subject us to the EU AI Act and depending on how the EU AI Act is implemented and interpreted, we may have to adapt our business practices, contractual arrangements, and services to comply with such obligations. We expect other jurisdictions will adopt similar laws.

Additionally, existing laws and regulations may be interpreted in ways that could affect the operation of our AI Technologies, or could be rescinded or amended as new administrations take differing approaches to evolving AI Technologies. For example, countries and states are applying their data and consumer protection laws to AI Technologies, and particularly generative AI Technologies and interactive chatbots. Certain privacy laws extend rights to consumers (such as the right to delete certain personal data) and regulate automated decision making, which may be incompatible with our use of AI Technologies. These obligations may make it harder for us to conduct our business using AI Technologies, lead to regulatory fines or penalties, require us to change our business practices, retrain our AI Technologies, or prevent or limit our use of AI Technologies. For example, the Federal Trade Commission has required other companies to turn over (or disgorge) valuable insights or trainings generated through the use of AI Technologies where they allege the company has violated privacy and consumer protection laws. If we cannot use AI Technologies or that use is restricted, our business may be less efficient, or we may be at a competitive disadvantage.

As a result, implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet completely determine the impact future laws, regulations, standards or market perception of their requirements may have on our business and may not always be able to anticipate how to respond to these laws or regulations. Any actual or perceived failure to comply with such laws and regulations could adversely affect our business, financial condition and results of operations.

Further, any sensitive information (including confidential, competitive, proprietary or personal data) that we input into a third-party generative AI Technology could be leaked or disclosed to others, including if sensitive information is used to train the third parties' AI Technology.

Moreover, AI Technologies models may create flawed, incomplete or inaccurate outputs, some of which may appear correct. This may happen if the inputs that the model relied on were inaccurate, incomplete or flawed (including if a bad actor "poisons" the AI Technology with bad inputs or logic), or if the logic of the AI Technology is flawed (a so-called "hallucination"), all or any of which could cause the performance of our business, as well as our reputation, to suffer or incur liability under contractual breach allegations or civil claims. We use AI Technologies' outputs in the ordinary course of business and may use such outputs to make certain decisions. Due to these potential inaccuracies or flaws, the outputs could be biased and could lead us to make decisions that could bias certain individuals (or classes of individuals) and adversely impact their rights or employment.

Our business could be adversely affected by the effects of health pandemics or epidemics, which could cause significant disruptions in our operations and those of our current or future third-party manufacturers, CROs, and other third parties upon whom we rely.

Health pandemics or epidemics have in the past and could again in the future result in quarantines, stay-at-home orders, remote work policies or other similar events that may disrupt businesses, delay our research and development programs and timelines, negatively impact productivity and increase risks associated with cybersecurity, the future magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations. More specifically, these types of events may negatively impact personnel at third-party manufacturing facilities or the availability or cost of materials, which could disrupt our supply chain. Moreover, our clinical trials may be negatively affected. Clinical site initiation and patient enrollment may be delayed due to prioritization of hospital resources. Some patients may not be able or willing to comply with trial protocols if quarantines impede patient movement or interrupt healthcare services. Our ability to recruit and retain patients, principal investigators and site staff (who as healthcare providers may have heightened exposure) may be hindered, which would adversely affect our trial operations. Disruptions or restrictions on our ability to travel to monitor data from our trials, or to conduct trials, or the ability of patients enrolled in our trials or staff at trial sites to travel, as well as temporary closures of our trial partners and third-party manufacturers' facilities, would negatively impact our trial activities. In addition, we rely on independent clinical investigators, CROs and other third-party service providers to assist us in managing, monitoring and otherwise carrying out certain of our preclinical studies and clinical trials, including the collection of data from our trials, and the effects of health pandemics or epidemics may affect their ability to devote sufficient time and resources to our programs or to travel to sites to perform work for us. Similarly, our trials could be delayed and/or disrupted. As a result, the expected timeline for data readouts, including incompleteness in data collection and analysis and other related activities, and certain regulatory filings may be negatively impacted, which would adversely affect our ability to obtain regulatory approval for and to commercialize our product candidates, if approved, increase our operating expenses, and adversely affect our business, financial condition, results of operations and prospects. In addition, impact on the operations of the FDA or comparable foreign regulatory authorities could negatively affect our planned trials and approval processes. Finally, economic conditions and business activity may be negatively impacted and may not recover as quickly as anticipated.

Our business could be affected by litigation, government investigations and enforcement actions.

We currently operate in a number of jurisdictions in a highly regulated industry and we could be subject to litigation, government investigation and enforcement actions on a variety of matters in the United States or foreign jurisdictions, including, without limitation, intellectual property, regulatory, product liability, environmental, whistleblower, false claims, privacy, anti-kickback, anti-bribery, securities, commercial, contract, employment and other claims and legal proceedings that may arise from conducting our business. Any determination that our operations or activities are not in compliance with existing laws or regulations could result in the imposition of fines, civil and criminal penalties, equitable remedies, including disgorgement, injunctive relief and/or other sanctions against us, and remediation of any such findings could have an adverse effect on our business operations.

Legal proceedings, government investigations and enforcement actions can be expensive and time-consuming. An adverse outcome resulting from any legal proceedings, investigations or enforcement actions could result in significant damages awards, fines, penalties, exclusion from the federal healthcare programs, healthcare debarment, injunctive relief, product recalls, reputational damage and modifications of our business practices, which could have a material adverse effect on our business, financial condition, results of operations and prospects. Even if such a proceeding, investigation or enforcement action is ultimately decided in our favor, the investigation and defense thereof could require substantial financial and management resources.

Our future growth may depend, in part, on our ability to operate 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, for which we may rely on collaboration with third parties. We are not permitted to market or promote our product candidates before we receive regulatory approval from the applicable regulatory authority in that foreign market and may never receive such regulatory approval for our product candidates. To obtain separate regulatory approval in many other countries, we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our product candidates, and we cannot predict success in these jurisdictions. If we fail to comply with the regulatory requirements in international markets and receive applicable regulatory approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business will be adversely affected. We may not obtain foreign regulatory approvals on a timely basis, if at all. Our failure to obtain approval of our product candidates by regulatory authorities in another country may significantly diminish the commercial prospects of that product candidate and our business, financial condition, results of operations and prospects could be adversely affected. Moreover, even if we obtain approval of our product candidates and ultimately commercialize our product candidates in foreign markets, we would be subject to the risks and uncertainties, including the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements, and reduced protection of intellectual property rights in some foreign countries.

We identified a material weakness in our internal control over financial reporting. If we fail to remediate this material weakness, or if we identify additional material weaknesses in the future or otherwise fail to maintain effective 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.

In connection with the preparation of our financial statements for the years ended December 31, 2024 and 2025, we identified a material weakness in our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements would not be prevented or detected on a timely basis.

We did not design and maintain effective controls related to the period-end financial reporting process to ensure adequate segregation of duties, including controls related to account reconciliations and journal entries. Specifically, certain personnel have incompatible duties including the ability to (i) create and post manual journal entries without an independent review and (ii) prepare and review account reconciliations. The material weakness did not result in a misstatement to our financial statements. However, this material weakness could result in a misstatement of substantially all of our accounts or disclosures that would result in a material misstatement of our annual or interim financial statements that would not be prevented or detected.

To remediate the material weakness, we have designed and started to implement control activities in response to the risks posed as a result of the lack of segregation of duties in the period-end financial reporting process, including control activities related to journal entries and account reconciliations, and control activities related to journal entries in the information systems.

The material weakness will not be considered remediated until management completes the design and implementation of the measures described above and the controls operate for a sufficient period of time and management has concluded, through testing, that these controls are effective. The measures we have taken to date, and are continuing to design and implement, may not be sufficient to remediate the material weakness we have identified or avoid potential future material weaknesses. If the steps we take do not correct this material weakness in a timely manner, we will be unable to conclude that we maintain effective internal control over financial reporting. Accordingly, there could continue to be a reasonable possibility that a material misstatement of our financial statements would not be prevented or detected on a timely basis.

If we fail to remediate the existing material weakness or identify new material weaknesses in our internal control over financial reporting, if we are unable to comply with the disclosure and attestation requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, 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 the market price of our common stock could be negatively affected. As a result, we could also become subject to investigations by Nasdaq, the SEC or other regulatory authorities, and become subject to litigation from investors and stockholders, which could harm our reputation and financial condition or divert financial and management resources from our regular business activities.

Risks Related to Intellectual Property

If we are unable to obtain, maintain and protect sufficient patent and other intellectual property rights for our product candidates and technology, or if the scope of patent and other intellectual property rights obtained is not sufficiently broad, we may not be able to compete effectively in our market.

We rely, and may in the future rely, upon a combination of patents, know-how, trademark, trade secrets and confidentiality agreements to protect the intellectual property related to our technologies and product candidates and to prevent third parties from eroding our competitive position in our market. We also rely on protection afforded by in-licensed intellectual property rights and proprietary technology of third parties. These legal measures afford only limited protection, and competitors or others may gain access to or use our intellectual property and proprietary information.

Our success depends in significant part on our ability and the ability of our licensors, or future licensors, licensees or collaborators to obtain, maintain, enforce and defend patents and other intellectual property rights with respect to the lead development candidate, or any other product candidates we may develop and to operate our business without infringing, misappropriating or otherwise violating the intellectual property rights of others.

Our patent applications may not issue or may issue with limited scope, and issued patents can be challenged or circumvented, reducing our ability to prevent competitors from developing similar therapies. Oppositions, post-grant reviews, inter partes reviews, or litigation can narrow, invalidate, or render patents unenforceable, increasing costs and impacting collaborations and financing.

Prosecution, maintenance, or enforcement errors, or lack of alignment with licensors, may compromise protection or priority.

We can provide no assurance that any of these current patent applications or future patent applications will result in issued patents or that any issued patents will provide us with any competitive advantage. Failure to obtain issued patents could have a material adverse effect on our ability to develop and commercialize our lead development candidate or any other product candidates we may develop.

Furthermore, other parties may successfully challenge, invalidate or circumvent our issued patents so that our patent rights do not create an effective competitive barrier or revenue source.

A U.S. provisional patent application is not eligible to become an issued patent until, among other things, we file a nonprovisional patent application within 12 months of filing of the provisional patent application. With regard to such U.S. provisional patent applications, if we do not timely file any nonprovisional patent applications, we may lose our priority dates with respect to our provisional patent applications and any patent protection on the inventions disclosed in our provisional patent applications. While we intend to timely file nonprovisional patent applications relating to our provisional patent applications, we cannot predict whether any such patent applications will result in the issuance of patents that provide us with any competitive advantage. If our licensors are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised.

If there are material defects in the form, preparation, prosecution, or enforcement of our or our licensors' patents or patent applications, such patents may be invalid and unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad.

Our owned and in-licensed patent applications may be subject to third-party pre-issuance submissions of prior art to the U.S. Patent and Trademark Office (USPTO), and our owned or in-licensed patents may be subject to opposition, derivation, revocation, re-examination, *inter partes* review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others, or other proceedings in the USPTO or applicable foreign offices that challenge priority of invention or other features of patentability.

An adverse determination in any such submission, proceeding or litigation could result in loss of exclusivity or freedom to operate, patent claims being narrowed, invalidated or held unenforceable, in whole or in part, limit the scope or duration of the patent protection of our lead development candidate or any other product candidates, all of which could limit our ability to stop others from using or commercializing similar or identical product candidates or technology to compete directly with us, without payment to us, or result in our inability to manufacture or commercialize product candidates or approved products (if any) without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize our lead development candidate or any other product candidates, or could have a material adverse effect on our ability to raise funds necessary to continue our research programs or clinical trials. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us.

We cannot be certain that the USPTO and courts in the United States or the patent offices and courts in foreign countries will consider the claims in our current or future patents and applications covering our lead development candidate and any other product candidates as patentable. In addition, we cannot be certain that the claims of such patents and patent applications, if granted, will be sufficiently broad to effectively prevent competitors from working around our claimed inventions by developing alternative products and thereby competing with us without infringing our patent rights.

Method-of-use patents protect the use of a product for the specified method or indication. In the absence of separate composition of matter protection, 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 competitor products off-label. Although off-label prescriptions may infringe or contribute to the infringement of method-of-use patents, the practice is common and such infringement is difficult to prevent, including through legal action.

If we cannot obtain or lose patent protection for our product candidates, it could have a material adverse impact on our business. Additionally, as a licensee, we rely on third parties to file and prosecute patent applications and maintain patents and otherwise protect the licensed intellectual property under some of our current or future license agreements. For example, under the license agreement with Lieber Institute, Lieber Institute is responsible for prosecuting and maintaining intellectual property protection in consultation with us. We have not had and do not have primary control over these activities for certain of our in-licensed patents or patent applications and other intellectual property rights. For example, we cannot be certain that such activities by Lieber Institute or other licensors will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights.

We have limited control over the manner in which Lieber Institute or our other licensors may initiate an infringement proceeding against a third-party infringer of such intellectual property rights, or defend certain intellectual property that may be licensed to us. It is possible that Lieber Institute or our other licensors' infringement proceeding or defense activities may be less vigorous than if we conduct them ourselves. We cannot be certain that such activities by third parties have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights.

If our licensor or any of our future licensors or future collaborators fail to appropriately prosecute and maintain patent protection for patents covering our product candidates, our ability to develop and commercialize our 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 prosecution of patent applications we have acquired or licensed from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensors and their counsel that took place prior to our assuming control over patent prosecution. The patent prosecution process is expensive and time-consuming. We and our licensors, and any future licensors, licensees or collaborators, may not be able to prepare, file, prosecute, maintain, enforce or license all necessary or desirable patent applications or maintain and enforce patents that may issue based on such patent applications at a reasonable cost or in a timely manner.

It is also possible that we or our licensor or any of our future licensors or future collaborators will fail to identify patentable aspects of our research and development output in time to obtain patent protection or fail to file patent applications covering inventions made in the course of development and commercialization activities before a competitor or another third party files a patent application covering, or publishes information disclosing, a similar, independently-developed invention. Such competitor's or other third party's patent application may pose obstacles to our ability to obtain patent protection or limit the scope of the patent protection we may obtain.

Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, collaborators, CROs, CDMOs, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after the initial filing date, or in some cases not at all. Therefore, we cannot be certain that we or our licensor or any of our future licensors were the first to make the inventions claimed in our owned or any future licensed patents or pending patent applications, or were the first to file for patent protection of such inventions. If a third party can establish that we or our current or future licensors were not the first to make or the first to file for patent protection of such inventions, such patent applications may not issue as patents and even if issued, may be challenged and invalidated or rendered unenforceable. As a result, the issuance, inventorship, scope, validity, enforceability and commercial value of our patent rights are highly uncertain.

In addition, our technology acquired or licensed from various third parties, including our licensor, may be subject to retained rights. Our licensor often retains certain rights under their agreement with us, including the right to use the underlying technology for use in fields other than the fields licensed to us or for use in 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 licensor limits their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to its licensed technology in the event of misuse by the licensor.

The patent position of biotechnology and pharmaceutical companies generally is uncertain, involves complex legal and factual questions and is the subject of much litigation, resulting in court decisions, including U.S. Supreme Court decisions, which have increased uncertainties as to the ability to enforce patent rights in the future. As a result, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors' patent rights are uncertain.

Our and our licensor's pending and future patent applications may not result in patents being issued that protect our technology or product candidates, in whole or in part, or which effectively exclude others from commercializing competitive technologies and product candidates. The patent examination process may require us or our current or future licensors to narrow the scope of the claims of our pending and future patent applications, and therefore, even if such patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage.

Our and our licensor's patent applications cannot be enforced against third parties practicing the technology claimed in pending applications unless and until a patent issues from such applications, and then only to the extent the issued claims cover such technology. Any patents that we hold or in-license, or may in-license in the future, may be challenged, narrowed, circumvented or invalidated by third parties. Consequently, we do not know whether our lead development candidate or any other product candidates will be protectable or remain protected by valid and enforceable patents.

Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. Any of the foregoing could impair our competitive position and harm our business.

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. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. In addition, we may not develop additional proprietary technologies that are patentable. Any failure to obtain or maintain patent protection with respect to our product candidates or their uses could impair our competitive position and harm our business.

We rely on certain in-licensed patents and other intellectual property rights in connection with our development of our product candidates and may be required to acquire or license additional patents or other intellectual property rights to continue to develop and commercialize our product candidates.

We rely, in part, on patents, know-how and other intellectual property licensed from others, including the Lieber Institute for Brain Development (Lieber Institute). We are party to a license agreement with Lieber Institute pursuant to which we are granted rights to intellectual property that are important to our product candidates.

Additionally, we may need to acquire or license intellectual property rights from additional third parties in the future in order to continue to develop or commercialize our product candidates. Our existing license agreement imposes, and we expect that any future license agreements pursuant to which we in-license intellectual property may impose, on us various development, regulatory or commercial diligence obligations, payment of milestones and royalties, and other obligations.

If we or our current and future licensors are unable to obtain, maintain, defend or enforce sufficient patent and other intellectual property rights, or if those rights are limited in scope, we may not be able to compete effectively or to develop, manufacture, or commercialize our product candidates.

Licenses and collaborations may include diligence, milestone, royalty, field-of-use, or territorial restrictions; failure to comply can lead to termination and loss of rights. Complex license terms and disputes (scope, sublicensing, ownership, payments) can impact our freedom to operate, timelines, and costs.

If we fail to comply with any of the obligations under any such license agreement, including payment terms and diligence terms, or we are subject to bankruptcy-related proceedings, the licensor may have the right to terminate such agreement, in which case we may lose important intellectual property rights and we may not be able to develop, manufacture, market or sell our product candidates covered by the license or may face other penalties under such agreement or be subject to litigation for breach of such agreement. In addition, such a termination could result in the licensor reacquiring the intellectual property rights and subsequently enabling a competitor to access the technology. Any such occurrence could materially adversely affect the value of any of our product candidates. Termination of license agreements or reduction or elimination of our rights under them may result in us having to negotiate a new or reinstated agreement, which may not be available on equally favorable or commercially reasonable terms, if at all, which may mean we are unable to develop or commercialize our product candidates.

Licenses to additional third-party proprietary technology or intellectual property rights that may be required for our technology and our product candidates may not be available in the future or may not be available on commercially reasonable terms. In that event, we may be required to expend significant time and resources to redesign our technology or the methods for manufacturing or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis.

Further, the agreement under which we currently license, and any agreements under which we may license in the future, intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. Accordingly, material disputes may arise between us and our licensors, regarding intellectual property subject to such license agreement, including those relating to:

- the scope of rights, if any, granted under the license agreement and other interpretation-related issues;
- the scope and practice of any rights reserved by our licensors;
- whether a licensor had the right to grant the license agreement;
- whether and the extent to which our product candidates, technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- whether third parties are entitled to compensation or equitable relief, such as an injunction, for our use of the intellectual property without their authorization;
- its right to sublicense patent and other rights to third parties under license arrangements or collaborative development relationships;
- whether we are complying with our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates;
- our involvement in the prosecution of the licensed patents and our licensors' overall patent enforcement strategy;
- the allocation of ownership of inventions and know-how resulting from the creation or use of intellectual property by our licensors and by us and our partners, including jointly developed intellectual property; and
- the amounts of royalties, milestones or other payments due under the license agreement.

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, increase what we believe to be our financial or other obligations under the relevant agreement, or decrease the financial or other benefits it might otherwise receive under the relevant agreement. If material disputes over intellectual property that we have licensed prevent or impair our ability to maintain licensing arrangements on commercially acceptable terms or are insufficient to provide us the necessary rights to use the licensed intellectual property, we may be unable to successfully develop and commercialize our product candidates.

Furthermore, despite our efforts, our current or future licensors might conclude that we have materially breached our obligations under such license agreements and might therefore terminate the license agreements, thereby removing or limiting our ability to develop and commercialize products and technology covered by these license agreements. Any material disputes with licensors or any termination of the licenses on which we depend would have a material adverse effect on our business, results of operations, financial condition and prospects.

We may not have the right to control the preparation, filing, prosecution and enforcement of patent applications, or to maintain the patents, covering our product candidates that we license from third parties. In addition, our future licensors may require us to obtain consent from the licensor before we can enforce patent rights, and our licensor may withhold such consent or may not provide it on a timely basis. Therefore, we cannot be certain that our licensors or collaborators will prosecute, maintain, enforce and defend such intellectual property rights in a manner consistent with the best interests of our business, including by taking reasonable measures to protect the confidentiality of know-how and trade secrets, or by paying all applicable prosecution and maintenance fees related to intellectual property registrations for any of our product candidates. We also cannot be certain that our licensors have drafted or prosecuted the patents and patent applications licensed to us in compliance with applicable laws and regulations, which may affect the validity and enforceability of such patents or any patents that may issue from such applications. This could cause us to lose rights in any applicable intellectual property that we in-license, and as a result our ability to develop and commercialize product candidates may be adversely affected and we may be unable to prevent competitors from making, using and selling competing products.

The patent protection we obtain for our product candidates and technologies may be challenged in court or before administrative bodies in the United States or abroad and rendered invalid or unenforceable.

Patent challenges, including oppositions, post-grant reviews, inter partes reviews, derivations, and litigation, can narrow, invalidate, or render our patents unenforceable, reducing exclusivity and enabling competitors to commercialize similar technologies. Adverse outcomes may limit our ability to prevent competition, shorten patent duration, or require costly and time-consuming legal proceedings.

Even if our owned, co-owned, or in-licensed patent applications issue as patents, the issuance of any such patents is not conclusive as to their inventorship, scope, validity or enforceability, and such patents or patents we license from third parties, may be challenged, invalidated, narrowed or held to be unenforceable, including in the courts or patent offices in the United States or foreign jurisdictions, or circumvented.

We or our licensor may be subject to a third-party pre-issuance submission of prior art to the USPTO or equivalent foreign bodies, or become involved in opposition, derivation, revocation, re-examination, post-grant and inter partes review or interference proceedings challenging our or our licensors' patent rights or the patent rights of others.

An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our or our licensors' patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we may have to participate in interference or derivation proceedings declared by the USPTO to determine priority or ownership of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge priority of invention or other features of patentability. Such proceedings and any other patent challenges may result in loss of patent rights, loss of exclusivity, loss of priority or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products or limit the duration of the patent protection of our technology and product candidates. Such proceedings also may result in substantial costs and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Moreover, there could be public announcements of the results of hearings, motions or other developments related to any of the foregoing proceedings. If securities analysts or investors perceive those results to be negative, it could cause the price of shares of our common stock to decline. Any of the foregoing could harm our business.

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.

Our reliance on third parties for development, manufacturing, and other services requires us to share trade secrets and confidential information, increasing the risk of misappropriation, inadvertent disclosure, or incorporation into others' technology. While we use confidentiality and related agreements, these may not provide adequate protection or remedies, and monitoring compliance is challenging. If competitors lawfully obtain or independently develop our trade secrets, or if unauthorized disclosure occurs, our competitive position could be impaired.

We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees 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, such as trade secrets. Despite these contractual agreements with third parties, sharing trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are intentionally or 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 and despite our efforts to protect our trade secrets, a competitor's discovery of our trade secrets and confidential information or other unauthorized use or disclosure would impair our competitive position and may harm our business.

We may become involved in lawsuits to protect or enforce our patents, the patents of our licensors or other intellectual property, which could be expensive, time-consuming and unsuccessful, and issued patents covering our technology and product candidates could be found invalid or unenforceable if challenged.

Intellectual property litigation can be costly and time-consuming; adverse outcomes (invalidity, unenforceability, narrow claim construction) can limit our ability to prevent competition and harm our business. Litigation may also result in disclosure of confidential information and distract management, and enforcement can be especially challenging in some jurisdictions.

Competitors and other third parties may infringe, misappropriate or otherwise violate our owned, co-owned and licensed patents, trademark or other intellectual property. In addition, our owned, co-owned and licensed patents may become involved in inventorship or priority disputes. Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent is issued from such applications. To counter infringement, misappropriation or other unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents or that our patents are invalid or unenforceable or both.

In a patent infringement proceeding, a court may decide that an owned, co-owned or licensed patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our owned, co-owned and licensed patents do not cover the technology, or decide that the other party's use of our technology at issue falls under the safe harbor to patent infringement under 35 U.S.C. §271(e). An adverse result in any litigation or proceeding could put one or more of our owned, co-owned or licensed patents at risk of being invalidated, held unenforceable or interpreted narrowly. We may find it impractical or undesirable to enforce our intellectual property against some third parties.

In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement, insufficient written description or failure to claim patent eligible subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution.

Third parties may also raise similar claims before the USPTO or an equivalent foreign body, even outside the context of litigation. Potential proceedings include re-examination, post-grant review, inter partes review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of, or amendment to our patents in such a way that they no longer cover our technology or any product candidates that we may develop.

The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art of which we, our current or future licensors and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on the applicable product candidates or technology covered by the patent rendered invalid or unenforceable. Such a loss of patent protection would harm our business.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the ownership or priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Such licenses may not be available on commercially reasonable terms, or at all, or may be non-exclusive, allowing our competitors to gain access to the same technology.

If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture and commercialization of one or more of the product candidates we may develop. In addition, if we, our existing licensors or any future licensors are unsuccessful in any inventorship disputes to which we or they are subject, we may lose valuable intellectual property rights, such as exclusive ownership of, or the exclusive right to use, our owned, in-licensed or any future in-licensed patents. The loss of exclusivity or the narrowing of such patent claims could limit our ability to stop others from using or commercializing similar or identical technology and products. Any of the foregoing could harm our business. Even if we are successful in any of the foregoing disputes, it could result in substantial costs and be a distraction to management and other employees. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or proceeding.

Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately.

Most of our competitors are larger than we are and have substantially greater resources. They are, therefore, likely to 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. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing, misappropriating or otherwise violating our intellectual property. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims could result in substantial costs and diversion of management resources, which could harm our business. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to initiate anticipated clinical trials, continue our internal research programs or in-license needed technology or other product candidates. There could also be public announcements of the results of the hearing, motions or other interim proceedings or developments. If securities analysts or investors perceive those results to be negative, it could cause the price of shares of our common stock to decline. Any of the foregoing events could harm our business.

We may not be able to protect our intellectual property rights throughout the world.

Legal protections for proprietary intellectual property vary in jurisdictions throughout the world.

The enforcement of intellectual property rights can be difficult and costly, and some jurisdictions provide weaker protection than the United States.

Competitors may use our technology in countries where we lack protection or where enforcement is limited and may export infringing products into protected markets. Efforts to enforce rights abroad can be expensive, time-consuming, and may not yield meaningful remedies, limiting our ability to secure a commercial advantage. Filing, prosecuting, maintaining, defending and enforcing patents and other intellectual property rights on our lead development candidate or any other product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States.

Prosecution of foreign patent applications is often a longer process, and patents may grant at a later date, and with a shorter term, than in the United States and the requirements for patentability differ in certain jurisdictions and countries. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States.

Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions.

Competitors may use our technologies in jurisdictions where we have not obtained patent protection or other intellectual property rights to develop their own products and may export otherwise infringing, misappropriating or violating products to territories where we have patent or other intellectual property protection, but enforcement rights are not as strong as those in the United States. These products may compete with our lead development candidate or any other product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Furthermore, some jurisdictions, such as Europe, Japan and China, may have a heightened standard for patentability than the United States, including, for example, the requirement of claims having literal support in the original patent filing and the limitation on using supporting data that is not in the original patent filing. Under those heightened patentability requirements, we may not be able to obtain sufficient patent protection in certain jurisdictions even though the same or similar patent protection can be secured in the United States and other jurisdictions.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of some countries do not favor the enforcement of patents and other intellectual property rights, which could make it difficult for us to stop the infringement, misappropriation or other violation of our intellectual property rights generally.

Proceedings to enforce our intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful.

Many countries have compulsory licensing laws under which a patent owner may be compelled under specified circumstances to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In those countries, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of those patents. 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, which could harm our business.

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

As the pharmaceutical industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. There can be no assurance that our operations do not, or will not in the future, infringe, misappropriate, or otherwise violate existing or future third-party patents or other intellectual property rights. Identification of third-party patent rights that may be relevant to our operations is difficult due to differences in terminology among patents, incomplete databases, and the difficulty in assessing the meaning of patent claims. We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending patent application in the United States and abroad that is relevant to or necessary for the commercialization of our lead development candidate or any other product candidates in any jurisdiction. For example, freedom-to-operate analyses may miss relevant third-party rights or misinterpret scope or expiration, leading to infringement risk, redesigns, licensing costs, or delays. If we fail to identify or correctly interpret relevant patents, we may face costly litigation, delays, or be forced to obtain licenses on unfavorable terms, which could adversely affect the development and commercialization of our product candidates.

Patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Certain U.S. applications that will not be filed outside the United States can remain confidential until patents issue. Therefore, patent applications covering our lead development candidate or any other product candidates could have been filed by third parties without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our lead development candidate or any other product candidates or their use.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a 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. For example, we may incorrectly determine that our product candidates 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 ability to identify all relevant third-party patents is limited by the imperfection of patent searches and the evolving nature of the patent landscape. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect.

Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market such product candidates. If we fail to identify and correctly interpret relevant patents or if we are unable to obtain licenses to relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, which may be significant, we may be temporarily or permanently prohibited from commercializing any of our product candidates that are held to be infringing.

We might, if possible, also be forced to redesign product candidates so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business and could harm our business.

If we fail to comply with our obligations in the agreement under which we license intellectual property rights from our licensor, otherwise experience disruption to our business relationships with our licensor, or we are unable to obtain licenses from other third parties on commercially reasonable terms or fail to comply with our obligations under such agreements, we could lose license rights that are important to our business and our business could be harmed.

We are a party to a license agreement with Lieber Institute under which we are granted rights to intellectual property that are important to our business, and we may enter into additional license agreements in the future for our lead development candidate or any other product candidates.

Our existing license agreement imposes on us, and we expect that any future license agreements where we in-license intellectual property will impose on us, various development, regulatory and commercial diligence obligations, payment of milestones and royalties and other obligations and require us to meet development and/or regulatory timelines in order to maintain the licenses. If we fail to comply with our obligations under these agreements, or we are subject to bankruptcy-related proceedings, our licensors may have the right to terminate our licenses, or we may be subject to litigation for breach of these agreements, in which case, we would not be able to market products covered by the licenses. Additionally, non-compliance with license terms (e.g., payment, diligence, reporting, or other obligations) can lead to termination or repurchase of assets, loss of rights or restrictions that delay development and commercialization of our product candidates.

Loss of licensed rights may require renegotiation on less favorable terms, if at all, or may enable competitors to access the technology, materially harming our business. We may need to obtain additional licenses from third parties to advance our research, develop or commercialize our lead development candidate or any other product candidates, and we cannot provide any assurances that third-party patents do not exist that might be enforced against our lead development candidate or such other product candidates in the absence of such a license. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several 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 may fail to obtain any of these licenses on commercially 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 develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize our lead development candidate or any other product candidates, which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation. Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. Disputes may arise between us and our licensors regarding intellectual property subject to a license agreement, including:

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

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may not be able to successfully develop and commercialize our product candidates, which would have a material adverse effect on our business.

Moreover, some of our patents and patent applications in the future may be co-owned with third parties. If we are unable to obtain an exclusive license to any such co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, who could market competing products and technology. In addition, we may need the cooperation of any such co-owners to enforce such patents against third parties, and such cooperation may not be provided to us.

Patent terms may be inadequate to protect our competitive position on our lead development candidate or any other product candidates for an adequate amount of time.

Patents have a limited lifespan. Even with possible extensions, patent protection may expire before or shortly after commercialization, enabling earlier competition and potentially reducing the amount of revenue we are able to generate from sale of any of our product candidates that receive approval. If we do not have sufficient patent life to protect our product candidates, our business and competitive position may be adversely affected. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. nonprovisional or international patent application filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our lead development candidate or any other product candidates are obtained, once the patent life has expired for a product candidate, we may be open to competition from competitive products, including generics.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned, co-owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours.

Depending upon the timing, duration and conditions of any FDA regulatory approval of lead development candidate, or any other product candidates, one or more of our U.S. owned, co-owned or licensed patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, and one or more of our foreign owned, co-owned or licensed patents may be eligible for patent term extension under similar legislation, for example, in the EU. In the United States, the Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during the FDA regulatory review process. The length of the patent term extension is calculated based on the length of time it takes for regulatory review. Similar patent term restoration provisions to compensate for commercialization delay caused by regulatory review are also available in certain foreign jurisdictions, such as the EU Regulation (EC) No 469/2009 concerning the Supplementary Protection Certificate for medicinal products. However, there are no assurances that the FDA or any comparable foreign regulatory authority or national patent office will grant such extensions, in whole or in part. For example, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. In addition, to the extent we wish to pursue patent term extension based on a patent that we in-license from a third party, we would need the cooperation of that third party.

Moreover, the length of the extension could be less than we request. Only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from the date of product approval, and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. In addition, a patent term extension is available only for the first approved use of the drug, and thus, no extension is available if a product is approved for a subsequent use.

If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for the applicable product candidate will be shortened, and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced.

Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case, and our competitive position and business could be harmed.

Changes in patent law or their interpretations could diminish the value of our patents in general, thereby impairing our ability to protect our intellectual property for our lead development candidate, or any other product candidates.

Our success is heavily dependent on intellectual property, particularly patents. Obtaining, maintaining and enforcing patents in the pharmaceutical industry is inherently uncertain, due in part to ongoing changes in the patent laws. Legal and policy changes can alter patentability, validity standards, and challenge mechanisms, affecting our ability to obtain, maintain, and enforce intellectual property protections. Court decisions, legislative reforms, and evolving international standards may narrow patent scope, increase uncertainty, and raise costs for intellectual property prosecution, enforcement, and defense. Depending on decisions by Congress, the federal courts, and the USPTO and equivalent institutions in other jurisdictions, the laws and regulations governing patents, and interpretation thereof, could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce existing or future patents.

For example, 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.

Therefore, there is increased uncertainty with regard to our ability to obtain patents in the future, as well as uncertainty with respect to the value of patents once obtained.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued and licensed patents. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while most jurisdictions outside the United States, the first to file a patent application was entitled to the patent.

After March 2013, under the Leahy-Smith America Invents Act (Leahy-Smith Act) enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability 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. Consequently, if a third party files a patent application in the USPTO before we or our current or future licensors file an application covering the same invention, the third party could therefore be awarded a patent covering an invention of ours or of our licensors even if we or our licensors had made the invention before it was made by such third party. 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 current or future 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 owned or in-licensed patents or patent applications. Even if we have a valid and enforceable patent, we may not be able to exclude others from practicing the claimed invention if the other party can show that they used the invention in commerce before our filing date or if the other party benefits from a compulsory license.

The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, inter partes review and derivation proceedings. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, particularly the first inventor-to-file provisions. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business.

Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in 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 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 on June 1, 2023, which will significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, all European patents, including those issued prior to June 1, 2023, now by default automatically fall under the jurisdiction of a new European Unified Patent Court (the UPC) for litigation involving such patents. As the UPC is a relatively new court system, there is uncertainty regarding litigation at the UPC. Our European patent applications, if issued, could be challenged in the UPC. During the first seven years of the UPC's existence, the UPC legislation allows a patent owner to opt its European patents out of the jurisdiction of the UPC. We may decide to opt out our future European patents from the UPC, but doing so may preclude us from realizing the benefits of the UPC. Moreover, if we do not meet all of the formalities and requirements for opt-out under the UPC, our future European patents could remain under the jurisdiction of the UPC. The UPC will provide our competitors with a new forum to centrally revoke our European patents and allow for the possibility of a competitor to obtain a pan-European injunction. It is uncertain how the UPC will impact granted European patents in the pharmaceutical industry.

Additionally, recent reforms and changes at U.S. government agencies and those of non-U.S. jurisdictions could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications, and the maintenance, enforcement or defense of our issued patents. For example, the ability of the USPTO and other applicable patent authorities to properly administer their functions is highly dependent on the levels of funding available to the agency and their ability to retain key personnel and fill key leadership appointments, among various factors. Termination of employees or delays in replacing or hiring for key positions could significantly impact the ability of the USPTO and other applicable patent authorities to fulfill their functions and could greatly impact our ability to timely and adequately prosecute or maintain our patent applications, and our ability to timely and adequately maintain, enforce or defend our issued patents.

The Leahy-Smith Act and other similar changes in patent law and regulations in other countries or jurisdictions and their implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued or licensed patents, all of which could harm our business.

Obtaining and maintaining 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 if we fail to comply with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on any patents and patent applications are required to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of a patent. In certain circumstances, we may rely on our current and future licensors to pay these fees. The USPTO and various foreign patent agencies also require compliance with a number of procedural, documentary, fee payment and other similar requirements during the patent application and prosecution process. In addition, in some countries, including the United States, China, India and some European countries, a foreign filing license is required before certain patent applications are filed. The foreign filing license requirements vary by country and depend on various factors, including where the inventive activity occurred, citizenship status of the inventors, the residency of the inventors and the invention owner, the place of business for the invention owner and the nature of the subject matter to be disclosed (e.g., items related to national security or national defense). In some, but not all cases, for example in China and India, a foreign filing license cannot be obtained retroactively in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment of a pending patent application or can be grounds for revoking or invalidating an issued patent, resulting in the loss of patent rights in the relevant jurisdiction.

Administrative errors or missed deadlines (by us or licensors) can lead to abandonment or loss of rights. Failure to pay fees, respond to official actions, or submit required documents can result in loss of patent protection in relevant jurisdictions. If we or our licensors, or any future licensors or collaborators, fail to maintain the patents and patent applications covering our lead development candidate, or any other product candidates, our competitors might be able to enter the market with similar or identical products or technology, which would harm our business.

Third-party claims of intellectual property infringement, misappropriation, or other violations against us or our current or future licensors could be expensive and time consuming and may prevent or delay the development and commercialization of our development candidate, or any other product candidates.

Our commercial success depends, in part, upon our ability and the ability of any of our collaborators to develop, manufacture, market and sell our lead development candidate, or any other product candidates, and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and other proprietary rights of third parties.

There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our therapeutic programs and commercializing activities may give rise to claims of infringement of the patent rights of others. We may become party to, or be threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our lead development candidate, or any other product candidates and technology, including re-examination, interference, post-grant review, inter partes review or derivation proceedings before the USPTO or an equivalent foreign body.

Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we are developing our product candidates. In the event that any of these patents were asserted against us, we believe that we would have defenses against any such action, including that such patents are not valid or that we would be able to replace such technology with alternative, non-infringing technology.

However, if any such patents were to be asserted against us and our defenses to such assertion were unsuccessful and such alternative technology was not available or technologically or commercially practical, unless we obtain a license to such patents, we could be liable for damages, which could be significant and include treble damages and attorneys' fees if we are found to willfully infringe such patents, and we could be precluded from commercializing any product candidates that were ultimately held to infringe such patents. Any potential future legal proceedings relating to these patents could cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. If we are unsuccessful in our challenges to these patents and become subject to litigation or are unable to obtain a license on commercially reasonable terms with respect to these patents, it could harm our business.

Third parties may allege that we are infringing, misappropriating or otherwise violating their intellectual property rights. Defending such claims, with or without merit, is unpredictable and can be costly, time-consuming, and distracting. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysis or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of our common stock. If we are found to infringe, we may be required to obtain licenses (which may not be available on reasonable terms), pay damages, or cease development or commercialization of affected products.

We may also be required to indemnify collaborators or licensors, further increasing costs. Any of these outcomes could materially harm our business.

We may be subject to claims by third parties asserting that we, our employees, consultants or advisors have infringed upon, misappropriated or otherwise violated their intellectual property rights, or claiming ownership of what we regard as our own intellectual property.

Many of our employees, consultants, or advisors were previously employed at other biotechnology or pharmaceutical companies. 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.

Employee or consultant background intellectual property claims can lead to disputes, costs, delays, or loss of rights. We may face allegations that our personnel used or disclosed proprietary information from prior employers, or that we do not own inventions developed by our team. Litigation or disputes over intellectual property ownership can be costly, distract management, and may result in loss of rights or personnel. Litigation may be necessary to defend against these claims.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our technologies or product candidates. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs, delay development of our product candidates and be a distraction to management. Any of the foregoing events would harm our business.

In addition, we may in the future be subject to claims by former employees, consultants, or other third parties asserting an ownership right in our patents or patent applications. An adverse determination in any such submission or proceeding may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated, or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar technology and therapeutics, without payment to us, or could limit the duration of the patent protection covering our technologies and product candidates. Such challenges may also result in our inability to develop, manufacture, or commercialize our technologies and product candidates without infringing third-party patent rights. 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 technologies and product candidates. Any of the foregoing could adversely affect our business.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Intellectual property litigation can be expensive, time-consuming, and may divert management and technical personnel from core business activities. Even successful outcomes can result in significant costs and operational disruption. Public proceedings may also impact our reputation or stock price.

In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities.

We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources.

Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace, including compromising our ability to raise the funds necessary to initiate anticipated clinical trials, continue our research programs, license necessary technology from third parties or enter into development collaborations that would help us commercialize our lead development candidate, or any other product candidates, if approved. Any of the foregoing events would harm our business.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

We rely on trade secrets and know-how to protect proprietary technology, especially where patent protection is unavailable or inappropriate. Trade secrets can be difficult to protect, and confidentiality agreements and security measures may be breached, and remedies may be inadequate. If our trade secrets are disclosed, misappropriated, or independently developed by competitors, our competitive position could be harmed.

Trade secrets and know-how can be difficult to protect. We seek to protect these trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, licensors, collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. 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. 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. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. We cannot guarantee that any potential trade secrets and other proprietary and confidential information will not be disclosed or that competitors will not otherwise gain access to trade secrets. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be harmed.

As is common in the pharmaceutical and biotechnology industry, we engage the services of consultants to assist us in the development of our product candidates. Many of these consultants were previously employed at, or may have previously provided or may be currently providing consulting services to, other biopharmaceutical companies including our competitors or potential competitors.

We may become subject to claims that we or our consultants inadvertently or otherwise used or disclosed trade secrets or other information proprietary to our consultants' former employers or their former or current clients. 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, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team.

We may not be able to protect and enforce our trademarks and trade names or build name recognition in our markets of interest, and we may encounter delays and additional expense if our preferred names are not available, thereby harming our competitive position.

We intend to rely on both registered and common law rights for our trademarks. We plan to apply to register these trademarks with the USPTO and may in the future seek to register additional trademarks in the United States and other countries. However, we have not yet sought registration for any of our marks internationally, and we have not yet obtained regulatory or trademark approvals for any drug names. The process of obtaining such approvals can be lengthy and uncertain, and our preferred names may not be available or approvable in particular jurisdictions or for particular uses.

Trademark protection may be limited or unavailable in some jurisdictions, and third parties may oppose, cancel, or infringe our marks. Failure to secure or enforce trademarks can diminish brand value, create confusion, and harm our competitive position. 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.

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, does not infringe the existing rights of third parties, and is 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. Building name recognition in our markets of interest may be challenging, and litigation or administrative proceedings to protect trademarks can be costly and uncertain. Additionally, if we are unable to use our preferred drug names in certain jurisdictions, we may face significant delays and expense in rebranding or developing alternative names, which could adversely affect our commercialization efforts and market position.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. Even robust intellectual property may not prevent all competition; alternative technologies, off-label use, safe-harbor R&D, and missed filings can erode intellectual property exclusivity.

Competitors may independently develop similar or alternative technologies, design around our patents, or benefit from aspects of our inventions that are not patentable or not protected. Intellectual property rights may not cover all threats, and the patents of others may adversely affect our business.

For example:

- others may be able to make products that are similar to any product candidates we may develop or utilize similar technology but that are not covered by the claims of the patents that we own, co-own or license now or own, co-own or license in the future;
- we, or our current or future licensors, might not have been the first to make the inventions covered by the issued patent or pending patent application that we own, co-own or license now or own, co-own or license in the future;
- we, or our current or future licensors, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending owned, co-owned or licensed patent applications or those that we may own, co-own or license in the future will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in the United States under FDA-related safe harbor patent infringement exemptions or in countries where we or our current or future licensors do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- we may fail to identify potential patentable subject matter and may fail to file on it;
- the patents or other intellectual property rights of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent application covering such intellectual property or disclose information resulting in a loss of protection for such trade secrets.

Should any of these events occur, they could harm our business.

Risks Related to Our Reliance on Third Parties

We rely on third parties to conduct our preclinical studies and clinical trials. If these third parties that we rely on to execute our preclinical studies or clinical trials do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates.

We do not independently conduct our preclinical studies or clinical trials. We rely on medical institutions, contract laboratories and other third parties, such as CROs, to conduct or otherwise support our preclinical studies and clinical trials for our product candidates. We rely heavily on these parties for execution of our preclinical studies and clinical trials for our product candidates and control only certain aspects of their activities. There are a limited number of CROs with demonstrated expertise in acute and chronic pain clinical trial design and execution, and competition for these organizations' services is intense. We have recently transitioned, or are in the process of transitioning, our CRO relationship and may face disruptions associated with such transitions, including delays in site activation, protocol implementation, and data collection. Because acute pain trials are typically conducted over shorter durations, with enrollment windows measured in weeks rather than years, any delay in site selection, patient enrollment, or CRO performance can have a disproportionate impact on our study timelines. We cannot assure that our CRO partners will perform to our expectations or that the CRO transition will not adversely affect the conduct of our planned clinical trials.

Further, while we have and will have agreements governing the activities of our third-party contractors, we have limited influence over their actual performance. Nevertheless, we are responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the applicable protocol and legal and regulatory requirements and scientific standards, and our reliance on CROs and other third parties will not relieve us of our regulatory responsibilities. For any violations of laws and regulations during the conduct of our preclinical studies and clinical trials, we could be subject to untitled letters, warning letters or enforcement action that may include civil penalties up to and including criminal prosecution.

We and the third parties on which we rely for clinical trials are required to comply with regulations and requirements, including GLP and GCP for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial patients are adequately informed of the potential risks of participating in clinical trials and their rights are protected. These regulations are enforced by the FDA and comparable foreign regulatory authorities for any drugs in clinical development. The FDA and comparable foreign regulatory authorities enforce GCP requirements through periodic inspections of clinical trial sponsors, principal investigators and trial sites. If we or these third parties fail to comply with applicable GCP, 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 clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA or comparable foreign regulatory authorities will determine that any of our future clinical trials will comply with GCP. In addition, our clinical trials must be conducted with product candidates produced under cGMP regulations. Our failure or the failure of these third parties to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action. We also are required to register certain ongoing clinical trials and provide certain information, including information relating to the trial's protocol, on a government-sponsored database, *www.clinicaltrials.gov*, within specific timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Although we design our clinical trials for our product candidates, we will rely on third parties to conduct our clinical trials. As a result, many important aspects of our clinical development, including clinical trial conduct and timing, will be outside of our direct control. Our reliance on third parties to conduct future clinical trials will also result in less direct control over the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff.

Communicating with outside parties can also be challenging, potentially leading to mistakes, as well as difficulties in coordinating activities. Outside parties may:

- have staffing difficulties;
- fail to comply with contractual obligations;
- experience regulatory compliance issues;
- undergo changes in priorities or become financially distressed; or
- form relationships with other entities, some of which may be our competitors.

If third parties do not perform our clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, we would be unable to rely on clinical data collected by these third parties and may be required to repeat, extend the duration of or increase the size of any clinical trials we conduct, which could significantly delay commercialization and require significantly greater expenditures.

If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties on commercially reasonable terms, or at all. Our CROs have the right to terminate their agreements with us in the event of an uncured material breach and under other specified circumstances. If third parties 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 are compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any clinical trials such third parties are associated with 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, we believe that our financial results and the commercial prospects for our product candidates in the subject indication would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected the interpretation of the trial. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, refusal to accept or rejection of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of regulatory approval of our product candidates.

We may, from time to time, establish partnerships in relation to our clinical trials, receiving advisory services and other support from third parties. Although we believe that these partnerships will enable us to accelerate the development of our product candidates and clinical trials, we cannot guarantee that such collaborations will be successful and, in the event they are not, we may lose our competitive advantage and/or incur additional costs.

We rely on third-party manufacturers and suppliers to supply our product candidates. The loss of our third-party manufacturers or suppliers, or their failure to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, within acceptable timeframes, or at all, would materially and adversely affect our business.

We do not own or operate facilities for drug manufacturing, storage, distribution, or quality testing and have no current plans to develop our own clinical or commercial-scale manufacturing capabilities. We currently rely, and expect to continue to rely, on third-party contract developers and manufacturers to manufacture bulk drug substances, drug products, raw materials and other components for our product candidates, as well as for commercial manufacture if our product candidates receive regulatory approval. Any change in our relationships with our third-party manufacturers or changes to contractual terms of our agreements with them could adversely affect our business, financial condition, results of operations and prospects.

Reliance on third-party manufacturers may expose us to different risks than if we were to manufacture the product candidates ourselves. There can be no assurance that our clinical development product supplies will not be limited, interrupted, terminated or will be of satisfactory quality or be available at acceptable prices. In addition, any replacement of our manufacturer could require significant effort and time because there may be a limited number of qualified replacements. Further, we do not have any long-term commitments or supply agreements with our third-party manufacturers. We may be unable to establish any long-term supply agreements with third-party manufacturers or to do so on acceptable terms or at all, which increases the risk of failing to timely obtain sufficient quantities of our product candidates or such quantities at an acceptable cost.

Establishing additional or replacement suppliers for these supplies, and obtaining regulatory clearance or approvals that may result from adding or replacing suppliers, could take a substantial amount of time, result in increased costs and impair our ability to produce our products, which would adversely impact our business, financial condition, results of operations and prospects. Any such interruption or delay may force us to seek similar supplies from alternative sources, which may not be available at reasonable prices, or at all. Any interruption in the supply of limited source components for our product candidates would adversely affect our ability to meet scheduled timelines and budget for the development and commercialization of our product candidates, could result in higher expenses and would harm our business. Although we have not experienced any significant disruption as a result of our reliance on our suppliers, we have a limited operating history and cannot assure you that we will not experience disruptions in our supply chain in the future as a result of such reliance or otherwise.

The manufacturing process for our product candidates will be subject to the FDA's review and, in the future, may be subject to comparable foreign regulatory authority review. We, our suppliers and our manufacturers 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, and to ensure the quality and safety of our product candidates. Securing regulatory approval for our product candidates will also require the submission of detailed information about the product manufacturing process to, and inspection of manufacturing facilities by, the FDA and comparable foreign regulatory authorities. If our third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable foreign regulatory authorities, they will not be able to secure and/or maintain regulatory approval for the use of their manufacturing facilities to produce our product candidates.

Moreover, we do not conduct the manufacturing process ourselves and are completely dependent on our third-party manufacturers for manufacturing our product candidates in compliance with cGMP and other applicable 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 projected manufacturing capacity or supply of materials becomes limited, interrupted or more costly than anticipated, we may be forced to enter into an agreement with another third party, which we may not be able to do timely or on reasonable terms, if at all.

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 applicable quality standards and regulations and guidelines; and we may be required to repeat some of the development program with the new manufacturer. The delays and costs associated with the verification of a new manufacturer could negatively affect our ability to develop our product candidates in a timely manner or within budget, or obtain regulatory approval for or market our product candidates.

We expect to continue to rely on third-party manufacturers if we receive regulatory approval for any product candidate. To the extent that we have existing, or enter into future, manufacturing arrangements with third parties, 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 product candidates will be subject to periodic review and inspection by the FDA and comparable 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 our 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 comparable foreign regulatory authorities could adversely affect our business in a number of other ways, including:

- an inability to initiate or complete clinical trials of a product candidate in a timely manner;
- delay in submitting regulatory applications, or receiving regulatory approvals, for a product candidate;
- subjecting third-party manufacturing facilities to additional inspections by regulatory authorities;
- loss of the cooperation of existing or future collaborators;
- requirements to cease development 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 products.

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

Reliance on third-party manufacturers entails additional risks such as limitations on supply availability resulting from capacity and scheduling constraints of third parties; the possible breach of manufacturing agreements by third parties because of factors beyond our control; the possible termination or non-renewal of the manufacturing agreements by the third party, at a time that is costly or inconvenient to us; failure to manufacture our product according to our schedule or at all; and the possible misappropriation of our proprietary information, including our trade secrets and know-how.

Additionally, our third-party manufacturers may experience difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If any of our third-party manufacturers were to encounter any of these difficulties, our ability to provide our product candidates to participants in clinical trials, or to provide product for treatment of patients if approved, would be jeopardized. Any performance failure on the part of our existing or future manufacturers could delay clinical development or regulatory approval, and any related remedial measures may be costly or time-consuming to implement, which would have a material adverse impact on our financial position.

We may form or seek collaborations or strategic alliances, enter into licensing arrangements or other business transactions in the future, and we may not realize the benefits of such transactions.

We may enter into licensing arrangements and strategic transactions to acquire and advance new assets or product candidates in the future, including strategic partnerships, in-licensing of product candidates, strategic collaborations, joint ventures, restructurings, divestitures, acquisitions of companies, asset purchases, business combinations and investments.

Any future transactions that we enter into may not be successful. In particular, the success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators.

Collaborations are subject to numerous risks, which may include that:

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on trial or test results, changes in their strategic focus due to the acquisition of competitive products, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates;
- a collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our future product candidates or that results in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable future product candidates;
- collaborators may own or co-own intellectual property covering our product candidates that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

Additionally, we may have conflicts with our future collaborators, such as conflicts concerning the interpretation of preclinical or clinical data, the achievement of milestones, the interpretation of contractual obligations, payments for services, development obligations or the ownership of intellectual property developed during our collaboration. If any conflicts arise with any of our collaborators, such collaborator may act in a manner that is adverse to our best interests. Any such disagreement could result in one or more of the following, each of which could delay or prevent the development or commercialization of our product candidates, and in turn prevent us from generating revenue: disputes regarding milestone payments or royalties; uncertainty regarding ownership of intellectual property rights arising from our collaborative activities, which could prevent us from entering into additional collaborations; unwillingness by the collaborator to cooperate in the development or manufacture of a product candidate, including providing us with data or materials; unwillingness on the part of a collaborator to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities; initiating of litigation or alternative dispute resolution options by either party to resolve the dispute; or attempts by either party to terminate the agreement. Collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates. In addition, any future transactions could increase our near and long-term expenditures, result in potentially dilutive issuances of our equity securities, including our common stock, or the incurrence of debt, contingent liabilities, amortization expenses or acquired in-process research and development expenses, any of which could affect our financial condition, liquidity and results of operations.

Future acquisitions may also require us to obtain additional financing, which may not be available on favorable terms or at all. These transactions may never be successful and may require significant time and attention of our management. In addition, the integration of any business that we may acquire in the future may disrupt our existing business and may be a complex, risky and costly endeavor for which we may never realize the full benefits of the acquisition. Accordingly, although there can be no assurance that we will undertake or successfully complete any additional transactions of the nature described above, any additional transactions that we do complete could adversely affect our business, financial condition, results of operations and prospects.

We have vendors and service providers located outside of the United States that subject us to additional risks that are beyond our control and that could harm our business, financial condition, results of operations and prospects.

Currently, we have vendors and service providers located outside of the United States. As a result of our global supplier network, we are subject to risks associated with doing business abroad, including:

- political unrest, terrorism, labor disputes and economic instability resulting in the disruption of trade from foreign countries in which our product candidates are manufactured;
- the imposition of new laws and regulations, including those relating to labor conditions, quality, and safety standards, imports, duties, taxes and other charges on imports, as well as trade restrictions and restrictions on currency exchange or the transfer of funds, particularly new or increased tariffs imposed on imports from countries where our suppliers operate;
- greater challenges and increased costs with enforcing and periodically auditing or reviewing our suppliers' and manufacturers' compliance with cGMPs or status acceptable to the FDA or comparable foreign regulatory authorities;
- reduced protection for intellectual property rights, including trademark protection, in some countries;
- disruptions in operations due to global, regional or local public health crises or other emergencies or natural disasters;
- disruptions or delays in shipments; and
- changes in local economic conditions in countries where our manufacturers or suppliers are located.

These and other factors beyond our control could interrupt our vendor and service providers' operations, influence the ability of these companies to render services and export our clinical supplies cost-effectively or at all, and inhibit their ability to procure certain materials.

Contract manufacturing organizations (CMOs) may become subject to legislation, trade restrictions, sanctions, tariffs, and other regulatory requirements by the U.S. government, which could restrict or even prohibit our ability to work with such entities, thereby potentially disrupting the supply of material to us. For example, the United States has recently passed legislation, namely the BIOSECURE Act (BIOSECURE Act), to prohibit U.S. federal executive agencies from procuring or obtaining any biotechnology equipment or service produced or provided by a "biotechnology company of concern" or entering into or renewing a contract, loan, or grant with an entity that uses such biotechnology equipment or services. Specifically, on October 9, 2025, the U.S. Senate passed a revised version of the BIOSECURE Act as an amendment to the National Defense Authorization Act (NDAA) for fiscal year 2026. The final version of the NDAA containing this legislative language was passed by the Senate and House of Representatives and signed into law by President Trump on December 18, 2025. The BIOSECURE Act prohibits the U.S. government from procuring or obtaining biotechnology equipment or services produced or provided by a "biotechnology company of concern" (BCC); entering into, extending, or renewing government contracts with an entity that directly or indirectly (e.g., via a subcontractor) uses biotechnology equipment or services from a BCC in performance of that federal contract; and/or issuing grants or loans to purchase, obtain, or use biotechnology equipment or services produced by a BCC. The BIOSECURE Act also prohibits U.S. government loan and grant recipients from using federal loan or grant money to enter into contracts with entities that use equipment from BCCs in the performance of any federal prime contract or subcontract. Companies designated as a BCC include those that are identified on the U.S. Department of Defense's annual List of Chinese Military Companies, also known as the 1260H List, and the U.S. Government also has the ability to designate entities as BCCs through a separate designation process. While the U.S. BIOSECURE Act has a grandfathering period of five years for existing contracts and has carveouts for manufacture of drugs for supply under Medicaid and Medicare Part B, subject to the Secretary of Veteran Affairs' discretion, the impact of the U.S. BIOSECURE Act on the biotechnology industry is uncertain. Given the BIOSECURE Act, we may be restricted in our ability to work with certain Chinese biotechnology companies to the extent we would contract with, or otherwise receive funding from, the U.S. government. Such disruption could have adverse effects on the development of our product candidates. Furthermore, any U.S. executive action, legislative action or potential sanctions including the imposition of higher tariffs on imports into the United States and other governmental regulations affecting trade between the United States and China, and any retaliatory actions by China could materially impact our work or potential work in the future with Chinese biotechnology companies. U.S. executive agencies may 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. Such disruption could have adverse effects on the development of our product candidates. We are investigating alternative suppliers or manufacturers outside of China for materials and services for our product candidates. Without an alternative manufacturing plan, there is a risk that, if supplies are interrupted, or the quality of ingredients provided by such alternative sources is not to our specification, it would cause delays in our supply chain and increase the cost of manufacturing our drugs, which could materially harm our business.

Risks Related to Commercialization of Our Product Candidates

Competitive products may reduce or eliminate the commercial opportunity for our product candidates for our current or future indications. If our competitors develop technologies or product candidates more rapidly than we do, or their technologies are more effective or safer than ours, our ability to develop and successfully commercialize our product candidates may be adversely affected.

The pharmaceutical industry is characterized by rapid innovation and intense competition. While we believe that our clinical programs provide us with competitive advantages, we face competition from multiple companies that are similarly working to develop therapeutics targeting similar indications, as well as from academic institutions, governmental agencies, and public and private research institutions. Many of our potential competitors, either alone or with collaboration partners, have significantly greater financial resources than we do, as well as equal or greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of products and the commercialization of those products. Accordingly, our potential competitors may be more successful than we are in achieving regulatory approvals and commercializing their products. We anticipate that we will face intense and increasing competition from existing, approved drugs, as well as new drugs entering the market and emerging technologies that become available.

We expect our current and future product candidates to face immediate competition from existing treatments for musculoskeletal pain. These consist of over-the-counter analgesics for mild to moderate symptoms, while moderate to severe pain is treated through a combination of opioids, NSAIDs, long-acting local anesthetics (for postoperative pain), acetaminophen, and recently approved Journavx, Vertex Pharmaceuticals Incorporated's selective $Na_v1.8$ inhibitor. In moderate to severe pain, opioids have historically been heavily relied on due to their strong analgesic effect, which has set the standard reference for efficacy. Commonly used opioids include morphine, oxycodone (e.g. under brand names OxyContin, Percocet), hydrocodone bitartrate/acetaminophen (e.g. Vicodin) and tramadol (e.g. Ultram). In addition to opioids, NSAIDs are also used in mono- and multi-modal regimens to manage pain, including products such as ibuprofen (e.g. Motrin), naproxen, diclofenac (e.g. Zorvolex, Zipsor, Voltaren), celecoxib (e.g. Celebrex), and intravenous meloxicam (e.g. Anjeso).

While we are primarily focused on addressing the demand for non-opioid musculoskeletal pain alternatives, we may in the future pursue development of our portfolio in neuropathic pain. If we pursue neuropathic pain, we could compete directly with established generic adjunctive analgesic therapies, notably: anticonvulsants such as pregabalin (e.g. Lyrica) or gabapentin (e.g. Neurontin) for neuropathic pain and fibromyalgia; antidepressants, such as duloxetine (e.g. Cymbalta) and amitriptyline (e.g. Elavil), for conditions such as diabetic peripheral neuropathy, fibromyalgia, and chronic musculoskeletal pain.

In addition to approved pain treatments, we are aware of several companies developing drug candidates for acute and chronic pain across multiple modalities. In $Na_v1.8$ specifically, Vertex Pharmaceuticals Incorporated, AbbVie Inc., Eli Lilly and Company (through its acquisition of SiteOne Therapeutics, Inc. in May 2025), Grünenthal GmbH, and Merck Sharp & Dohme LLC have the most notable and advanced drug candidates in various stages and pain indications. Beyond the $Na_v1.8$ class, the competitive landscape is expanding into novel targets, including $Na_v1.7$ inhibitors (e.g., Xenon Pharmaceuticals' XEN1701) and Kv7 potassium channel activators (e.g., Biohaven's BHV-7000 and Xenon Pharmaceuticals' XEN1120).

The standard of care for pain management may also evolve to favor multi-modal or combination therapeutic regimens that incorporate multiple agents with complementary mechanisms of action. We currently lack clinical data demonstrating the safety or efficacy of onzotrigine, LTG-321 and LTG-418 in combination with other pain therapies, and we have not established partnerships to pursue combination regimens. If the market moves toward combination approaches and we are unable to generate relevant combination data or enter into appropriate collaborations, our product candidates may be viewed as less competitive, and we may be required to conduct additional studies or seek additional partnerships before achieving meaningful commercial acceptance.

Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make our product candidates less competitive. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, discovering, developing, receiving regulatory approval for or commercializing drugs before we do, which would have an adverse impact on our business and results of operations. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies.

Further, emerging therapies in adjacent therapeutic categories, including glucagon-like peptide-1 (GLP-1) receptor agonists used for weight management, may indirectly reduce demand for pain therapies. Clinical and real-world evidence suggests that weight loss can ameliorate certain pain conditions, including musculoskeletal and inflammatory pain. As GLP-1 therapies become more widely prescribed, the addressable patient population for certain pain indications may contract, and market expectations for pain drug revenues may be revised downward. We cannot predict the magnitude of this indirect competitive effect or the extent to which it may reduce the commercial opportunity for our product candidates.

Our profitability and financial position will suffer if our product candidates receive regulatory approval but cannot compete effectively in the marketplace.

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

We have never commercialized a product candidate for any indication. Even if our product candidates are approved by the appropriate regulatory authorities for marketing and sale, our product candidates may not gain acceptance among patients, patients' families, advocacy groups, physicians, third-party payors and others in the medical community. If the product candidates for which we obtain regulatory approval do not gain an adequate level of market acceptance, we may not generate sufficient product revenue or become profitable. Further, the number of patients that our product candidates is designed to treat may be smaller than expected.

The degree of market acceptance of our product candidates, if approved and commercialized, will depend on a number of factors, some of which are beyond our control, including:

- the pricing and cost-effectiveness of our product candidates, as well as the ease of administration, time burden and market acceptance;
- the safety, efficacy and tolerability of our product candidates;
- acceptance of our product candidates by patients and their families, the medical community and third-party payors vis-à-vis existing pain medications and therapies;
- changes in the standard of care for targeted indications and the reluctance of physicians to switch their patients' current standard of care;

- the clinical indications for which our product is approved and the scope of efficacy/safety claims that we may make for the product;
- the ability of our product candidates to receive opioid-free labels;
- any restrictions on the use of our product, and the prevalence and severity of any adverse effects;
- any distribution and use restrictions imposed by the FDA as part of a mandatory REMS with respect to such product candidate or to which we agree under a voluntary risk management plan;
- the availability of adequate coverage and reimbursement by third parties, such as insurance companies and other healthcare payors, and by government healthcare programs, including Medicare and Medicaid;
- the willingness of patients to pay all, or a portion of, out-of-pocket costs associated with our products in the absence of sufficient third-party coverage and adequate reimbursement;
- the extent and strength of our marketing and distribution of such product candidate, including our ability to overcome any pre-existing stigmas around pain medication and dependency concerns;
- the timing of market introduction of such product candidate, as well as competitive products;
- our ability to offer our product candidates for sale at competitive prices;
- adverse publicity about our product or favorable publicity about competitive products; and
- potential product liability claims.

Our efforts to educate the medical community and third-party payors about the benefits of our product candidates may require significant resources and may never be successful. Even if our product candidates, if approved, are safe and effective for their approved indications, physicians and patients (and their families, as applicable) may not immediately be receptive to such product candidates and may be slow to adopt them as an accepted treatment for the approved indications. For example, the commercial launch of Journavx (suzetrigine) as the first approved non-opioid $Na_v1.8$ inhibitor for acute pain has established a pricing and reimbursement precedent for this class of drugs. Suzetrigine has been priced at approximately $31 per day, compared to inexpensive generic opioids, and reports indicate that certain third-party payors have denied or restricted coverage on the basis of cost and the availability of cheaper alternatives. These payor dynamics may create an unfavorable precedent for the entire class, including our product candidates, and may cause third-party payors and formulary decision-makers to perceive a ceiling on the clinical differentiation that non-opioid $Na_v1.8$ inhibitors can demonstrate. As a result, we may be required to engage in prolonged advocacy, legislative, and policy efforts, potentially spanning multiple years, before achieving meaningful formulary placement or broad reimbursement coverage, and there can be no assurance that such efforts will be successful or timely. If our current or future product candidates are approved but do not achieve an adequate level of acceptance among physicians, patients and third-party payors, we may not generate meaningful revenue from our product candidates and may never become profitable.

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

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

The successful commercialization of our product candidates, if approved, will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels, and favorable pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates could limit our ability to market those products and decrease our ability to generate revenue.

The availability of coverage and the adequacy of reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers, and other third-party payors are essential for most patients to be able to afford prescription medications such as our product candidates, if approved. Our ability to achieve coverage and acceptable levels of reimbursement for our product(s) by third-party payors will have an effect on our ability to successfully commercialize any products we may successfully develop. Even if we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States or elsewhere will be available for any product 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 and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug or a less expensive therapy is available. It is possible that a third-party payor may consider our product candidates as substitutable and only offer to reimburse patients for the less expensive product. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in product development. As a result, if reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our products, if approved, and may not be able to obtain a satisfactory financial return on products that we may develop. See the risk factor above titled *"Even if our product candidates receive regulatory approval, they may fail to achieve the degree of market acceptance by physicians, patients and others in the medical community necessary for commercial success, in which case we may not generate significant revenues or become profitable"* for an example related to the commercial launch of suzetrigine.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. Regulatory approvals, pricing and reimbursement for new drug products vary widely from country to country. 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 will be covered. Some third-party payors may require prior authorization before covering new or innovative drug therapies and reimbursing healthcare providers who use such therapies. It is difficult to predict at this time what third-party payors will decide with respect to coverage and reimbursement for our products, if approved.

Obtaining and maintaining reimbursement status is time-consuming, costly and uncertain. 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. However, no uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Further, coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we or our collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely.

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 newly approved products and, as a result, they may not cover or provide adequate payment for our products. For example, the U.S. Department of Health and Human Services (HHS) imposes rebates on many Medicare Part B and Medicare Part D products to penalize price increases that outpace inflation. HHS has also been empowered to negotiate the price of certain single-source drugs that have been on the market for at least seven years covered under Medicare as part of the Medicare Drug Price Negotiation Program. Each year up to 20 products will be selected by HHS for the Medicare Drug Price Negotiation Program. Products subject to the Medicare Drug Price Negotiation Program are expected to experience a significant reduction in reimbursement from the Medicare program on a per unit basis. We expect to experience pricing pressures in connection with the sale of our product candidates, if approved for marketing, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

Risks Related to Government Regulation

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

Healthcare providers, physicians and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. Our current and future arrangements with healthcare providers, third-party payors and customers can expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, which may constrain the business or financial arrangements and relationships through which we research, and if approved, sell, market and distribute our products. In particular, the research of our product candidates, as well as the promotion, sales and marketing of a future approved product, is subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring, and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials.

The applicable federal, state and foreign healthcare laws and regulations laws that may affect our ability to operate now or in the future include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order, or recommendation of any good, facility, item, or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other;
- the civil monetary penalties statute which imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to, among others, a federal healthcare program that the person knows or should know is for a medical or other item or service that was not provided as claimed or is false or fraudulent;
- the federal civil and criminal false claims laws, including the federal False Claims Act (FCA), which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by Medicare, Medicaid, or other federal healthcare programs, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money to the federal government, or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government healthcare programs if they are deemed to "cause" the submission of false or fraudulent claims. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;
- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (*e.g.*, public or private), and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact, or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items, or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating the health care fraud statute under HIPAA without actual knowledge of the statute or specific intent to violate it;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH) and its implementing regulations, which also imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy and security of individually identifiable health information of covered entities subject to the rule, including health plans, healthcare clearinghouses and certain healthcare providers and their business associates, independent contractors of a covered entity that perform certain services involving the use or disclosure of individually identifiable health information for or on their behalf, as well as their covered subcontractors;

- the federal Physician Payments Sunshine Act and its implementing regulations, which require some manufacturers of drugs, devices, biologicals, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program (with certain exceptions) to report annually to HHS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (such as physician assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and may be broader in scope than their federal equivalents; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and local laws that require the registration of pharmaceutical sales representatives.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products. Distribution of prescription drug samples to licensed prescribers is also highly regulated within the United States.

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

It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations, or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal, and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Any action for violation of these laws, even if successfully defended, could cause us to incur significant legal expenses and divert management's attention from the operation of our business. Prohibitions or restrictions on sales or withdrawal of future marketed products could adversely affect our business, results of operations and financial condition.

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

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

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

Any regulatory approvals that we may receive for our product candidates will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of the product candidate, and such approvals may be subject to significant limitations on the approved indicated uses for which the product may be marketed (*e.g.*, use restrictions for specified age groups, warnings, precautions or contraindications), and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a REMS program as a condition of approval of our product candidates or similar risk management measures, which could entail requirements for long-term patient follow-up, a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools.

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

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or product recalls;
- restrictions on product distribution or use, or requirements to conduct post-marketing studies or clinical trials;
- fines, restitutions, disgorgement of profits or revenues, warning letters, untitled letters or holds on clinical trials;
- refusal by the FDA or comparable foreign regulatory authorities to approve pending applications or supplements to approved applications submitted by us or suspension or revocation of approvals;
- product seizure or detention or refusal to permit the import or export of our products; and
- injunctions or the imposition of civil or criminal penalties.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

The policies of the FDA and comparable regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. 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 our business, results of operations and financial condition could be adversely affected.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

The FDA and comparable foreign regulatory authorities strictly regulate the marketing, labeling, advertising, and promotion of prescription drugs. These regulations include standards for direct-to-consumer advertising (in the United States only), industry-sponsored scientific and educational activities and promotional activities involving the internet, as well as restrictions on promoting approved drugs for unapproved uses or patient populations (known as "off-label promotion"). Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. While physicians in the United States may choose, and are generally permitted, to prescribe drugs for off-label uses, manufacturers may not market or promote such uses. However, companies may share truthful and not misleading information that is not inconsistent with the labeling, and the FDA has recently published a draft guidance with recommendations for how drug manufacturers can share scientifically sound and clinically relevant information on unapproved uses with health care providers so long as such presentations are not promotional.

If we are found to have promoted any off-label uses of our future approved products, or to have engaged in the promotion of an unapproved product candidate, we may become subject to significant liability. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our future approved products, we could become subject to significant liability, which would materially adversely affect our business, results of operations and financial condition.

Ongoing healthcare legislative and regulatory reform measures may adversely affect our business, results of operations and financial condition.

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. By way of example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, (collectively, ACA), was signed into law, intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose taxes and fees on the healthcare industry and impose additional health policy reforms.

There have been executive, judicial and congressional challenges to certain aspects of the ACA. For example, on July 4, 2025, the One Big Beautiful Bill Act (OBBBA) was signed into law, which narrowed access to ACA marketplace exchange enrollment and declined to extend the ACA enhanced advanced premium tax credits that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expired ACA subsidies.

The current administration is pursuing policies to reduce regulations and expenditures across government agencies including at HHS, the FDA, the U.S. Centers for Medicare & 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. For example, the current administration has announced agreements with certain pharmaceutical companies that require the drug manufacturers to offer, through a direct-to-consumer platform, U.S. patients and Medicaid programs prescription drug Most-Favored Nation pricing equal to or lower than those paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of foreign revenues. Other recent actions, for example, include (1) directing agencies to reduce agency workforce and cut programs; (2) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives, including by establishing Most-Favored-Nation pricing for pharmaceutical products and launching an online clearinghouse (TrumpRx) for patients to purchase certain products from manufacturers on a cash pay basis; (3) imposing tariffs on certain imported pharmaceutical products; and (4) as part of the Make America Healthy Again Commission's Strategy Report released in September 2025, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan," to codify and expand Most-Favored Nation pricing, lower government subsidies to private insurance companies, increase healthcare price transparency, expand pharmaceutical drugs available for over-the-counter purchase, and enact restrictions on pharmacy benefit manager payment methodologies, among other things. As part of these initiatives, the administration is implementing or considering various CMS Center for Medicare and Medicaid Innovation models, under which manufacturers may owe rebates for certain prescription drugs under Medicaid or Medicare if the price of a drug included in an applicable model exceeds an international benchmark calculated based on prices available in certain reference countries. These include the finalized Global Benchmark for Efficient Drug Pricing Model (GLOBE) Model for certain Medicare Part B drugs; and the proposed Guarding United States Medicare Against Rising Drug Costs (GUARD) Model for certain Medicare Part D drugs, among others. These actions and policies may significantly reduce U.S. drug prices, potentially impacting manufacturers' global pricing strategies and profitability, while increasing their operational costs and compliance risks. In June 2024, the U.S. Supreme Court's Loper Bright decision greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program.

At the state level, individual states in the United States have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, marketing cost disclosure, drug price reporting and other transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Some states have enacted legislation creating so-called prescription drug affordability boards with the goal of imposing price limits on certain drugs in these states, while some states are also seeking to implement general, across the board price caps for pharmaceuticals, or are seeking to regulate drug distribution.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures. We cannot predict with certainty what impact any federal or state health reforms will have on us, but such changes could impose new or more stringent regulatory requirements on our activities or result in reduced reimbursement for our products, if approved, any of which could adversely affect our business, results of operations and financial condition.

Disruptions to the operations of the FDA, the SEC, other U.S. governmental agencies or comparable foreign regulatory authorities caused by funding shortages, leadership changes, staffing cuts or other staffing shortages, along with uncertainty regarding the potential for new initiatives, laws, regulations, policies and guidance affecting our product candidates or other aspects of our business, could materially and adversely affect our business.

The ability of the FDA or other comparable foreign regulatory authorities to review and approve new products or take action with respect to other regulatory matters can be affected by a variety of factors, including government budget and funding levels, leadership changes, the ability to hire and retain key personnel and accept payment of user fees, the availability of personnel and other resources, changes in statutes, regulations and policies that affect the FDA's or comparable foreign regulatory authorities' ability to perform routine functions, and other business disruptions. Average review times at the FDA and comparable foreign regulatory authorities have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. In addition, there have recently been terminations of large numbers of federal employees at various federal agencies, including the FDA. Changes and cuts in FDA staffing could result in delays in the FDA's responsiveness or in its ability to review IND submissions or applications, issue regulations or guidance or implement or enforce regulatory requirements in a timely fashion, or at all. A prolonged government shutdown and/or employee terminations or resignations could significantly impact the ability of the FDA or other federal agencies to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns and/or employee terminations or resignations at the SEC could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

There is substantial uncertainty as to whether and how the current U.S. Presidential administration will seek to modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates and any products for which we obtain approval. This uncertainty could present new challenges as we navigate development and approval of our product candidates. Some of these efforts have manifested to date in the form of personnel cuts and measures that could impact the FDA's ability to hire and retain key personnel, which could result in delays or limitations on our ability to obtain guidance from the FDA regarding our product candidates and obtain the requisite regulatory approvals in the future. There is uncertainty as to whether we will be materially and negatively impacted by governmental orders, regulations, policies or guidance or disruptions to the normal operations of government agencies.

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 using third-party suppliers in several countries outside the United States. There is inherent risk, based on the complex relationships among the United States 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 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. The Bureau of Industry and Security, U.S. Department of Commerce, has initiated an investigation to determine whether pharmaceutical ingredients, including finished drug product, manufactured outside the United States pose a national security risk and should be subject to additional tariffs.

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, our suppliers are located outside of the United States: India (starting materials and active pharmaceutical ingredients) and China (starting materials). We also rely on specialized laboratory equipment, supplies, materials and precursor compounds, 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 will result in increased research and development expenses, including with respect to increased costs associated with APIs, raw materials, laboratory equipment and research materials and components. To the extent we continue to use suppliers located outside of the United States for supply of starting materials and APIs for a commercial product, if approved, we will experience increased expenses, and our financial results could be materially and adversely impacted.

In addition, such tariffs will increase our supply chain complexity and could also potentially disrupt our existing supply chain. While we may pursue alternative suppliers located in the United States or in territories that are less likely to be impacted by tariffs, there is no guaranty that we will be successful. Unlike consumer goods, pharmaceuticals face unique regulatory constraints that make rapid supply chain adjustments particularly difficult and costly. 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 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 on 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 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. In addition, tariffs and other trade developments have and may continue to heighten the risks related to the other risk factors described elsewhere in this *Quarterly Report*.

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 and the third parties with whom we work 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, sensitive third-party data, business plans, transactions, financial information and information from and about clinical trial participants and results (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 (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). We may obtain health information from third parties, such as research institutions with which we collaborate, that are subject to privacy and security requirements under HIPAA. Although we do not believe that we are directly subject to HIPAA, other than potentially with respect to providing certain employee benefits, we could be subject to criminal penalties if we knowingly obtain or disclose individually identifiable health information maintained by a HIPAA covered entity in a manner that is not authorized or permitted by HIPAA. In addition, other federal and state laws have established and may in the future establish requirements for protecting the privacy and security of health information that is not protected by HIPAA.

Additionally, 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 information, such as conducting data privacy impact assessments. For example, the California Consumer Privacy Act of 2018 (CCPA), applies to personal information of California residents and requires businesses subject to the CCPA to provide specific disclosures in privacy notices and respond to requests of such individuals to exercise certain privacy rights. Although there are minimum revenue or personal data processing thresholds for entities to be subject to many of these laws and there are limited exemptions for clinical trial data under the CCPA and similar U.S. state comprehensive privacy laws, such laws may impact (possibly significantly) our business activities depending on how they are interpreted, should we become subject to the CCPA or other such state comprehensive privacy laws in the future. In addition, similar laws are being considered in other states, as well as at the international, federal and local levels, and we expect more laws related to personal data to become effective in the future. These developments may further complicate compliance efforts and increase our legal risk and compliance costs for us and the third parties upon whom we rely.

Outside the United States, an increasing number of laws, regulations, and industry standards may govern data privacy and security, including in relation to clinical trial data. For example, we may be subject to the European Union's General Data Protection Regulation (EU GDPR), the United Kingdom's General Data Protection Regulation and Data Protection Act 2018 (collectively, the UK GDPR) (the EU GDPR and UK GDPR together referred to as the GDPR), and China's Personal Information Protection Law (PIPL), each of which impose strict requirements for processing personal data of individuals within the European Economic Area (EEA), the United Kingdom (UK) and China. The PIPL and GDPR impose comprehensive data privacy compliance obligations in relation to our collection and use of data relating to an identifiable living individual or "personal data", including a principle of accountability and the obligation to demonstrate compliance through policies, procedures, training and audit, as well as regulating cross-border transfers of personal data out of the EEA and the UK (in respect of the GDPR) and China (in respect of the PIPL). In addition, some of the personal data we process in respect of clinical trial participants is special category or sensitive personal data under the GDPR and PIPL, and subject to additional compliance obligations and to local law derogations.

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 the annual global revenues of the non-compliant undertaking, 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; or regulatory investigations, reputational damage, orders to cease/ change our data processing activities, enforcement notices and/or assessment notices (for a compulsory audit). Failure to comply with PIPL can result in fines of up to RMB 50 million or 5% of the prior year's total annual revenue for the personal information processor and/or a suspension of services or data processing activities. Other potential penalties include a fine of up to RMB 1 million on the person in charge or directly responsible personnel and, in serious cases, individuals and entities may be exposed to criminal liabilities under other local Chinese law, such as the Criminal Law of the People's Republic of China. The PIPL also prohibits responsible personnel for violations of the PIPL from holding high level management or data protection officer positions in relevant enterprises.

In addition, we may be unable to transfer personal data or we may have to implement additional measures to enable the transfer of data to the United States or other countries due to data localization requirements or limitations on cross-border data flows. For example, the PIPL imposes data localization requirements on important data processors and critical information infrastructure operators and personal information processors which process personal information above a certain threshold prescribed by the relevant authorities, unless a security assessment (Security Assessment) is passed. The PIPL also requires data processors to rely on a data export mechanism and comply with certain requirements prior to the transfer of Personal Information outside of China, such as compliance with a Security Assessment or certification by an agency designated by the relevant authorities or entering into standard form model contracts approved by the relevant authorities with the overseas recipient, unless an exemption applies. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the EEA and the United States remains uncertain. Case law from the Court of Justice of the European Union states that reliance on the standard contractual clauses – a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case-by-case basis. We expect the existing legal complexity and uncertainty regarding international personal data transfers to continue and international transfers to the United States and to other jurisdictions more generally to continue to be subject to enhanced scrutiny by regulators. As the regulatory guidance and enforcement landscape in relation to data transfers continue to develop, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we operate our business, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

Additionally, the U.S. Department of Justice (DoJ) 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 (e.g., China, Russia, Iran) and covered persons (i.e., individuals and entities who are designated as such by the U.S. Attorney General or are (1) foreign entities organized under the laws of, or with a principal place of business in, a country of concern or 50% or more owned, individually or in the aggregate, by one or more countries of concern or other covered persons; (2) foreign entities 50% or more owned, individually or in the aggregate, by a country of concern or another covered person; (3) foreign individuals that are employees or contractors of a country of concern or covered person; and (4) foreign individuals who are primarily a resident in a country of concern) that may impact certain business or management activities such as vendor engagements, licensing arrangements, partnership 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. We may in the future engage in data transactions that could be subject to the rule. Although the DoJ issued compliance guidance and responded to industry questions, we are not aware of the existence of enforcement data or case law that would provide additional guidance on how the rule will be interpreted, and there is a risk that our interpretation of its applicability, scope and requirements could be incorrect, incomplete, or misapplied. 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 enter into certain agreements.

Our employees and personnel use AI 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 and regulations regulating AI 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 Technologies, it could make our business less efficient and result in competitive disadvantages.

In addition to data privacy and security laws, we are contractually subject to industry standards adopted by industry groups and may become subject to such obligations in the future. We are also bound by other contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful.

We publish privacy policies, marketing materials, whitepapers, and other statements concerning data privacy, and security. Regulators 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 (or be perceived to have failed) 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 (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans or restrictions on processing personal data; or orders to destroy or not use personal data.

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 but not limited to: interruptions or stoppages in our business operations; loss of customers; 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; potentially significant financial penalties if we are found to be in violation of our privacy obligations; adverse publicity; or substantial changes to our business model or operations.

Additional laws and regulations governing international operations could adversely affect our business, results of operations and financial condition.

If we further expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The FCPA prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate, and other related parties for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our research and development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations (collectively, Trade Laws). We can face serious consequences for violations.

We are subject to Trade Laws. Among other things, Trade Laws prohibit companies and their employees, agents, clinical research organizations, contractors and other partners from authorizing, promising, offering, providing, soliciting or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences. We have direct or indirect interactions with officials and employees of government authorities or government-affiliated hospitals, universities and other organizations. We also expect our non-U.S. activities to increase over time. We plan to engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals, and we can be held liable for the corrupt or other illegal activities of our personnel, agents or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

We maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees, but this insurance may not provide adequate coverage against potential liabilities. However, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Environmental laws and regulations may impair our research, development or production efforts. In addition, failure to

comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

Risks Related to the Ownership of Our Common Stock

Our quarterly and annual operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts or any guidance we may publicly provide, each of which may cause our stock price to fluctuate or decline.

We expect our operating results to be subject to quarterly and annual fluctuations which may, in turn, cause the price of our common stock to fluctuate substantially. Our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of expense related to the ongoing development of onzotrigine, LTG-321, LTG-418 or future development programs;
- results and timing of preclinical studies and ongoing and future clinical trials, or the addition or termination of any such clinical trials;
- the timing of payments we may make or receive under existing license and collaboration arrangements or the termination or modification thereof;
- our execution of any strategic transactions, including acquisitions, collaborations, licenses or similar arrangements, and the timing and amount of payments we may make or receive in connection with such transactions;
- any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which we may become involved;
- recruitment and departures of key personnel;
- if our product candidates receive regulatory approval in the future, the terms of such approval and market acceptance and demand for such products;
- regulatory developments affecting our product candidates or those of our competitors;
- global or regional public health emergencies, including any health epidemics and their residual effects, natural disasters or major catastrophic events;
- adverse macroeconomic conditions or geopolitical events and conflicts, any health epidemics and their residual effects, bank failures, or inflation and increased interest rates, on our preclinical and clinical development or operations;
- the impacts of inflation and rising interest rates on our business and operations; and
- changes in general market and economic conditions.

If our quarterly or annual operating results fall below the expectations of investors or securities analysts or any forecasts or guidance we may provide to the market, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide. We believe that quarterly or annual comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

The trading price of our common stock is likely to be volatile and you could lose all or part of your investment.

The trading price of our common stock is likely to be volatile. The stock market in general and the market for stock of biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your shares of our common stock at or above the price at which you paid for such shares. The market price for our common stock may be influenced by those factors discussed in this “Risk Factors” section and many other factors, including:

- volatility and instability in the financial and capital markets;
- announcements relating to our product candidates, including the results of clinical trials by us or our collaborators;
- market acceptance of our product candidates, if approved, and the recognition of our brand;
- introduction of proposed products, technologies or treatment techniques by us or our competitors;
- announcements of significant contracts, acquisitions, divestitures or partnerships by us, our competitors or our collaboration partners;

- regulatory clearance, certification or approval of our product candidates or those products of our competitors or collaboration partners, or the failure to obtain such clearances, certifications or approvals on the projected timeline or at all;
- the announcement of a product recall, suspension or other safety notice associated with our products or the products of our competitors, or other similar regulatory enforcement actions;
- financial and operating results relative to the expectations of securities analysts and other market participants and the issuance of securities analysts' reports or recommendations;
- threatened or actual litigation, regulatory proceedings or government investigations;
- the costs and timing of manufacturing for our product;
- the success and market acceptance of existing or new competitive therapies, products or technologies, including suzetrigine;
- development of new products that may address our markets and make our product candidates less attractive;
- failure or discontinuation of any of our research or development programs;
- changes in the level of expenses related to any of our research or development programs;
- developments related to any existing or future collaborations;
- the recruitment or departure of key personnel;
- regulatory or legal developments in the United States and other countries;
- announcements by us, our partners or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- changes in the structure of healthcare payment systems;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- actual or expected changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- announcement or expectation of additional financing efforts;
- sales of common stock by us, our executive officers, directors or principal stockholders, or others;
- variations in our financial results or those of companies that are perceived to be similar to us;
- market conditions in the pharmaceutical and biotechnology sector;
- general economic, political and market conditions and other factors;
- changes in accounting principles; and
- the other factors described in this "Risk Factors" section and elsewhere in this *Quarterly Report*.

Following price volatility, holders of securities may institute securities class action litigation against the issuer. If any holders of our common stock were to bring such a lawsuit against us, we could incur substantial costs defending the lawsuit and the attention of our board of directors and senior management would be diverted from the operation of our business. Any adverse determination in litigation could also subject us to significant liabilities. As a result of this volatility, you may not realize any return on, or you may lose some or all of your investment. Broad market and industry factors such as these could materially and adversely affect the market price of our stock, regardless of our actual operating performance.

Our executive officers, directors and principal stockholders, if they choose to act together, will continue to have the ability to control or significantly influence all matters submitted to stockholders for approval.

Our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially own a significant percentage of our outstanding common stock. As a result, if these stockholders 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 persons, if they choose to act together, would control or significantly influence the election of directors, the composition of our management and approval of any merger, consolidation, sale of all or substantially all of our assets or other business combination that other stockholders may desire. The interests of these stockholders may not always coincide with your interests or the interests of other stockholders, and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock. Any of these actions could adversely affect the market price of our common stock.

A significant portion of our total outstanding shares are eligible to be sold into the market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market, or the perception in the market that the holders of a large number of shares of our common stock intend to sell shares of our common stock, could reduce the market price of our common stock.

Approximately 44,219,347 shares of our common stock are initially restricted as a result of securities laws, market standoff provisions or lock-up agreements, but will become eligible to be sold after the IPO.

Moreover, certain of our stockholders have rights, subject to specified conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders, until such shares can otherwise be sold without restriction under Rule 144 under the Securities Act, or until the rights terminate pursuant to the terms of the stockholder agreements between us and such holders. We also registered all shares of our common stock subject to equity awards issued or reserved for future issuance under our equity compensation plans on a registration statement on Form S-8 filed with the SEC on August 10, 2026. These shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates under Rule 144 under the Securities Act and the market standoff provisions and lock-up agreements described above. Any sales of securities by these stockholders could have a negative impact on the trading price of our common stock.

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

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act (JOBS Act). For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including (i) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, (ii) reduced disclosure obligations regarding executive compensation in this *Quarterly Report* and our periodic reports and proxy statements, and (iii) exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not approved previously. In addition, as an emerging growth company, we are only required to provide two years of audited financial statements and two years of selected financial data in this *Quarterly Report*.

We could be an emerging growth company for up to five years following the closing of our IPO, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (i) the last day of the fiscal year (a) following the fifth anniversary of our IPO, (b) in which we have total annual gross revenue of at least $1.235 billion and (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed $700.0 million as of the prior June 30th, and (ii) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period. Investors may find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the JOBS Act, emerging growth companies also can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this exemption, and, as a result, our operating results and financial statements may not be comparable to the operating results and financial statements of companies who have adopted the new or revised accounting standards.

We also are a "smaller reporting company," meaning the market value of our voting and non-voting common stock held by non-affiliates is less than $700.0 million and our annual revenue is less than $100.0 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than $250.0 million or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700.0 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our annual report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Future sales and issuances of our securities, including pursuant to our equity incentive plans, may cause dilution to our stockholders or decrease our stock price.

We expect that significant additional capital may be necessary to continue our planned operations, including to expand product development and commercialize our products. We may seek additional capital through public or private equity or debt financings or other capital sources, which may include strategic collaborations and other strategic arrangements with third parties, to enable us to complete the development and potential commercialization of our product candidates. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder.

Pursuant to our 2026 Equity Incentive Plan (2026 Plan), our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants. Additionally, the number of shares of our common stock reserved for issuance under our 2026 Plan will automatically increase on January 1 of each calendar year, beginning on January 1, 2027 and continuing through and including January 1, 2036, by 5.0% of the total number of shares of our common stock (including shares issuable upon exercise, conversion, or exchange of all then-outstanding pre-funded warrants, or other rights exercisable for or convertible into, directly or indirectly, shares of common stock (whether vested or unvested), but excluding shares issuable upon the exercise of then-outstanding options and the shares reserved and available for issuance under our then-existing equity incentive plan(s) and employee stock purchase plan(s), if any) outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors. In addition, pursuant to our ESPP, the number of shares of our common stock reserved for issuance will automatically increase on January 1 of each calendar year, beginning on January 1, 2027 and continuing through and including January 1, 2036, by the lesser of (i) 1.0% of the total number of shares of our common stock (including shares issuable upon exercise, conversion, or exchange of all then-outstanding pre-funded warrants, or other rights exercisable for or convertible into, directly or indirectly, shares of common stock (whether vested or unvested), but excluding shares issuable upon the exercise of then-outstanding options and the shares reserved and available for issuance under our then-existing equity incentive plan(s) and employee stock purchase plan(s), if any) outstanding on the last day of the calendar month before the date of the automatic increase and (ii) 1,882,035 shares; provided that before the date of any such increase, our board of directors may determine that such increase will be less than the amount set forth in clauses (i) and (ii). Unless our board of directors elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution, which could cause our stock price to fall.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, would be your sole source of gain.

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. As a result, capital appreciation, if any, of our common stock would be your sole source of gain on an investment in our common stock for the foreseeable future.

Delaware law and provisions in our amended and restated certificate of incorporation and amended and restated bylaws which are in effect could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of our common stock.

Provisions of our amended and restated certificate of incorporation and amended and restated bylaws, which are in effect, may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares or transactions that our stockholders might otherwise deem to be in their best interests.

Therefore, these provisions could adversely affect the price of our common stock. Among other things, our amended and restated certificate of incorporation and amended and restated bylaws:

- permit our board of directors to issue up to 10,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate (including the right to approve an acquisition or other change in our control);
- provide that the authorized number of directors may be changed only by resolution of the board of directors;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- provide that the board of directors or any individual director may only be removed with cause and the affirmative vote of the holders of at least 66-2/3% of the voting power of all of our then outstanding common stock;
- divide our board of directors into three classes, with each class serving staggered three-year terms;
- require that any action to be taken by our stockholders be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;

- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner and also specify requirements as to the form and content of a stockholder's notice;
- do not provide for cumulative voting rights, therefore allowing the holders of a majority of the shares of our common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose; and
- provide that special meetings of our stockholders may be called only by the Chairman of the board, our Chief Executive Officer or by the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors.

The amendment of any of these provisions, with the exception of the ability of our board of directors to issue shares of preferred stock and designate any rights, preferences and privileges thereto, would require approval by the holders of at least 66-2/3% of our then-outstanding common stock.

In addition, as a Delaware corporation, we are subject to Section 203 of the Delaware General Corporation Law (DGCL). These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us for a certain period of time. A Delaware corporation may opt out of this provision by express provision in its original certificate of incorporation or by amendment to its certificate of incorporation or bylaws approved by its stockholders. However, we have not opted out of this provision.

These and other provisions in our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law make it more difficult or costly for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including delay or impede a merger, tender offer or proxy contest involving our company. The existence of these provisions could negatively affect the price of our common stock and limit opportunities for you to realize value in a corporate transaction.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and any appellate court therefrom are the exclusive forums for substantially all disputes between us and our stockholders, other than any complaint asserting a cause of action arising under the Exchange Act or the Securities Act, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative action or proceeding brought on our behalf;
- any action asserting a breach of fiduciary duty;
- any action asserting a claim against us arising under the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws;
- any action seeking to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws;
- any action to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine.

This provision does not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. Additionally, investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid and several state trial courts have enforced such provisions and required that suits asserting Securities Act claims be filed in federal court, there is no guarantee that courts of appeal will affirm the enforceability of such provisions and a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and the provisions may not be enforced by a court in those

other jurisdictions. If a court were to find either exclusive forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with litigating Securities Act claims in state court, or both state and federal court, which could seriously harm our business, results of operations and financial condition.

This exclusive forum provision may result in increased costs to stockholders to bring a claim. Further, this exclusive forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business.

Our operations are concentrated in two locations within California, and we or the third parties upon whom we depend may be adversely affected by a wildfire and earthquake or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our current operations are predominantly located in California. Any unplanned event, such as a flood, wildfire, explosion, earthquake, extreme weather condition, epidemic or pandemic, power outage, telecommunications failure or other natural or manmade accidents or incidents that result in us being unable to fully utilize our facilities may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Any similar impacts of natural or manmade disasters on our third-party CMOs and CROs could cause delays in our clinical trials and may have a material and adverse effect on our ability to operate our business and have significant negative consequences on our financial and operating conditions. If a natural disaster, power outage or other event occurred that prevented us from using our clinical sites, impacted clinical supply or the conduct of our clinical trials, that damaged critical infrastructure, such as the manufacturing facilities of our third-party CMOs, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we and our CMOs and CROs have in place may prove inadequate in the event of a serious disaster or similar event. In the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance we currently carry will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our CMOs or CROs, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our development programs may be harmed. Any business interruption could adversely affect our business, financial condition, results of operations and prospects.

General Risk Factors

Our ability to use our net operating loss (NOL) carryforwards and certain other tax attributes to offset taxable income or taxes may be limited.

Under U.S. federal income tax law, federal NOLs incurred in tax years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal NOLs is limited to 80% of taxable income. In addition, under Sections 382 and 383 of the Code, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to utilize its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We have undergone ownership changes in the past for purposes of Sections 382 and 383 of the Code, and therefore our ability to utilize certain of our NOLs and other tax attributes is limited. Moreover, future changes in our share ownership, some of which are outside of our control, could result in one or more subsequent ownership changes under Sections 382 and 383 of the Code and impose additional limitations on our ability to utilize our NOLs and other tax attributes. As a result, even if we attain profitability, our NOLs and other tax attributes may be subject to material usage limitations, which could negatively impact our future cash flows. In addition, for state income tax purposes, there may be periods during which the use of NOL carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. For example, California imposed limits on the usability of California state NOLs to offset taxable income and certain business credits to offset California state tax liabilities in tax years beginning after 2023 and before 2027.

Changes and evolving requirements in tax laws or their interpretation could adversely affect our business.

The tax regimes we are subject to or operate under, including with respect to income and non-income taxes, are unsettled and may be subject to significant change. The OBBBA enacted in 2025, the IRA enacted in 2022, the Coronavirus Aid, Relief, and Economic Security Act enacted in 2020, and the Tax Cuts and Jobs Act enacted in 2017 made many significant changes to the Code. Future guidance from the Internal Revenue Service and other tax authorities with respect to any legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation or sunset in future years. It is possible that changes in or interpretations under the OBBBA, the Tax Cuts and Jobs Act or other tax legislation, or the enactment of new tax legislation, could increase our future tax liability, which could in turn adversely impact our business and future profitability. The U.S. government may enact further changes to the taxation of business entities including, among others, an increase in the corporate income tax rate, the imposition of minimum taxes or surtaxes on certain types of income and significant changes to the taxation of income derived from international operations. We are unable to predict what changes to the tax laws of the United States and other jurisdictions may be proposed or enacted in the future or what effect such changes would have on our business. Any of these or similar developments or changes to tax laws or rulings (which changes may have retroactive application) could result in adverse impacts to our financial condition, operating results and prospects and a material change to the tax considerations described herein.

Unstable economic and market conditions may have serious adverse consequences on our business, financial condition and stock price.

Global economic and business activities continue to face widespread uncertainties, and global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, rising inflation and monetary supply shifts, rising interest rates, bank failures, labor shortages, declines in consumer confidence, declines in economic growth, increases in unemployment rates, recession risks and uncertainty about economic and geopolitical stability (such as the geopolitical tensions between the United States and China, the Russia/Ukraine conflict, conflicts in the Middle East). While we do not expect further developments with any such banks to have a material impact on our cash, cash equivalents and restricted cash balance, expected results of operations or financial performance for the foreseeable future, if further failures in financial institutions occur where we hold deposits, we could experience additional risk. Any such loss or limitation on our cash, cash equivalents and restricted cash would adversely affect our business.

The extent of the impact of these conditions on our operational and financial performance, including our ability to execute our business strategies and initiatives in the expected timeframe, as well as that of third parties upon whom we rely, will depend on future developments which are uncertain and cannot be predicted. There can be no assurance that further deterioration in economic or market conditions will not occur, or how long these challenges will persist. If the current equity and credit markets further deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Furthermore, our stock price may decline due in part to the volatility of the stock market and the general economic downturn.

We will incur increased costs and become subject to additional regulations and requirements as a result of being a public company, and our management will be required to devote substantial time to compliance with our public company responsibilities and corporate governance practices, which could impact our financial condition and results of operations and make it more difficult to run our business.

As a public company, and particularly after we are no longer an emerging growth company or smaller reporting company, we will incur significant legal, accounting and other expenses that we did not incur as a private company, including costs associated with public company reporting requirements. We also have incurred and will continue to incur costs associated with the Sarbanes-Oxley Act, and related rules implemented by the SEC and Nasdaq. The expenses generally incurred by public companies for reporting and corporate governance purposes have been increasing. We expect these rules and regulations to increase our legal and financial compliance costs and to make some activities more time-consuming and costly, although we are currently unable to estimate these costs with any degree of certainty. These laws and regulations also could make it more difficult or costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. These laws and regulations could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on our board committees or as our executive officers. Furthermore, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. We cannot predict or estimate the amount of additional costs we will incur as a public company or the timing of such costs. Furthermore, if we are unable to satisfy our obligations as a public company, we could be subject to delisting of our common stock, fines, sanctions, other regulatory action and potentially civil litigation.

Accordingly, increases in costs incurred as a result of becoming a publicly-traded company may adversely affect our business, financial condition and results of operations.

If we fail to maintain effective internal control over financial reporting, we may not be able to accurately report our financial results or prevent or detect misstatements, whether due to fraud or error. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

SEC rules that implement Section 404(a) of the Sarbanes-Oxley Act require that, beginning with our second annual report following our IPO, management assess and report annually on the effectiveness of our internal control over financial reporting and identify any material weaknesses in our internal control over financial reporting. Although SEC rules that implement Section 404(b) of the Sarbanes-Oxley Act require our independent registered public accounting firm to issue an annual report that addresses the effectiveness of our internal control over financial reporting, we have opted to rely on the exemptions provided in the JOBS Act, and consequently will not be required to comply with SEC rules that implement Section 404(b) of the Sarbanes-Oxley Act until such time as we are no longer an emerging growth company or smaller reporting company.

Effective internal control over financial reporting is necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inadequate internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

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

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

These inherent limitations include the 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 party 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 could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business. Additionally, the increase in the cost of directors' and officers' liability insurance may cause us to opt for lower overall policy limits or to forgo insurance that we may otherwise rely on to cover significant defense costs, settlements and damages awarded to plaintiffs.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on our company. If no or only very few securities analysts commence coverage of us, or if industry analysts cease coverage of us, the trading price for our common stock would be negatively affected. If one or more of the analysts who cover us downgrade our common stock or publish inaccurate or unfavorable research about our business, our common stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our common stock price and trading volume to decline.

Our insurance policies may be inadequate, may not cover all of our potential liabilities and may potentially expose us to unrecoverable risks.

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include property, general liability, employee benefits liability, workers' compensation, clinical trials/products liability, directors' and officers' and employment practices insurance. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. No assurance can be given that an insurance carrier will not seek to cancel or deny coverage after a claim has occurred. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our financial position and results of operations. For example, although we maintain product liability insurance coverage that also covers our clinical trials, this insurance may not be adequate to cover all liabilities that we may incur, and we may be required to increase our product liability insurance coverage. We anticipate that we will need to increase our insurance coverage each time we commence a clinical trial and successfully commercialize any product candidate. Insurance availability, coverage terms and pricing continue to vary with market conditions. We endeavor to obtain appropriate insurance coverage for insurable risks that we identify. However, we may fail to correctly anticipate or quantify insurable risks, we may not be able to obtain appropriate insurance coverage and insurers may not respond as we intend to cover insurable events that may occur. Any significant uninsured liability may require us to pay substantial amounts, which would materially adversely affect our business, financial condition, results of operations and growth.

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

Unregistered Sales of Equity Securities

Stock Option Awards

During the nine months ended September 30, 2026, we granted options to purchase shares of our common stock under our equity incentive plan. The stock options were issued pursuant to written compensatory plans or arrangements with our employees and directors, in reliance on the exemption from the registration requirements provided by Rule 701 promulgated under the Securities Act or the exemption set forth in Section 4(a)(2) under the Securities Act and Rule 506 promulgated thereunder as a transaction not involving any public offering.

Common Stock Issued Upon Conversion of Preferred Stock

Immediately prior to the completion of our IPO, we filed an Amended and Restated Certificate of Incorporation, which authorized a total of 999,999,999 shares of common stock and 10,000,000 shares of preferred stock. Upon such filing and immediately prior to the completion of the IPO, 41,155,082 outstanding shares of redeemable convertible preferred stock converted into 41,155,082 shares of common stock. The issuance of such shares of our common stock was exempt from registration under Section 3(a)(9) or Section 4(2) of the Securities Act.

Common Stock Issued Upon Conversion of Convertible Promissory Notes

In connection with the closing of the IPO, we had outstanding convertible promissory notes in an aggregate principal amount of $35.0 million that, together with accrued interest of $0.2 million, automatically converted into 1,957,755 shares of our common stock based on the IPO Price (as defined below).

Use of Proceeds

In August 2026, we completed our IPO, pursuant to which we issued and sold 22,080,000 shares of our common stock at a public offering price of $18.00 per share (IPO Price), including 2,880,000 additional shares of our common stock pursuant to the exercise in full by the underwriters of their option to purchase shares of common stock from us at the IPO Price. The offer and sale of all of the shares of our common stock in the IPO were registered under the Securities Act pursuant to our Registration Statement on Form S-1, as amended (File No. 333-297518) (Registration Statement), which was declared effective by the SEC on August 6, 2026. Goldman Sachs & Co. LLC, Jefferies LLC, Leerink Partners LLC and Guggenheim Securities, LLC acted as joint book-running managers for the IPO. Shares of our common stock began trading on The Nasdaq Global Select Market under the symbol "LTGO" on August 7, 2026.

We received gross proceeds from the IPO of approximately $397.4 million, which resulted in net proceeds of approximately $364.4 million, after deducting underwriting discounts and commissions and other offering expenses payable by us. None of the underwriting discounts and commissions or other offering expenses were incurred or paid, directly or indirectly, to any of our directors or officers or their associates or to persons owning 10% or more of our common stock or to any of our affiliates.

There has been no material change in the expected use of the net proceeds from our IPO as described in the Prospectus that forms a part of our Registration Statement, which was filed with the SEC on August 7, 2026 pursuant to Rule 424(b)(4).

Issuer Repurchases of Equity Securities

None.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Rule 10b5-1 Trading Arrangements

During the three months ended September 30, 2026, our directors and officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted, modified, or terminated trading plans for the orderly disposition of the Company's securities as set forth in the table below.

			Type of Trading Arrangement			
Name and Position	Action	Adoption / Termination Date	Rule 10b5-1(1)	Non-Rule 10b5-1(2)	Total Shares of Common Stock to be Sold	Expiration Date
Nima Farzan Former Director, President and Chief Executive Officer	Adoption	21-Aug-26	X		420,000(3)	31-Dec-27
Neha Krishnamohan Chief Financial Officer and Chief Business Officer	Adoption	21-Aug-26	X		68,600(3)	31-Dec-27

(1) Contract, instruction or written plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act.
(2) "Non-Rule 10b5-1 trading arrangement" as defined in Item 408(c) of Regulation S-K under the Exchange Act.
(3) Pursuant to the terms of a lock-up agreement entered into with the underwriters in connection with the Company's IPO, none of the securities subject to the trading arrangement will be transferred, sold or otherwise disposed of during the lock-up period, which expires after February 2, 2027.

Item 6. Exhibits

Exhibit number	Description of document	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
3.1	Amended and Restated Certificate of Incorporation.	8-K	8/10/2026	3.1	
3.2	Amended and Restated Bylaws.	S-1/A	8/03/2026	3.4	
4.1	Form of Common Stock Certificate.	S-1/A	8/03/2026	4.1	
4.2†	Amended and Restated Investors' Rights Agreement, dated January 28, 2025, by and among the Registrant and the investors named therein.	S-1	7/17/2026	4.2	
10.1	Form of Indemnification Agreement, between the Registrant and each of its directors and executive officers.	S-1	7/17/2026	10.1	
10.2*	Latigo Biotherapeutics, Inc. 2026 Equity Incentive Plan	S-8	8/10/2026	99.3	
10.3*	Forms of Stock Option Grant Notice, Option Agreement and Notice of Exercise under the Latigo Biotherapeutics, Inc. 2026 Equity Incentive Plan.	S-1	7/17/2026	10.5	
10.4*	Latigo Biotherapeutics, Inc. 2026 Employee Stock Purchase Plan.	S-8	8/10/2026	99.5	
10.5*	Non-Employee Director Compensation Policy.	S-1/A	8/03/2026	10.7	
10.6*	Latigo Biotherapeutics, Inc. Severance Plan.	S-1	7/17/2026	10.14	
10.7*	Executive Employment Agreement, dated July 15, 2026, between the Registrant and Nima Farzan.	S-1	7/17/2026	10.11	
10.8*	Executive Employment Agreement, dated July 15, 2026, between the Registrant and Neil Singla, M.D.	S-1	7/17/2026	10.12	
10.9*	Executive Employment Agreement, dated July 15, 2026, between the Registrant and Neha Krishnamohan.	S-1	7/17/2026	10.13	
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.				X
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.				X
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.				X
101.INS	Inline XBRL Instance Document				X
101.SCH	Inline XBRL Taxonomy Extension Schema With embedded Linkbase Documents				X
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)				X

* Indicates a management contract or any compensatory plan, contract or arrangement.

† Certain schedules and exhibits to this exhibit have been omitted pursuant to Item 601(a)(5) of Regulation S-K.

+ This certification is deemed not filed for purpose of section 18 of the Exchange Act or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

Signatures

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

LATIGO BIOTHERAPEUTICS, INC.

Date: November 5, 2026

By: /s/Todd N. Smith
Todd N. Smith
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 5, 2026

By: /s/ Neha Krishnamohan
Neha Krishnamohan
Chief Financial Officer and Chief Business Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Todd N. Smith, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Latigo Biotherapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (c) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 5, 2026

/s/ Todd N. Smith
Todd N. Smith
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Neha Krishnamohan, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Latigo Biotherapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (c) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 5, 2026

/s/ Neha Krishnamohan
Neha Krishnamohan
Chief Financial Officer & Chief Business Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Todd N. Smith, President and Chief Executive Officer of Latigo Biotherapeutics, Inc. (the "Company"), and Neha Krishnamohan, Chief Financial Officer and Chief Business Officer of the Company, each hereby certifies that, to the best of his or her knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2026, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

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

In Witness Whereof, the undersigned have set their hands hereto as of the 5th day of November, 2026.

/s/ Todd N. Smith
Todd N. Smith
President and Chief Executive Officer
(Principal Executive Officer)

/s/ Neha Krishnamohan
Neha Krishnamohan
Chief Financial Officer and Chief Business Officer
(Principal Financial Officer and Principal Accounting Officer)

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Latigo Biotherapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.