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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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: 001-43331

Parabilis Medicines, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**47-4505725**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
30 Acorn Park Drive Cambridge, MA	**02140**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 945-9510

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	PBLS	The Nasdaq Stock Market LLC

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of November 9, 2026, the registrant had 123,676,615 shares of common stock, $0.0001 par value per share, and 1,581,210 shares of non-voting common stock, $0.0001 par value per share, outstanding.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q (this "Quarterly Report") contains forward-looking statements. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements other than statements of historical facts, including statements regarding our future results of operations and financial position, business strategy, product candidates, planned nonclinical studies and clinical trials, results of nonclinical studies, clinical trials, research and development costs, regulatory approvals, commercial strategy, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. These statements involve known and unknown risks, uncertainties, and other important factors that are in some cases beyond our control and 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.

In some cases, forward-looking statements can be identified by terms such as "may," "will," "should," "would," "expect," "plan," "anticipate," "could," "intend," "target," "project," "believe," "estimate," "predict," "potential," or "continue" or the negative of these terms or other similar expressions. Forward-looking statements contained in this Quarterly Report may include, but are not limited to, statements about:

- the initiation, timing, progress and results of our research and development programs, nonclinical studies and clinical trials;
- the ability of clinical trials to demonstrate safety and efficacy of our product candidates, and other positive results, and the ability of our nonclinical studies to predict later clinical trial results;
- the timing, scope and likelihood of regulatory filings and approvals of our product candidates;
- the implementation of our business model, and strategic plans for our business, platform, programs, and current and future product candidates;
- our ability to obtain additional cash and the sufficiency of our existing cash and cash equivalents to fund our future operating expenses and capital expenditure requirements;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets;
- our potential and ability to successfully manufacture and supply our current and future product candidates for clinical trials and for commercial use, if approved;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates;
- developments relating to our competitors and our industry, including competing product candidates and therapies;
- existing regulations and regulatory developments in the United States and other jurisdictions;
- expectations regarding future events under collaboration and licensing agreements, including potential future payments, as well as our plans and strategies for entering into further collaboration and licensing agreements;
- general economic, industry and market conditions, including fluctuating interest rates and rising inflation;
- our ability to attract and retain the continued service of our key personnel and to identify, hire and then retain additional qualified personnel;
- our expectations regarding the period during which we will qualify as an EGC under the JOBS Act; and

- our anticipated use of our existing cash and cash equivalents, including the proceeds from our initial public offering and concurrent private placement.

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations and prospects, and these forward-looking statements are not guarantees of future performance or development. These forward-looking statements speak only as of the date of this Quarterly Report and are subject to a number of risks, uncertainties and assumptions described in "*Risk Factors*" and elsewhere in this Quarterly Report. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. No forward-looking statement is a guarantee of future performance. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events or otherwise. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, collaborations, joint ventures, or investments that we may make or enter into.

This Quarterly Report includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third-parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. We are responsible for all of the disclosure contained in this Quarterly Report, and we believe that these sources are reliable; however, we have not independently verified the information contained in such publications.

SUMMARY OF MATERIAL RISKS ASSOCIATED WITH OUR BUSINESS

Our business is subject to a number of risks of which you should be aware before making an investment decision. These risks include, but are not limited to, the following:

- We are a clinical-stage biotechnology company with a limited operating history and no products approved by regulators for commercial sale, which may make it difficult to evaluate our current and future business prospects.
- We will require substantial additional capital to finance our operations in the future. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce or eliminate programs, product candidates (including clinical trials), investment in our Helicon discovery platform, or future commercialization efforts.
- We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future.
- We are dependent on the success of our product candidates, including zolucatetide, and our ongoing and anticipated trials may not be successful.
- Some of our product candidates modulate pathways for which there are currently no approved or effective therapies, and utilize novel binding locations, which may result in greater research and development expenses, regulatory issues that could delay or prevent approval, or discovery of unknown or unanticipated adverse effects.
- Nonclinical and clinical development is inherently lengthy and uncertain. Nonclinical and clinical trials of our product candidates may be delayed, and certain programs may never advance into or through the clinic or may be more costly to conduct than we anticipate, any of which would have a material adverse impact on our business.
- We are conducting clinical trials for product candidates outside the United States, and Regulatory Authorities (as defined in the section titled "*Risk Factors*") may not accept data from such trials.
- If our clinical trials fail to replicate positive results from earlier nonclinical studies or clinical trials conducted by us or third parties, we may be unable to successfully develop, obtain regulatory approval for, or commercialize our product candidates.
- Interim, initial, topline, and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.
- Regulatory approval processes are lengthy, time-consuming, and inherently unpredictable, and if we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize, or will be delayed in commercializing, product candidates we may develop, and our ability to generate revenue will be materially impaired.
- Our approach to the engineering and development of our programs is unproven, and we may not be successful in our efforts to identify and develop any programs and product candidates of commercial value by leveraging our Helicon discovery platform.
- We are substantially dependent on the successful application of our Helicon discovery platform to develop programs and product candidates that can be commercialized by us or our current or future collaboration partners.
- Issues relating to our use of AI in the identification of our programs and the engineering and development of our product candidates could adversely affect our business and operating results.

- We rely on third parties for the supply and manufacture of our product candidates for our research, nonclinical and clinical activities, and may do the same for commercial supplies of our products, if approved.

- We depend on sole source and limited source suppliers for certain drug substances, drug products, raw materials, samples, components, and other materials used in our product candidates. If we are unable to source these supplies on a timely basis, or establish longer-term contracts with our suppliers, we will not be able to complete our clinical trials on time and the development of our product candidates may be delayed.

- We rely on and expect to continue to rely on third parties to conduct aspects of our research, nonclinical studies, clinical protocol development, and clinical trials for our programs and product candidates. If these third parties do not perform satisfactorily, comply with regulatory requirements or meet expected deadlines, we may not be able to develop product candidates in a timely or cost-effective manner, or obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

- Our success is largely based upon our intellectual property and proprietary technologies, and we may be unable to adequately protect and/or enforce our intellectual property.

- The biopharmaceutical market is intensely competitive. If we are unable to compete effectively with existing drugs, new treatment methods and new technologies, we may be unable to successfully commercialize any drugs that we develop.

- The price of our common stock may be volatile and fluctuate substantially, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations.

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

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

Parabilis Medicines, Inc.
Condensed Consolidated Balance Sheets
(in thousands, except share and per share amounts)
(unaudited)

	September 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 521,198	$ 27,711
Accounts receivable - related party	443	—
Marketable securities	350,425	—
Prepaid expenses and other current assets	6,953	1,647
Total current assets	879,019	29,358
Property and equipment, net	9,506	6,715
Restricted cash	2,855	2,855
Operating lease right-of-use assets	34,291	39,360
Marketable securities, non-current	201,309	—
Other assets	4,262	2,532
Total assets	$ 1,131,242	$ 80,820
Liabilities, convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 20,209	$ 17,272
Accrued expenses and other current liabilities	24,012	18,630
Operating lease liabilities, current portion	7,810	7,174
Deferred revenue, current portion	13,544	—
Finance lease liabilities, current portion	684	638
Term loan, net of discount	2,000	13,077
Total current liabilities	68,259	56,791
Operating lease liabilities, net of current portion	30,381	36,341
Finance lease liabilities, net of current portion	951	1,470
Deferred revenue, net of current portion	27,304	—
Other liabilities	—	2,742
Total liabilities	126,895	97,344
Commitments and contingencies (Note 11)		
Convertible preferred stock, $0.0001 par value; no shares and 53,296,426 shares authorized at September 30, 2026 and December 31, 2025, respectively; no shares and 53,296,426 shares issued and outstanding at September 30, 2026 and December 31, 2025, respectively (liquidation preference of $0 and $658,972 at September 30, 2026 and December 31, 2025, respectively)	—	509,971
Stockholders' equity (deficit):		
Preferred stock, $0.0001 par value; 10,000,000 shares and no shares authorized at September 30, 2026 and December 31, 2025, respectively; no shares issued and outstanding at September 30, 2026 and December 31, 2025	—	—
Common stock, $0.0001 par value; 600,000,000 and 81,000,000 shares authorized at September 30, 2026 and December 31, 2025, respectively; 122,076,506 and 2,035,357 shares issued and outstanding at September 30, 2026 and December 31, 2025, respectively	12	—
Non-voting common stock, $0.0001 par value; 200,000,000 shares and no shares authorized at September 30, 2026 and December 31, 2025, respectively; 1,581,210 shares and no shares issued and outstanding at September 30, 2026 and December 31, 2025, respectively	—	—
Additional paid-in capital	1,690,022	15,009
Accumulated other comprehensive loss	(1,913)	—
Accumulated deficit	(683,774)	(541,504)
Total stockholders' equity (deficit)	1,004,347	(526,495)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 1,131,242	$ 80,820

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

Parabilis Medicines, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Revenue:				
Collaboration revenue	$ 671	$ —	$ 819	$ —
Collaboration revenue - related party	1,443	—	1,443	—
Total revenue	2,114	—	2,262	—
Operating expenses:				
Research and development	45,597	28,199	122,727	92,230
General and administrative	11,253	6,646	32,610	19,376
Total operating expenses	56,850	34,845	155,337	111,606
Loss from operations	(54,736)	(34,845)	(153,075)	(111,606)
Other income (expense):				
Interest income	10,369	711	16,987	3,017
Interest expense	(124)	(398)	(626)	(1,193)
Sublease income - related party	—	1,057	—	3,171
Change in fair value of simple agreement for future equity	—	—	(5,556)	—
Total other income, net	10,245	1,370	10,805	4,995
Net loss	$ (44,491)	$ (33,475)	$ (142,270)	$ (106,611)
Cumulative dividends on convertible preferred stock	—	(10,395)	(32,181)	(30,360)
Deemed dividend upon down-round of convertible preferred stock	—	—	(7,875)	—
Net loss allocable to common stockholders	$ (44,491)	$ (43,870)	$ (182,326)	$ (136,971)
Net loss per share allocable to common stockholders, basic and diluted	$ (0.36)	$ (21.66)	$ (3.51)	$ (67.78)
Weighted average common shares outstanding, basic and diluted	123,593,149	2,025,284	51,962,288	2,020,689
Comprehensive loss:				
Net loss	$ (44,491)	$ (33,475)	$ (142,270)	$ (106,611)
Change in unrealized gains (losses) on marketable securities	(1,895)	—	(1,913)	(21)
Comprehensive loss	$ (46,386)	$ (33,475)	$ (144,183)	$ (106,632)

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

Parabilis Medicines, Inc.
Condensed Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)
(in thousands, except share amounts)
(unaudited)

	Convertible Preferred Stock		Common Stock		Non-Voting Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' (Deficit) Equity
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at December 31, 2024	**42,459,887**	**$ 440,375**	**2,017,588**	**$ —**	**—**	**$ —**	**$ 11,658**	**$ 21**	**$ (395,615)**	**$ (383,936)**
Issuance of Series E convertible preferred stock, inclusive of preferred stock tranche right liability of $2,167, net of issuance costs of $62	10,836,539	69,596	—	—	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	852	—	—	852
Change in unrealized gains (losses) on marketable securities	—	—	—	—	—	—	—	(16)	—	(16)
Net loss	—	—	—	—	—	—	—	—	(38,326)	(38,326)
Balance at March 31, 2025	**53,296,426**	**$ 509,971**	**2,017,588**	**$ —**	**—**	**$ —**	**$ 12,510**	**$ 5**	**$ (433,941)**	**$ (421,426)**
Issuance of common stock upon exercise of stock options	—	—	5,791	—	—	—	9	—	—	9
Stock-based compensation expense	—	—	—	—	—	—	823	—	—	823
Change in unrealized gains (losses) on marketable securities	—	—	—	—	—	—	—	(5)	—	(5)
Net loss	—	—	—	—	—	—	—	—	(34,810)	(34,810)
Balance at June 30, 2025	**53,296,426**	**$ 509,971**	**2,023,379**	**$ —**	**—**	**$ —**	**$ 13,342**	**$ —**	**$ (468,751)**	**$ (455,409)**
Issuance of common stock upon exercise of stock options	—	—	2,469	—	—	—	10	—	—	10
Stock-based compensation expense	—	—	—	—	—	—	820	—	—	820
Net loss	—	—	—	—	—	—	—	—	(33,475)	(33,475)
Balance at September 30, 2025	**53,296,426**	**$ 509,971**	**2,025,848**	**$ —**	**—**	**$ —**	**$ 14,172**	**$ —**	**$ (502,226)**	**$ (488,054)**

	Convertible Preferred Stock		Common Stock		Non-Voting Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' (Deficit) Equity
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at December 31, 2025	**53,296,426**	**$ 509,971**	**2,035,357**	**$ —**	**—**	**$ —**	**$ 15,009**	**$ —**	**$ (541,504)**	**$ (526,495)**
Issuance of common stock upon exercise of stock options	—	—	92,699	—	—	—	187	—	—	187
Issuance of Series F convertible preferred stock, net of issuance costs of $680	49,518,175	304,569	—	—	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	1,304	—	—	1,304
Net loss	—	—	—	—	—	—	—	—	(45,316)	(45,316)
Balance at March 31, 2026	**102,814,601**	**$ 814,540**	**2,128,056**	**$ —**	**$ —**	**$ —**	**$ 16,500**	**$ —**	**$ (586,820)**	**$ (570,320)**
Issuance of common stock upon exercise of stock options	—	—	328,614	—	—	—	584	—	—	584
Issuance of common stock in initial public offering, net of underwriting discounts and commissions and offering expenses of $57,612	—	—	38,525,000	4	—	—	712,884	—	—	712,888
Issuance of common stock in concurrent private placement	—	—	4,166,666	—	—	—	83,333	—	—	83,333
Conversion of convertible preferred stock into common stock and non-voting common stock	(102,814,601)	(814,540)	73,992,071	8	1,581,210	—	814,532	—	—	814,540
Conversion of simple agreement for future equity into common stock	—	—	2,777,777	—	—	—	55,556	—	—	55,556
Net exercise of warrants to purchase common stock	—	—	20,468	—	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	3,634	—	—	3,634
Change in unrealized gains (losses) on marketable securities	—	—	—	—	—	—	—	(18)	—	(18)
Net loss	—	—	—	—	—	—	—	—	(52,463)	(52,463)
Balance at June 30, 2026	**—**	**$ —**	**121,938,652**	**$ 12**	**1,581,210**	**$ —**	**$ 1,687,023**	**$ (18)**	**$ (639,283)**	**$ 1,047,734**
Issuance of common stock upon exercise of stock options	—	—	137,854	—	—	—	262	—	—	262
Stock-based compensation expense	—	—	—	—	—	—	2,737	—	—	2,737
Change in unrealized gains (losses) on marketable securities	—	—	—	—	—	—	—	(1,895)	—	(1,895)
Net loss	—	—	—	—	—	—	—	—	(44,491)	(44,491)
Balance at September 30, 2026	**—**	**$ —**	**122,076,506**	**$ 12**	**1,581,210**	**$ —**	**$ 1,690,022**	**$ (1,913)**	**$ (683,774)**	**$ 1,004,347**

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

Parabilis Medicines, Inc.
Condensed Consolidated Statements of Cash Flows
(in thousands)
(unaudited)

	Nine Months Ended September 30,	
	2026	2025
Cash flows from operating activities		
Net loss	$ (142,270)	$ (106,611)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,801	1,884
Accretion of discounts and amortization of premiums on marketable securities	(2,531)	609
Stock-based compensation expense	7,675	2,495
Non-cash interest expense	173	249
Non-cash lease expense	5,069	4,630
Change in fair value of simple agreement for future equity	5,556	—
Changes in operating assets and liabilities:		
Accounts receivable - related party	(443)	—
Rent receivable - related party	—	189
Due to related party	—	509
Due from related party	—	102
Prepaid expenses and other assets	(7,594)	11
Operating lease liabilities	(5,324)	(4,672)
Deferred revenue	40,848	—
Accounts payable, accrued expenses and other liabilities	3,139	3,826
Net cash used in operating activities	(93,901)	(96,779)
Cash flows from investing activities		
Purchases of marketable securities	(560,985)	(16,664)
Proceeds from maturities of marketable securities	9,869	56,728
Purchases of property and equipment	(1,596)	(183)
Net cash (used in) provided by investing activities	(552,712)	39,881
Cash flows from financing activities		
Proceeds from issuance of Series E convertible preferred stock and preferred stock tranche right liability	—	67,491
Proceeds from issuance of Series F convertible preferred stock	305,249	—
Payments of convertible preferred stock issuance costs	(680)	(62)
Proceeds from issuance of simple agreement for future equity	50,000	—
Proceeds from initial public offering, net of underwriting discounts and commissions	718,240	—
Payments of initial public offering costs	(5,352)	—
Proceeds from concurrent private placement of common stock	83,333	—
Principal payments on finance leases	(473)	(431)
Principal payments on debt	(11,250)	—
Proceeds from exercise of stock options	1,033	19
Net cash provided by financing activities	1,140,100	67,017
Increase in cash, cash equivalents and restricted cash	493,487	10,119
Cash, cash equivalents and restricted cash at beginning of period	30,566	50,139
Cash, cash equivalents and restricted cash at end of period	$ 524,053	$ 60,258
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 520	$ 947
Supplemental disclosure of non-cash investing and financing activities:		
Purchases of property and equipment included in accounts payable and accrued expenses	$ 3,056	$ 60
Conversion of convertible preferred stock into common stock and non-voting common stock	$ 814,540	$ —
Conversion of simple agreement for future equity into common stock	$ 55,556	$ —
Settlement of Series E preferred stock tranche right liability	$ —	$ 2,167

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

Parabilis Medicines, Inc.
Notes to Condensed Consolidated Financial Statements
(unaudited)

1. Nature of the Business and Basis of Presentation

Nature of Business

Parabilis Medicines, Inc. (the "Company") is a clinical-stage biopharmaceutical company developing medicines addressing some of the most consequential, yet historically undruggable, protein targets driving human disease. The Company leverages its platform to pioneer a therapeutic modality, Helicons, which are stabilized helical peptides engineered to bind and precisely modulate proteins. The Company was incorporated in Delaware on July 10, 2015. The Company is developing nonclinical and clinical drug candidates, primarily operates in the United States of America, and, to date, has devoted substantially all its efforts to research and development and fundraising activities.

Risk and Uncertainties

The Company is subject to risks and uncertainties common to clinical-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, and ability to secure additional capital to fund operations. Product candidates resulting from the Company's current discovery efforts will require significant additional research and development efforts, including extensive nonclinical and clinical testing and regulatory approval prior to commercialization. These efforts will require significant amounts of additional capital, adequate personnel, infrastructure, and extensive compliance reporting capabilities. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

Reverse Stock Split

On June 3, 2026, the Company effected a 1-for-1.5389 reverse stock split of its issued and outstanding shares of common stock and a proportional adjustment to the existing conversion ratios of each series of the Company's convertible preferred stock and the IPO Discount Price (see Note 10, *Simple Agreement for Future Equity*) of the Company's simple agreement for future equity ("SAFE"). Accordingly, all share and per share amounts for all periods presented in the accompanying condensed consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect this reverse stock split and adjustments of the convertible preferred stock conversion ratios and the IPO Discount Price for the SAFE.

Liquidity

The Company's condensed consolidated financial statements have been prepared on the basis of continuity of operations, the realization of assets and satisfaction of liabilities in the ordinary course of business. In June 2026, the Company closed its initial public offering ("IPO") pursuant to which it issued and sold 38,525,000 shares of common stock, inclusive of 5,025,000 shares of common stock sold pursuant to the underwriters' full exercise of their option to purchase additional common stock, at a public offering price of $20.00 per share. In addition, the Company issued and sold 4,166,666 shares of common stock to Regeneron Pharmaceuticals, Inc. ("Regeneron") in a concurrent private placement at a price per share of $18.00, or 90% of the public offering price. The aggregate net proceeds received by the Company from the IPO and concurrent private placement were $787.9 million, after deducting underwriting discounts and commissions and offering expenses of $57.6 million. Additionally, in June 2026, the Company received a non-refundable upfront payment in the amount of $50.0 million under its License and Collaboration Agreement (the "Regeneron Agreement") with Regeneron. Prior to the IPO, the Company received aggregate gross proceeds of $811.8 million from sales of convertible preferred stock, $15.0 million from borrowings under a term loan, and $50.0 million of gross proceeds from the issuance of a SAFE. The Company has incurred net losses and negative operating cash flows since inception and has an accumulated deficit of $683.8 million at September 30, 2026. The Company expects that its cash, cash equivalents and marketable securities will be sufficient to fund its operations for at least twelve months from the date these condensed consolidated financial statements were issued.

The Company will need additional financing to support its continuing operations and pursue its growth strategy. Until such time as the Company can generate significant revenue from product sales, if ever, the Company expects to finance its cash needs through a combination of equity offerings, debt or royalty financings, and collaborations. The Company may not be able to obtain financing on acceptable terms, or at all, and the Company may not be able to enter into collaborations or other arrangements. The terms of any financing may adversely affect the holdings or the rights of the Company's stockholders. If the Company is unable to raise additional funds through these sources or other sources of funding when needed, the Company could be forced to delay, reduce or eliminate its research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect its

business prospects. Although management continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, Parabilis Security Corporation and Parabilis Medicines (Shanghai) Ltd. Co. All intercompany accounts and transactions have been eliminated in consolidation.

The Company's unaudited condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP") for interim reporting and as required by Regulation S-X, Rule 10-01. Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

The condensed consolidated interim financial statements have been prepared on the same basis as the audited annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for a fair statement of the Company's financial position as of September 30, 2026, and the results of its operations for the three and nine months ended September 30, 2026 and 2025, and cash flows for the nine months ended September 30, 2026 and 2025. The condensed balance sheet as of December 31, 2025 was derived from audited annual financial statements but does not include all disclosures required by GAAP. The results of operations for the interim periods are not necessarily indicative of results to be expected for the year ending December 31, 2026, any other interim periods, or any future year or period.

2. Summary of Significant Accounting Policies

The Company's significant accounting policies are disclosed in Note 2 of the "Notes to Consolidated Financial Statements" in the audited annual financial statements included in the Company's final prospectus filed with the Securities and Exchange Commission (the "SEC") pursuant to Rule 424(b)(4) on June 10, 2026. During the nine months ended September 30, 2026, there were no material changes to the Company's significant accounting policies, except as discussed below.

Use of Estimates

The preparation of the Company's condensed consolidated financial statements in conformity with GAAP requires management to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported amounts of expenses during the reporting periods. Significant estimates reflected within these condensed consolidated financial statements include the estimated fair value of the Company's common stock utilized in the determination of stock-based compensation expense prior to the IPO, the determination of the incremental borrowing rate for leases, the estimated fair value of the convertible preferred stock and SAFE, revenue recognition, as well as accrued research and development expenses. On an ongoing basis, management evaluates its estimates as there are changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results may differ from those estimates or assumptions.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less at the date of purchase to be cash equivalents. The Company's cash equivalents consist of funds deposited in money market mutual funds, U.S. Treasury securities, and commercial paper and are recorded at fair value.

A reconciliation of the cash, cash equivalents, and restricted cash reported within the condensed consolidated balance sheets that sum to the total of the same amounts shown in the condensed consolidated statements of cash flows is as follows (in thousands):

	September 30,	
	2026	2025
Cash and cash equivalents	$ 521,198	$ 57,403
Restricted cash – long-term	2,855	2,855
Total cash, cash equivalents and restricted cash	$ 524,053	$ 60,258

Restricted Cash

As of September 30, 2026 and December 31, 2025, restricted cash consists of $2.9 million serving as collateral for a letter of credit required under the Company's facility lease arrangement.

Marketable Securities

The Company's marketable securities consist of investments in debt securities, including U.S. Treasury securities and commercial paper, with original maturities beyond three months at the date of purchase. Marketable securities with a remaining maturity date greater than one year are classified as non-current assets where the Company has the intent and ability to hold these securities for at least the next 12 months. The Company's marketable securities are classified as available-for-sale and are carried at fair value, with any unrealized gains or losses reported as a component of accumulated other comprehensive loss within stockholders' equity (deficit). Unrealized gains or losses are recorded in other comprehensive loss in the condensed consolidated statements of operations and comprehensive loss. Premiums and discounts on marketable securities are amortized and accreted, respectively, to earliest call date and maturity, respectively, and are included in interest income in the condensed consolidated statements of operations and comprehensive loss.

Marketable securities in an unrealized loss position are evaluated for impairment at least quarterly. For marketable securities in an unrealized loss position, the Company first assesses whether it intends to sell, or it is more likely than not that it will be required to sell the security before recovery of its amortized cost basis. If either of the criteria regarding intent or requirement to sell is met, the investment security's amortized cost basis is written down to fair value through net loss.

For marketable securities that do not meet the aforementioned criteria, the Company evaluates whether the decline in fair value has resulted from credit losses or other factors. In conducting this assessment for marketable securities in an unrealized loss position, management evaluates the extent to which fair value is less than amortized cost, any changes to the rating of the security by a rating agency, and adverse conditions specifically related to the security, among other factors.

If this assessment indicates that a credit loss exists, the present value of cash flows expected to be collected from the investment security are compared to the amortized cost basis of the security. If the present value of cash flows expected to be collected is less than the amortized cost basis, a credit loss exists and an allowance for credit losses is recorded for the credit loss, limited by the amount that the fair value is less than the amortized cost basis. Any unrealized loss that has not been recorded through an allowance for credit loss is recognized in other comprehensive loss. There were no credit losses recorded during the nine months ended September 30, 2026 and 2025.

Concentration of Risk

Financial instruments that potentially subject the Company to credit risk consist of cash and cash equivalents, and marketable securities. The Company's cash deposits generally do not exceed Federal Deposit Insurance Corporation ("FDIC") limits. The Company's cash equivalents consist of money market funds that are not insured by the FDIC; however, the Company has not experienced any losses in such accounts and believes that such funds are not exposed to any significant credit or concentration risk beyond the risks associated with commercial banking relationships. The Company maintains each of its cash and cash equivalents balances with financial institutions that management believes are creditworthy. The Company's investment policy includes guidelines on the quality of the financial institutions and financial instruments and defines allowable investments that the Company believes minimize exposure to concentration of credit risk. The Company's marketable securities consist of U.S. Treasury securities and commercial paper. The Company believes these investments present minimal credit risk.

The Company relies, and expects to continue to rely, on a small number of vendors and contract research organizations to manufacture certain supplies and raw materials for its research and development programs and to conduct clinical trials. These programs could be adversely affected by a significant interruption in these manufacturing services or the availability of raw materials, or an interruption in the provision of services provided by the Company's contract research organizations.

Stock-Based Compensation

The Company measures all stock options and other stock-based awards granted to employees, directors and non-employees based on the award's fair value on the date of the grant and recognizes compensation expense related to those awards over the requisite service period, which is generally the vesting period of the respective award. The Company primarily issues stock options with only service-based vesting conditions and records the expense for these awards using the straight-line method. To a lesser extent, the Company has also granted awards with either service and performance-based vesting conditions or market and performance-based vesting conditions, and records expense based on the grant-date fair value over the requisite service period using the accelerated

attribution method if the achievement of the performance condition is considered probable. At each reporting date, the Company estimates the probability that specified performance criteria will be achieved and does not begin to recognize compensation expense until it is probable that the performance-based vesting condition will be achieved.

The Company classifies stock-based compensation expense in its condensed consolidated statements of operations and comprehensive loss in the same manner in which the award recipient's payroll costs or service payments are classified.

The fair values of stock options with only service-based or performance-based conditions are estimated using the Black-Scholes option-pricing model. Prior to the IPO, the Company's board of directors (the "Board of Directors") determined the fair value of the Company's common stock, with input from management, considering the Company's most recently available third-party valuations of common stock, as well as additional factors which may have changed since the date of the most recent valuation through the date of grant. Subsequent to the completion of the IPO, the fair value of the Company's common stock underlying its stock options is based on the quoted market price of the Company's common stock on the grant date. The expected volatility of the Company's stock options is based upon the historical volatility of a set of publicly-traded peer companies, as there is limited stock price data available for the Company's common stock since the IPO. The Company will continue to apply this process until sufficient historical information regarding the volatility of its own stock price becomes available. The expected term of the Company's stock options granted has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options, which is presumed to be the midpoint between the vesting date and the end of the contractual term. If vesting is subject to a performance condition, the expected term is based on the mid-point between the explicit service period and the contractual term of the option. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. The expected dividend yield is zero, because the Company has never paid cash dividends on common stock and does not expect to pay any such dividends in the foreseeable future. The Company accounts for forfeitures of share-based compensation awards as they occur.

Revenue Recognition

The Company enters into license and collaboration agreements which are within the scope of ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606"), under which the Company licenses rights to its technology and certain of the Company's drug candidates and performs research and development services for third parties. The terms of these arrangements typically include payment of one or more of the following: non-refundable, up-front fees; reimbursement of research and development costs; development, regulatory and commercial milestone payments; and royalties on net sales of licensed products.

Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine the appropriate amount of revenue to be recognized for arrangements determined to be within the scope of ASC 606, the Company performs the following five steps: (i) identification of contract(s) with a customer; (ii) identification of the performance obligations; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. The Company only applies the five-step model to contracts when it is probable that the Company will collect consideration to which it is entitled in exchange for the goods or services it transfers to the customer.

The promised goods or services in the Company's arrangements typically consist of license rights to the Company's intellectual property and research and development services. The Company also has optional additional items in contracts, which are considered marketing offers and are accounted for as separate contracts with the customer if such option is elected by the customer, unless the option provides a material right which would not be provided without entering into the contract. Performance obligations are promised goods or services in a contract to transfer a distinct good or service to the customer. Promised goods or services are considered distinct when (i) the customer can benefit from the good or service on its own or together with other readily available resources and (ii) the promised good or service is separately identifiable from other promises in the contract. In assessing whether promised goods or services are distinct, the Company considers factors such as the stage of development of the underlying intellectual property, the capabilities of the customer to develop the intellectual property on their own and the availability of the required expertise.

The Company estimates the transaction price based on the amount expected to be received for transferring the promised goods or services in the contract. The consideration may include both fixed consideration and variable consideration. At the inception of each arrangement that includes variable consideration and at each reporting period, the Company evaluates the amount of potential payment and the likelihood that the payments will be received. The Company utilizes either the most likely amount method or expected value method to estimate the amount expected to be received based on which method better predicts the amount of consideration to which the Company will be entitled. If it is probable that a significant revenue reversal would not occur, the variable consideration is included in the transaction price.

The Company's contracts often include development, regulatory and commercial milestone payments. At contract inception and at each reporting period, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's control or the licensee's control, such as regulatory approvals, are not included in the transaction price. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such development milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect license, collaboration and other revenues and earnings in the period of adjustment.

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue resulting from its license and collaboration arrangements.

The Company allocates the transaction price based on the estimated standalone selling price of the underlying performance obligations or in the case of certain variable consideration to one or more performance obligations. The Company must develop assumptions that require judgment to determine the standalone selling price for each performance obligation identified in the contract. The Company utilizes key assumptions to determine the standalone selling price, which may include other comparable transactions, pricing considered in negotiating the transaction and the estimated costs to complete the respective performance obligation. Certain variable consideration is allocated specifically to one or more performance obligations in a contract when the terms of the variable consideration relate to the satisfaction of the performance obligation and the resulting amounts allocated to each performance obligation are consistent with the amounts the Company would expect to receive for each performance obligation.

For performance obligations consisting of licenses and other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company will recognize revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license.

The Company receives payments from its customers based on billing schedules established in each contract. Up-front payments and fees are recorded as a contract liability (deferred revenue) upon receipt or when due until the Company performs its obligations under these arrangements. Amounts are recorded as accounts receivable when the right to consideration is unconditional and only the passage of time is required before payment is due. If the right to consideration is subject to a condition other than the passage of time, then the amount is recorded as a contract asset until the right to payment becomes unconditional. In accordance with ASC 606, the Company presents contract assets and contract liabilities on a net basis by customer contract.

Deferred Offering Costs

The Company capitalizes certain legal, professional, accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of the equity financing, these costs are recorded as a reduction of the proceeds from the offering, either as a reduction of the carrying value of the convertible preferred stock or in stockholders' equity (deficit) as a reduction of additional paid-in capital. Should the planned equity financing be abandoned, the deferred offering costs are expensed immediately as a charge to operating expenses in the condensed consolidated statements of operations and comprehensive loss. At the closing of the IPO, a total of $5.4 million of deferred offering costs were reclassified to additional paid-in capital within stockholders' equity (deficit). As such, no deferred offering costs were capitalized as of September 30, 2026. As of December 31, 2025, the Company had $0.6 million of deferred offering costs included in other assets on the condensed consolidated balance sheets.

Net Loss Per Share

Basic net loss per common share is calculated by dividing net loss adjusted for cumulative dividends on convertible preferred stock accrued during the period, whether or not declared, and the value of any deemed dividends resulting from down-round adjustments to convertible preferred stock, where applicable, 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 is computed by dividing the net loss allocable to common stockholders by the weighted-average number of shares of common stock and potentially dilutive securities

outstanding for the period. For purposes of the diluted net loss per share calculation, the convertible preferred stock, common stock warrants, preferred stock tranche rights, stock options, and SAFE are considered potentially dilutive securities.

Basic and diluted net loss allocable to common stockholders per share is presented in conformity with the two-class method required for participating securities as all series of convertible preferred stock and SAFE are considered participating securities. The Company's participating securities do not have a contractual obligation to share in the Company's losses. As such, the net loss was attributed entirely to common stockholders.

Following the closing of the IPO, the Company has two series of common stock outstanding comprised of voting common stock and non-voting common stock. The rights of the holders of voting common stock and non-voting common stock are identical, except with respect to voting and conversion. Each share of non-voting common stock may be converted into one share of voting common stock at any time at the option of the holder, subject to certain beneficial ownership limitations. Net loss per share for each series of common stock issued is the same as they are entitled to the same liquidation and dividend rights.

Segment Information

Operating segments are defined as components of an enterprise for which separate and discrete information is available for evaluation by the chief operating decision-maker ("CODM"), in deciding how to allocate resources and assess performance. The Company's CODM, its chief executive officer, manages the Company's operations on a consolidated basis for the purpose of allocating resources. All of the Company's long-lived assets are held in the United States. Refer to Note 16, *Segment Reporting*, for further disclosure regarding the Company's segment information.

Recently Issued Accounting Pronouncements Not Yet Adopted

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by the Company as of the specified effective date. The Company qualifies as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 and has elected not to "opt out" of the extended transition related to complying with new or revised accounting standards, which means that when a standard is issued or revised and it has different application dates for public and non-public companies, the Company can adopt the new or revised standard at the time non-public companies adopt the new or revised standard and can do so until such time that the Company either (i) irrevocably elects to "opt out" of such extended transition period or (ii) no longer qualifies as an emerging growth company. The Company may choose to adopt any new or revised accounting standards early whenever such early adoption is permitted for non-public companies.

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses* ("ASU 2024-03"). ASU 2024-03 requires disclosure of disaggregated information about certain income statement expense line items on an annual and interim basis, including purchases of inventory, employee compensation, depreciation, intangible asset amortization and depletion for each income statement line item that contains those expenses. ASU 2024-03 also requires certain amounts already disclosed under existing GAAP to also be disclosed as a separate category in disaggregated expense tables, if those amounts are recognized in the relevant expense line item. The amendments in ASU 2024-03 will be effective for the Company in annual reporting periods beginning after December 15, 2026, and interim reporting periods within annual reporting periods beginning after December 15, 2027, with early adoption permitted. The standard may be applied prospectively or retrospectively. The Company is currently evaluating the impact of adopting ASU 2024-03.

Recently Adopted Accounting Pronouncements

In May 2025, the FASB issued ASU No. 2025-04*, Compensation—Stock Compensation (Topic 718) and Revenue from Contracts with Customers (Topic 606): Clarifications to Share-Based Consideration Payable to a Customer* ("ASU 2025-04"), which requires that a grantor apply the guidance in ASC Topic 718, *Compensation—Stock Compensation* ("ASC 718") to measure and classify share-based consideration payable to a customer. The amended guidance also requires a reporting entity to assess if share-based consideration payable to a customer contains vesting conditions, including whether or not those vesting conditions represent service conditions or performance conditions. During the three months ended June 30, 2026, the Company early adopted this standard on a modified retrospective basis effective January 1, 2026. The adoption of ASU 2025-04 did not have a material impact on the condensed consolidated financial statements.

3. Fair Value Measurements

The carrying values of cash, accounts receivable - related party, prepaid expenses and other current assets, accounts payable, and accrued expenses and other current liabilities approximate their fair values due to their short-term nature. The carrying value of the Company's term debt (refer to Note 9, *Term Loan*) approximates its fair value due to its time to maturity.

The following tables present information about the Company's financial assets measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values (in thousands):

	Fair Value Measurements as of September 30, 2026:			
	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents:				
Money market funds	$ 489,638	$ —	$ —	$ 489,638
U.S. Treasury securities	—	5,987	—	5,987
Commercial paper	—	24,473	—	24,473
Marketable securities, current:				
U.S. Treasury securities	—	130,472	—	130,472
Commercial paper	—	219,953	—	219,953
Marketable securities, non-current:				
U.S. Treasury securities	—	201,309	—	201,309
Total assets	$ 489,638	$ 582,194	$ —	$ 1,071,832

	Fair Value Measurements as of December 31, 2025:			
	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents:				
Money market funds	$ 27,133	$ —	$ —	$ 27,133
Total assets	$ 27,133	$ —	$ —	$ 27,133

During the nine months ended September 30, 2026 and 2025, there were no transfers among the Level 1, Level 2 and Level 3 categories.

Money market funds are classified within Level 1 of the fair value hierarchy as they are highly liquid investments based on a quoted price with a net asset value of $1 per share.

The fair values of the Company's marketable securities are based on prices obtained from independent pricing sources. Marketable securities with validated quotes from pricing services are reflected within Level 2 of the fair value hierarchy as they are primarily based on observable pricing for similar assets or other market observable inputs. Typical inputs used by these pricing services include, but are not limited to, reported trades, benchmark yields, issuer spreads, bids, offers or estimates of cash flow, prepayment spreads and default rates.

The following table summarizes the gross unrealized gains and losses of the Company's marketable securities (in thousands):

	September 30, 2026			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Marketable securities, current:				
U.S. Treasury securities	$ 130,698	$ —	$ (226)	$ 130,472
Commercial paper	220,360	—	(407)	219,953
Total marketable securities, current	351,058	—	(633)	350,425
Marketable securities, non-current:				
U.S. Treasury securities	202,589	5	(1,285)	201,309
Total marketable securities, non-current	202,589	5	(1,285)	201,309
Total marketable securities	$ 553,647	$ 5	$ (1,918)	$ 551,734

The following table summarizes the estimated fair value and gross unrealized losses for the Company's marketable securities in a loss position (in thousands):

	September 30, 2026	
	Less than 12 Months	
	Fair Value	Unrealized Losses
U.S. Treasury securities	$ 326,920	$ (1,511)
Commercial paper	216,609	(407)
Total	$ 543,529	$ (1,918)

The Company does not intend to sell such securities and it is not more likely than not that it will be required to sell them before recovery of their amortized cost basis. The Company held no marketable securities as of December 31, 2025.

As of September 30, 2026 and December 31, 2025, there was no allowance for credit losses recorded on the Company’s condensed consolidated balance sheets.

Valuation of Preferred Stock Tranche Right Liability

The preferred stock tranche right liability represented the fair value of an obligation to issue shares of Series E convertible preferred stock. The fair value of the preferred stock tranche right liability was determined based on significant inputs not observable in the market, which represented a Level 3 measurement within the fair value hierarchy.

The Company estimated the fair value of the preferred stock tranche right liability at the time of issuance and subsequently remeasured its fair value at each reporting period and prior to settlement.

As of December 31, 2024, in light of the near-term completion of the Series E convertible preferred stock second closing in January 2025, the fair value of the preferred stock tranche right liability was determined based on the difference between the estimated fair value of the Series E convertible preferred stock, or $6.43 per share, and its contractual purchase price, or $6.23 per share. The Company estimated the fair value per share of the underlying Series E convertible preferred stock by taking into consideration the results obtained from third-party valuations which included the most recent sales of its preferred stock, market conditions and trends since the last preferred stock issuance.

The following table presents changes in the aggregate fair value of the Company’s Series E preferred stock tranche right liability (in thousands):

	Amount
Balance as of December 31, 2024	$ 2,167
Settlement of Series E preferred stock tranche right liability	(2,167)
Balance as of September 30, 2025	$ —

Valuation of Simple Agreement for Future Equity

On March 27, 2026, the Company issued a SAFE to an investor (refer to Note 10, *Simple Agreement for Future Equity*). The SAFE was accounted for as a liability and represented a Level 3 measurement within the fair value hierarchy.

The fair value of the SAFE upon issuance was determined to be equal to the proceeds received of $50.0 million. In connection with the IPO, the SAFE automatically converted into 2,777,777 shares of common stock based on the IPO Discount Price (see Note 10, *Simple Agreement for Future Equity*) of $18.00 per share in June 2026. The fair value of the SAFE upon conversion was determined to be $55.6 million based on the fair value of the common stock issued upon conversion.

The following table presents changes in the aggregate fair value of the SAFE (in thousands):

	Amount
Balance as of December 31, 2025	$ —
Fair value of SAFE at issuance	50,000
Change in fair value of SAFE	5,556
Conversion of SAFE into common stock	(55,556)
Balance as of September 30, 2026	$ —

4. Property and Equipment, Net

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

	September 30, 2026	December 31, 2025
Laboratory equipment	$ 14,516	$ 13,830
Leasehold improvements	5,009	4,563
Computer equipment	609	307
Furniture and fixtures	936	697
Assets not yet in service	3,004	131
Property and equipment	24,074	19,528
Less: accumulated depreciation and amortization	(14,568)	(12,813)
Property and equipment, net	$ 9,506	$ 6,715

Included in laboratory equipment are finance lease right-of-use assets with a cost basis of $2.9 million as of September 30, 2026 and December 31, 2025, and accumulated amortization expense of $1.1 million and $0.7 million as of September 30, 2026 and December 31, 2025, respectively.

During each of the three months ended September 30, 2026 and 2025, depreciation and amortization expense amounted to $0.6 million, which includes $0.1 million of finance lease right-of-use asset amortization in each period. During the nine months ended September 30, 2026 and 2025, depreciation and amortization expense amounted to $1.8 million and $1.9 million, respectively, which includes $0.4 million of finance lease right-of-use asset amortization in each period.

5. Accrued Expenses and Other Current Liabilities

The following table summarizes accrued expenses and other current liabilities (in thousands):

	September 30, 2026	December 31, 2025
Accrued employee compensation and benefits	$ 8,328	$ 9,079
Accrued research and development expenses	11,088	8,334
Accrued offering costs	—	491
Other	4,596	726
Total	$ 24,012	$ 18,630

6. Convertible Preferred Stock

On January 6, 2026, the Company entered into the Series F Preferred Stock Purchase Agreement (the "Series F Agreement") and issued to certain investors an aggregate of 49,518,175 shares of Series F convertible preferred stock (the "Series F Preferred Stock") at a purchase price of $6.16 per share for gross proceeds of $305.2 million. The gross proceeds were offset by $0.7 million of issuance costs.

In accordance with the terms of the Company's certificate of incorporation, the issuance of the Series F Preferred Stock triggered adjustments to the respective conversion prices of the Series A convertible preferred stock (the "Series A Preferred Stock"), the Series B convertible preferred stock (the "Series B Preferred Stock"), the Series C convertible preferred stock (the "Series C Preferred Stock"), the Series D convertible preferred stock (the "Series D Preferred Stock") and the Series E convertible preferred stock (the "Series E Preferred Stock") (as described further below). As a result, the Company recorded an increase to additional paid-in capital and a deemed dividend of $7.9 million which is equal to the change in fair value of the Series A Preferred Stock, Series B Preferred Stock, Series C Preferred Stock, Series D Preferred Stock and Series E Preferred Stock due to the triggering of the down-round feature. As the Company did not have retained earnings at the time the Series F Preferred Stock was issued, the deemed dividend was charged against additional paid-in capital resulting in no net impact to additional paid-in capital. The fair value of each preferred share class was determined using a "with-and-without" model under which the equity value of the Company was allocated using a hybrid method, whereby the equity value in the IPO scenario was allocated to each class of shares using the fully-diluted shares outstanding and whereby the equity value in the non-IPO scenario was allocated using an option-pricing model to reflect the full distribution of possible non-IPO outcomes, both before and after the adjustment to the respective conversion price. The following table summarizes the significant Level 3 unobservable inputs used to estimate the fair value of the Series A Preferred Stock, Series B Preferred Stock, Series C Preferred Stock, Series D Preferred Stock and Series E Preferred Stock at the Series F Preferred Stock issuance date:

	January 6, 2026
Expected volatility	78.0%
Expected dividend yield	—
Expected term (in years)	0.85 - 2.5
Risk-free interest rate	3.6%

Upon the issuance of each series of convertible preferred stock, the Company assessed the embedded conversion and liquidation features of the securities and determined that the Company was not required to separately account for these features.

Convertible preferred stock consisted of the following at December 31, 2025 (in thousands, except share and per share amounts):

	Shares of Preferred Stock Authorized	Original Issuance Price Per Share	Shares of Preferred Stock Issued and Outstanding	Carrying Value	Liquidation Preference	Shares of Common Stock Issuable Upon Conversion
Series A	1,434,062	$ 7.75	1,434,062	$ 14,914	$ 19,477	1,002,805
Series B	4,658,112	$ 14.06	4,658,112	65,388	106,351	4,069,102
Series C	7,384,710	$ 14.49	7,384,710	106,674	152,175	6,540,022
Series D	16,537,979	$ 10.76	16,537,979	177,581	225,956	12,669,755
Series E	23,281,563	$ 6.23	23,281,563	145,414	155,013	15,128,745
	53,296,426		53,296,426	$ 509,971	$ 658,972	39,410,429

Upon the closing of the IPO in June 2026, each series of convertible preferred stock was converted into common stock and non-voting common stock, as follows:

	Shares of Common Stock Issued Upon Conversion	Shares of Non-Voting Common Stock Issued Upon Conversion
Series A	1,062,074	—
Series B	4,839,338	—
Series C	7,811,705	—
Series D	14,493,574	—
Series E	15,188,963	—
Series F	30,596,417	1,581,210
	73,992,071	1,581,210

7. Stockholders' Equity (Deficit)

Common Stock Warrants

The Company issued common stock warrants as part of the Loan Agreement (refer to Note 9, *Term Loan*) which were determined to be a freestanding instrument and met the criteria for equity classification as they are indexed to the Company's own common stock and settled in a fixed number of shares for a fixed exercise price, with no cash settlement feature. As of December 31, 2025, warrants to purchase 24,152 shares of common stock with an exercise price of $4.82 per share were outstanding. In June 2026, the warrants were net exercised resulting in the issuance of 20,468 shares of common stock and no cash proceeds to the Company.

Common Stock and Non-Voting Common Stock

As of September 30, 2026, the Company's certificate of incorporation authorized the issuance of 600,000,000 shares of common stock, 200,000,000 shares of non-voting common stock, and 10,000,000 shares of undesignated preferred stock, each with a par value of $0.0001 per share. As of September 30, 2026, 122,076,506 shares of common stock and 1,581,210 shares of non-voting common stock were outstanding.

In June 2026, the Company completed its IPO. In connection with the IPO, the Company issued and sold 38,525,000 shares of its common stock at a public offering price of $20.00 per share, including 5,025,000 shares of common stock sold pursuant to the underwriters' full exercise of their option to purchase additional shares of common stock. As a result, the Company received $712.9 million in net proceeds, after deducting underwriting discounts and commissions and offering expenses of $57.6 million.

In connection with the IPO, the Company issued and sold 4,166,666 shares of its common stock in a concurrent private placement to Regeneron at a price per share of $18.00, or 90% of the public offering price, and received proceeds of $75.0 million (see Note 12, *Collaboration Agreements*).

In connection with the IPO, the SAFE automatically converted into 2,777,777 shares of common stock at a price per share of $18.00, or 90% of the public offering price (see Note 10, *Simple Agreement for Future Equity*).

The voting, dividend and liquidation rights of the holders of common stock and non-voting common stock are subject to and qualified by the rights, powers, and preferences of the holders of any outstanding preferred stock. Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Holders of non-voting common stock are not entitled to any votes per share of non-voting common stock. Holders of common stock and non-voting common stock are entitled to receive dividends, as may be declared by the Board of Directors, if any, subject to the preferential dividend rights of holders of all series of any outstanding preferred stock. As of September 30, 2026, the Company has neither declared nor paid any dividends. Each share of non-voting common stock may be converted into one share of voting common stock at any time at the option of the holder, subject to certain beneficial ownership limitations.

The Company has reserved shares of common stock for the conversion or exercise of the following securities:

	September 30, 2026	December 31, 2025
Series A Preferred Stock	—	1,002,805
Series B Preferred Stock	—	4,069,102
Series C Preferred Stock	—	6,540,022
Series D Preferred Stock	—	12,669,755
Series E Preferred Stock	—	15,128,745
Common stock warrants	—	24,152
Outstanding stock options	15,431,906	9,098,233
Unissued stock-based awards under the 2016 Employee, Director and Consultant Equity Incentive Plan	—	1,097,518
Unissued stock-based awards under the 2026 Stock Option and Incentive Plan	11,013,929	—
Unissued stock-based awards under the 2026 Employee Stock Purchase Plan	1,110,000	—
Total	27,555,835	49,630,332

8. Stock-Based Compensation

2016 Employee, Director and Consultant Equity Incentive Plan

The Company's 2016 Employee, Director and Consultant Equity Incentive Plan, as amended (the "2016 Plan"), provides for the Company to sell or award restricted common stock or to grant incentive and nonqualified stock options for the purchase of common stock (or other stock-based awards) to its founders, employees, officers, directors and consultants.

As of December 31, 2025, 10,826,224 shares of common stock were authorized and reserved for issuance under the 2016 Plan. The remaining shares reserved for issuance under the 2016 Plan ceased to be available for issuance at the time the January 2026 Plan was adopted. There will be no further awards granted under the 2016 Plan, but all outstanding awards under the 2016 Plan will continue to be governed by the 2016 Plan.

2026 Stock Option and Grant Plan

On January 6, 2026, the Board of Directors adopted and the Company's stockholders approved the 2026 Stock Option and Grant Plan (the "January 2026 Plan"). The January 2026 Plan provides for the grant of incentive stock options, nonqualified stock options, restricted stock awards and other stock-based awards to the Company's officers, employees, directors, consultants, and other key persons.

The number of shares of common stock authorized and reserved for issuance under the January 2026 Plan was initially 8,873,223 shares. The remaining shares reserved for issuance under the January 2026 Plan ceased to be available for issuance at the time the 2026 Plan became effective. There will be no further awards granted under the January 2026 Plan, but all outstanding awards under the January 2026 Plan will continue to be governed by the January 2026 Plan.

2026 Stock Option and Incentive Plan

In May 2026, the Board of Directors adopted, and in June 2026 the Company's stockholders approved, the 2026 Stock Option and Incentive Plan (the "2026 Plan"), which became effective in June 2026. The 2026 Plan provides for the grant of incentive stock options, nonqualified stock options, restricted stock units and other stock-based awards to the Company's officers, employees, directors and consultants.

The number of shares of common stock authorized and reserved for issuance under the 2026 Plan was initially 11,070,000 shares. The 2026 Plan provides that the number of shares reserved and available for issuance under the 2026 Plan will automatically increase on January 1, 2027 and each January 1 thereafter during the term of the 2026 Plan, by (i) 5% of the sum of (A) the number of shares of common stock issued and outstanding on the immediately preceding December 31, (B) the number of shares underlying the Company's outstanding preferred stock (determined on an as-converted basis) on the immediately preceding December 31, and (C) the number of shares of common stock issuable pursuant to the exercise of any outstanding pre-funded warrants on the immediately preceding December 31, or (ii) such lesser number of shares as determined by the compensation committee of the Board of Directors.

The shares of common stock underlying any awards under the 2026 Plan, the January 2026 Plan and 2016 Plan that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by the Company prior to vesting, satisfied without the issuance of stock, expire, or are otherwise terminated (other than by exercise) will be added back to the shares of common stock available for issuance under the 2026 Plan. As of September 30, 2026, there were 11,013,929 shares available for future issuance under the 2026 Plan.

Upon stock option exercise, the Company delivers newly issued shares to the participant. Stock option vesting typically occurs over four years for employees and directors and is at the discretion of the Board of Directors. Stock options typically have a maximum term of ten years.

2026 Employee Stock Purchase Plan

In May 2026, the Board of Directors adopted, and in June 2026 the Company's stockholders approved, the 2026 Employee Stock Purchase Plan (the "ESPP"), which became effective in June 2026. A total of 1,110,000 shares of common stock were initially reserved for issuance under the ESPP. The ESPP provides that the number of shares reserved and available for issuance will automatically increase on January 1, 2027 and each January 1 thereafter through January 1, 2036, by the least of (i) 1,110,000 shares of common stock, (ii) 1% of the sum of (A) the number of shares of common stock issued and outstanding on the immediately preceding December 31, (B) the number of shares underlying the Company's outstanding preferred stock (determined on an as-converted basis) on the immediately preceding December 31, and (C) the number of shares of common stock issuable pursuant to the exercise of any outstanding pre-funded warrants on the immediately preceding December 31, or (iii) such lesser number of shares of common stock as determined by the administrator of the ESPP. As of September 30, 2026, there were 1,110,000 shares available for future issuance under the ESPP.

Stock Option Valuation

The fair value of each stock option granted was estimated on the date of grant using the Black-Scholes option-pricing model and the assumptions summarized in the following table:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Expected volatility	74.50% - 79.93%	91.99%	74.50% - 90.15%	91.99% - 93.00%
Expected dividend yield	—	—	—	—
Expected term (in years)	5.77 - 6.08	6.25	5.50 - 6.25	6.25
Risk-free interest rate	4.28% - 4.63%	3.66%	3.70% - 4.63%	3.66% - 4.04%
Fair value of common stock	$29.20 - $39.77	$2.42	$3.14 - $39.77	$2.42

The following table presents a summary of all stock option activity:

	Shares	Weighted-Average Exercise Price per Share	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2025	9,098,233	$ 2.64	7.72	$ 3,386
Granted	7,797,574	5.22		
Exercised	(559,167)	1.85		
Canceled or forfeited	(904,734)	2.47		
Outstanding at September 30, 2026	15,431,906	$ 3.98	8.04	$ 437,968
Vested and expected to vest at September 30, 2026	15,431,906	$ 3.98	8.04	$ 437,968
Vested and exercisable at September 30, 2026	6,998,217	$ 2.97	6.85	$ 205,193

The weighted-average grant date fair values of stock options granted during the nine months ended September 30, 2026 and 2025 were $3.89 and $1.88 per share, respectively. The intrinsic values of stock options exercised were $7.3 million and less than $0.1 million during the nine months ended September 30, 2026 and 2025, respectively.

Total unrecognized compensation expense related to unvested stock options was approximately $27.2 million as of September 30, 2026, which the Company expects to recognize over a weighted-average period of approximately 2.9 years.

Total unrecognized compensation expense related to unvested stock options with a market condition was approximately $0.1 million as of September 30, 2026, which the Company expects to recognize over a weighted-average period of approximately 0.5 years.

In May 2026, the Company entered into an advisory agreement with a former member of its Board of Directors following the individual's resignation. Pursuant to the agreement, the Company granted the former board member an option to purchase 71,479 shares of common stock and provided for the continued vesting and exercisability of existing stock option awards. The Company concluded that the advisory services are not substantive for accounting purposes and recognized $1.1 million of stock-based compensation expense, representing the grant-date fair value of the new award, and $0.5 million related to the modification of the existing awards. The amounts are included in general and administrative expenses in the condensed consolidated statements of operations and comprehensive loss during the nine months ended September 30, 2026.

Stock-Based Compensation Expense

The following table presents the classification of stock-based compensation expense included in the Company's condensed consolidated 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	$ 985	$ 184	$ 2,173	$ 588
General and administrative	1,752	636	5,502	1,907
Total	$ 2,737	$ 820	$ 7,675	$ 2,495

9. Term Loan

On September 21, 2021, the Company entered into a Loan and Security Agreement with Silicon Valley Bank (the "Lender"), which was subsequently amended (the "Loan Agreement"), which provided for aggregate term loans of $15.0 million. In connection with the Loan Agreement, the Company also issued common stock warrants to the Lender (refer to Note 7, *Stockholders' Equity (Deficit)*).

On November 22, 2024, the Company and the Lender executed an amendment to the Loan Agreement under which the Lender extended the term loan amortization date to April 1, 2025 and added two interest-only extension events that could further extend the term loan amortization date. The amendment also required the Company to maintain the lesser of $60.0 million or 50% of the Company's consolidated cash within the Company's primary operating account with the Lender. The amendment was accounted for as a debt modification, rather than an extinguishment, as the difference in the present value of the cash flows under the terms of the original debt agreement and the terms immediately after the amendment was less than 10%. As a result, issuance costs paid to the Lender in connection with the amendment, which were not significant, were recorded as a reduction of the carrying amount of the debt liability. Unamortized issuance costs as of the date of the modification are amortized to interest expense using the effective interest method through the loan maturity date.

Term loan balances, including final payments, are summarized as follows (in thousands):

	September 30, 2026	December 31, 2025
Total term loan principal	$ 1,250	$ 12,500
Final payments	750	647
Unamortized debt discount and issuance costs	—	(70)
Term loan, net of discount	$ 2,000	$ 13,077

The term loan matured and was fully paid on October 1, 2026.

For the nine months ended September 30, 2026 and 2025, the effective interest rate of the term loan was 8.8% during each period.

10. Simple Agreement for Future Equity

On March 27, 2026, the Company issued a SAFE to an investor for gross proceeds of $50.0 million. The SAFE had no interest rate or maturity date. The SAFE investor had no voting rights prior to conversion, and if the Company paid a dividend on outstanding shares of its common stock while the SAFE was outstanding, the investor would have also received a dividend.

The SAFE was automatically convertible into the number of shares of common stock obtained by dividing (i) $50.0 million by (ii) the IPO Discount Price upon the closing of an IPO. The "IPO Discount Price" in connection with an IPO was the offering price in the IPO (the "IPO Price") multiplied by 90% (such product, the "Initial IPO Discount Price"), provided that (i) if the IPO Price was greater than or equal to $9.4864 per share, and (ii) the Initial IPO Discount Price was equal to or less than $9.4864 per share, then the IPO Discount Price would have equaled $9.4864 per share; and provided further that if the IPO Price was less than $9.4864, the IPO Discount Price would have equaled the IPO Price. The SAFE was also automatically convertible into preferred stock or common stock upon an equity financing other than an IPO based on similar conversion terms and discount rate.

The Company concluded the SAFE was a freestanding financial instrument that required liability classification pursuant to the guidance in ASC Topic 480, *Distinguishing Liabilities from Equity,* as it embodied a conditional obligation to issue a variable number of shares based predominantly on a fixed monetary amount known at inception. The SAFE was initially recorded at fair value upon the issuance date, with subsequent changes in fair value recorded in the condensed consolidated statements of operations and comprehensive loss through the settlement date. The fair value of the SAFE at issuance was $50.0 million. In connection with the IPO, the SAFE automatically converted into 2,777,777 shares of common stock based on the IPO Discount Price of $18.00 per share. The fair value of the SAFE upon conversion was determined to be $55.6 million based on the fair value of the common stock issued upon conversion. The change in fair value of the SAFE of $5.6 million was recognized in other income (expense) during the three months ended June 30, 2026.

11. Commitments and Contingencies

Harvard Agreement

In August 2017, the Company entered into a license agreement, as amended (the "Harvard Agreement"), with the President and Fellows of Harvard College ("Harvard"), to obtain a worldwide, exclusive, royalty-bearing license to certain intellectual property which was developed by the Company's founder.

Under the terms of the Harvard Agreement, the Company is required to make payments to Harvard upon the achievement of certain development, regulatory and sales milestones up to an aggregate of $18.3 million, as well as future royalty payments, based on a percentage of aggregate net sales ranging in the low single digits. In addition, the Company is required to make payments to Harvard for non-royalty income received under sublicenses or strategic partnerships with third parties, with the applicable payment based on the stage of development of the first licensed product at the time the Company enters into such agreement (before or after enrollment of the first patient in a Phase 2 clinical study of a licensed product), ranging from a single-digit percentage to a mid-teens percentage. During the year ended December 31, 2025, the Company met one milestone of $0.2 million which is included in accounts payable on the condensed consolidated balance sheet as of December 31, 2025 and which the Company paid during the nine months ended September 30, 2026. As of September 30, 2026, the Company has achieved milestones totaling $0.3 million under the Harvard Agreement. None of the remaining milestones were deemed probable of achievement as of September 30, 2026.

The Company is also required to pay a low six-digit annual maintenance fee for the duration of the Harvard Agreement, which can be credited against future royalty payments.

Legal Proceedings

From time to time, the Company may become involved in legal proceedings or other litigation relating to claims arising in the ordinary course of business. The Company accrues a liability for such matters when it is probable that future expenditures will be made and that such expenditures can be reasonably estimated. Legal fees and other costs associated with such proceedings are expensed as incurred. As of September 30, 2026 and December 31, 2025, the Company was not a party to any material legal proceedings or claims.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into

indemnification agreements with members of its Board of Directors that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not aware of any indemnification arrangements that could have a material effect on its financial position, results of operations or cash flows, and it has not accrued any liabilities related to such obligations in its condensed consolidated financial statements as of September 30, 2026 and December 31, 2025.

12. Collaboration Agreements

Research Collaboration Agreement with ARTBIO, Inc.

In May 2024, the Company entered into a research collaboration agreement with ARTBIO, Inc. ("ARTBIO") to co-develop multiple Helicon-enabled alpha particle radioligand therapies (HEARTs) for the treatment of cancer. Under the terms of this agreement, the Company is responsible for equally participating on joint committees and carrying out at least four research programs with respect to each collaboration target. The Company and ARTBIO share in the costs of the research programs equally, with ARTBIO responsible for funding the first $10.0 million of development costs incurred by both parties and the Company responsible for funding the next $10.0 million of development costs. Any further development costs beyond these initial funding amounts will also be shared equally by both parties. Under certain circumstances, either party can terminate the agreement, or opt out of further participation in any research programs, and the Company may be obligated to refund, to ARTBIO, amounts received during the initial funding periods, such that the total costs incurred through the effective date of termination would be shared equally.

Upon later regulatory approval and commercialization of related product(s), the parties will share equally in all net profits or losses. The agreement expires upon (1) the date on which products arising from the collaboration are no longer commercialized or developed for commercialization, or (2) termination by one or both parties.

The Company determined the agreement was a collaboration arrangement under ASC Topic 808, *Collaborative Arrangements*. The agreement provides for the parties to jointly oversee and actively participate in the research and development activities under the agreement. In addition, both parties are exposed to the significant risks and potential rewards under the agreement.

No costs were incurred by the Company during the three and nine months ended September 30, 2026 or during the three months ended September 30, 2025. During the nine months ended September 30, 2025, the Company incurred $2.4 million in costs related to the research programs within the scope of the agreement, which have been fully reimbursed by ARTBIO. Pursuant to the contract termination and funding provisions noted above, and based on the current development plan, the Company recorded a liability representing its portion of the research and development expense incurred to date. No increase in the liability balance was recorded during the three and nine months ended September 30, 2026 or during three months ended September 30, 2025. During the nine months ended September 30, 2025, the Company recorded an increase to the liability of $1.4 million. The Company recorded the remaining amount of $1.0 million as a reduction of research and development expenses within the condensed consolidated statements of operations and comprehensive loss for the nine months ended September 30, 2025. As of September 30, 2026 and December 31, 2025, the liability balance totaled $2.7 million and is classified in accrued expenses and other current liabilities and other liabilities, respectively, on the condensed consolidated balance sheets.

On April 16, 2026, ARTBIO sent notice of its intent to opt out of all the research programs under the research collaboration agreement. On May 26, 2026, the Company sent a notice of termination of the research collaboration agreement to ARTBIO. No eligible costs were incurred by the Company or ARTBIO during the nine months ended September 30, 2026.

License and Collaboration Agreement with Regeneron

On May 15, 2026, the Company entered into the Regeneron Agreement with Regeneron to discover, develop, and commercialize Helicons, with a particular focus on Antibody-Helicon Conjugates ("AHCs"), directed to a set of specified targets (each, a "Collaboration Target").

Under the terms of the Regeneron Agreement and during the research term for each Collaboration Target, the Company will perform certain research and nonclinical development activities, including screening, generating, testing and evaluating new Helicons and AHCs directed to such Collaboration Target (each, a "Product"). Under the Regeneron Agreement, there are five initial Collaboration Targets, with Regeneron having the right to replace up to two targets for no additional consideration and the option to nominate up to five additional Collaboration Targets, subject to an additional option payment from Regeneron. For one initial Collaboration Target, Regeneron may add one or more additional programs with respect to such Collaboration Target, subject to payment of additional program fees. Following Regeneron's nomination of a Product to be a "Licensed Product" during the research term for the applicable Collaboration Target (including additional Collaboration Targets), Regeneron has the sole right to advance

through development, manufacturing and worldwide commercialization of Licensed Products, including clinical and regulatory strategy, pricing, and promotion.

Under the terms of the Regeneron Agreement, Regeneron agreed to make a $50.0 million upfront payment, which the Company received in June 2026, and invest $75.0 million in the Company's next equity financing if such financing occurred prior to the second anniversary of the execution of the Regeneron Agreement (the "Regeneron Equity Commitment"). The IPO triggered Regeneron's $75.0 million equity investment whereby Regeneron purchased 4,166,666 shares of common stock in a concurrent private placement at a per share price equal to 90% of the public offering price, or $18.00 per share. For the initial Collaboration Targets, the Company is eligible to receive: (i) up to $470.0 million in development milestone payments; (ii) up to $575.0 million in regulatory milestone payments; (iii) up to $1.15 billion in commercial milestone payments; and (iv) tiered royalty payments, ranging in the high single digits to low double digits during the period commencing upon the first commercial sale of such Licensed Product in a given country and expiring on the latest of: (a) expiration of the last valid claim of a royalty term-extending patent right of such Licensed Product in such country, (b) 12 years after the first commercial sale of such Licensed Product in such country, and (c) loss of regulatory exclusivity for such Licensed Product in such country, subject to customary reductions.

Under the terms of the Regeneron Agreement, the Company is subject to an exclusivity obligation for each Collaboration Target until the last to expire royalty term for Licensed Products directed to such Collaboration Target. Unless earlier terminated pursuant to its terms, the Regeneron Agreement will remain in effect until the expiration of the last royalty term for the last Licensed Product under the Regeneron Agreement. Regeneron has the right to terminate the Regeneron Agreement for convenience and for certain violations of the Company's exclusivity covenants.

The Company determined that the Regeneron Agreement represents a contract with a customer within the scope of ASC 606. ASC 606 requires that share based consideration granted to a customer in connection with a revenue transaction be accounted for under ASC 718. More specifically, the discount associated with the Regeneron Equity Commitment of $8.3 million was accounted for in accordance with the guidance in ASC 718 and was recognized as a reduction of the ASC 606 transaction price upon the completion of the Company's IPO. The Company recorded the common stock issued in conjunction with the Regeneron Equity Commitment at its fair value of $83.3 million.

The Company identified the following promises under the agreement: (i) exclusive licenses granted to Regeneron for each Collaboration Target (the "Exclusive License") and (ii) nonclinical research and development services for each Collaboration Target (the "Research Services"). In addition, the Company concluded that Regeneron's right to replace up to two Collaboration Targets (each, a "Replacement Collaboration Target") for no additional consideration represents material rights under the agreement.

The Company concluded that the Exclusive License and Research Services for each Collaboration Target should be combined into one performance obligation as the licenses are not capable of being distinct. Regeneron can only benefit from the license with the services to be provided by the Company which are specialized in nature. Further, the specialized services, which include the Company's expertise using its Helicon platform to identify potential binding sites and Helicons that are capable of binding to such sites, further modify and enhance the exclusive license such that the exclusive license is not distinct in the context of the contract. As such, the Company has identified five performance obligations related to each of the five Collaboration Targets that include the combined obligation to provide an exclusive license and research services and two performance obligations related to the material right to replace two Collaboration Targets.

The transaction price, which subsequent to the recognition of the Regeneron Equity Commitment is $41.7 million, was allocated to the performance obligations on a relative selling price basis. As of September 30, 2026, the aggregate amount of the transaction price allocated to unsatisfied or partially unsatisfied performance obligations was $40.8 million. The Company expects to recognize this amount as collaboration revenue through at least 2029, although the timing of recognition will depend on the performance of the research services and the exercise or expiration of the replacement-target rights.

The Company determined the estimated standalone selling price for each Exclusive License and Research Services performance obligation using a discounted cash flow model that determined the present value of the probability weighted cash inflows and outflows associated with each Collaboration Target. The Company determined the estimated standalone selling price for material rights by estimating the incremental costs to perform the additional services and estimating the probability the replacement right will be exercised. For sales-based milestones and royalties, the Company will recognize revenue when the underlying product revenue is recognized by Regeneron. All other contingent payments are fully constrained as of September 30, 2026, as the achievement of the milestones underlying such contingent payments is based on either the Company or Regeneron's ability to execute under the research plans, which is not certain at contract inception.

Revenue associated with the Exclusive License and Research Services performance obligations is recognized as the underlying services are provided as control is transferred over time. The Company measures progress based on the amount of costs incurred relative to the total costs expected to fulfill the combined performance obligation. In management's judgment, this input method is the best measure of progress towards satisfying the combined performance obligation and reflects a faithful depiction of the transfer of goods and services. Revenue associated with the material rights will be recognized upon expiry if the option is not exercised. The

amounts allocated to the material rights, if exercised, will be recognized over the period of performance of the underlying performance obligations.

During the three and nine months ended September 30, 2026, the Company recognized revenue of $0.7 million and $0.8 million, respectively. Deferred revenue as of September 30, 2026 was $40.8 million, of which $13.5 million was recorded as a current liability on the condensed consolidated balance sheet.

Research Collaboration and Option Agreement with Altos Labs, Inc.

In August 2026, the Company entered into a research collaboration and option agreement with Altos Labs, Inc. ("Altos"), a related party, to conduct certain nonclinical research and development and activities to design and generate a Helicon peptide directed to a specified target (refer to Note 13, *Related Party Transactions*). Pursuant to the agreement, the Company will research and develop potential compounds during the research period that will be evaluated for potential further development by Altos during a defined evaluation period. Altos has the option to negotiate a license agreement in good faith during a defined negotiation period.

The Company received a $1.0 million up-front fully refundable and creditable payment from Altos and is entitled to receive reimbursement for all internal and external costs incurred by the Company to perform the nonclinical research and development activities under the agreement subject to an agreed upon cap. The upfront payment will offset any payments due from Altos to reimburse the Company for its costs incurred, including the pre-effective date activities under the agreement.

The Company determined the transaction represented a contract with a customer within the scope of ASC 606. The Company concluded the agreement contains one performance obligation, the performance of nonclinical research and development services. The transaction price, which consists entirely of variable consideration related to the expected reimbursement of all internal and external costs incurred by the Company inclusive of an applicable profit margin in its performance under the agreement, was estimated using the most likely amount method. Revenue associated with the performance obligation is recognized as services are provided as control is transferred over time. The Company measures progress based on the amount of costs incurred relative to the total costs expected to fulfill the performance obligation. During the three and nine months ended September 30, 2026, the Company recognized revenue of $1.4 million which is reflected in collaboration revenue – related party on the condensed consolidated statements of operations and comprehensive loss. During the three months ended September 30, 2026, the upfront payment was fully applied against amounts owed by Altos for the Company's performance of the services under the agreement, including the pre-effective date costs incurred. As of September 30, 2026, the Company recorded accounts receivable – related party of $0.4 million on the condensed consolidated balance sheet.

13. Related Party Transactions

Sublease Arrangement

In December 2019, the Company entered into a non-cancelable sublease arrangement with a related party to sublease approximately 50% of the Company's leased space at 30 Acorn Park Drive in Cambridge, Massachusetts through February 2025. In January 2024, the Company and the sublessee amended the sublease arrangement to extend the sublease date through December 2025. The sublessee is considered a related party due to common board members and stockholders. The related party was required to make lease payments and payments for its proportionate share of related occupancy costs to the Company. The sublease expired in December 2025.

The Company recorded sublease income of $1.1 million and $3.2 million for the three and nine months ended September 30, 2025, respectively. In addition, the Company received payments from the related party of $0.5 million and $1.6 million during the three and nine months ended September 30, 2025, respectively, representing the related party's share of occupancy costs. Of the amounts received, $0.5 million and $1.5 million were recorded as a reduction of research and development expense for the three and nine months ended September 30, 2025, respectively, and less than $0.1 million and $0.1 million was recorded as a reduction of general and administrative expense for the three and nine months ended September 30, 2025, respectively, in the condensed consolidated statements of operations and comprehensive loss.

Research Collaboration and Option Agreement with Altos

As further described in Note 12, *Collaboration Agreements*, the Company entered into a research collaboration and option agreement in August 2026 with Altos to conduct certain research, nonclinical development and manufacturing activities to design and generate a Helicon peptide directed to a specified target. Altos is considered a related party due to a member of the Company's Board of Directors also being an operating executive of the entity.

14. Net Loss Per Share

The following table sets forth the outstanding shares of common stock equivalents, presented based on amounts outstanding at each period end, which were excluded from the calculation of diluted net loss per share allocable to common stockholders for the periods indicated because including them would have been anti-dilutive:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Series A Preferred Stock	—	1,002,805	—	1,002,805
Series B Preferred Stock	—	4,069,102	—	4,069,102
Series C Preferred Stock	—	6,540,022	—	6,540,022
Series D Preferred Stock	—	12,669,755	—	12,669,755
Series E Preferred Stock	—	15,128,745	—	15,128,745
Common stock warrants	—	24,152	—	24,152
Outstanding stock options	15,012,400	8,710,026	15,012,400	8,710,026
Total	15,012,400	48,144,607	15,012,400	48,144,607

The amounts of outstanding stock options in the table above for the three and nine months ended September 30, 2026 and 2025 exclude 419,506 potentially dilutive securities as these outstanding stock options relate to contingently issuable shares for which the market condition was not satisfied as of the respective period end.

15. Retirement Plan

The Company has a U.S. tax-qualified employee savings and retirement 401(k) plan, covering all qualified employees. Participants may elect a salary deferral up to the statutorily prescribed annual limit for tax-deferred contributions. The Company may make matching contributions to each eligible participant's account based on a percentage of the participant's elective deferral contribution. Matching contributions amounted to $0.3 million and $0.2 million for three months ended September 30, 2026 and 2025, respectively, and $1.1 million and $0.9 million for the nine months ended September 30, 2026 and 2025, respectively.

16. Segment Reporting

The Company manages its operations as a single operating and reportable segment that is focused on developing Helicon medicines targeting historically undruggable proteins. The CODM manages the Company's operations on a consolidated basis and uses consolidated net loss to assess financial performance and allocate resources. Consolidated net loss is used by the CODM to make key operating decisions, such as the determination of the rate at which the Company seeks to grow its research and development initiatives and the allocation of capital between research and development and general and administrative expenses. The CODM does not review assets in evaluating the results of the segment, and therefore, such information is not presented.

The following table presents selected financial information with respect to the Company's single operating segment (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Revenue:				
Collaboration revenue	$ 671	$ —	$ 819	$ —
Collaboration revenue - related party	1,443	—	1,443	—
Operating expenses:				
External research and development expense - Zolucatetide	17,844	8,153	43,611	30,677
External research and development expense - ß-Catenin Degrader	614	44	1,829	956
External research and development expense - ERG	1,237	1,475	6,119	4,957
External research and development expense - AR^{ON}	1,944	1,020	5,309	2,636
External research and development expense - Early discovery and other programs	1,500	1,324	3,515	3,563
Other research and development expenses	8,549	7,672	24,518	21,706
Personnel-related research and development expenses (excluding stock-based compensation expense)	12,368	7,741	33,962	25,350
Personnel-related general and administrative expenses (excluding stock-based compensation expense)	2,551	2,166	8,147	6,829
Other general and administrative expenses	6,904	3,818	18,851	10,553
Depreciation and amortization expense	602	612	1,801	1,884
Stock-based compensation expense	2,737	820	7,675	2,495
Other segment items[(1)]	(10,245)	(1,370)	(10,805)	(4,995)
Consolidated net loss	$ (44,491)	$ (33,475)	$ (142,270)	$ (106,611)

Notes

(1) Other segment items consist of interest income, interest expense, sublease income – related party, and change in fair value of simple agreement for future equity.

17. Subsequent Events

Lease Amendment

On October 30, 2026, the Company entered into an amendment (the "Lease Amendment") with the landlord of its leased space at 30 Acorn Park Drive in Cambridge, Massachusetts (the "Existing Premises"). Under the Lease Amendment, the Company agreed to extend the lease term of the Existing Premises from February 28, 2031 to December 31, 2037.

Additionally, the Company agreed to lease approximately 33,525 square feet of additional office, research and manufacturing space at 20 Acorn Drive in Cambridge, Massachusetts with the same landlord (the "Expansion Premises"). The Expansion Premises are expected to be delivered to the Company no later than January 1, 2028 and base rent will commence on January 1, 2029. The Expansion Premises will be co-terminus with the lease for the Existing Premises.

Total additional aggregate base rent payments related to the extension of the Existing Premises and the Expansion Premises will be approximately $91.6 million and will be payable beginning in 2029 through 2037. Additionally, the Company shall not be obligated to pay base rent for the Existing Premises for a period of 8 months as designated by the landlord prior to February 28, 2031.

Further, under the terms of the Lease Amendment, the landlord agreed to provide the Company a tenant improvement allowance of up to approximately $8.5 million to be used toward the Existing Premises and Expansion Premises. The Company shall also have two five-year renewal options to extend the Existing Premises and Expansion Premises.

Clinical Collaboration Agreement with Revolution Medicines, Inc.

On November 11, 2026, the Company entered into a Clinical Collaboration Agreement (the "RevMed Agreement") with Revolution Medicines, Inc. ("RevMed") to evaluate the Company's lead investigational Helicon peptide, zolucatetide, in combination with RevMed's zoldonrasib and a third-party compound (cetuximab) in a Phase 1/2 trial for patients with previously treated RAS G12D mutant microsatellite stable metastatic colorectal cancer. The Company will sponsor and conduct the study. The Company will supply zolucatetide, and RevMed will supply zoldonrasib. All other costs will be equally shared by the Company and RevMed.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes and other financial information included elsewhere in this Quarterly Report and with our audited financial statements and the notes thereto for the year ended December 31, 2025 included in our final prospectus dated June 10, 2026 filed with the Securities and Exchange Commission pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to our plans and strategy for our business, includes forward-looking statements based upon our current plans and expectations that involve risks, uncertainties and assumptions, such as statements regarding our plans, strategies, objectives, expectations, intentions and beliefs. As a result of many factors, including those factors set forth in the "Cautionary Note Regarding Forward-Looking Statements" and "Risk Factors" sections included elsewhere in this Quarterly Report, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical-stage biopharmaceutical company built to develop transformative medicines addressing some of the most consequential, yet historically undruggable, protein targets driving human disease. We leverage our proprietary platform to pioneer a novel therapeutic modality, Helicons, which are stabilized helical peptides engineered to bind and precisely modulate proteins that have long been beyond the reach of conventional medicines.

To our knowledge, our lead product candidate, zolucatetide, is the first-ever drug to directly target the interaction between β-catenin and the T-cell factor ("TCF") family of transcription factors. This is the central node in the Wnt/β-catenin cell signaling pathway which regulates cell proliferation and differentiation and whose hyperactivation is a driver of millions of cancer cases annually across many tumor types. Drugging this critical node eluded three decades of intensive efforts to do so across the pharmaceutical industry. Zolucatetide has generated promising clinical data in a range of solid tumors driven by alterations in the Wnt/β-catenin pathway. We presented updated desmoid tumor data as of our June 22, 2026 data cut at the European Society for Medical Oncology (ESMO) Congress 2026. Among response-evaluable patients who began treatment at a starting dose of ≥450 mg, zolucatetide demonstrated an objective response rate (ORR) of 72.2% (13/18) in a 32-week landmark analysis.

Objective responses have been observed across patients who have failed γ-secretase inhibitors ("GSIs") and those who have never taken GSIs. Importantly, zolucatetide has been able to generate this rate of response with a tolerability profile that we believe is more favorable than that of currently available drug therapy. We plan to initiate a global registrational Phase 3 trial for zolucatetide in patients with desmoid tumors in the first half of 2027 with topline results anticipated in 2029.

We believe zolucatetide provides clinical validation of our first-in-industry Helicon approach and represents an expansive opportunity for medical and commercial impact. Our nonclinical pipeline provides additional examples of the repeatability of our Helicon approach and includes programs targeting two key drivers of prostate cancer, the ETS-related gene ("ERG") and the androgen receptor in its active state ("AR^{ON}"). Our current pipeline is focused on various cancers and tumor types; however, we believe Helicons could also have broad applicability against targets in many diseases with substantial unmet need outside oncology, and we plan to evaluate other therapeutic areas in the future.

An estimated 80% of biologically validated disease targets are considered undruggable, largely because the majority reside inside cells and present flat interaction surfaces. Small molecules can enter cells but cannot bind flat surfaces, and antibodies and other highly-selective biologics can selectively bind flat protein surfaces but cannot enter cells to access these targets. To our knowledge, Helicons are the only modality to date that can consistently solve this problem as they are engineered for cell penetration and capable of binding to flat intracellular protein target surfaces with high specificity. Helicons combine the precision of antibodies and biologics with the intracellular access and tunability of small molecules in a single modality – enabling direct engagement of historically inaccessible protein targets. Our proprietary Helicon discovery platform allows us to integrate ligands and additional functionalities at multiple positions to precisely tune potency, selectivity, and pharmacologic properties. While our initial programs are focused on disrupting protein-protein interactions and inducing targeted protein degradation, we believe our platform can incorporate other advances in small molecule drug design and extend them to targets that are likely to remain out of reach for other modalities.

Our Helicon discovery platform integrates advanced artificial intelligence ("AI") and physics-based computational modeling with high-throughput peptide synthesis and experimental screening to discover and develop drug candidates. Since our founding, we have advanced computational models as well as custom design, synthesis, handling and manufacturing know-how to position us to produce Helicons reliably and at scale. A decade of applying these capabilities to Helicon drug discovery has generated vast proprietary datasets, comprising millions of data points for hundreds of thousands of Helicons across dozens of drug-like properties. These data power a continuous learning loop that refines our models from target selection through lead optimization, enhancing our

speed, precision, and ability to generate high quality molecules against difficult targets. As a result, our platform produces unique complex synthetic molecules at scale and a compounding advantage that we believe is difficult to replicate.

We are advancing a wholly-owned pipeline of Helicon-based product candidates against high-value targets.

In May 2026, we entered into a license and collaboration agreement (the "Regeneron Agreement") with Regeneron Pharmaceuticals, Inc. ("Regeneron") to discover, develop, and commercialize Helicons, with a particular focus on Antibody-Helicon Conjugates ("AHCs"), directed to a set of specified targets. Under the terms of the Regeneron Agreement, Regeneron agreed to make a non-refundable upfront payment in the amount $50.0 million, which we received in June 2026, and a commitment to invest $75.0 million in our then next equity financing, subject to certain conditions. We are also eligible to receive milestone payments for development, regulatory and commercial milestones, as well as tiered royalties up to the low double-digits on future net sales of any approved medicines resulting from the collaboration. With five initial targets, the Regeneron Agreement provides the potential for up to approximately $2.2 billion in total milestone payments to us. Under the terms of the Regeneron Agreement, additional targets may be pursued upon additional option payments from Regeneron. For more information on the Regeneron Agreement, see the section titled "*License and Collaboration Agreements*" below.

In June 2026, we closed our initial public offering ("IPO") pursuant to which we issued and sold 38,525,000 shares of common stock, inclusive of 5,025,000 shares of common stock sold pursuant to the underwriters' full exercise of their option to purchase additional common stock, at a public offering price of $20.00 per share. In addition, we issued and sold 4,166,666 shares of common stock to Regeneron in a concurrent private placement at a price per share of $18.00, or 90% of the public offering price, pursuant to Regeneron's equity commitment under the Regeneron Agreement. The aggregate net proceeds received by us from the IPO and concurrent private placement were $787.9 million, after deducting underwriting discounts and commissions and offering expenses of $57.6 million. Prior to the IPO, we received aggregate gross cash proceeds of $876.8 million, including $811.8 million from sales of our convertible preferred stock, $15.0 million from borrowings under our term loan and $50.0 million from the issuance of a Simple Agreement for Future Equity ("SAFE").

We have incurred significant operating losses since inception and we expect to continue to incur substantial losses for the foreseeable future. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our product candidates and any additional product candidates we may develop. Our net losses were $44.5 million and $33.5 million for the three months ended September 30, 2026 and 2025, respectively, and $142.3 million and $106.6 million for the nine months ended September 30, 2026 and 2025, respectively. As of September 30, 2026, we had an accumulated deficit of $683.8 million.

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

- expand the number of our development programs;
- continue or expand our scope of research or development of our current programs and product candidates in nonclinical development;
- continue or expand the scope of our clinical trials for our product candidates;
- initiate additional nonclinical, clinical or other studies or trials for our programs and product candidates, including pursuant to our licensing and collaboration arrangements;
- change or add additional manufacturers or suppliers;
- add additional infrastructure to our quality control and quality assurance groups to support our operations as we progress our product candidates toward commercialization;
- attract and retain skilled personnel;
- create additional infrastructure to support our operations as a public company and our product development and planned future commercialization efforts;
- seek marketing approvals and reimbursement for our product candidates and products;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- acquire or in-license technologies;
- make payments under any in-license agreements;

- maintain, protect and expand our intellectual property portfolio; and
- experience any delays or encounter issues with any of the above.

We will not generate revenue from product sales unless and until we successfully initiate and complete clinical development and obtain regulatory approval for one or more of our product candidates, which may not occur for several years, if at all. If we obtain regulatory approval for any of our product candidates and do not enter into a commercialization partnership, we expect to incur significant expenses related to developing our commercialization capability to support product sales, manufacturing, marketing, market access and distribution.

Our net losses may fluctuate significantly from period to period, depending on the timing of our planned clinical trials and expenditures related to our research and development activities. Furthermore, we expect to continue to incur additional costs associated with operating as a public company, including significant audit, legal, and regulatory expenses, as well as director and officer insurance premiums and investor relations costs that we did not incur as a private company prior to the IPO. As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of equity offerings, debt or royalty financings, and collaborations, strategic alliances, and marketing, distribution or licensing arrangements with third parties. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. Our failure to raise capital or enter into such agreements or arrangements as, and when, needed, could have a material adverse effect on our business, results of operations, and financial condition, including requiring us to delay, reduce or eliminate product development or future commercialization efforts, or grant rights to develop and market development product candidates that we would otherwise prefer to develop and market ourselves.

As there are 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 achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

As a result, we will need substantial additional capital to support our continuing operations and pursue our strategy. As of September 30, 2026, we had total cash, cash equivalents and marketable securities of $1,072.9 million. We believe that our existing cash, cash equivalents and marketable securities will enable us to fund our operating expenses and capital expenditure requirements into 2030. See the section titled "*—Liquidity and Capital Resources*" below and Note 1 to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report.

Components of Results of Operations

Collaboration Revenue

For the foreseeable future, we expect substantially all of our revenues to be generated from the Regeneron Agreement and the research collaboration and option agreement with Altos Labs, Inc. ("Altos"), a related party. For more information on the Regeneron Agreement and the research collaboration and option agreement with Altos, see the section titled "*License and Collaboration Agreements*" below and Note 12 to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report. We have not generated any product revenue. We do not expect to generate any revenue from product sales unless and until we successfully complete development and obtain regulatory approval for one or more of our product candidates, which may not occur for several years, if at all. If our development efforts for our product candidates are successful and result in regulatory approval or we successfully enter into collaboration or license agreements with third parties, we may generate revenue in the future from product sales, or payments from such collaboration or license agreements, or any combination thereof.

Operating Expenses

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

Research and Development

Research and development expenses consist primarily of costs incurred in connection with the research and development of our programs. These expenses include:

- external expenses, including expenses incurred under arrangements with third parties, such as contract research organizations ("CROs"), contract manufacturing organizations ("CMOs"), consultants and our clinical and scientific advisors;

- personnel-related costs, including salaries, bonuses, benefits, and stock-based compensation for employees engaged in research and development functions;
- expenses incurred for the procurement of materials, third-party license fees, laboratory supplies and non-capital equipment used in the research and development process; and
- depreciation, amortization and other direct and allocated expenses, including rent, insurance, maintenance of facilities and other operating costs, incurred as a result of our research and development activities.

We expense research and development costs as incurred. We recognize external development costs based on an evaluation of the progress to completion of specific deliverables using information provided to us by our vendors. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in our consolidated financial statements as prepaid expenses or accrued research and development expenses. Significant judgments and estimates are made in determining the prepaid or accrued expense balances at the end of any reporting period. Non-refundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

We use our personnel and infrastructure resources for our research and development efforts, including the advancement and development of our product candidates and managing external research and development efforts. A significant portion of our research and development costs have been, and will continue to be, external costs. Because we are working on multiple research and development programs at one time, we track many of our external expenses on a program-by-program basis. Due to our ability to use certain resources across several programs, personnel-related expenses and indirect or shared operating costs incurred for our research and development programs are not recorded or maintained on a program-by-program basis.

We expect that our research and development expenses will increase substantially in connection with our ongoing clinical trials and our planned clinical development activities in the near term and in the future. However, we cannot reasonably estimate the costs or timing of the efforts that will be necessary to complete the development of any of our product candidates due to the numerous risks and uncertainties associated with their development, including the uncertainty of:

- the scope, timing, costs and progress of clinical development activities related to zolucatetide, our ERG degrader and our allosteric AR^{ON} degrader, including expansion into other indications, and our other product candidates;
- the number and scope of additional nonclinical and clinical programs we decide to pursue, and the number of product candidates we decide to develop further;
- our successful enrollment in and completion of clinical trials;
- seeking regulatory approvals for any of our product candidates that successfully complete clinical trials;
- securing access rights to external products, technologies or intellectual property;
- hiring additional clinical, quality control, manufacturing and other scientific personnel;
- the terms and timing of any partnership, collaboration, or license arrangement, including the terms and timing of any milestone payments thereunder, if any; and
- general economic conditions, including inflation.

Any changes in the outcome of any of these variables with respect to the development of our product candidates or any future product candidates that we may identify could result in a significant change in the costs and timing associated with the development of that product candidate. We may never succeed in achieving regulatory approval for any of our product candidates or any future product candidates that we may identify.

General and Administrative

General and administrative expenses consist primarily of personnel-related expenses, including salaries, bonuses, benefits, and stock-based compensation expense for employees in certain executive, accounting and finance, business development, human resources, information technology, legal, and other administrative functions. Other significant general and administrative expenses include allocated facility and related costs, legal fees relating to corporate and intellectual property matters, professional fees for accounting, audit and tax services, consulting fees, information technology costs and insurance costs. General and administrative costs are expensed as incurred. These costs relate to the operation of the business, unrelated to the research and development function, or any individual program.

We expect that our general and administrative expenses will increase substantially for the foreseeable future as we increase our headcount to support the expected growth in our research and development activities and the potential commercialization of our product candidates, if approved. We also expect to incur increased expenses associated with being a public company, including increased costs of accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and the U.S. Securities and Exchange Commission ("SEC") requirements, director and officer insurance costs, and investor and public relations costs. Additionally, we expect to incur additional intellectual property-related expenses as we file patent applications to protect innovations arising from our research and development activities.

Interest Income

Interest income consists of interest earned from our cash, cash equivalents and marketable securities.

Interest Expense

Interest expense consists of interest incurred on our term loan, as amended, including amortization of debt discount and debt issuance costs, and interest expense associated with our finance leases for certain laboratory equipment. The term loan matured and was fully paid on October 1, 2026.

Sublease Income - Related Party

Sublease income – related party consists of income earned from our sublease of office and laboratory space to a related party. The sublease expired in December 2025.

Change in Fair Value of Simple Agreement for Future Equity

On March 27, 2026, we issued a SAFE to an investor for gross proceeds of $50.0 million. The amount invested by the investor in the SAFE was automatically convertible into common stock upon an IPO based on a discount of up to 10% to the public offering price. We concluded the SAFE was a freestanding financial instrument that required liability classification as it embodied a conditional obligation to issue a variable number of shares based predominately on a fixed monetary amount known at inception. The SAFE was initially recorded at fair value at the issuance date and was subsequently remeasured to fair value at each reporting date and immediately prior to the conversion date in June 2026 in connection with the IPO.

Income Taxes

No provision for income taxes was recorded for the three or nine months ended September 30, 2026 and 2025 due to our net losses and maintenance of a full valuation allowance against our net deferred tax assets. As of December 31, 2025, we had net operating loss carryforwards for federal income tax purposes of $357.9 million, of which $348.9 million can be carried forward indefinitely and the remainder of which begins to expire in 2036. In addition, we had state net operating loss carryforwards of $347.4 million as of December 31, 2025, of which $2.7 million can be carried forward indefinitely and the remainder of which begin to expire in 2036.

As of December 31, 2025, we had federal and state research and development tax credit carryforwards of $17.2 million and $7.7 million, respectively, which are available to reduce future tax liabilities, and which begin to expire in 2030.

Results of Operations

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

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

	Three Months Ended September 30,		Change	
	2026	2025	$	%
Revenue:				
Collaboration revenue	$ 671	$ —	$ 671	*
Collaboration revenue - related party	1,443	—	1,443	*
Total revenue	2,114	—	2,114	*
Operating expenses:				
Research and development	45,597	28,199	17,398	61.7%
General and administrative	11,253	6,646	4,607	69.3%
Total operating expenses	56,850	34,845	22,005	63.2%
Loss from operations	(54,736)	(34,845)	(19,891)	57.1%
Other income (expense):				
Interest income	10,369	711	9,658	1,358.4%
Interest expense	(124)	(398)	274	(68.8)%
Sublease income - related party	—	1,057	(1,057)	(100.0)%
Total other income, net	10,245	1,370	8,875	647.8%
Net loss	$ (44,491)	$ (33,475)	$ (11,016)	32.9%

* Not meaningful

Collaboration Revenue

Collaboration revenue was $2.1 million for the three months ended September 30, 2026 and consisted of $0.7 million of revenue generated under the Regeneron Agreement, which was entered into in May 2026, and $1.4 million of revenue generated under a research collaboration and option agreement entered into with Altos, a related party, in August 2026. Revenue under these agreements is recognized as we conduct research activities based on costs incurred as compared to the total estimated costs to complete the services. We expect our collaboration revenue to increase as the research activities under the agreements are performed.

Research and Development Expense

The following table summarizes our research and development expense for the periods presented (in thousands, except percentages):

	Three Months Ended September 30,		Change	
	2026	2025	$	%
External research and development expenses by program:				
Zolucatetide	$ 17,844	$ 8,153	$ 9,691	118.9%
β-Catenin Degrader	614	44	570	1,295.5%
ERG Degrader	1,237	1,475	(238)	(16.1)%
AR^{ON} Degrader	1,944	1,020	924	90.6%
Early discovery and other programs	1,500	1,324	176	13.3%
Unallocated research and development expenses:				
Personnel-related expenses	13,353	7,925	5,428	68.5%
Other research and development expenses	5,921	5,286	635	12.0%
Facility-related expenses	3,184	2,972	212	7.1%
Total research and development expense	$ 45,597	$ 28,199	$ 17,398	61.7%

Research and development expense was $45.6 million for the three months ended September 30, 2026, as compared to $28.2 million for the three months ended September 30, 2025. The increase of $17.4 million, or 61.7%, was primarily due to:

- an increase in external expenses for our lead product candidate, zolucatetide, of $9.7 million, which was primarily attributable to increases in costs incurred for CROs, CMOs and consultants as we continued to advance zolucatetide through a Phase 1/2 clinical trial in patients with advanced solid tumors; and
- an increase in personnel-related expenses of $5.4 million, which was primarily the result of an increase in headcount to support our research and development operations and an increase in stock-based compensation expense.

General and Administrative Expense

The following table summarizes our general and administrative expense for the periods presented (in thousands, except percentages):

	Three Months Ended September 30,		Change	
	2026	2025	$	%
Personnel-related expenses	$ 4,303	$ 2,802	$ 1,501	53.6%
Professional and consulting fees	4,000	1,884	2,116	112.3%
Other general and administrative expenses	2,950	1,960	990	50.5%
Total general and administrative expense	$ 11,253	$ 6,646	$ 4,607	69.3%

General and administrative expense was $11.3 million for the three months ended September 30, 2026, as compared to $6.6 million for the three months ended September 30, 2025. The increase of $4.6 million, or 69.3%, was primarily due to:

- an increase in personnel-related expenses of $1.5 million, which was primarily the result of an increase in headcount within our general and administrative functions and an increase in stock-based compensation expense; and
- an increase in professional and consulting fees of $2.1 million, which was primarily the result of additional external costs related to being a public company and recruitment costs.

Interest Income

Interest income was $10.4 million for the three months ended September 30, 2026, as compared to $0.7 million for the three months ended September 30, 2025. The increase of $9.7 million, or 1,358.4%, was primarily due to increases in our average balances of cash, cash equivalents and marketable securities resulting from the Series F convertible preferred stock financing in January 2026 and our IPO in June 2026.

Interest Expense

Interest expense was $0.1 million for the three months ended September 30, 2026, as compared to $0.4 million for the three months ended September 30, 2025. The decrease of $0.3 million, or 68.8%, was primarily attributable to payments of principal on our term loan, which matured and was fully paid in October 2026.

Sublease Income - Related Party

Sublease income – related party was $1.1 million for the three months ended September 30, 2025. The sublease expired in December 2025, and, as a result, no sublease income was recognized during the three months ended September 30, 2026.

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

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

	Nine Months Ended September 30,		Change	
	2026	2025	$	%
Revenue:				
Collaboration revenue	$ 819	$ —	819	*
Collaboration revenue - related party	1,443	—	1,443	*
Total revenue	2,262	—	2,262	*
Operating expenses:				
Research and development	122,727	92,230	30,497	33.1%
General and administrative	32,610	19,376	13,234	68.3%
Total operating expenses	155,337	111,606	43,731	39.2%
Loss from operations	(153,075)	(111,606)	(41,469)	37.2%
Other income (expense):				
Interest income	16,987	3,017	13,970	463.0%
Interest expense	(626)	(1,193)	567	(47.5)%
Sublease income - related party	—	3,171	(3,171)	(100.0)%
Change in fair value of simple agreement for future equity	(5,556)	—	(5,556)	*
Total other income, net	10,805	4,995	5,810	116.3%
Net loss	$ (142,270)	$ (106,611)	$ (35,659)	33.4%

* Not meaningful

Collaboration Revenue

Collaboration revenue was $2.3 million for the nine months ended September 30, 2026 and consisted of $0.8 million of revenue generated under the Regeneron Agreement, which was entered into in May 2026, and $1.4 million of revenue generated under a research collaboration and option agreement entered into with Altos, a related party, in August 2026. Revenue under these agreements is recognized as we conduct research activities based on costs incurred as compared to the total estimated costs to complete the services. We expect our collaboration revenue to increase as the research activities under the agreements are performed.

Research and Development Expense

The following table summarizes our research and development expense for the periods presented (in thousands, except percentages):

	Nine Months Ended September 30,		Change	
	2026	2025	$	%
External research and development expenses by program:				
Zolucatetide	$ 43,611	$ 30,677	$ 12,934	42.2%
β-Catenin Degrader	1,829	956	873	91.3%
ERG Degrader	6,119	4,957	1,162	23.4%
AR^{ON} Degrader	5,309	2,636	2,673	101.4%
Early discovery and other programs	3,515	3,563	(48)	(1.3)%
Unallocated research and development expenses:				
Personnel-related expenses	36,135	25,938	10,197	39.3%
Other research and development expenses	16,606	14,744	1,862	12.6%
Facility-related expenses	9,603	8,759	844	9.6%
Total research and development expense	$ 122,727	$ 92,230	$ 30,497	33.1%

Research and development expense was $122.7 million for the nine months ended September 30, 2026, as compared to $92.2 million for the nine months ended September 30, 2025. The increase of $30.5 million, or 33.1%, was primarily due to:

- an increase in external expenses for our lead product candidate, zolucatetide, of $12.9 million, which was primarily attributable to increases in costs incurred for CROs, CMOs and consultants as we continued to advance zolucatetide through a Phase 1/2 clinical trial in patients with advanced solid tumors;
- an increase in personnel-related expenses of $10.2 million, which was primarily the result of an increase in headcount to support our research and development operations and an increase in stock-based compensation expense;
- an increase in other research and development expenses of $1.9 million, which was primarily due to increases in laboratory supplies, consumables, external services, and other operating costs incurred as a result of our research and development activities; and
- increases in external expenses for our ERG and AR^{ON} degrader nonclinical programs of $1.2 million and $2.7 million, respectively, which were primarily due to increases in costs for *in vivo* development studies.

General and Administrative Expense

The following table summarizes our general and administrative expense for the periods presented (in thousands, except percentages):

	Nine Months Ended September 30,		Change	
	2026	2025	$	%
Personnel-related expenses	$ 13,649	$ 8,736	$ 4,913	56.2%
Professional and consulting fees	11,941	5,598	6,343	113.3%
Other general and administrative expenses	7,020	5,042	1,978	39.2%
Total general and administrative expense	$ 32,610	$ 19,376	$ 13,234	68.3%

General and administrative expense was $32.6 million for the nine months ended September 30, 2026, as compared to $19.4 million for the nine months ended September 30, 2025. The increase of $13.2 million, or 68.3%, was primarily due to:

- an increase in personnel-related expenses of $4.9 million, which was primarily the result of an increase in headcount within our general and administrative functions, severance charges and an increase in stock-based compensation expense;
- an increase in professional and consulting fees of $6.3 million, which was primarily the result of additional external costs incurred related to being a public company, intellectual property legal fees and recruitment costs; and
- an increase in other general and administrative expenses of $2.0 million, which was primarily driven by increases in information technology costs.

Interest Income

Interest income was $17.0 million for the nine months ended September 30, 2026, as compared to $3.0 million for the nine months ended September 30, 2025. The increase of $14.0 million, or 463.0%, was primarily due to increases in our average balances of cash, cash equivalents and marketable securities resulting from the Series F convertible preferred stock financing in January 2026 and our IPO in June 2026.

Interest Expense

Interest expense was $0.6 million for the nine months ended September 30, 2026, as compared to $1.2 million for the nine months ended September 30, 2025. The decrease of $0.6 million, or 47.5%, was primarily attributable to payments of principal on our term loan, which matured and was fully paid in October 2026.

Sublease Income - Related Party

Sublease income – related party was $3.2 million for the nine months ended September 30, 2025. The sublease expired in December 2025 and as a result, no sublease income was recognized during the nine months ended September 30, 2026.

Change in Fair Value of Simple Agreement for Future Equity

Change in fair value of simple agreement for future equity for the nine months ended September 30, 2026 consisted of an increase in the fair value of the SAFE liability of $5.6 million. In connection with the IPO, the SAFE automatically converted into 2,777,777 shares of common stock at a price per share of $18.00, or 90% of the public offering price. The fair value of the SAFE upon conversion was determined to be $55.6 million based on the fair value of the common stock issued at the time conversion.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have incurred significant losses. We have not yet commercialized any of our product candidates, which are in clinical or nonclinical development, and we do not expect to generate any revenue from product sales unless and until we successfully complete development and obtain regulatory approval for one or more of our product candidates, which may not occur for several years, if at all.

In June 2026, we closed our IPO pursuant to which we issued and sold 38,525,000 shares of common stock. In addition, we issued and sold 4,166,666 shares of common stock to Regeneron in a concurrent private placement. The aggregate net proceeds received by us from the IPO and concurrent private placement were $787.9 million. Additionally, in June 2026, we received a non-refundable upfront payment in the amount of $50.0 million under our license and collaboration agreement with Regeneron. Prior to the IPO, we received aggregate gross cash proceeds of $876.8 million, including $811.8 million from sales of our convertible preferred stock, $15.0 million from borrowings under our term loan and $50.0 million from the issuance of a SAFE.

Cash Flows

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

The following table provides information regarding our cash flows for the periods presented (in thousands, except percentages):

	Nine Months Ended September 30,		Change	
	2026	2025	$	%
Net cash (used in) provided by:				
Operating activities	$ (93,901)	$ (96,779)	$ 2,878	(3.0)%
Investing activities	(552,712)	39,881	(592,593)	(1,485.9)%
Financing activities	1,140,100	67,017	1,073,083	1,601.2%
Net increase in cash, cash equivalents and restricted cash	$ 493,487	$ 10,119	$ 483,368	4,776.8%

Operating Activities

Our cash flows from operating activities are greatly influenced by our use of cash for operating expenses and working capital requirements to support our business. We have historically experienced negative cash flows from operating activities as we invested in developing our Helicon platform, drug discovery and development efforts and related infrastructure. The cash used in operating activities resulted primarily from our net losses adjusted for non-cash charges, which are generally due to stock-based compensation, depreciation and amortization and non-cash lease expense, as well as changes in components of operating assets and liabilities, which are generally due to increased expenses and timing of vendor payments.

For the nine months ended September 30, 2026, net cash used in operating activities was $93.9 million, primarily due to a net loss of $142.3 million, which was offset by net non-cash expenses of $17.7 million and changes in operating assets and liabilities of $30.6 million. The changes in operating assets and liabilities were primarily driven by an increase in deferred revenue under the Regeneron Agreement of $40.8 million, partially offset by a decrease in operating lease liabilities of $5.3 million and an increase in prepaid expenses and other assets of $7.6 million.

For the nine months ended September 30, 2025, net cash used in operating activities was $96.8 million, primarily due to a net loss of $106.6 million, offset by net non-cash expenses of $9.9 million.

Investing Activities

During the nine months ended September 30, 2026, net cash used in investing activities was $552.7 million, which primarily consisted of purchases of marketable securities of $561.0 million, offset by proceeds from maturities of marketable securities of $9.9 million.

During the nine months ended September 30, 2025, net cash provided by investing activities was $39.9 million, which primarily consisted of maturities of marketable securities of $56.7 million, partially offset by purchases of marketable securities of $16.7 million.

Financing Activities

During the nine months ended September 30, 2026, net cash provided by financing activities was $1,140.1 million, which primarily consisted of proceeds from our IPO, net of underwriting discounts and commissions, of $718.2 million, gross proceeds from our concurrent private placement of common stock with a fair value of $83.3 million, gross proceeds from the issuance of our Series F convertible preferred stock of $305.2 million and gross proceeds from the issuance of a SAFE of $50.0 million, partially offset by principal payments on our term loan of $11.3 million and payments of initial public offering costs of $5.4 million.

During the nine months ended September 30, 2025, net cash provided by financing activities was $67.0 million, which primarily consisted of gross proceeds from the issuance of our Series E convertible preferred stock and preferred stock tranche right of $67.5 million, partially offset by principal payments on our finance leases of $0.4 million.

Future Funding Requirements

We have not generated any revenue from product sales. We do not expect to generate any revenue from product sales unless and until we successfully complete development and obtain regulatory approval for one or more of our product candidates, which may not occur for several years, if at all. We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we continue nonclinical activities and studies, advance ongoing clinical trials of our product candidates and conduct future clinical trials. In addition, if we obtain regulatory approval for any of our product candidates, we expect to incur significant expenses related to product sales, marketing, and distribution to the extent that such sales, marketing and distribution are not the responsibility of potential collaborators. Further, we expect to incur additional costs associated with operating as a public company. The timing and amount of our operating expenditures will depend largely on the factors set out above.

Inflation generally affects us by increasing our cost of labor and certain services. We do not believe that inflation had a material effect on our consolidated financial statements included elsewhere in this Quarterly Report. However, the United States has recently experienced historically high levels of inflation. If the inflation rate continues to increase, it may affect our expenses, such as employee compensation and research and development charges due to, for example, increases in the costs of labor and supplies.

As of September 30, 2026, we had total cash, cash equivalents and marketable securities of $1,072.9 million. We believe that our existing cash, cash equivalents and marketable securities will enable us to fund our operating expenses and capital expenditure requirements into 2030. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. We will require additional funding in order to finance operations and complete our ongoing and planned clinical trials. Access to such funding on acceptable terms cannot be assured.

Because of the numerous risks and uncertainties associated with product development, and because the extent to which we may enter into collaborations with third parties for the development of our product candidates is unknown, we may incorrectly estimate the timing and amounts of increased capital outlays and operating expenses associated with completing the research and development of our product candidates. Our funding requirements and timing and amount of our operating expenditures will depend on many factors, including, but not limited to:

- the progress, results and costs of, discovery and nonclinical studies for our programs and development candidates;
- our ability to advance our clinical-stage product candidates into later-stage trials, which we expect will be required in order to seek marketing approval of our product candidates;
- the costs associated with maintaining and improving our Helicon platform;

- our ability to scale up our manufacturing processes and capabilities, or arrange for a third party to do so on our behalf, to support our clinical trials of our product candidates and commercialization of any of our product candidates for which we obtain marketing approval;
- our ability to seek regulatory and marketing approvals for any of our product candidates that successfully complete clinical trials;
- the costs associated with acquiring or in-licensing products, product candidates or technologies or intellectual property;
- the costs associated with maintaining, expanding, enforcing, defending and protecting our intellectual property;
- the costs associated with hiring additional clinical, quality control, manufacturing and other scientific personnel;
- the costs and timing of establishing or securing sales and marketing capabilities if any current or future product candidate is approved; and
- the costs associated with making any milestone, royalty or other payments under any existing collaboration or license agreements or any that we enter into.

Identifying potential product candidates and conducting nonclinical studies and clinical trials is a time consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if ever. Accordingly, we will need to obtain substantial additional funds to achieve our business objectives.

Our expectation with respect to our ability to fund current planned operations is based on estimates that are subject to risks and uncertainties. Our operating plan may change as a result of many factors currently unknown to management and there can be no assurance that the current operating plan will be achieved in the time frame anticipated by us, and we may need to seek additional funds sooner than planned. If we are unable to raise this capital when needed, we may be forced to delay, reduce or eliminate one or more of our research and development programs or other operations.

Adequate additional funds may not be available to us on acceptable terms, or at all. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or issuance of convertible debt securities, the ownership interests of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Additional 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 debt, making capital expenditures or declaring dividends and may require the issuance of warrants, which could potentially dilute the ownership interests of our existing stockholders. If we raise additional funds through strategic collaborations or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or development product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit or terminate our product development programs or any future commercialization efforts or grant rights to develop and market development product candidates to third parties that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Other Commitments

Leases

As of September 30, 2026, we leased office, research and manufacturing space in Cambridge, Massachusetts under a non-cancelable operating lease which, prior to the amendment in October 2026, expired in February 2031, as well as space at a vivarium facility under a non-cancelable operating lease that expires in December 2027. We also entered into finance lease agreements for laboratory equipment. Future minimum commitments under these leases are $46.9 million as of September 30, 2026. These commitments are also recognized as operating lease liabilities and finance lease liabilities, respectively, on our condensed consolidated balance sheets.

In October 2026, we entered into an amendment to our existing operating lease to extend the term from February 2031 to December 2037 and lease additional office, research and manufacturing space beginning no later than January 2028 through December 2037. Total incremental future minimum commitments related to the extension of the existing leased premises and additional leased space is approximately $91.6 million. The amended lease also provides a tenant improvement allowance of up to $8.5 million. As part of the lease amendment, the landlord provided us an 8 month base rent abatement for the existing leased premises.

Term Loan

In September 2021, we entered into a Loan and Security Agreement with Silicon Valley Bank, which was subsequently amended (the "Loan Agreement"), under which we borrowed $15.0 million. The term loan bore interest at a floating rate equal to the greater of (i) 6.75% and (ii) the prime rate plus a margin; provided that the interest rate would not exceed 6.75%. The amounts borrowed under the Loan Agreement were scheduled to mature on October 1, 2026. After triggering an interest-only extension upon the sale of our Series E convertible preferred stock in January 2025, we began paying principal in 12 equal monthly payments of approximately $1.3 million each on November 1, 2025. In addition, we were also required to pay final payment fees of approximately $0.8 million, due upon (a) the term loan maturity date, (b) the repayment of the term loan in full, (c) as required pursuant to permitted prepayment or mandatory prepayment upon an acceleration, or (d) the termination of the Loan Agreement. As of September 30, 2026, $2.0 million of total principal remained outstanding under the Loan Agreement. On October 1, 2026, the term loan matured and was fully paid. Refer to Note 9 to our unaudited condensed consolidated financial statements appearing elsewhere in this Quarterly Report for more information on our term loan.

Harvard License Agreement

In August 2017, we entered into a license agreement, as amended (the "Harvard License"), with the President and Fellows of Harvard College ("Harvard"), to obtain a worldwide, exclusive, royalty-bearing license to certain intellectual property which was developed by our founder.

Under the terms of the Harvard License, we are required to make payments to Harvard upon the achievement of certain development, regulatory and sales milestones up to an aggregate of $18.3 million, as well as future royalty payments, based on a percentage of aggregate net sales ranging in the low single digits. In addition, we are required to make payments to Harvard for non-royalty income received under sublicenses or strategic partnerships with third parties, with the applicable payment based on the stage of development of the first licensed product at the time we enter into such agreement (before or after enrollment of the first patient in a Phase 2 clinical study of a licensed product), ranging from a single-digit percentage to a mid-teens percentage. We are also required to pay an annual maintenance fee for the duration of the Harvard License, which can be credited against future royalty payments. As of September 30, 2026, we have achieved milestones totaling $0.3 million under the Harvard License. Refer to Note 11 to our unaudited condensed consolidated financial statements appearing elsewhere in this Quarterly Report for more information on the Harvard License.

Purchase and Other Obligations

We enter into contracts in the normal course of business with third-party CROs, CMOs and other third-party vendors for nonclinical, clinical trials and testing and manufacturing services. These contracts do not contain minimum purchase commitments and are cancellable by us upon written notice. Payments due upon cancellation generally consist of payments for services provided or expenses incurred up to the date of cancellation, including non-cancelable obligations of our service providers and, in some cases, wind-down costs.

License and Collaboration Agreements

Below is a summary of the key terms of our license and collaboration agreements. For more information on our research collaboration agreement with ARTBIO, Inc. ("ARTBIO") and the Regeneron Agreement, refer to Note 12 to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report.

ARTBIO Collaboration Agreement

In May 2024, we entered into a research collaboration agreement with ARTBIO, to co-develop multiple Helicon-enabled alpha particle radioligand therapies for the treatment of cancer. Under the terms of this agreement, we are responsible for equally participating on joint committees and carrying out at least four research programs with respect to each collaboration target. We and ARTBIO share in the costs of the research programs equally, with ARTBIO responsible for the first $10.0 million of development costs incurred by both parties, and we are responsible for the second $10.0 million of development costs incurred by both parties. Any further development costs beyond these initial funding amounts will be shared equally by both parties. Upon later regulatory approval and commercialization of related product(s), the parties will share equally in all net profits or losses. The agreement expires upon (i) the date on which products arising from the collaboration are no longer commercialized or developed for commercialization, or (ii) termination by one or both parties. As of September 30, 2026, we have incurred $5.0 million of development costs under the collaboration arrangement, which have been reimbursed by ARTBIO.

Under certain circumstances, either party can terminate the agreement, or opt out of further participation in any research programs, and we may be obligated to refund amounts received during the initial funding periods to ARTBIO, such that the total costs incurred through the effective date of termination would be shared equally. As of September 30, 2026, we have recorded a liability of $2.7 million representing fifty percent of the total costs incurred by both parties.

On April 16, 2026, ARTBIO sent notice of its intent to opt out of all the research programs under the research collaboration agreement. On May 26, 2026, we sent a notice of termination of the research collaboration agreement to ARTBIO. No eligible costs were incurred by us or ARTBIO during the nine months ended September 30, 2026.

License and Collaboration Agreement with Regeneron

In May 2026, we entered into the Regeneron Agreement with Regeneron to discover, develop, and commercialize Helicons, with a particular focus on Antibody-Helicon Conjugates ("AHCs"), directed to a set of specified targets (each, a "Collaboration Target").

Under the terms of the Regeneron Agreement and during the research term for each Collaboration Target, we will collaborate with Regeneron to perform certain research and nonclinical development activities, including screening, generating, testing and evaluating new Helicons and AHCs directed to such Collaboration Target (each, a "Product"). Under the Regeneron Agreement, there are five initial Collaboration Targets, with Regeneron having the right to replace up to two targets for no additional consideration and the option to nominate up to five additional Collaboration Targets, subject to an additional option payment from Regeneron. For one initial Collaboration Target, Regeneron may add one or more additional programs with respect to such Collaboration Target, subject to payment of additional program fees. Following Regeneron's nomination of a Product to be a "Licensed Product" during the research term for the applicable Collaboration Target (including additional Collaboration Targets), Regeneron has the sole right to advance through development, manufacturing and worldwide commercialization of Licensed Products, including clinical and regulatory strategy, pricing, and promotion.

Under the terms of the Regeneron Agreement, Regeneron agreed to make a $50.0 million upfront payment, which we received in June 2026, and invest $75.0 million in our then next equity financing, subject to certain conditions. The IPO triggered Regeneron's $75.0 million equity investment whereby Regeneron purchased 4,166,666 shares of our common stock in a concurrent private placement at a per share price equal to 90% of the public offering price, or $18.00 per share. For the initial Collaboration Targets, we are eligible to receive: (i) up to $470.0 million in development milestone payments; (ii) up to $575.0 million in regulatory milestone payments; (iii) up to $1.15 billion in commercial milestone payments; and (iv) tiered royalty payments, ranging in the high single digits to low double digits during the period commencing upon the first commercial sale of such Licensed Product in a given country and expiring on the latest of: (a) expiration of the last valid claim of a royalty term-extending patent right of such Licensed Product in such country, (b) 12 years after the first commercial sale of such Licensed Product in such country, and (c) loss of regulatory exclusivity for such Licensed Product in such country, subject to customary reductions.

Research Collaboration and Option Agreement with Altos

In August 2026, we entered into a research collaboration and option agreement with Altos, a related party, to conduct certain nonclinical research and development activities to design and generate a Helicon peptide directed to a specified target. Pursuant to the

agreement, we will research and develop potential compounds during the research period that will be evaluated for potential further development by Altos during a defined evaluation period. Altos has the option to negotiate a license agreement in good faith during a defined negotiation period.

We received a $1.0 million up-front fully refundable and creditable payment from Altos and we are entitled to receive reimbursement for all internal and external costs incurred us to perform the nonclinical research and development activities under the agreement subject to an agreed upon cap. The upfront payment will offset any payments due from Altos to reimburse us for costs we incur, including the pre-effective date activities under the agreement.

Critical Accounting Estimates and Significant Judgments

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States ("GAAP"). The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated 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 value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Except for the revenue recognition policy described below, there were no material changes to our critical accounting policies and estimates described under "Management's Discussion and Analysis of Financial Condition and Results of Operations - Critical Accounting Estimates and Significant Judgments" which are included in our final prospectus filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act on June 10, 2026.

Revenue Recognition

We enter into license and collaboration agreements which are within the scope of ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606"), under which we license rights to our technology and certain of our drug candidates and perform research and development services for third parties. The terms of these arrangements typically include payment of one or more of the following: non-refundable, up-front fees; reimbursement of research and development costs; development, regulatory and commercial milestone payments; and royalties on net sales of licensed products.

Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine the appropriate amount of revenue to be recognized for arrangements determined to be within the scope of ASC 606, we perform the following five steps: (i) identification of contract(s) with a customer; (ii) identification of the performance obligations; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) we satisfy each performance obligation. We only apply the five-step model to contracts when it is probable that we will collect consideration we are entitled to in exchange for the goods or services we transfer to the customer.

The promised goods or services in our arrangements typically consist of license rights to our intellectual property and research and development services. We also have optional additional items in contracts, which are considered marketing offers and are accounted for as separate contracts with the customer if such option is elected by the customer, unless the option provides a material right which would not be provided without entering into the contract. Performance obligations are promised goods or services in a contract to transfer a distinct good or service to the customer. Promised goods or services are considered distinct when (i) the customer can benefit from the good or service on its own or together with other readily available resources and (ii) the promised good or service is separately identifiable from other promises in the contract. In assessing whether promised goods or services are distinct, we consider factors such as the stage of development of the underlying intellectual property, the capabilities of the customer to develop the intellectual property on their own and the availability of the required expertise.

We estimate the transaction price based on the amount expected to be received for transferring the promised goods or services in the contract. The consideration may include both fixed consideration and variable consideration. At the inception of each arrangement that includes variable consideration and at each reporting period, we evaluate the amount of potential payment and the likelihood that the payments will be received. We utilize either the most likely amount method or expected amount method to estimate the amount expected to be received based on which method better predicts the amount expected to be received. If it is probable that a significant revenue reversal would not occur, the variable consideration is included in the transaction price.

Our contracts often include development, regulatory and commercial milestone payments. At contract inception and at each reporting period, we evaluate whether the milestones are considered probable of being reached and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the

associated milestone value is included in the transaction price. Milestone payments that are not within our control or the licensee's control, such as regulatory approvals, are not included in the transaction price. At the end of each subsequent reporting period, we re-evaluate the probability of achievement of such development milestones and any related constraint, and if necessary, adjust our estimate of the overall transaction price.

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

We allocate the transaction price based on the estimated standalone selling price of the underlying performance obligations or in the case of certain variable consideration to one or more performance obligations. We must develop assumptions that require judgment to determine the standalone selling price for each performance obligation identified in the contract. We utilize key assumptions to determine the standalone selling price, which may include other comparable transactions, pricing considered in negotiating the transaction and the estimated costs to complete the respective performance obligation. Certain variable consideration is allocated specifically to one or more performance obligations in a contract when the terms of the variable consideration relate to the satisfaction of the performance obligation and the resulting amounts allocated to each performance obligation are consistent with the amounts we would expect to receive for each performance obligation.

For performance obligations consisting of licenses and other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition. If the license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we will recognize revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license.

JOBS Act Transition Period and Smaller Reporting Company Status

We qualify as an "emerging growth company" ("EGC") as defined in the Jumpstart Our Business Startups Act (the "JOBS Act"). As an EGC, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

- being permitted to present only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in this filing;
- reduced disclosure about our executive compensation arrangements;
- not being required to hold advisory votes on executive compensation or to obtain stockholder approval of any golden parachute arrangements not previously approved;
- an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act of 2002; and
- an exemption from compliance with the requirements of the Public Company Accounting Oversight Board regarding the communication of critical audit matters in the auditor's report on the financial statements.

We may take advantage of these exemptions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.235 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of our IPO; (iii) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC. We may choose to take advantage of some but not all of these exemptions. We have taken advantage of reduced reporting requirements in this filing. Accordingly, the information contained herein may be different from the information you receive from other public companies in which you hold stock.

Additionally, the JOBS Act provides that an EGC can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an EGC to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, therefore, while we are an EGC we may not be subject to new or revised accounting standards at the same time that they become applicable to other public companies that are not EGCs. As a result of this election, our financial statements may not be comparable to those of other public companies that

comply with new or revised accounting pronouncements as of public company effective dates. We have in the past chosen and may in the future choose to early adopt any new or revised accounting standards whenever such early adoption is permitted.

We are also a "smaller reporting company," as defined in the Securities Exchange Act of 1934, as amended (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 (i) the market value of our common stock 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 (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of our common stock and non-voting common stock held by non-affiliates is less than $700.0 million as measured on the last business day of our second fiscal quarter.

Recently Issued Accounting Pronouncements

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

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

Item 4. Controls and Procedures.

Management's Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Our disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

In designing and evaluating the disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. As required by Rule 13a-15(b) or Rule 15d-15(b) promulgated by the SEC under the Exchange Act, we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report. Based on the foregoing, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this Quarterly Report at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended September 30, 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 be involved in legal proceedings arising in the ordinary course of business. As of the date of this Quarterly Report, we are not a party to any legal proceedings that we believe will have, individually or in the aggregate, a material adverse effect on our business, financial condition or results of operations.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the following risks and uncertainties, together with all other information in this Quarterly Report, including our consolidated financial statements and related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," and our audited financial statements and related notes for the year ended December 31, 2025 included in our final prospectus dated June 10, 2026 filed with the Securities and Exchange Commission pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended, before investing in our common stock. Any of the risk factors we describe below could adversely affect our business, financial condition or results of operations. The market price of our common stock could decline if one or more of these risks or uncertainties actually occur, causing you to lose all or part of the money you paid to buy our common stock. Certain statements below are forward-looking statements. See the section titled "Cautionary Note Regarding Forward-Looking Statements" appearing elsewhere in this Quarterly Report.

Risks Related to Our Business, Financial Position, and Capital Needs

We are a clinical-stage biotechnology company with a limited operating history and no products approved by regulators for commercial sale, which may make it difficult to evaluate our current and future business prospects.

Since our inception in 2015, we have focused substantially all of our efforts and financial resources on developing our Helicon discovery platform and researching and developing programs and product candidates, including our lead product candidate, zolucatetide. All of our programs and product candidates are still in the research, nonclinical development or clinical development stages. We have not yet demonstrated our ability to successfully initiate or complete Phase 3 or other pivotal clinical trials, obtain regulatory approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales, marketing, and distribution activities necessary for successful product commercialization. Additionally, we expect our financial condition and operating results to continue to fluctuate significantly from period to period due to a variety of factors, many of which are beyond our control. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history.

We have no products approved for commercial sale and we can provide no assurance that we will obtain regulatory approvals to market and sell any products in the future. We therefore have never generated any revenue from product sales, and we do not expect to generate any revenue from product sales for the foreseeable future. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. If we do not address these risks and difficulties successfully, our business will suffer.

We will require substantial additional capital to finance our operations in the future. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce or eliminate programs, product candidates (including clinical trials), investment in our Helicon discovery platform, or future commercialization efforts.

Developing biopharmaceutical products, including conducting nonclinical studies and clinical trials, is a time-consuming, expensive and uncertain process that takes years to complete. We expect to spend substantial amounts to (i) continue our research and development activities, perform nonclinical studies, and conduct clinical trials of our current and future programs and product candidates, (ii) continue to develop our Helicon discovery platform, (iii) seek regulatory approvals for our product candidates, including zolucatetide and (iv) launch and commercialize any product candidates for which we receive regulatory approval, including potentially building our own commercial sales, marketing, and distribution organization.

As of September 30, 2026, we had approximately $1,072.9 million in cash, cash equivalents and marketable securities. We believe, based on our current operating plan, that our existing cash, cash equivalents and marketable securities will be sufficient to fund our operations into 2030. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings, royalty financings, government or other third-party grants, asset sales, partnership, collaboration, or licensing arrangements, such as our collaboration with Regeneron Pharmaceuticals, Inc. ("Regeneron"), or a combination of these approaches. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific

strategic considerations. Our spending will vary based on new and ongoing research and development and corporate activities. Because the length of time and activities associated with research and development of our programs and product candidates are highly uncertain, we are unable to estimate the actual funds we will require for research, development, marketing, and commercialization activities. Our future funding requirements, both near and long term, will depend on many factors, including, but not limited to the:

- number of programs that result in product candidates we choose to develop further;
- initiation, progress, timing, costs, and results of nonclinical or nonclinical studies and clinical trials for our product candidates;
- resources required to further develop our Helicon discovery platform;
- clinical development plans we establish for our product candidates;
- terms of any agreements with our current or future collaboration partners;
- outcome, timing, and cost of meeting regulatory requirements established by the U.S. Food and Drug Administration (the "FDA"), the Medicines and Healthcare products Regulatory Agency (the "MHRA"), the European Medicines Agency (the "EMA"), the Pharmaceuticals and Medical Devices Agency, and other comparable foreign regulatory authorities (collectively, the "Regulatory Authorities");
- cost of filing, prosecuting, maintaining, defending, and enforcing our patent claims and other intellectual property ("IP") rights,
- effect of competing technological and market developments, including other products that may compete with one or more of our product candidates;
- cost and timing of completion and further expansion of clinical and commercial scale manufacturing activities sufficient to support all of our current and future product candidates; and
- cost of establishing sales, marketing, and distribution capabilities for any product candidates for which we may receive marketing approval and reimbursement in regions where we choose to commercialize our products on our own.

To date, we have financed our operations primarily with proceeds from our IPO and the concurrent private placement, a non-refundable upfront payment received under the License and Collaboration Agreement with Regeneron (the "Regeneron Agreement"), sales of our convertible preferred stock, borrowings under a term loan and the issuance of a SAFE.

We cannot be certain that additional funding will be available on favorable terms, or at all. Any fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop our programs, develop and, if approved, commercialize our product candidates, or develop our Helicon discovery platform. In addition, we cannot guarantee that future financing will be available in sufficient amounts, at the right time, on favorable terms, or at all. Among other possibilities, negative clinical trial data or setbacks, or perceived setbacks, in our programs or product candidates, or with respect to our Helicon discovery platform, could impair our ability to raise additional financing or grants, or our ability to enter into partnership, collaboration, and licensing arrangements, in each case, on favorable terms, or at all. Moreover, the terms of any equity or debt financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, or the possibility of such issuance, may cause the market price of our shares to decline. If we raise additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that may adversely affect our stockholders' rights.

Further, to the extent that we raise additional capital through the sale of common stock or securities convertible into or exchangeable for common stock, your ownership interest will be diluted. If we raise additional capital through debt financing, we would be subject to fixed payment obligations and may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional capital from third parties through public or private equity or debt financings, government or other third-party grants, asset sales, royalty financings, partnership, collaboration and licensing arrangements, or a combination of these approaches, we may have to relinquish certain valuable rights to our programs or product candidates, technologies, or future revenue streams. We also could be required to seek collaboration partners for one or more of our current or future programs and product candidates at an earlier stage than otherwise would be desirable or relinquish our rights to programs and product candidates or intellectual property that we otherwise would seek to develop or commercialize ourselves. If we are unable to raise additional capital in sufficient amounts, at the right time, on favorable terms, or at all, we may have to significantly delay, scale back, or discontinue the development of one or more of our programs, the development and commercialization of one or more of our product candidates, if approved, or one or more of our other research and development initiatives. Any of the above events could significantly harm our business, prospects, financial condition, and results of operations, cause the price of our common stock to decline, and negatively impact our ability to fund operations.

We may decide to collaborate for the future development and potential commercialization of our product candidates, and such collaborations may include funding for which we are responsible. However, we cannot guarantee that either we or any collaboration partners will have the available funds to fund the research and development activities contemplated by such agreements. If we determine to fund development or commercialization activities on our own, we will need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our programs and product candidates or bring them to market and generate product revenue.

We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future.

We have no products approved for commercial sale and have not generated any revenue from product sales. We will continue to incur significant research and development and other expenses related to our programs, product candidates, Helicon discovery platform, and ongoing operations. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity (deficit) and working capital. We have incurred net losses in each year since our inception in 2015. Our net losses were $44.5 million and $33.5 million for the three months ended September 30, 2026 and 2025, respectively, and $142.3 million and $106.6 million for the nine months ended September 30, 2026 and 2025, respectively. As of September 30, 2026, we had an accumulated deficit of $683.8 million.

We have devoted most of our financial resources to research and development, including our clinical and nonclinical development activities and the development of our Helicon discovery platform. The amount of our future net losses will depend, in part, on the rate of our future expenditures and our ability to obtain funding, including through our licensing and collaboration arrangements. We have not initiated pivotal clinical trials for any of our product candidates, and it will be several years, if ever, before we or a collaboration partner have a product candidate ready for commercialization. Even if we or a collaboration partner obtain regulatory approval to market a product, our future revenues will depend upon the size of any markets in which such product have received approval, and our ability to achieve sufficient market acceptance, reimbursement from third-party payors, and adequate market share in those markets. We may never achieve profitability.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we:

- expand the number of our research and development programs;
- continue or expand our scope of research or development of our current programs and product candidates in nonclinical development;
- continue or expand the scope of our clinical trials for our product candidates;
- initiate additional nonclinical, clinical, or other studies or trials for our programs and product candidates, including pursuant to our licensing and collaboration arrangements;
- change or add additional manufacturers or suppliers, or create and scale internal manufacturing capabilities;
- add additional infrastructure to our quality control and quality assurance groups to support our operations as we progress our product candidates toward commercialization;
- attract and retain skilled personnel;
- create additional infrastructure to support our operations as a public company and our product development and planned future commercialization efforts;
- seek marketing approvals and reimbursement for our product candidates and products;
- establish a sales, marketing, and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- acquire or in-license technologies;
- make payments under any in-license agreements;
- maintain, protect, and expand our intellectual property portfolio; and
- experience any delays or encounter issues with any of the above.

Biopharmaceutical product development entails substantial upfront capital expenditures and significant risk that any program or product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval, secure market

access and reimbursement, and become commercially viable, and therefore any investment in us is highly speculative. Accordingly, before making an investment in us, you should carefully consider our prospects, factoring in the costs, uncertainties, delays, and difficulties frequently encountered by companies in clinical development, especially clinical-stage biotechnology companies such as ours. Any predictions about our future success or viability may not be as accurate as they would otherwise be if we had a longer operating history or a history of successfully developing and commercializing biopharmaceutical products. We may encounter unforeseen expenses, difficulties, complications, delays, and other known or unknown factors in achieving our business objectives.

Additionally, our expenses could increase beyond our expectations if we are required by any Regulatory Authorities to perform clinical trials in addition to those that we currently expect, or if there are any delays in the development of zolucatetide and our other product candidates, such as delays in completing clinical trials.

We are dependent on the success of our product candidates, including zolucatetide, and our ongoing and anticipated trials may not be successful.

Our future success is dependent on our ability to timely obtain marketing approval for, and then successfully commercialize, our product candidates, including zolucatetide. We are investing a majority of our financial resources into the research and development of our product candidates, including our clinical trial for zolucatetide for desmoid tumors and across additional indications. We may not be able to successfully develop or obtain regulatory approval for zolucatetide in any of these indications.

Our product candidates will require additional clinical development, evaluation of clinical, nonclinical, and manufacturing activities, marketing approval in multiple jurisdictions, substantial investment, and significant marketing efforts before we generate any revenues from product sales. We are not permitted to market or promote product candidates before we receive marketing approval from the applicable Regulatory Authorities, and we may never receive such marketing approvals.

The success of our product candidates will depend on a variety of factors. We do not have control over many of these factors, including certain aspects of clinical development and the regulatory submission and review process, potential threats to our intellectual property rights, and our manufacturing, marketing, distribution, and sales efforts of those of any current or future collaborator. In addition, we do not have control over whether products that target the same indications as our product candidates are introduced, which could impact the competitiveness of our product candidates. Accordingly, we cannot assure you that we will ever be able to generate revenue through the sale of these product candidates, even if approved. If we are not successful in commercializing zolucatetide or any other product candidate, or are significantly delayed in doing so, our business will be materially harmed.

Some of our product candidates modulate pathways for which there are currently no approved or effective therapies, and utilize novel binding locations, which may result in greater research and development expenses, regulatory issues that could delay or prevent approval, or discovery of unknown or unanticipated adverse effects.

Some of our product candidates modulate pathways for which there are currently no approved or effective therapies, which may result in uncertainty regarding our current and future development efforts and ability to obtain regulatory approval for such candidates. We select programs for cancer driver targets based on what we believe are compelling biological rationales. We explore new programs based on extensive nonclinical data analysis which sometimes cannot predict efficacy or safety in humans.

Some of our product candidates utilize novel binding locations, which may result in greater research and development expenses, regulatory issues that could delay or prevent drug candidate development and approval, or discovery of unknown or unanticipated adverse effects. Even though there may be approved therapies to treat the conditions we are targeting, our product candidates are being developed to direct our therapies to a novel target, or to target a different binding site on a known target. We utilize structural biology in tight integration with our medicinal chemistry and biology capabilities to predict and design the compounds that we believe will achieve the most desirable characteristics, including potency, selectivity, bioavailability, and drug-like properties. A disruption in any of these capabilities may have significant adverse effects in our ability to expand our pipeline of product candidates, and we cannot predict whether we will continue to have access to these capabilities in the future to support our pipeline development. In addition, there can be no assurance that we will be able to identify, design and synthesize the necessary compounds or that these or other problems related to the development of product candidates will not arise in the future, which may cause significant delays or raise problems we may not be able to resolve.

Regulatory approval of novel product candidates such as ours can be more expensive, riskier, and take longer than for other, more well-known or extensively studied pharmaceutical or biopharmaceutical product candidates due to our and Regulatory Authorities' lack of experience with them. The novelty of the mechanism of action of any of our product candidates may lengthen the regulatory review process, require us to conduct additional studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates, or lead to significant post-approval limitations or restrictions. The novel mechanism of action also means that fewer people are trained in or

experienced with product candidates of this type, which may make it more difficult to find, hire and retain personnel for research, development, and manufacturing positions and to identify clinical trial investigators to use our product candidates in trials. Because our product candidates utilize a novel mechanism of action that has not been the subject of extensive study compared to more well-known product candidates, there is also an increased risk that we may discover previously unknown or unanticipated adverse effects during our nonclinical studies and clinical trials. Because our product candidates are designed to target novel protein binding sites, we may be required to provide more nonclinical and clinical data to demonstrate the potential of our product candidates. Any such events could adversely impact our business prospects, operating results, and financial condition.

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

From time to time, we estimate the timing of the anticipated accomplishment of various scientific, clinical, regulatory and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of scientific studies and clinical trials, the submission of regulatory filings or commercialization objectives, such as the expected timing of a potential Phase 3 registrational trial of zolucatetide for the treatment of desmoid tumors or our submission of an Investigational New Drug ("IND") application for any of our other product candidates. From time to time, we may publicly announce the expected timing of some of these milestones. All of these milestones are based on a variety of assumptions which, if not realized as expected, may cause the timing of achievement of the milestones to vary considerably from our estimates, in some cases for reasons beyond our control, including:

- our available capital resources or capital constraints we experience;
- the rate of progress, costs, and results of our clinical trials and research and development activities, including the extent of scheduling conflicts with participating clinicians and collaborators;
- our substantial reliance on third-party contract research organizations ("CROs") for the performance of certain research activities, including synthesis, biology, drug metabolism and pharmacokinetics ("DMPK"), toxicology, and other research activities for the discovery and development of products;
- our substantial reliance on third-party CROs to engage, qualify, and prepare clinical trial sites, complete these trials successfully, in compliance with regulatory requirements, and on schedule;
- our ability to identify and enroll patients who meet clinical trial eligibility criteria;
- our receipt of approvals by Regulatory Authorities and the timing thereof;
- other actions, decisions, or rules issued by regulators;
- our substantial reliance on third-party contract development and manufacturing organizations ("CDMOs") to manufacture our product candidates;
- our CDMOs' access to sufficient, reliable, and affordable supplies of materials used to manufacture our product candidates;
- the efforts of any collaboration partners with respect to the development, manufacturing and commercialization of our product candidates; and
- the securing of, costs related to, and timing issues associated with, product manufacturing as well as sales and marketing activities.

Any inability to meet milestones as publicly announced, or at all, may delay the commercialization of our product candidates or result in commercialization never being achieved and, as a result, our stock price may decline. Additionally, delays relative to our projected timelines are likely to cause overall expenses to increase, which may require us to raise additional capital sooner than expected and potentially on less favorable terms and prior to achieving targeted development milestones, and may decrease the attractiveness of our product candidates relative to competitive products expected to be approved by the applicable Regulatory Authorities prior to our product candidates.

Our quarterly and annual operating results may fluctuate in the future. As a result, we may fail to meet or exceed the expectations of research analysts or investors, which could cause our stock price to decline and negatively impact our financing or funding ability as well as negatively impact our ability to exist as a standalone company.

Our financial condition and operating results have varied in the past and will continue to fluctuate from quarter-to-quarter and year-to-year in the future due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include the following, as well as other factors described elsewhere in this Quarterly Report:

- inability to develop promising programs;
- delays or failures in advancement of existing or future product candidates into the clinic or in clinical trials;
- the feasibility of developing, manufacturing, and commercializing our product candidates;
- our ability to manage our growth;
- the outcomes of research programs, clinical trials, or other product development or approval processes conducted by us and any collaboration partners;
- our ability to develop or successfully commercialize product candidates;
- the ability of our current or any future collaboration partners to develop and successfully commercialize product candidates;
- our relationships, and any associated exclusivity terms, with any current or future collaboration partners, including Regeneron;
- our contractual or other obligations to provide resources to fund our programs and product candidates;
- our operation in a net loss position for the foreseeable future;
- risks associated with the international aspects of our business, including the conduct of clinical trials in international locations and potential commercialization in such locations, including in China;
- our ability to accurately report our financial results in a timely manner;
- our dependence on, and the need to attract and retain, key management and other personnel;
- our ability to obtain, protect, maintain, and enforce our IP rights;
- our ability to prevent the theft or misappropriation of our IP and know-how or proprietary technologies;
- potential advantages that our competitors and potential competitors may have in securing funding, obtaining and maintaining the rights to critical IP, or developing competing technologies or products;
- our ability to obtain additional capital that may be necessary to expand our business;
- our collaboration partners' ability to obtain additional capital that may be necessary to develop programs and develop and commercialize product candidates pursuant to our partnership, collaboration, and licensing arrangements;
- the effect of changes in government regulation;
- cybersecurity breaches and other business interruptions such as power outages, strikes, acts of terrorism, or natural disasters; and
- changes in tax policy and our ability to use our net operating loss ("NOL") carryforwards to offset future taxable income.

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

Nonclinical and clinical development is inherently lengthy and uncertain. Nonclinical and clinical trials of our product candidates may be delayed, and certain programs may never advance into or through the clinic or may be more costly to conduct than we anticipate, any of which would have a material adverse impact on our business.

Nonclinical and clinical testing is expensive and complex and can take many years to complete, and its outcome is inherently uncertain. We or our collaboration partner may not be able to initiate, may experience delays in, or may have to discontinue nonclinical studies and clinical trials for our product candidates.

Before we can initiate clinical trials for a product candidate, we must first complete extensive nonclinical studies, including IND-enabling good laboratory practices ("GLP") toxicology testing, which support our planned INDs in the United States, or similar applications in other jurisdictions. We cannot be certain of the timely completion or outcome of our nonclinical testing and studies. For example, while Regulatory Authorities like the FDA have signaled through draft guidance a movement away from animal testing for monoclonal antibodies, we have thus far depended on the availability of non-human primates ("NHPs") to conduct certain nonclinical studies that we are required to complete prior to submitting an IND or foreign equivalent prior to initiating clinical development, and prior to submitting a marketing application. During the past several years, there was a global shortage of NHPs available for drug development. If the shortages in NHPs or other laboratory animals occur in the future, this could significantly increase the costs of obtaining, or decrease the availability of, NHPs or other laboratory animals for our future nonclinical studies if regulators continue to require NHP data, or we require other laboratory animals, to support our nonclinical and clinical development programs. This could also result in delays in our development and approval timelines.

We must also complete extensive work on Chemistry, Manufacturing and Controls ("CMC") activities (including yield, purity, and stability data) to be included in any IND filing. CMC activities require extensive manufacturing processes and analytical development, which is uncertain and lengthy. For instance, batch failures have occurred and may occur in the future as we scale up our manufacturing. In addition, we may have difficulty identifying appropriate buffers and storage conditions to enable sufficient shelf life of batches of our nonclinical or clinical product candidates. If we are required to produce new batches of our product candidates due to insufficient shelf life, it may delay the commencement or completion of nonclinical or clinical trials of such product candidates.

We cannot predict whether Regulatory Authorities will accept the results of our nonclinical testing or our proposed clinical programs or whether the outcome of our nonclinical testing, studies, and CMC activities will ultimately support the further development of our programs. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our nonclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in Regulatory Authorities allowing clinical trials to begin.

Our failure to successfully initiate and complete clinical trials and to demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates would significantly harm our business. Our development costs will also increase if we experience delays in testing or obtaining regulatory approvals, and we may be required to obtain additional funds to complete clinical trials. There can be no assurance that our clinical trials will begin as planned or be completed on schedule, if at all, or that we will not need to restructure or otherwise modify our trials after they have begun. Regulatory Authorities may require us to submit additional data, such as long-term toxicology studies, or impose other requirements before permitting us to initiate a clinical trial.

We or our collaboration partner also may experience numerous unforeseen events during, or as a result of, any clinical trials that we conduct, which could delay or prevent us or our collaboration partner from successfully developing our product candidates, including:

- Regulatory Authorities, institutional review boards ("IRBs") or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site for any number of reasons, including concerns regarding safety and aspects of the clinical trial design;
- we may experience delays in reaching, or fail to reach, agreement on favorable terms with prospective trial sites and prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- we may experience challenges in manufacturing sufficient quantities of our product candidates, or obtaining sufficient quantities of combination therapies for use in clinical trials;
- we may experience challenges or delays in recruiting principal investigators or study sites to lead our clinical trials;

- the number of subjects or patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, and the number of clinical trials being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical trials at a higher rate than we anticipate;
- the outcome of our nonclinical studies and our early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results;
- we may have to amend clinical trial protocols submitted to Regulatory Authorities or conduct additional studies or add additional cohorts to reflect changes in regulatory requirements or guidance, which may be required to resubmit to an IRB, ethics committee and Regulatory Authorities for re-examination;
- clinical trials of any product candidates may fail to show safety or efficacy, or produce negative or inconclusive results, and we may decide, or Regulatory Authorities may require us, to conduct additional nonclinical studies or clinical trials, or we may decide to abandon development programs;
- our third-party contractors, including those manufacturing our product candidates or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- differences in clinical trial design between early-stage clinical trials and later-stage clinical trials may make it difficult to extrapolate the results of earlier clinical trials to later clinical trials;
- nonclinical and clinical data are often susceptible to varying interpretations and analyses, and many product candidates believed to have performed satisfactorily in nonclinical studies and clinical trials have nonetheless failed to obtain marketing approval;
- Regulatory Authorities or other reviewing bodies may find deficiencies with, fail to approve, or subsequently find fault with the manufacturing processes or facilities of our CDMOs, or the supply or quality of any product candidate or other materials necessary to conduct clinical trials of our product candidates may be insufficient, inadequate, or not available at an acceptable cost, or we may experience interruptions in supply;
- product candidates may have undesirable side effects or degradation products, any of which could lead to serious adverse events ("SAEs") or other unexpected characteristics;
- occurrence of SAEs in trials of the same class of product candidates conducted by other companies that could be considered similar to our product candidates; and
- the potential for approval policies or regulations of Regulatory Authorities to significantly change in a manner rendering our clinical data insufficient for approval.

For example, we are developing a new formulation of zolucatetide in a self-administered injectable formulation (the "Injectable Formulation") for ease of use. All patients in our current Phase 1/2 trial are dosed using an intravenous ("IV") infusion presentation. We intend ultimately to transition to an Injectable Formulation that will be delivered through an autoinjector, a pre-filled syringe or an on-body device for ease of patient dosing and for what we believe will be a greater commercial opportunity. In March 2026, in our healthy volunteers trial to bridge IV to injectable formulations, we observed several injection site reactions ("ISRs"), all at low levels (Grade 1 and Grade 2) with a first generation formulation. Although we plan to continue working toward an Injectable Formulation, we intend to conduct a pivotal Phase 3 trial of zolucatetide in desmoid tumors initially using only the IV infusion presentation. We expect Regulatory Authorities will require us to conduct, among other things, pharmacokinetic ("PK") compatibility studies to bridge the IV infusion presentation to these new planned injection presentations, human factors testing to support self-administration of zolucatetide, and potentially a separate Phase 2 trial to validate the equivalence of the current IV formulation to the Injectable Formulation. Any of these additional steps could delay marketing approval of zolucatetide in one or more formulations and jeopardize our ability to commence product sales and generate revenue from zolucatetide, if approved. There is no assurance that we will be successful in developing an Injectable Formulation or demonstrating the equivalence of any of these delivery methods in clinical trials, any other studies, or at all, and any failure would impede our development and commercialization strategy for zolucatetide.

We could also encounter delays if a clinical trial is suspended or terminated by us or any Regulatory Authority, ethics committee or the IRBs of the institutions in which such trials are being conducted, or if such trial is recommended for suspension or termination by the Data Safety Monitoring Board ("DSMB") for such trial. We may experience delays in gaining clearance from Regulatory Authorities to initiate clinical trials through the imposition of a clinical hold in order to address comments from such Regulatory Authorities on our clinical trial design or other elements of our clinical trials. 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 protocols, inspection of the clinical trial operations or trial site by a Regulatory Authority, unforeseen safety issues or adverse side

effects, failure to demonstrate a benefit or adequate benefit risk ratio from using a product candidate, 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. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Further, conducting clinical trials in foreign countries, as we intend to do for zolucatetide and as we may in the future for our other 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.

In addition, our ability to access and use clinical trial data for ongoing trials and any new trials conducted in China will be highly dependent on acceptance and approvals from Human Genetic Resources Administration of China ("HGRAC"). There is no guarantee that the HGRAC will not impede our ability to obtain and use clinical trial data for trials conducted in China in a timely manner or in a way that facilitates our use of such data. We intend to rely on our sites in China to provide us with significant data and other information related to our product candidates, including nonclinical and clinical data. We may not be able to independently verify or audit all of such data (including possibly material portions thereof). As a result, such data may be inaccurate, misleading, or incomplete.

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 Regulatory Authorities. A Regulatory Authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The 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, or rejection, of our marketing applications by the applicable Regulatory Authority, as the case may be, and may ultimately lead to the denial of regulatory approval of one or more of our product candidates.

Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize zolucatetide or any other product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates, which may harm our business, financial condition, results of operations, and growth prospects. In addition, many of the factors that cause, or lead to, delays of clinical trials may ultimately lead to the denial of regulatory approval of our product candidates. Any delays in the development of our product candidates may harm our business, financial condition, and prospects significantly.

We are conducting clinical trials for product candidates outside the United States, and Regulatory Authorities may not accept data from such trials.

We are conducting, and expect to continue to conduct clinical trials and arms of our clinical trials for our product candidates internationally. The acceptance of data from clinical trials conducted outside the United States or another jurisdiction by Regulatory Authorities may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, regardless of whether such trials were conducted under an IND, the FDA will generally not approve the application on the basis of foreign data alone unless the data are applicable to the U.S. population and U.S. medical practice, the trials were performed by clinical investigators of recognized competence and pursuant to Good Clinical Practice ("GCP") regulations, and the FDA can validate the data through on-site inspections or other appropriate means. If access to clinical trial sites or documentation is delayed or restricted, including for geopolitical reasons, the FDA may not accept such data in support of an IND or marketing application, which would adversely affect our development and approval plans. Many foreign regulatory authorities have similar approval requirements, including in relation to the use of data from clinical trials conducted in foreign jurisdictions. In addition, such foreign trials are subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that Regulatory Authorities will accept data from trials conducted outside of the United States or the applicable jurisdiction. If Regulatory Authorities do not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in any product candidates that we develop being delayed or not receiving approval for commercialization in the applicable jurisdiction. Recent policy proposals in the United States may make acceptance by the FDA or inclusion in a marketing application of foreign data more difficult or costly. In addition, the FDA recently signaled increased scrutiny of foreign clinical trial data submitted in support of marketing applications, indicating plans for increased foreign site inspections and increased transparency of inspection results.

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

The results observed from nonclinical studies or early-stage clinical trials of zolucatetide or any other product candidates may not necessarily be predictive of the results of later-stage clinical trials that we conduct. Similarly, positive results from nonclinical studies or early-stage clinical trials may not be replicated in our subsequent nonclinical studies or clinical trials. For example, results seen in our Phase 1/2 clinical trial for zolucatetide in patients with desmoid tumors may not translate to similar results in our planned registrational Phase 3 trial or in other future clinical trials in patients with such tumors and may not be predictive of outcomes for zolucatetide in other indications. Furthermore, our product candidates may not be able to demonstrate similar activity or adverse event profiles as those observed in earlier studies and trials, and we may not have generated sufficient safety data to support a marketing application by the time of our targeted submission as other third-party products or product candidates that we believe may have similar profiles. In addition, in our planned future clinical trials, we may utilize clinical trial designs or dosing regimens or methods of delivery that have not been tested in prior clinical trials.

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

Additionally, we intend to utilize an "open-label" clinical trial design for certain of our clinical trials, and are currently using such design in our Phase 1/2 clinical trial of zolucatetide for the treatment of advanced solid tumors. An "open-label" clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a "patient bias" where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical trials may be subject to an "investigator bias" where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The results from an open-label trial may not be predictive of future clinical trial results of a product candidate when studied in a controlled environment with a placebo or active control.

Moreover, nonclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in nonclinical studies and clinical trials nonetheless failed to obtain approval from Regulatory Authorities.

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

From time to time, we publicly disclose preliminary or topline data from our nonclinical 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 nonclinical study or clinical trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to evaluate all data fully and carefully. 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. Therefore, topline data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our nonclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as participants' enrollment continues and more participants' data become available or as participants from our clinical trials continue other treatments for their disease. Similarly, we may disclose data from a small initial number of patients, or a single patient, in a particular indication as we continue to accrue data, and while initial data may be positive, the final data in a larger number of participants may not ultimately support further development in that indication. For example, in our Phase 1/2 clinical trial studying desmoid tumor effect, administration with zolucatetide in a small number of patients who also had Familial Adenomatous Polyposis ("FAP") associated with desmoid tumor led to a significant improvement in duodenal polyp burden in these FAP patients including substantial reduction in polyp number and size. There can be no guarantee that these patients will continue to show improvement or that we will see similar results in a well-controlled, multi-patient clinical trial designed to study zolucatetide for the treatment of FAP. Adverse differences

between interim data and final data, and between limited data and more expanded data as it becomes available, could result in abandonment of a program or a product candidate and/or otherwise significantly harm our business prospects.

Further, others, including Regulatory Authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions, study population size, safety database size, or interpretations of data or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular product candidate or the approvability or commercialization of the particular product candidate and could adversely affect the success of our business. In addition, the information we choose to publicly disclose regarding a particular study or trial is based on what is typically extensive information, and investors 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 growth 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.

If we encounter difficulties identifying and enrolling participants in our clinical trials, including participants with the required or desired characteristics to achieve diversity in a trial, our clinical development activities could be delayed or otherwise adversely affected.

We depend on enrollment of participants in our clinical trials for our product candidates. We may find it difficult to enroll trial participants in our clinical trials, which could delay or prevent clinical trials of our product candidates.

Delays or difficulties in enrollment may result in increased costs or otherwise affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates, or result in termination of the clinical trials altogether. For example, in order to enroll a sufficient number of patients in our ongoing Phase 1/2 clinical trial for zolucatetide in patients with advanced solid tumors and our planned Phase 3 clinical trial in desmoid tumors, we are opening sites in Australia and China.

Identifying and qualifying trial participants to participate in clinical trials of our product candidates is critical to our success. Patient and subject enrollment is affected by factors including: severity of the disease under investigation; complexity and design of the trial protocol; size of the targeted patient population; eligibility criteria for the trial in question; proximity and availability of clinical trial for the disease or condition under investigation; available sites for prospective trial participants; availability of competing therapies and clinical trials, including between our own clinical trials; efforts to facilitate timely enrollment in clinical trials; patient referral practices of physicians; ability to monitor trial participants adequately during and after treatment; ability to recruit clinical trial investigators with the appropriate competencies and experience; clinicians' and trial participants' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating; our ability to obtain and maintain participant informed consent; and the risk that trial participants enrolled in clinical trials will not complete a clinical trial.

The timing of our clinical trials depends on the speed at which we can recruit trial participants to participate in testing our product candidates. If trial participants are unwilling to participate in our studies because of negative publicity from adverse events in our trials or other trials of similar products, or those related to specific therapeutic area, or for other reasons, including competitive clinical trials for similar patient populations, the timeline for recruiting trial participants, conducting studies, and obtaining regulatory approval of potential products may be delayed, which could also have significant commercial competitive impacts in the future.

In particular, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition may reduce the number and types of trial participants available to us, because some trial participants who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by a third party. Potential participants may elect to enroll in other clinical trials offering oral medications out of convenience, rather than participate in our clinical trials which provide for IV delivery of drug product. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which may reduce the number of trial participants who are available for our clinical trials at such clinical trial sites. Additionally, if new product candidates show encouraging results, potential trial participants and their doctors may be inclined to enroll trial participants in clinical trials using those product candidates. If such new product candidates show discouraging results or other adverse safety indications, potential trial participants and their doctors may be less inclined to enroll trial participants in our clinical trials.

Due to the significant resources required for drug development and depending on our ability to access capital, we intend to prioritize the development of zolucatetide for desmoid tumors and other rare tumors. As a result, we may not focus on other indications or potential product candidates that may have been more profitable.

Due to the significant resources required for drug development, we must decide which indications to pursue and advance and the amount of resources to allocate to each product candidate. Our decisions concerning the allocation of research, development, collaboration, management, and financial resources toward particular indications may not lead to the development of viable commercial products and may divert resources away from better opportunities. For example, our current strategy is to pursue regulatory approval of zolucatetide for the treatment of desmoid tumors and to evaluate a potential label expansion into other types of rare tumors and other conditions. If we make incorrect determinations regarding the viability or market potential of zolucatetide, or misread trends in the biotechnology industry, our business, financial condition, results of operations, and growth prospects could be materially and adversely affected. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases and disease pathways that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to our product candidates through collaboration, licensing, or royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain sole development and commercialization rights.

Regulatory approval processes are lengthy, time-consuming, and inherently unpredictable, and if we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize, or will be delayed in commercializing, product candidates we may develop, and our ability to generate revenue will be materially impaired.

Even if we complete the necessary nonclinical studies and clinical trials, the marketing approval process is expensive, time-consuming, and uncertain, and may prevent us from obtaining approvals for the commercialization of any product candidates we may develop. Any product candidate we may develop and the activities associated with its development and commercialization, including design, testing, manufacture, recordkeeping, labeling, storage, approval, advertising, promotion, sale, and distribution, are subject to comprehensive regulation by Regulatory Authorities. To obtain the requisite regulatory approvals to commercialize any of our product candidates, we and any collaboration partners must demonstrate through extensive nonclinical studies and clinical trials that our products are safe, pure and effective in humans, including the target population. Successful completion of clinical trials is a prerequisite to submitting a New Drug Application ("NDA") to the FDA, a Marketing Authorization Application ("MAA") to the EMA, and similar marketing applications to other Regulatory Authorities, for each product candidate and, consequently, the ultimate approval and commercial marketing of any product candidates.

Clinical evaluation of investigational drugs is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. Generally, two adequate and well-controlled Phase 3 clinical trials of a product candidate in the relevant patient population have been required by the FDA and other major Regulatory Authorities for approval of an NDA, although there are known exceptions, including in rare diseases and oncology. In February 2026, the then FDA Commissioner publicly indicated that a single adequate and well-controlled pivotal clinical trial supported by confirmatory evidence would be the FDA's default standard moving forward for novel products, rather than two such trials. This statement was not a formal agency action and the scope, implementation, and durability of this policy position remain uncertain. In June 2026, FDA issued revised draft guidance clarifying how sponsors can rely on one scientifically rigorous adequate and well-controlled clinical investigation with confirmatory evidence to satisfy the statutory substantial evidence of effectiveness standard. The FDA retains broad discretion to require additional clinical data for any product candidate, including a second adequate and well-controlled clinical trial. Regulatory Authorities may disagree with us about whether a clinical trial is adequate and well-controlled or may request that we conduct additional clinical trials prior to regulatory approval. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. In addition, there is no assurance that the doses, endpoints and trial designs that we intend to use for our planned clinical trials, including those that we have developed based on feedback from Regulatory Authorities or those that have been used for the approval of similar drugs, will be acceptable for future approvals. The clinical development of our product candidates is also susceptible to the risk of failure inherent at any stage of development, including failure to demonstrate purity, potency, or efficacy in a clinical trial or across a broad population of patients, the occurrence of adverse events that are severe or medically or commercially unacceptable, failure to comply with protocols or applicable regulatory requirements, and determination by Regulatory Authorities that a product candidate may not continue development or is not approvable. It is possible that even if our product candidates have a beneficial effect, that effect will not be detected during clinical evaluation as a result of one or more of a variety of factors, including the size, duration, design, measurements, conduct or analysis of our clinical trials. Conversely, as a result of the same factors, our clinical trials may indicate an apparent positive effect of such product candidate that is greater than the actual positive effect, if any. Similarly, in our clinical trials we may fail to detect toxicity of, or intolerability caused by, such product candidate, or mistakenly believe that our product candidates are toxic or not well tolerated when that is not in fact the case. Serious adverse events or other adverse events, as well as tolerability issues, could hinder or prevent market acceptance of the product candidate at issue.

Our product candidates could fail to receive regulatory approval, or regulatory approval could be delayed, for many reasons, including the following:

- Regulatory Authorities may disagree with the dosing regimen, clinical trial design, or conduct of our clinical trials;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- we may be unable to demonstrate to the satisfaction of Regulatory Authorities that a product candidate is safe and effective for any of its proposed indications;
- the results of clinical trials may not meet the level of statistical significance required by Regulatory Authorities for approval;
- Regulatory Authorities may disagree with our interpretation of data from clinical trials or nonclinical studies;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA to the FDA or other submission or to obtain regulatory approval in the United States, the European Union (the "EU"), or elsewhere;
- we may be unable to demonstrate that a new formulation of a product candidate is equivalent to the formulation of an existing product candidate;
- Regulatory Authorities may not file or accept our NDA or marketing application for substantive review;
- Regulatory Authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of our CDMOs;
- staffing changes and backlogs at Regulatory Authorities may create unexpected delays in the review and approval of any applications we may submit;
- the approval policies or regulations of Regulatory Authorities may significantly change in a manner rendering our clinical data insufficient for approval; and
- product labeling or product insert requirements or requirements to conduct post-marketing studies.

Failure to obtain marketing approval for a product candidate in a jurisdiction will prevent us from commercializing the product candidate in that jurisdiction. We have not received approval to market any product candidates from Regulatory Authorities in any jurisdiction, and it is possible that none of our product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval in any market. We have no experience as an organization in filing and supporting the applications necessary to gain marketing approvals and will need to rely on CROs or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive nonclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant Regulatory Authority. Any product candidates we develop may not be effective, may be only moderately effective, or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, and can vary substantially based upon a variety of factors, including the type, complexity, and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Regulatory Authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and may require additional nonclinical, clinical, or other studies. In addition, varying interpretations of the data obtained from nonclinical and clinical testing could delay, limit, or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable. Additional delays or non-approval may result if an FDA Advisory Committee or other Regulatory Authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory agency policy during the period of product development, clinical trials, and the review process. Any such delays may decrease the attractiveness of our product candidates relative to competitive products that are expected to be approved by the applicable Regulatory Authorities prior to our product candidates, and adversely affect our business.

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

Regulatory Authorities also may approve a product candidate for fewer or more limited indications than requested or may grant approval subject to the performance of potentially costly post-marketing studies, may not approve the price we intend to charge for our product candidates, or may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

Regulatory Authorities review the CMC section of regulatory filings. Any aspects found unsatisfactory by Regulatory Authorities may result in delays in clinical trials and commercialization. In addition, Regulatory Authorities conduct pre-approval inspections of clinical sites and manufacturing sites at the time of an NDA. Any findings by Regulatory Authorities and failure to comply with requirements may lead to delay in approval and failure to commercialize the product candidate.

If we fail to expand our development of zolucatetide into additional indications, or fail to develop and commercialize other product candidates, we may be unable to grow our business and our ability to achieve our strategic objectives would be impaired.

Although we are initially focused on developing and commercializing zolucatetide for the treatment of desmoid tumors, we also plan to evaluate developing zolucatetide for the treatment of FAP, ACP, HCC and other rare solid tumors and related conditions. For example, in October 2026, we announced the initiation of a dose-ranging clinical cohort evaluating zolucatetide in patients with FAP as part of our ongoing Phase 1/2 clinical trial of zolucatetide. Expansion into new indications will require additional, time-consuming development efforts and significant additional expense prior to commercial sale, including nonclinical studies, clinical trials and approval by Regulatory Authorities. All product candidates are prone to the risks of failure that are inherent in biopharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, there can be no assurance that any such products that are approved will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace or be more effective than other commercially available alternatives.

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

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, other Regulatory Authorities must also approve the manufacturing and marketing of the product candidate in non-U.S. jurisdictions. In order to eventually market any of our product candidates in any particular foreign jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a jurisdiction-by-jurisdiction basis regarding safety and efficacy. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve product testing and validation and administrative review periods different from, and greater than, those in the United States, including additional nonclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Seeking foreign regulatory approval could result in difficulties and costs for us and require additional nonclinical studies or clinical trials which could be costly and time-consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. The foreign regulatory approval process involves all of the risks associated with FDA approval. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required 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 products will be unrealized.

Our current and future clinical trials may reveal significant adverse events or undesirable side effects not seen in our nonclinical studies and may result in a safety profile that could halt clinical development, inhibit regulatory approval, limit commercial potential, or market acceptance of any of our product candidates.

There is typically an extremely high rate of attrition for product candidates across categories of medicines proceeding through clinical trials. These product candidates may fail to show the desired safety and efficacy or safety, purity and potency profile in later stages of clinical trials despite having progressed through nonclinical studies and initial clinical trials. A number of companies in the biotechnology industry have suffered significant setbacks in later-stage clinical trials due to lack of efficacy or unacceptable safety profiles, notwithstanding promising results in earlier trials. Most product candidates that commence clinical trials are never approved as products and there can be no assurance that any of our current or future clinical trials will ultimately be successful or support further clinical development of any of our product candidates.

Undesirable side effects caused by our product candidates, whether used alone or in combination with other therapies, could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by Regulatory Authorities. We may observe unexpected and undesirable safety or tolerability issues with our product candidates in ongoing or future clinical trials. For example, in March 2026, in our healthy volunteers trial to bridge IV to injectable formulations, we paused dosing of participants with the initial Injectable Formulation due to several ISRs, all at low levels (Grade 1 and Grade 2).

If significant adverse events or unacceptable side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting trial participants to any of our clinical trials, trial participants may withdraw from trials, or we may be required to abandon the trials or our development efforts of one or more product candidates altogether. We, Regulatory Authorities, or an IRB, may impose a clinical hold, suspend, or terminate clinical trials of a product candidate at any time for various reasons, including a belief that participants in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We may need to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of any of our product candidates could result in harm to patients that are administered any of our product candidates. Even if the side effects do not preclude the drug from obtaining or maintaining marketing approval, unfavorable benefit risk ratio may inhibit market acceptance of the approved product due to its tolerability versus other therapies. In addition, an extended half-life could prolong the duration of undesirable side effects, which could also inhibit market acceptance. Any of these developments could materially harm our business, financial condition and prospects.

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

In addition, even if we successfully advance our product candidates or any future product candidates through clinical trials, such trials will only include a limited number of patients and limited duration of exposure to our product candidates. As a result, we cannot be assured that adverse effects of our product candidates will not be uncovered when a significantly larger number of patients are exposed to the product candidate after approval. Further, any clinical trials may not be sufficient to determine the effect and safety consequences of using our product candidates over a multi-year period.

If any of the foregoing events occur or if one or more of our product candidates prove to be unsafe, our entire pipeline or our Helicon discovery platform could be affected, which would have a material adverse effect on our business, financial condition, results of operations and prospects.

Even if we obtain regulatory approval for a product candidate, 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.

Even if our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities. In addition, we will be subject to continued compliance with cGMP and GCP requirements for any clinical trials that we conduct post-approval. For example, the holder of an approved NDA is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the NDA. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws. If we fail to comply with applicable regulatory requirements following approval of any of our product candidates, a regulatory agency may: issue a warning letter asserting that we are in violation of the law and potentially restricting our ability to sell, manufacture, import or export our products; seek an injunction or impose civil or criminal penalties or monetary fines; suspend or withdraw regulatory approval or revoke a license; suspend any ongoing clinical trials; refuse to approve a pending NDA or supplements to a NDA submitted by us; seize product; or refuse to allow us to enter into supply contracts, including government contracts. Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize any approved products and generate revenues.

If we are successful in gaining approval for any of our product candidates, we and our CDMOs, which manufacture our products under contract, will continue to face significant regulatory oversight of the manufacturing and distribution of our products. Product manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by Regulatory Authorities for compliance with cGMP and adherence to commitments made in the NDA. If we or a regulatory agency discovers previously unknown problems with a product such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. Certain endpoint data we hope to include in any approved product labeling also may not make it into such labeling, including exploratory or secondary endpoint data such as patient-reported outcome measures. The FDA may also require a Risk Evaluation and Mitigation Strategy ("REMS") as a condition of approval of our product candidates, which could entail requirements for long-term patient follow-up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Comparable requirements may apply in foreign countries. In addition, if Regulatory Authorities approve any of our product candidates, we will have to comply with requirements including submissions of safety and other post-marketing information, reports and registration.

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

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

Additionally, Regulatory Authorities strictly regulate marketing, labeling, advertising and promotion of products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label.

The policies of Regulatory Authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. In addition, the U.S. Supreme Court's July 2024 decision to overturn established case law giving deference to Regulatory Authorities' interpretations of ambiguous statutory language has introduced ongoing uncertainty regarding the extent to which the FDA's regulations, policies and decisions may become subject to increasing legal challenges, delays and/or changes. 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 lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

We may develop certain of our product candidates in combination with other therapies or as add-ons to the standard of care. Developing combination treatments increases complexity and risk, including risks of drug-drug interactions, unforeseen side effects or failures in our clinical trials that could delay or prevent their regulatory approval or limit the commercial profile of an approved label.

We are currently evaluating zolucatetide in patients receiving standard-of-care chemotherapy and other agents, including in combination with FOLFOX plus bevacizumab, trifluridine/tipiracil plus bevacizumab, and nivolumab, for the treatment of CRC, and in combination with nivolumab for the treatment of solid tumors, to assess zolucatetide's potential as part of combination regimens for the treatment of and reduction in tumors in CRC and other solid tumors. The use of our product candidates in combination with each other and/or in patients already receiving other companies' treatments may subject us to risks that we would not face if our product candidates were to be administered as monotherapies.

For example, either the combination of our product candidates with each other, or when used in patients already receiving other companies' products or product candidates, may result in unexpected adverse side effects or toxicities that the product candidates or other therapy do not produce when used alone. In addition, the product candidates may interact with each other, or with other companies' products or product candidates that patients receiving our product candidates may also be receiving, in undesirable ways that could negatively impact the potency or efficacy and safety of our product candidates, or of the other companies' products or product candidates. Testing product candidates in patients already receiving other treatments may increase the risk of significant adverse effects or failed clinical trials. The timing, outcome and cost of the potential adverse effects of developing products to be used in patients already receiving other therapies is difficult to predict and dependent on a number of factors that are outside our reasonable control. If serious adverse or unexpected side effects are identified during development and are determined to be attributed to our product candidates, or the result of drug-drug interactions between our product candidate and any of the concomitant therapies given to the trial subjects, we, the Regulatory Authorities, or IRBs and other reviewing entities, could interrupt, delay, or halt clinical trials and could result in a more restrictive label or particularly narrow product indication (substantially limiting the product's commercial opportunities), a REMS or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities.

In addition, to the extent we choose to develop and commercialize a product candidate for use in patients receiving an already approved therapy, as is the case, in part, with zolucatetide, any safety, efficacy, regulatory, manufacturing or supply issues that could arise with respect to the approved therapy could have an adverse impact on us. Prescribing information for the approved therapy, such as risk information like a boxed warning, or limitations of use, could negatively impact our ability to develop and commercialize a product as an add-on or as further supportive care to the approved therapy. If the approved therapy is replaced as the standard of care, Regulatory Authorities may require us to conduct additional clinical trials, or we may not be able to obtain adequate reimbursement from third-party payors. Further, Regulatory Authorities could revoke approval of the therapy patients in our clinical trials are receiving. The occurrence of any of these risks could result in an add-on product candidate being developed as further supportive care, if successfully developed and approved, being removed from the market or being less successful commercially. If Regulatory Authorities revoke their approval of, or if safety, efficacy, manufacturing, or supply issues arise with respect to, therapies we choose to evaluate in conjunction with or as background or standard of care therapy for any of our product candidates, we may be unable to obtain regulatory approval of or to commercialize such product candidates in combination with these therapies. If we experience safety, tolerability or toxicity issues in any of our ongoing or planned clinical trials that allow patients to remain on other therapies, or if the efficacy data from these trials of our candidates administered to patients on other therapies are not favorable, our clinical development plans could be materially negatively affected or delayed, or we may not receive regulatory approval for our product candidates, which would materially harm our business and likely cause the market price of our common stock to decline.

In addition, because zolucatetide is expected to be administered in combination with other therapies for certain indications, payors may assess the overall cost of the treatment regimen, not solely the cost or value proposition of our licensed product. Combination regimens are subject to heightened reimbursement risk, as payors may:

- decline to cover the full regimen based on the aggregated cost of the component therapies;
- require step-through use of lower-cost or single-agent treatments before approving the combination;
- assign the combination to a more restrictive formulary tier, resulting in higher patient cost-sharing or reduced utilization;
- impose prior authorization, clinical criteria or other restrictions that limit prescribing; or
- negotiate price concessions with us based on the cost structure or formulary status of the companion therapy.

Even if our product candidate demonstrates clinical benefit as part of a combination regimen, payors may determine that the incremental value is insufficient to justify the overall cost and may refuse to reimburse at levels that are acceptable to us or that support commercial viability. In addition, we do not control the pricing, contracting strategy or reimbursement profile of the companion therapy, which may change over time and adversely impact the attractiveness or economics of the combination. If coverage for the companion therapy is reduced, withdrawn, or made more restrictive, the value proposition for our product candidate could be materially weakened.

We have received Fast Track Designation for zolucatetide in desmoid tumors, and we may in the future seek additional designations for our product candidates with Regulatory Authorities that are intended to confer benefits such as a faster development process, a streamlined review or regulatory exclusivity. There can be no assurance that we will successfully obtain additional designations, and even where our product candidates have been or are granted such designations, we may not be able to realize the intended benefits of such designations.

Regulatory Authorities offer certain designations for product candidates that are designed to encourage the research and development of product candidates that are intended to address serious conditions. These designations may confer benefits such as additional interaction with Regulatory Authorities, streamlined development pathways and expedited review procedures. However,

there can be no assurance that we will successfully obtain such designations for our product candidates, and if we do successfully obtain such designations, that a Regulatory Authority will not revoke such designation. In addition, while such designations could expedite the development or approval process, they generally do not change the standards for approval. Even if we obtain such designations for our product candidates, there can be no assurance that we will realize their intended benefits.

For example, if a product is intended for the treatment of a serious or life-threatening condition and nonclinical or clinical data demonstrate the potential to address an unmet medical need for this condition, the product sponsor may apply for Fast Track Designation from the FDA. 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 the 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, there can be no assurance that the FDA would decide to grant it. In November 2025, we obtained Fast Track Designation for zolucatetide in desmoid tumors, and we may seek additional designation for our current and future product candidates. Even where we have received and may in the future receive Fast Track Designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. Additionally, the FDA may rescind any Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development activities.

Even in the absence of obtaining certain designations, a sponsor can seek priority review at the time of submitting a marketing application. The FDA may designate an application for priority review if the product is intended to treat a serious condition and, if approved, would provide a significant improvement in safety or effectiveness when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting adverse reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, or evidence of safety and effectiveness in a new subpopulation. A priority review designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for acting on a marketing application from ten months to six months. Priority review designation may be rescinded if a product no longer meets the qualifying criteria, and a priority review designation does not guarantee that FDA will in fact act more quickly on the application than if it were a standard review application.

Where appropriate, we may secure approval from Regulatory Authorities through the use of expedited approval pathways, such as accelerated approval from the FDA or comparable foreign abbreviated pathways. Even if we receive accelerated approval from the FDA or approval following comparable foreign abbreviated pathways by foreign Regulatory Authorities, if our confirmatory trials do not confirm clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA or such Regulatory Authorities may seek to withdraw the accelerated approval.

Where possible, we plan to pursue accelerated development strategies in areas of high unmet need. We may seek an accelerated approval pathway for one or more of our potential future product candidates from Regulatory Authorities. Under the accelerated approval provisions in the Federal Food, Drug, and Cosmetic Act ("FDCA"), and the FDA's implementing regulations, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. Under the Food and Drug Omnibus Reform Act of 2022 ("FDORA"), the FDA is permitted to require, as appropriate, that a post-approval confirmatory study or studies be underway prior to approval or within a specified time period after the date of approval for a product granted accelerated approval. FDORA also gives the FDA increased authority to withdraw approval of a drug granted accelerated approval on an expedited basis if the sponsor fails to conduct such studies in a timely manner, send status updates on such studies to the FDA every 180 days to be publicly posted by the agency, or if such post-approval studies fail to verify the drug's predicted clinical benefit. The FDA is empowered to act, such as issuing fines, against companies that fail to conduct with due diligence any post-approval confirmatory study or submit timely reports to the agency on their progress.

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

We have been granted Orphan Drug Designation for zolucatetide for the treatment of desmoid tumors and we may seek Orphan Drug Designation for other indications or for our other product candidates, but we may be unsuccessful in obtaining or may be unable to maintain the benefits associated with Orphan Drug Designation, including the potential for market exclusivity.

As part of our business strategy, we have sought and may in the future seek Orphan Drug Designation for the product candidates we develop, and we may be unsuccessful in obtaining or maintain such designations. Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the United States, Orphan Drug Designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In January 2026, the FDA granted Orphan Drug Designation to zolucatetide for the treatment of desmoid tumors.

Similarly, in Europe, the European Commission grants Orphan Drug Designation after receiving the opinion of the EMA Committee for Orphan Medicinal Products on an Orphan Drug Designation application. Orphan Drug Designation is intended to promote the development of drugs that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than five in 10,000 persons in Europe and for which no satisfactory method of diagnosis, prevention or treatment has been authorized (or the product would be a significant benefit to those affected). Additionally, designation is granted for drugs intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in Europe would be sufficient to justify the necessary investment in developing the drug. In Europe, Orphan Drug Designation entitles a party to a number of incentives, such as protocol assistance and scientific advice specifically for designated orphan medicines, and potential fee reductions depending on the status of the sponsor.

Generally, if a drug with an Orphan Drug Designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the EMA, or the FDA from approving another marketing application for the same drug and for the same indication during the period of exclusivity, except in limited circumstances. The applicable period is seven years in the United States and 10 years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for Orphan Drug Designation or if the drug is sufficiently profitable such that market exclusivity is no longer justified.

Even though we have obtained Orphan Drug Designation for zolucatetide for the treatment of desmoid tumors, that exclusivity may not effectively protect such product candidate from competition because different therapies can be approved for the same condition and the same therapies can be approved for different conditions but used off-label. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Moreover, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Orphan Drug Designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. While we have received Orphan Drug Designation for zolucatetide for the treatment of desmoid tumors and may seek Orphan Drug Designation for applicable indications for our current and any future product candidates, we may be unable to maintain or obtain such designations. Even where we have and may in the future receive such designations, there is no guarantee that we will enjoy the benefits of such designations.

Disruptions at the FDA and other government agencies caused by funding shortages, leadership changes, staffing limitations, or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, prevent new or modified products from being developed, review, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA and Regulatory Authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's or foreign regulatory authorities' ability to hire and retain leadership and key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's or foreign Regulatory Authorities' ability to perform routine functions. Average review times at the FDA and foreign Regulatory Authorities have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs or modifications to approved drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, the U.S. government has shut down several times and certain Regulatory Authorities, such as the FDA, have had to furlough critical FDA employees and stop critical activities. In addition, the current U.S. presidential administration has issued certain policies and Executive Orders directed towards reducing the employee headcount and costs associated with U.S. administrative agencies, including the FDA, and it remains unclear the degree to which these efforts may limit or otherwise adversely affect the FDA's ability to conduct routine activities.

If a prolonged government shutdown occurs, or if renewed global health concerns, funding shortages or staffing limitations hinder or prevent the FDA or other Regulatory Authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other such regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Risks Related to Our Helicon Discovery Platform and Our Use of Artificial Intelligence

Our approach to the engineering and development of our programs is unproven, and we may not be successful in our efforts to identify and develop any programs and product candidates of commercial value by leveraging our Helicon discovery platform.

The Helicon discovery platform and our approach to drug engineering and development utilizes, among other things, our proprietary AI and machine learning solutions to create a pipeline of product candidates. Because our approach is both proprietary and pioneering, the cost and time needed to develop our programs and product candidates can be difficult to predict, and our efforts may not result in the engineering and development of commercially viable human therapeutics.

Any drug engineering and development that we are conducting with our Helicon discovery platform may not be successful in identifying programs and product candidates that have commercial value or therapeutic utility. The Helicon discovery platform may initially show promise in identifying potential programs and product candidates, yet fail to yield viable programs and product candidates for clinical development or potential commercialization for a number of reasons, including:

- research programs to identify new programs and product candidates will require substantial technical, financial and human resources, and we may be unsuccessful in our efforts to identify new programs and product candidates. If we are unable to identify suitable additional compounds for nonclinical and clinical development, our ability to develop programs and product candidates and obtain product revenues in future periods could be compromised, which could result in significant harm to our financial position and adversely impact our stock price;
- programs and product candidates engineered with our Helicon discovery platform may not demonstrate efficacy, safety or tolerability, including because they may demonstrate different chemical and pharmacological properties in patients than they do in laboratory studies, or otherwise may interact with human biological systems in unforeseen, ineffective or possibly harmful ways;
- programs and product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to receive marketing approval and achieve market acceptance;
- competitors may develop alternative therapies that render our programs and product candidates non-competitive or less attractive; or
- a potential product candidate may not be capable of being produced at an acceptable cost.

In addition, we may in the future seek to identify and develop programs and engineer and develop product candidates that are based on novel targets and technologies that are unproven. If our activities fail to identify novel targets or technologies for drug engineering and development, or such targets prove to be unsuitable for treating human disease, we may not be able to develop viable additional programs and product candidates. We may never receive approval to market and commercialize any product candidate. Even if we obtain regulatory approval, the approval may be for targets, disease indications or patient populations that are not as broad as we intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. If the

product candidates resulting from our programs prove to be ineffective, unsafe or commercially unviable, our programs and product candidates would have little, if any, value, which would have a material and adverse effect on our business, financial condition, results of operations and prospects.

We are substantially dependent on the successful application of our Helicon discovery platform to develop programs and product candidates that can be commercialized by us or our current or future collaboration partners.

Since our formation, we have focused on investing in our Helicon discovery platform to unlock a new way of developing programs and product candidates for development and, if approved, potential commercialization by us and our collaboration partners. The biotechnology industry is capital intensive, and our success depends significantly on our ability to apply our Helicon discovery platform to develop programs and engineer and develop product candidates that can be further developed by us or our current or future collaboration partners. Our ability to engineer and develop product candidates and increase revenue depends in large part on our ability to continue to enhance and improve our Helicon discovery platform. We have invested, and expect to continue to invest, in research and development efforts, acquisitions and licensing agreements that further enhance our Helicon discovery platform. These investments may involve significant time, risks and uncertainties, including the risks that any new software or hardware enhancement or the integration of software or hardware from a third-party licensor may not be introduced in a timely or cost-effective manner; may interfere with our intellectual property; may not keep pace with technological developments; may not achieve the functionality necessary to generate significant revenues; or other risks inherent to the use of AI to develop software. The success of any enhancement to our Helicon discovery platform depends on several factors, including (i) the development of more advanced AI models and algorithms; (ii) the generation of additional high quality and relevant data; (iii) innovation and investment in other experimental, computational and/or infrastructure technologies, including automation technologies; and (iv) increased computational storage and processing capacity.

The Helicon discovery platform depends upon the continuous, effective and reliable operation of our laboratory systems and AI solutions, including software, hardware, databases and related tools and functions, as well as the integrity of our data. We have from time to time found defects, vulnerabilities or other errors in such tools, functions and data, and new errors may be detected in the future. The risk of errors is particularly significant when new software code or hardware is first introduced or when new versions or enhancements of existing software code or hardware are implemented. Errors may also result from the interface of our proprietary software and hardware tools with our data or with third-party systems and data.

Further, the price of new equipment and hardware, including graphics processing units ("GPUs") and random access memory ("RAM"), is subject to market fluctuations. Such fluctuations are influenced by factors, including supply and demand for such equipment. In the case of GPUs and RAM for AI services, current demand for certain types of GPUs, RAM and networking equipment far exceeds supply, impacting the price and availability of such hardware. As a result, the cost of new equipment has been and may in the future be unpredictable, and may also be significantly higher than our historical costs.

If we are unable to successfully enhance our Helicon discovery platform, or if there are any defects or disruptions in our Helicon discovery platform that are not timely resolved, our ability to develop new innovations and ultimately gain market acceptance of our products and our Helicon discovery platform, could be materially and adversely impacted, and our reputation, business, operating results and prospects could be materially harmed.

We have limited clinical data on product candidates that were computationally engineered with our Helicon discovery platform demonstrating whether they are safe or effective for long-term treatment in humans. The long-term safety and efficacy of product candidates computationally engineered with our Helicon discovery platform is unknown. Our approach may not result in time savings, higher success rates or reduced costs as we expect it to, and if not, we may not attract collaborators or develop new product candidates as quickly or cost effectively as expected and we therefore may not be able to execute on our strategic approach as originally expected.

Product candidates engineered with our Helicon discovery platform require substantial technical, financial and human resources to develop and potentially commercialize. We may not be able to maintain sufficient resources and expertise to discover additional programs and product candidates. If we are unable to identify successful programs and product candidates for nonclinical and clinical development and regulatory approval in a timely matter or at all, we could experience significant delays or an inability to successfully pursue strategic alternatives, including identifying and consummating transactions with third-party partners, to further develop, obtain marketing approval for and/or commercialize our product candidates, which could harm our business.

Issues relating to our use of AI in the identification of our programs and the engineering and development of our product candidates could adversely affect our business and operating results.

We incorporate AI solutions, among other technologies and capabilities, into our Helicon discovery platform. There are risks involved in utilizing AI, including that AI-generated content, analyses, or recommendations we utilize could be deficient, that our competitors may more quickly or effectively adopt AI capabilities, or that our use of AI or other emerging technologies increases regulatory, cybersecurity and other significant risks. If our AI systems fail to achieve their intended purposes – such as identifying binding sites on proteins, identifying viable therapeutic candidates or targets, predicting biological outcomes, producing reproducible results, and other similar or related purposes – our product development efforts may be delayed or unsuccessful. If we are unable to successfully integrate and manage AI within our business, or if AI fails to deliver the expected benefits, our ability to develop our programs and product candidates could be materially adversely affected.

Issues relating to the use of new and evolving technologies such as AI may cause us to experience brand or reputational harm, competitive harm, legal liability and new or enhanced governmental or regulatory scrutiny, and we may incur additional costs to resolve such issues. Known risks of AI generally include inaccuracy, hallucinations, bias, intellectual property infringement or misappropriation, data privacy and cybersecurity issues and data provenance disputes. Perceived or actual technical, legal, compliance, privacy, security, ethical or other issues relating to the use of AI in biopharmaceutical development may cause public confidence in AI to be undermined, which could slow market acceptance of product candidates discovered and developed using AI. In addition, litigation or government regulation related to the use of AI may also adversely impact our ability to identify programs and engineer and develop product candidates using AI, as well as increase the cost and complexity of doing so. For example, regulators may limit our ability to develop or implement our proprietary AI models and algorithms and/or may eliminate or restrict the confidentiality of our proprietary technology, or may limit our ability to secure intellectual property rights to technologies created with the assistance of our proprietary AI models and algorithms, which could have an adverse effect on our business, results of operations and financial condition.

We also face increased competition from other companies that claim to use AI and related methods for drug engineering and development, some of which have more resources than we do and may have developed more effective methods than we and any third-party collaborators have, which may reduce our and any third-party collaborators' effectiveness in identifying potential product candidates and attracting additional collaborators to work with us. In particular, biotechnology companies based in China present both known and emerging competitive threats to our business. Many of these companies operate within innovation ecosystems characterized by substantial government investment, access to large and rapidly expanding biological and clinical datasets, and accelerated regulatory or funding pathways. These factors may allow Chinese biotechnology companies to develop, train and deploy advanced computational models, drug discovery platforms or design technologies more rapidly or at lower cost than we can. If our competitors are able to utilize new technologies more effectively (including but not limited to those that may involve AI or be created using AI) to discover, develop and commercialize products that compete with any of our programs and product candidates, such technologies could adversely impact our ability to compete.

Further, AI may have or produce errors or inadequacies that are not easily detectable. The quality of AI outputs depends heavily on the quality and quantity of input data. If the data used to train AI or the content, analyses or recommendations that AI applications assist in producing are or are alleged to be deficient, inaccurate, incomplete, hallucinatory, overbroad or biased, our business, financial condition and results of operations may be adversely affected. Developing, testing and deploying AI systems may also increase the cost profile of our product offerings due to the nature of the computing costs involved in such systems, which could impact our project margin and adversely affect our business and operating results.

The legal landscape and subsequent legal protection for the use of AI remains uncertain, and the increasing use of AI in drug discovery and development introduces new and evolving risks related to ownership, inventorship and protection of intellectual property generated by or with the assistance of AI technologies. For example, generative AI may be used improperly or inappropriately, which could lead to the tainting of our proprietary information and render us unable to qualify for certain patent or trade secret protection. Moreover, if our vendors, employees, suppliers or contractors with access to our proprietary and confidential information and know-how were to disclose such information as inputs to third-party AI tools this could lead to loss of trade secret protection and otherwise impact our ability to realize the benefit of our intellectual property. If we do not have sufficient rights to collect or use the data on which our AI relies or to the outputs produced by our Helicon discovery platform, we may incur liability through the alleged violation of certain laws, third-party privacy rights, online terms of service or other contracts to which we or our data providers are a party. In addition, we rely on third-party software and hardware for our Helicon discovery platform. If the relevant software or hardware, or updates to such software or hardware, were to become unavailable to us in the future on reasonable commercial terms, or if they became the subject of allegations of intellectual property infringement, our ability to continue to use our Helicon discovery platform could be affected. We also rely on public sources of data, such as the Protein Data Bank, Uniprot and DepMap, among others, which, if they became unavailable to us on reasonable terms, could affect our Helicon discovery platform.

Regulatory and legal frameworks governing inventions created with or using AI are still developing and may create uncertainty regarding our ability to secure and enforce rights in such inventions.

AI presents risks and challenges that can impact our business including by posing security risks to our confidential information, proprietary information, and personal data.

Issues in the development and use of AI, combined with an uncertain regulatory environment, may result in reputational harm, liability or other adverse consequences to our business operations. As with many technological innovations, AI presents risks and challenges that could impact our business. In addition to our Helicon discovery platform, we have adopted and integrated, and in the future may adopt and integrate additional generative AI tools into our systems for specific use cases reviewed by our legal department and information technology department. Our vendors may incorporate generative AI tools into their offerings without disclosing this use to us, and the providers of these generative AI tools may not meet existing or rapidly evolving regulatory or industry standards with respect to privacy and data protection and may inhibit our or our vendors' ability to maintain an adequate level of service and experience. If we, our vendors or our third-party partners experience an actual or perceived breach or privacy or security incident because of the use of generative AI, we may lose valuable intellectual property and confidential information and our reputation and the public perception of the effectiveness of our security measures could be harmed. Further, bad actors around the world use increasingly sophisticated methods, including the use of AI, to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. Any of these outcomes could damage our reputation, result in the loss of valuable property and information, and adversely impact our business.

Our use of AI may also lead to novel and urgent cybersecurity and privacy risks, which may adversely affect our operations and reputation, as well as the operations of any third-party collaborators. Emerging ethical issues surround the use of AI, and we may be subject to reputational and legal risk if our deployment or use of AI becomes controversial. Our use of AI may also, in the future, result in cybersecurity incidents that implicate personal data of customers or patients. Any such cybersecurity incidents related to our use of AI could adversely affect our reputation and results of operations.

A growing number of federal, state, and international legislators, agencies and regulators are adopting laws and regulations and have focused enforcement efforts on the adoption of AI, and use of such technologies in compliance with ethical standards and societal expectations. These developments may increase our compliance burden and costs in connection with use of AI and lead to legal liability if we fail to meet evolving legal standards or if use of such technologies results in harms or other causes of action we did not predict. For example, the EU's Artificial Intelligence Act entered into force on August 1, 2024, with most provisions becoming effective on August 2, 2026. This legislation imposes significant obligations on providers and deployers of AI systems and encourages providers and deployers of artificial intelligence systems to account for EU ethical principles in their development and use of these systems. The recently enacted United States Department of Justice Data Security Program (also known as the Bulk Data Transfer Rules), effective April 8, 2025, imposes complex additional restrictions on international data transfers, which may affect our ability to do business in manufacturing and clinical research in foreign countries. Likewise, in the United States, several states, including Colorado and California, passed laws to regulate various AI uses, including on deployment of AI in healthcare settings. At the federal level, the Trump Administration has endorsed a federal moratorium on the enforcement of state AI laws, including through a December 11, 2025, executive order on "Ensuring a National Policy Framework for Artificial Intelligence." So far, these efforts have not been successful at curtailing state action on AI regulation, contributing to a complicated legislative patchwork, which may be litigated in state and federal courts. In addition, various federal regulators have issued guidance and focused enforcement efforts on the use of AI in regulated sectors. The FDA, for example, issued draft guidance on the use of AI in regulatory decision-making for drug products that centers on the context of use while establishing a credibility assessment framework for establishing and evaluating AI model outputs intended to support regulatory decision-making. If we develop or use AI systems governed by these laws or regulations, including as informed by regulatory guidance, we would need to meet higher standards of data quality, transparency, monitoring and human oversight, and we would need to adhere to specific and potentially burdensome and costly ethical, accountability and administrative requirements, with the potential for significant enforcement or litigation in the event of any perceived non-compliance. We expect other jurisdictions will adopt similar laws. Uncertainty in the legal regulatory regime may require significant resources to modify and maintain business practices to comply with U.S. and non-U.S. laws, the nature of which cannot be determined at this time. The scope of requirements depends on legal and risk determinations that rely on novel legal provisions that have not yet been interpreted by courts or regulators, and non-compliance can lead to significant fines or significant restrictions on our ability to conduct our business activities.

We utilize third-party open-source software ("OSS"), which presents risks that could adversely affect our business and subject us to possible litigation.

We utilize software that is licensed from third parties under open-source licenses, and we expect to continue to use such OSS in the future. Use of OSS may entail greater risks than use of third-party commercial software because open-source licensors generally do not provide support, updates or warranties or other contractual protections regarding infringement claims or the quality of the code.

OSS may also be more susceptible to security vulnerabilities. The availability of OSS could be adversely affected by service outages, data loss, privacy breaches, cyber-attacks and other events relating to the availability of these applications and services they provide, which could diminish the utility of these services and harm our business. We also could be subject to lawsuits by third parties alleging that what we believe to be licensed OSS infringes such parties' intellectual property rights, which could be costly for us to defend and require us to devote additional research and development resources to change our solutions. Some OSS licenses contain requirements that we make available source code for modifications or derivative works we create based upon the type of OSS we use. If we combine our proprietary software with OSS in a certain manner, we could, under certain of the OSS licenses, be required to release the source code of our proprietary software to the public. This could allow our competitors to create similar products with lower development effort and time, and ultimately could result in a loss of product sales for us. Although we monitor our use of OSS, the terms of many OSS licenses have not been interpreted by U.S. courts, and there is a risk that those licenses could be construed in a manner that could impose unanticipated conditions or restrictions on our ability to commercialize our product candidates. We could be required to seek licenses from third parties in order to continue using our software, to re-engineer our software or to discontinue use of our software in the event re-engineering cannot be accomplished on a timely basis, any of which could materially and adversely affect our business, financial condition, results of operations and prospects.

Risks Related to the Manufacturing of Our Product Candidates and Our Future Pipeline

We rely on third parties for the supply and manufacture of our product candidates for our research, nonclinical and clinical activities, and may do the same for commercial supplies of our products, if approved. As our pipeline increases and matures, the increased demand for supplies from our manufacturers may increase the risk that we will not have sufficient supply when needed or at an acceptable cost.

We currently utilize, and expect to continue to utilize, CDMOs to, among other things, supply and manufacture raw materials, components, parts and consumables, and to perform quality testing for our nonclinical and clinical supply for all of our product candidates. For example, we are party to agreements with WuXi AppTec Co. Ltd. ("WuXi") and Bachem Americas, Inc. for our active pharmaceutical ingredient ("API"), and Alcami Corporation ("Alcami") for our drug product manufacturing. We intend to continue to rely on these manufacturers, and other manufacturers to manufacture zolucatetide. In order to produce sufficient quantities to meet the demand for clinical trials and, if approved, subsequent commercialization of our product candidates, our CDMOs will be required to increase their production and optimize their manufacturing processes while maintaining the quality of our product candidates, as applicable. The transition to larger scale production could prove difficult. If our third-party manufacturers are not able to optimize their manufacturing processes to increase the product yield for our product candidates, or if they are unable to produce increased amounts of our product candidates while maintaining the same quality, then we may not be able to meet the demands of clinical trials or market demands, which could adversely impact our ability to timely conduct our clinical trials or commercialize our product candidates, if approved, and have a material adverse impact on our business and results of operations. Furthermore, with the increase of companies developing complex synthetic therapeutics, there may be increased competition for the supply of the raw materials that are necessary to manufacture our product candidates, which could severely impact the manufacturing of our product candidates.

Even if we are able to maintain arrangements with our CDMOs, reliance on CDMOs entails additional risks, including:

- the failure of the CDMO to comply with applicable regulatory requirements and reliance on third parties for manufacturing process development, regulatory compliance and quality assurance;
- manufacturing delays if our CDMOs give greater priority to the supply of other products over our product candidates or otherwise do not perform satisfactorily according to the terms of the agreement between us;
- limitations on supply availability resulting from capacity and scheduling constraints of third parties;
- the possible breach of manufacturing agreements by our CDMOs because of factors beyond our control;
- the possible termination or non-renewal of the manufacturing agreements by our CDMOs, at a time that is costly or inconvenient to us; and
- the possible misappropriation of our proprietary technology and IP, including our know-how.

If we are unable to maintain our key manufacturing relationships, we may fail to find replacement CDMOs, which could delay or impair our ability to obtain regulatory approval for our product candidates. If we do find replacement CDMOs, we may not be able to enter into agreements with them on terms and conditions favorable to us and there could be a substantial delay before new facilities could be qualified and registered with the Regulatory Authorities.

We do not currently have long-term supply contracts with all of our suppliers and they are not obligated to supply materials to us for any period, in any specified quantity or at any certain price beyond the delivery contemplated by the relevant purchase orders. As a result, our suppliers could stop selling to us at commercially reasonable prices, or at all. While we intend to enter into long-term

master supply agreements with certain of our suppliers and manufacturers in the future as we advance our clinical trials or commercialization plans, we may not be successful in negotiating such agreements on favorable terms or at all. Our failure to secure these arrangements as needed could have a material adverse effect on our ability to complete the development of our product candidates or, to commercialize them, if approved. If we do enter into such long-term master supply agreements, or enter into such agreements on less favorable terms than we currently have with such manufacturers, we could be subject to binding long-term purchase obligations that may be harmful to our business, including in the event that we do not conduct our trials on planned timelines or utilize the materials that we are required to purchase.

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

If any of our product candidates are approved by any Regulatory Authority, we will likely utilize arrangements with CDMOs for the commercial production of such product. This process is difficult and time-consuming and we may face competition for access to manufacturing facilities as there are a limited number of CDMOs operating under cGMPs that are capable of manufacturing our product candidates. Consequently, we may not be able to reach agreement with CDMOs on satisfactory terms, which could delay our commercialization.

The operations of our suppliers and CDMOs, some of which are located outside of the United States, are subject to additional risks that are beyond our control and that could harm our business, financial condition, results of operations and prospects. As a result of our global suppliers, 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 products 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 CDMOs' compliance with cGMPs or status acceptable to 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 CDMOs or suppliers are located.

In particular, there is currently significant uncertainty about the future relationship between the United States and various other countries, including China, with respect to trade policies, treaties, government regulations and tariffs. It is possible further tariffs may be imposed that could affect imports of active pharmaceutical ingredients used in our product candidates, or our business may be adversely impacted by retaliatory trade measures taken by China or other countries, including restricted access to such raw materials used in our product candidates. Given the unpredictable regulatory environment in China and the United States and uncertainty regarding how the U.S. or foreign governments will act with respect to tariffs, international trade agreements and policies, further governmental action related to tariffs, additional taxes, contracting matters, regulatory changes or other retaliatory trade measures in the future could occur with a corresponding detrimental impact on our business, financial condition, results of operations and growth prospects. These and other factors beyond our control could interrupt our suppliers and CDMOs' production, influence their ability to

export and manufacture our clinical supplies, cost-effectively or at all, and inhibit their ability to procure certain materials, any of which could harm our business, financial condition, results of operations and prospects.

We depend on sole source and limited source suppliers for certain drug substances, drug products, raw materials, samples, components, and other materials used in our product candidates. If we are unable to source these supplies on a timely basis, or establish longer-term contracts with our suppliers, we will not be able to complete our clinical trials on time and the development of our product candidates may be delayed.

We depend on sole source and limited source suppliers for certain raw materials, APIs, drug products, drug substances and other materials used in our product candidates. For example, we are party to an agreement with Alcami, which is currently our sole supplier for drug product. Any change in our relationships with such suppliers or changes to contractual terms of our agreements with them could adversely affect our business, financial condition, results of operations and prospects. Moreover, there may be difficulties in scaling up the clinical or commercial quantities of our product candidates despite such agreements, and the costs of manufacturing could become prohibitive.

Furthermore, any of the sole source and limited source suppliers upon whom we rely could stop producing our supplies, cease operations or be acquired by, or enter into exclusive arrangements with, our competitors. In addition, geopolitical tensions may impact our suppliers. For example, the U.S. BIOSECURE Act, which was enacted in December 2025, prohibits federal agencies from procuring or using any biotechnology equipment or services provided or produced by "biotechnology companies of concern," or entering, extending, or renewing any contracts with entities that use such biotechnology equipment or services from "biotechnology companies of concern" To perform on those contracts. The Office of Management and Budget ("OMB") will issue a list of "biotechnology companies of concern" no later than December 2026. Under the terms of the BIOSECURE Act, the OMB's list of "biotechnology companies of concern" will include companies that are named in the Department of Defense's 1260H List of Chinese military companies and that OMB determines are involved in the manufacturing, distribution, provision or procurement of biotechnology equipment or services, and companies that OMB designates as a "biotechnology company of concern," which are entities under the control of a foreign adversary (like China) and that pose a risk to national security based on its research with foreign government militaries or multiomic data collection (*e.g.*, collection of genomic information) without consent. On June 8, 2026, the Department of Defense named WuXi to its 1260H List of Chinese military companies. WuXi challenged the designation in the U.S. District Court for the District of Columbia, and on August 7, 2026, the court preliminarily enjoined the Department of Defense from giving effect to the designation while the litigation proceeds. The injunction is preliminary and remains subject to further proceedings, the Department of Defense may be permitted to redesignate WuXi, and OMB, which is not a party to the litigation, may designate WuXi under the BIOSECURE Act's separate OMB designation pathway, which does not depend on the 1260H List. While the U.S. BIOSECURE Act has a grandfathering period of five years for existing contracts, and has carveouts that protect drugs paid under Medicaid, subject to the Secretary of Veteran Affairs' discretion, the impact of the U.S. BIOSECURE Act on the biotechnology industry is uncertain. If WuXi is designated a "biotechnology company of concern" and any government funding or contracts in which we may participate are implicated, we may be required to transition away from WuXi, which could disrupt our supply chain and make our costs of good higher and require us to utilize and qualify alternative CDMOs.

Establishing additional or replacement suppliers, 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 sole source or 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 limited or sole source 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 product candidates we develop may be complex and difficult to manufacture. We may encounter difficulties in manufacturing, product release, shelf life, testing, storage, supply chain management or shipping. If we or any of our CDMOs encounter such difficulties, our ability to supply material for clinical trials or any approved product could be delayed or stopped.

The manufacturing processes for our product candidates are complex and, if not developed and manufactured under well-controlled conditions, can adversely impact pharmacological activity. We may encounter difficulties in manufacturing, product release, shelf life, testing, storage and supply chain management or shipping. These difficulties could be due to any number of reasons, including, but not limited to, complexities of producing batches at larger scale, equipment failure, choice and quality of raw materials and excipients, analytical testing technology and product instability. Moreover, we are currently conducting, and will in the future conduct, our clinical trials internationally. For example, we plan to enroll patients in our ongoing Phase 1/2 clinical trial for zolucatetide in patients with advanced solid tumors in Australia and China, and we plan to conduct our registrational Phase 3 clinical

trial for zolucatetide in patients with desmoid tumors in these countries. Logistical issues associated with shipping our product candidates and other materials globally from manufacturing sites to clinical sites, such as errors or improper handling by third-party carriers, transportation restrictions, or interruptions caused by natural disasters or force majeure events, could result in loss or destruction of, or damage to, our clinical supply, which may in turn cause delays in initiating or completing clinical trials.

As our product candidates proceed through nonclinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as the vendors used to manufacture drug product or manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Our rate of innovation is high, which has caused, and will continue to cause, a high degree of technological change. As we scale the manufacturing output for particular product candidates, we plan to continuously improve yield, purity and the pharmaceutical properties of our product candidates from IND-enabling studies through commercial launch, including shelf-life stability, and solubility properties of product and drug substance. Because of continuous improvement in manufacturing processes, we may switch processes for a particular product candidate during development. However, after a change in process, additional time is required for pharmaceutical property testing, such as 6- or 12-month stability testing. Such testing may require resupplying clinical material, or making additional cGMP batches to keep up with clinical trial demand before such pharmaceutical property testing is completed.

Such technological changes can negatively impact product comparability during and after clinical development. Furthermore, technological changes may drive the need for changes in, modification to or the sourcing of new manufacturing infrastructure or may adversely affect third-party relationships. Such technological changes also carry the risk that they will not achieve these intended objectives. Any of these technological changes could cause our product candidates to perform differently and affect the results of planned or future clinical trials conducted with the materials manufactured using altered processes, such as impacting the specification and stability of the product. Such changes may also require additional testing, notification or approval by Regulatory Authorities. This could delay or prevent completion of clinical trials, require conducting bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay or prevent approval of our product candidates and jeopardize our ability to commence sales and generate revenue. Changes in our manufacturing processes may lead to failure of lots and this could lead to a substantial delay in our clinical trials. Our product candidates may also prove to have a stability profile that leads to a lower than desired shelf life of the final approved product. This poses risk in supply requirements, wasted stock and higher cost of goods.

We have established a number of analytical assays, and may have to establish several more, to assess the quality of our product candidates. We may subsequently identify gaps in our analytical testing strategy that might prevent release of product or could require product withdrawal or recall. For example, we may discover new impurities that have an impact on product safety, efficacy or stability. This may lead to an inability to release product candidates until the manufacturing or testing process is rectified.

Moreover, there are risks inherent in biopharmaceutical manufacturing operations that could affect our ability and the ability of the CDMOs or contract manufacturing organizations to meet our delivery requirements or provide adequate amounts of material. The convergence of process and analytical technology, raw materials, consumables, equipment, physical infrastructure, including a clean room environment, and air handling and other utilities, results in complex procedures and systems that must work effectively to manufacture our product candidates. Failure or process defects in any of the interrelated systems at either our manufacturing facilities or those of our third-party providers could adversely impact our ability to manufacture and supply our product candidates.

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

Certain of our product candidates are sensitive to temperature, storage and handling conditions. They must be stored at very low temperatures in specialized freezers or specialized shipping containers until immediately prior to use. The handling and administration of our product candidates may need to be performed according to specific instructions and in some steps within specific time periods. Failure to correctly handle our product candidates could negatively impact the efficacy and/or safety of our product candidates, or cause a loss of product candidates. In addition, because it is necessary to ship our product candidates and other materials globally from manufacturing sites to clinical sites, our product candidates will need to be frozen using specialized equipment and maintained following specific procedures in order to be shipped and stored without damage in a cost-efficient manner and without degradation. For administration, the cryopreserved product container must be carefully removed from storage, and rapidly thawed under controlled temperature conditions in an area proximal to the patient's bedside and administered into the patient. The handling, thawing and administration of the cryopreserved therapy product must be performed according to specific instructions, typically using specific disposables, specific bags and in some steps within specific time periods. Failure to correctly handle our product candidates, including the potential breakage of the cryopreservation bags or to follow the instructions for thawing and administration and or failure to administer our product candidates within the specified period post-thaw could negatively impact the efficacy and/or safety of our product candidates, or cause a loss of our clinical supply.

If any of our product candidates are approved, we will need to scale-up a cost-effective and reliable cold-chain distribution and logistics network, which we may be unable to accomplish. Failure to effectively scale-up our cold-chain supply logistics, by us or third parties, could in the future lead to additional manufacturing costs and delays in our ability to supply required quantities for our commercial supply, if approved. For these and other reasons, we may not be able to manufacture our current or future product candidates at commercial scale or in a cost-effective manner. Even if we or our CDMOs are able to manufacture and distribute the products, if our products require specific procedures to maintain and use them, we may be limited in commercial opportunity.

We are subject to significant regulatory oversight with respect to manufacturing our product candidates. The manufacturing facilities of our CDMOs or suppliers may not meet regulatory requirements. Failure to meet cGMP requirements set forth in regulations promulgated by Regulatory Authorities could result in significant delays in and costs of our products.

The manufacturing of therapeutics for clinical trials or commercial sale is subject to extensive regulation. Components of a finished product approved for commercial use or used in clinical trials must be manufactured in accordance with cGMP requirements. These regulations govern manufacturing processes and procedures, including recordkeeping, and the implementation and operation of quality systems to control and assure the quality of products and materials used in clinical trials. Poor control of the cGMP production processes can lead to product quality failures that can impact our ability to supply product, resulting in cost overruns and delays to clinical timelines, which could be extensive.

Such production process issues include, but are not limited to: critical deviations in the manufacturing process; facility and equipment failures; contamination of the product due to an ineffective quality control strategy; facility contamination as assessed by the facility and utility environmental monitoring program; ineffective process, equipment or analytical change management, resulting in failed lot release criteria; raw material failures due to ineffective supplier qualification or regulatory compliance issues at critical suppliers; ineffective product stability; failed lot release or facility and utility quality control testing; ineffective corrective actions or preventative actions taken to correct or avoid critical deviations due to our developing understanding of the manufacturing process as we scale; and failed or defective components or consumables.

We must supply all necessary documentation in support of an NDA or other marketing authorization application on a timely basis and must adhere to the cGMP requirements of the Regulatory Authorities which are enforced, in the case of the FDA, in part through its facilities inspection program.

Regulatory Authorities typically require representative manufacturing site inspections to assess adequate compliance with cGMPs and manufacturing controls as described in the filing. If either we or one of our third-party manufacturing sites fails to provide sufficient quality assurance or control, the product approval to commercialize may not be granted. Inspections by Regulatory Authorities may occur at any time during the development or commercialization phase of products. The inspections may be product specific or facility specific for broader cGMP inspections or as a follow up to market or development issues that the regulatory agency may identify. Deficient inspection outcomes may influence the ability of our CDMOs or suppliers to fulfill their supply obligations, impacting or delaying supply or delaying product candidates.

The manufacturing process for any products that we may develop is subject to the approval process of the Regulatory Authorities, and we will need to contract with CDMOs who we believe can meet such requirements on an ongoing basis. If we or our CDMOs are unable to reliably produce product candidates to specifications acceptable to Regulatory Authorities, we or our collaboration partners may not obtain or maintain the approvals we or they need to commercialize such products. Even if we or our collaboration partners obtain regulatory approval for any of our product candidates, there is no assurance that either we or our contract manufacturing organizations will be able to manufacture the approved product to specifications acceptable to the Regulatory Authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates, impair commercialization efforts or increase our cost of goods. The occurrence of any of the foregoing could have an adverse effect on our business, financial condition, results of operations and growth prospects.

We have limited control over the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with cGMPs. If our CDMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of Regulatory Authorities, we may not be able to secure and/or maintain regulatory approval for our product candidates manufactured at these facilities. In addition, we have limited control over the ability of our CDMOs to maintain adequate quality control, quality assurance and qualified personnel. Furthermore, all of our CDMOs are engaged with other companies to supply or manufacture materials or products for such companies, which exposes our CDMOs to regulatory risks for the production of such materials and products. As a result, failure to meet the regulatory requirements for the production of those materials and products may generally affect the regulatory status of our CDMOs' facility. Our failure, or the failure of our CDMOs, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays,

suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products and product candidates (including those of our collaboration partners) and our overall business operations. Our dependence upon others for the manufacture of our product candidates and raw materials may adversely affect our future profit margins and our ability to commercialize any products that receive regulatory approval on a timely and competitive basis.

Regulatory Authorities may require us to submit product samples of any lot of any approved product together with the protocols showing the results of applicable tests at any time. Under some circumstances, the Regulatory Authorities may require that we do not distribute a lot or lots until the relevant agency authorizes such release. Deviations in the manufacturing process, including those affecting quality attributes and stability, may result in unacceptable changes in the product that could result in lot failures or product recalls. Lot failures or product recalls with respect to products produced by either our own facilities or those of our CDMOs could cause us and our collaboration partners to delay clinical trials or product launches, which could be costly to us and otherwise harm our business, financial condition, results of operations and prospects.

We also may encounter problems hiring and retaining the experienced scientific, quality-control and manufacturing personnel needed to operate our manufacturing processes and operations, which could result in delays in production or difficulties in maintaining compliance with applicable regulatory requirements. While we will train and qualify all personnel around the appropriate handling of our products and materials, we may not be able to control or ultimately detect intentional sabotage or negligence by any employee or contractor.

Risks Related to Our Reliance on Third Parties

We rely on and expect to continue to rely on third parties to conduct aspects of our research, nonclinical studies, clinical protocol development and clinical trials for our programs and product candidates. If these third parties do not perform satisfactorily, comply with regulatory requirements or meet expected deadlines, we may not be able to develop product candidates in a timely or cost-effective manner, or obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We currently rely and expect to continue to rely on third parties, such as CROs to perform early stage research work such as synthesis and biology, clinical data management organizations, medical institutions and clinical investigators, to conduct our clinical trials, including our ongoing Phase 1/2 clinical trial for zolucatetide in patients with advanced solid tumors. We currently rely and expect to continue to rely on third parties to conduct certain research and nonclinical testing activities. In some cases, these third parties may terminate their engagements with us. If we need to enter into alternative arrangements, it could delay our product development activities or increase our costs.

Our reliance on these third-parties for research and development activities will reduce our control over these activities but will not relieve us of our regulatory or contractual responsibilities. We will be responsible for ensuring that each of our nonclinical studies and clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with GCPs for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. For any violations of laws and regulations during the conduct of our nonclinical studies and clinical trials, we could be subject to warning letters or enforcement action that may include civil penalties up to and including criminal prosecution.

We and our CROs will be required to comply with regulations, including GCPs, for conducting, monitoring, recording and reporting the results of nonclinical studies and clinical trials to ensure that the data and results are scientifically credible and accurate and that the trial participants are adequately informed, among other things, of the potential risks of participating in clinical trials. We are also responsible for ensuring that the rights of our clinical trial participants are protected. These regulations are enforced by Regulatory Authorities for any product candidates in clinical development. The FDA enforces GCP regulations through periodic inspections of clinical trial sponsors, principal investigators and trial sites. If we or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and Regulatory Authorities may require us to perform additional clinical trials before approving our marketing applications. There is no assurance that the FDA or other Regulatory Authorities, upon inspection, will determine that any of our future clinical trials will comply with GCPs. In addition, our clinical trials must be conducted with product candidates produced in accordance with the requirements in cGMP regulations. Our failure or the failure of our CROs 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.

Although we intend to design the clinical trials for certain of our product candidates, our collaboration partners may design the clinical trials that they are managing (in some cases, with our input) and in the case of clinical trials controlled by us, we expect that CROs will perform many of the activities required to conduct clinical trials. As a result, many important aspects of our development programs, including their conduct and timing, will, in many respects, be outside of our direct control. Our reliance on third parties to conduct future nonclinical studies and clinical trials will also result in less direct control over the management of data developed through nonclinical studies and clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also potentially lead 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; form relationships with other entities, some of which may be our competitors; have human errors or be subject to cyber-attacks.

These factors may materially adversely affect the willingness or ability of third parties to conduct our nonclinical studies and clinical trials and may subject us to unexpected cost increases that are beyond our control. If the CROs do not perform nonclinical studies and clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development, regulatory approval and commercialization of our product candidates may be delayed, we may not be able to obtain regulatory approval and commercialize our product candidates, or our development programs may be materially and irreversibly harmed. If we are unable to rely on nonclinical and clinical data collected by our CROs, we could be required to repeat, extend the duration of or increase the size of any clinical trials we conduct and this could significantly delay commercialization and require significantly greater expenditures.

We also expect to rely on other third parties to transport, store and distribute the required materials for our clinical trials. In the past, certain of our third-party vendors have mishandled our materials, resulting in loss of full or partial lots of material. Any further performance failure on the part of these third-parties could result in damaged products and could delay clinical development or marketing approval of any product candidates we may develop or commercialization of our products, if approved, producing additional losses and depriving us of potential product revenue, causing us to default on our contractual commitments, result in losses that are not covered by insurance, and damage our reputation and overall perception of our products in the marketplace.

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

We have in the past entered into, and in the future may enter into, partnership, collaboration, and licensing arrangements with third parties to support development and potential commercialization of programs and product candidates. If these partnership, collaboration, and licensing arrangements are not successful, our business could be adversely affected.

We have entered into and may in the future seek to enter into partnership, collaboration, and licensing arrangements with third parties, which we refer to generally as our "collaboration partners" for strategic purposes, including for purposes of collaborating with collaboration partners with distinctive capabilities or experience with different modalities, working with collaboration partners capable of advancing the development and commercialization of our product candidates, and providing access to additional capital.

For example, we are party to a collaboration arrangement with Regeneron, pursuant to which we collaborate on research and nonclinical development programs directed toward certain targets. We may enter into additional partnership, collaboration, and licensing arrangements to take advantage of our Helicon discovery platform, including for purposes of accessing additional capabilities, expertise and funding in the future. Our existing partnership, collaboration, and licensing arrangements, and any future partnership, collaboration, and licensing arrangements we may enter into, could pose a number of risks, including the following:

- collaboration partners may not perform their obligations as expected;
- the clinical trials conducted as part of such partnership, collaboration, and licensing arrangement may not be successful;
- collaboration partners may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization of programs based on clinical trial results, changes in the strategic collaborators' focus or available funding, or external factors, such as an acquisition, which divert resources or create competing priorities;

- collaboration partners may delay clinical trials, provide insufficient funding for clinical trials, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaboration partners could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the strategic collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates developed in partnership, collaboration, and licensing arrangements with us may be viewed by our collaboration partners as competitive with their own candidates or products, which may cause collaboration partners to cease to devote resources to the development of our programs or the development or commercialization of our product candidates;
- a collaboration partner with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of any such product;
- a collaboration partner may exercise its right to terminate under a collaboration agreement which may require us to pay certain cancellations fees or reimburse such partner for certain expenses;
- disagreements with collaboration partners, including disagreements over proprietary rights, contract interpretation or the preferred course of development of any product candidates, may cause delays or termination of the research, development or commercialization of such product candidates, may lead to additional responsibilities for us with respect to such product candidates or may result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaboration partners may not properly maintain or defend our IP rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- disputes may arise with respect to the interpretation of key terms regarding control, economic rights, or the ownership of intellectual property developed pursuant to our partnership, collaboration, and licensing arrangements;
- collaboration partners may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- partnership, collaboration, and licensing arrangements may, in certain instances, be terminated for the convenience of the collaboration partner and, if terminated, the development of our programs and product candidates may be delayed, or we may lose rights to IP or expertise related to such programs and products candidates, and we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates;
- future relationships may require us to incur non-recurring and other charges, assume indebtedness or contingent liabilities, increase our near- and long-term expenditures, acquire intangible assets, issue securities that dilute our existing stockholders, disrupt our management and business, or otherwise impact our ability to generate revenue from acquired intellectual property, technology and/or products sufficient to meet our objectives or even to offset the associated transaction and maintenance costs;
- we could face significant competition in seeking appropriate collaboration partners and the negotiation process and diligence process is time-consuming and complex; and
- our international operations, through any future partnerships, collaborations, acquisitions or joint ventures, may expose us to certain operating, legal, and other risks not encountered in the United States.

Whether we reach a definitive agreement for a partnership, collaboration, or licensing arrangement will depend, among other things, on our assessment of the collaboration partner's resources and expertise, the terms and conditions of the proposed partnership, collaboration, or licensing arrangement, and the potential collaboration partner's evaluation of a number of factors. Those factors may include, among others: (i) our technologies and capabilities, including our Helicon discovery platform; (ii) our intellectual property position with respect to the subject program or product candidate; (iii) the design or results of clinical trials; (iv) the likelihood of approval by Regulatory Authorities; (v) the potential market for the subject product candidate; (vi) potential competing products; and (vii) industry and market conditions generally. In addition, the significant number of business combinations among large pharmaceutical and biotechnology companies has reduced the number of potential future collaboration partners with whom we can partner.

Partnership, collaborations, and licensing arrangements are complex and time-consuming to negotiate and document. We may have to relinquish valuable rights to our programs and product candidates, intellectual property or future revenue streams, or grant licenses on terms that are not favorable to us or in instances where it would have been more advantageous for us to retain sole

development and commercialization rights. For some programs and product candidates, we depend on collaboration partners to design and conduct the clinical trials. As a result, we may not control the manner or time schedule in which these clinical trials are conducted, which may negatively impact our business operations. In addition, if any of our collaboration partners withdraws support for one or more of our programs or product candidates or otherwise impairs their development, our business could be negatively affected. In addition, management of our relationships with collaboration partners requires (i) significant time and effort from our management team; (ii) coordination of our marketing and research and development programs with the marketing and research and development priorities of our collaborators; and (iii) effective allocation of our resources across multiple projects.

Partnerships, collaborations, and licensing arrangements may never result in the successful development of programs or development and commercialization of product candidates or the generation of sales revenue. The success of these arrangements will depend heavily on the efforts and activities of our collaboration partners. Collaboration partners generally have significant discretion in determining the efforts and resources that they will apply to the development of programs and the development and commercialization of product candidates, and they may not pursue or prioritize the development and commercialization of such programs and product candidates in a manner that is in our best interests. Product revenues arising from partnership, collaboration, and licensing arrangements are likely to be lower than if we directly marketed and sold products. Disagreements with collaboration partners regarding clinical development or commercialization matters can lead to delays in the development process or commercialization of the applicable product candidate and, in some cases, the termination of the partnership, collaboration, or licensing arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority. Partnership, collaboration, and licensing arrangements are often terminable by the collaboration partner, and any such termination or expiration would adversely affect us financially and could harm our business reputation. If we were to become involved in arbitration or litigation with any of our collaboration partners, it would consume time and divert management resources away from operations, damage our reputation, impact our ability to enter into future partnership, collaboration, and licensing arrangements and may further result in substantial payments from us to our collaboration partners to settle those disputes.

We may not be able to establish additional partnership, collaboration, and licensing arrangements on a timely basis, on acceptable terms, or at all, and to maintain and successfully conclude them. Such arrangements with third parties could cause us to expend significant resources and incur substantial business risk with no assurance of financial return. If we are unable to establish or maintain partnership, collaboration, and licensing arrangements on terms favorable to us and realize the intended benefits of those arrangements, our research and development efforts and potential to generate revenue may be limited and our business and operating results could be materially and adversely impacted.

As part of these collaborations, we may not fully control the progression, clinical development, regulatory strategy or eventual commercialization, if approved, of our jointly-developed product candidates. As a result, our future success and the potential to receive revenues under these partnership, collaboration, and licensing arrangements are significantly dependent on our collaboration partners' efforts, over which we have little control. If our partnership, collaboration, and licensing arrangements do not result in the successful development and commercialization of product candidates, a collaboration partner determines not to proceed with the future development of a program or product candidate initially engineered or developed utilizing our Helicon discovery platform, a collaboration partner implements a clinical or regulatory strategy that ultimately does not enable the further development, approval or commercialization of the product candidate, or a collaboration partner terminates its arrangement with us, we may not receive any future research funding or milestone, earnout, royalty or other contingent payments under such arrangement, which may have a material and adverse effect on our business and revenues. In addition, our ability to monitor the achievement of clinical, regulatory and commercial milestones by our collaboration partners and enforce the payment of any corresponding fees is limited. If we do not receive the funding we expect under these agreements, the development of our and our other collaboration partners' product candidates could be delayed and we may need additional resources to develop such product candidates.

In addition, our collaboration partners have, and future collaboration partners may have, the right to terminate their agreements with us for convenience. If one of our collaboration partners terminates its arrangement with us, we may be required to pay certain fees, may find it more difficult to attract new partnership, collaboration, and licensing arrangements and the perception of us in the business and financial communities could be adversely affected. We cannot assure investors that we will be able to maintain or expand our existing collaboration partners or that our Helicon discovery platform will achieve adequate market acceptance among new collaboration partners. Any failure to increase penetration in our existing markets or new markets would adversely affect our ability to improve our operating results from our collaboration, partnership and licensing strategy.

All of the risks relating to product development, regulatory approval and commercialization described in this Quarterly Report apply to the activities of our current and future collaboration partners. If we or our collaboration partners do not achieve regulatory approval for a sufficient number of product candidates, we may not be able to sustain our business model.

Risks Related to Our Intellectual Property

Our success is largely based upon our intellectual property related to our proprietary technologies, and we may be unable to adequately obtain, maintain, protect, defend and/or enforce our intellectual property.

Our success depends, in large part, on our ability to obtain, maintain, protect, defend and/or enforce patent, trademark, and other intellectual property, including trade secret and know-how, protection of our product candidates, Helicon discovery platform and other proprietary technologies, as well as our ability to operate, develop, manufacture and commercialize our product candidates without infringing, misappropriating or otherwise violating the intellectual property or other proprietary rights of our competitors or any other third parties, including any non-practicing entities or patent assertion entities. If we (or our licensees or licensors who may have the right to prosecute, obtain, maintain, defend and/or enforce certain patents within our portfolio) fail to appropriately prosecute or are unable to obtain, maintain, defend and/or enforce patents for our product candidates (or aspects thereof), our ability to develop, manufacture, license and/or commercialize these product candidates may be adversely affected and we may not be able to prevent competitors from making, using, offering to sell, selling or importing competing products. Our failure or inability to properly and adequately protect the intellectual property rights relating to our product candidates could have a material adverse effect on our business, financial condition, results of operations and/or growth prospects.

We generally seek to protect our intellectual property position by filing and/or licensing patent applications in the United States and, in various patent families certain but not all foreign jurisdictions, related to our Helicon discovery platform, product candidates and other proprietary technologies that are important to our business. Our patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent that the issued claims cover third parties' activities in the jurisdictions in which they are performed. We cannot be certain that the claims in any of our patent applications will be considered patentable by the United States Patent and Trademark Office ("USPTO"), courts in the United States or the patent offices and courts in other jurisdictions, including Europe, nor can we be certain that the claims in our issued patents will not be found invalid or unenforceable if challenged. Accordingly, there can be no assurance that our patent applications or those of our licensors will result in additional patents being issued or that issued patents will adequately cover our product candidates or otherwise afford sufficient protection against competitors, nor can there be any assurance that the patents issued will not be infringed, designed around, invalidated or held unenforceable. Furthermore, we may not be able to apply for patents on certain aspects of our current or future Helicon discovery platform, product candidates, or other proprietary technologies in a timely fashion, at a reasonable cost, in all jurisdictions, or at all, and any potential patent protection we obtain may not be sufficient to prevent substantial competition.

The use of AI to design, develop and engineer proteins is a relatively new scientific field, the continued development and potential use of which has resulted in many different patents and patent applications from organizations and individuals seeking to obtain intellectual property protection in the field. In general, patents are reserved for human inventors and significant and novel legal questions remain in flux about the contributory roles of AI versus the human inventors in securing intellectual property rights. We may not be able to obtain, maintain, protect, defend, and/or enforce patent protection for our AI technologies including their uses in the development of Helicons including those utilized in our product candidates. Our current programs, in addition to AI technologies, include many other non-AI technologies and involve significant and critical input, direction, design optimization and/or decision-making from humans. Despite the significant and critical involvement of humans in the development of our current Helicon discovery platform and product candidates, our intellectual property rights including patents related thereto may be challenged, and we may not be able to adequately defend and/or enforce such intellectual property rights. Many aspects of our AI technologies are protected as trade secrets or otherwise as confidential information. We may not be able to preserve the confidentiality of our trade secrets and other confidential information; if confidentiality is lost, third parties including our competitors may be able to use such trade secrets and other confidential information.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or our partners will be successful in protecting our product candidates by obtaining, maintaining, enforcing and defending patents. Patent applications are processed by various national patent offices around the world. There is uncertainty about which patents will issue, and, if they do, as to when, to whom, and with what claims. These risks and uncertainties include the following:

- the USPTO and various foreign government patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application or a finding that a patent is unenforceable, and partial or complete loss of patent rights in the relevant jurisdiction;
- patent applications may not result in any patent being issued;
- patents that may be issued may not include claims that cover a broad enough scope to prevent competitor activities including alternative solutions by competitors;

- patents that may be issued may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide adequate barriers to entry or any competitive advantage;
- because of the extensive time required for development, testing and regulatory review of a product candidate, it is possible that before a potential product can be commercialized, any related patent may expire, or remain in existence for only a short period following commercialization thereby reducing, or eliminating any advantage of the patent;
- our competitors, many of which have substantially greater resources than we or our partners do, and many of which have made significant investments in competing technologies, may seek, or may already have sought or obtained, patents that will limit, interfere with or eliminate our ability to make, use, offer to sell, sell, import or otherwise exploit our product candidates or other technologies;
- other parties may design or may have designed around our patent claims, or may develop or may have developed technologies that may be related or competitive to our product candidates or other technologies, may file and may have filed or may file patent applications and may receive or may have received patents that overlap or conflict with our patent filings, either by claiming the same or overlapping methods, products, reagents or devices or by claiming subject matter that could dominate one or more of our patent claims;
- any successful opposition to any patents owned by or in-licensed to us could deprive us of rights necessary for the development and exploitation of our product candidates and other technologies or the successful commercialization of any product candidates and other technologies that we may develop;
- because patent applications in the United States and most other jurisdictions are confidential for a period of time after filing, we cannot be certain that we or our licensors were the first to file any patent application related to our product candidates or other proprietary technologies;
- a court or patent office proceeding, such as a derivative action or interference, can be provoked or instituted by a third party or a patent office, and might determine that one or more of the inventions described in our patent filings, or in those we licensed, was first invented by someone else, so that we may lose rights to such invention(s);
- a court or other patent proceeding, such as an inter partes review, post grant review or opposition, can be instituted by a third party to challenge the inventorship, scope, validity and/or enforceability of our patent claims and might result in invalidation or revision of one or more of our patent claims, or in a determination that such claims are unenforceable;
- there may be significant pressure on the U.S. government and other governmental bodies to limit the scope of patent protection or impose compulsory licensing of patent rights for disease treatments that prove successful as a matter of public policy; such a limit of the scope of our patent protection or compulsory licenses may render ineffective any patent protection we might obtain for our products and product candidates and/or could lead us to earning no or an inadequate return on our investments;
- countries other than the United States may have patent laws less robust and/or less favorable to patentees than those of the United States, allowing competitors the ability to exploit these laws to create, develop, and market competing products using our technologies; and
- we may be involved in lawsuits and/or proceedings before government agencies, such as patent offices, to defend or enforce our patents or the patents we have rights to enforce, which could be expensive, time-consuming, distracting and/or unsuccessful.

The patent position of biotechnology and biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. The standards that the USPTO and its counterparts use to grant patents are not always applied predictably or uniformly and can change. Similarly, the ultimate degree of protection that will be afforded to biotechnology inventions, including ours, in the United States and other countries, remains uncertain and is dependent upon the scope of the protection decided upon by patent offices, courts and lawmakers. Moreover, there are periodic changes in patent law, as well as discussions in the U.S. Congress and in foreign jurisdictions about modifying various aspects of patent law. There is no uniform, worldwide policy regarding the subject matter and scope of claims granted or allowable in pharmaceutical or biotechnology patents. In certain countries, for example, methods for the medical treatment of humans are not patentable. More generally, the laws of some countries do not protect intellectual property rights to the same extent as U.S. laws, and those countries may lack adequate rules and procedures for granting, maintaining, protecting, defending and enforcing our intellectual property rights.

Furthermore, the patent prosecution process is also expensive and time-consuming, and we may not be able to file, prosecute, maintain, protect, defend, enforce or license all necessary or desirable patents or patent applications, as applicable, at a reasonable cost or in a timely manner. It is possible that we will fail to identify patentable aspects of our research and development output in time to

obtain patent protection. 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, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. We also rely to a certain extent on trade secrets, know-how, and other technologies, which are not protected by patents, to maintain our competitive position. If any trade secret, know-how or other technologies not protected by a patent were to be disclosed to or independently developed by a competitor, our business and financial condition could be materially adversely affected.

The issuance of a patent is not conclusive as to its inventorship, priority date, scope, term, validity or enforceability so that any patents that may issue or that we may license may be challenged in the courts or patent offices in the United States, Europe and other jurisdictions. Once granted, patents may remain open to a variety of challenges, including opposition, interference, re-examination, post-grant review, inter partes review, nullification or derivation action in court or before patent offices or similar proceedings, and furthermore, may be challenged as a defense in any enforcement action that we might bring. Such challenges may result in loss of exclusivity or in patent claims being narrowed, terminated, disclaimed, invalidated, assigned to others or held unenforceable, any or all of which could limit our ability to stop others from using or commercializing similar or identical products, or limit the scope and/or term of patent protection of our products and product candidates and/or eliminate it altogether, thus hindering or removing our ability to limit third parties from making, using or selling products or technologies that are similar or identical to ours, and/or reduce or eliminate royalty payments to us from our licensees. 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. Furthermore, our pending and future patent applications may not result in patents being issued which protect our technology or product candidates or which effectively prevent others from commercializing competitive technologies and product candidates. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Our ability to enforce our owned and in-licensed patent and other intellectual property rights depends on our ability to detect infringement, misappropriation and other violation of such patents and other intellectual property. It may be difficult to detect infringers, misappropriators and other violators who do not advertise the components or methods that are used in connection with their products and services. Moreover, it may be difficult or impossible to obtain evidence of infringement, misappropriation or other violation in a competitor's or potential competitor's product or service, and in some cases we may not be able to introduce obtained evidence into a proceeding or otherwise utilize it to successfully demonstrate infringement. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful.

In addition, proceedings to enforce or defend our owned or in-licensed patents could put our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable. Such challenges may result in loss of patent rights, loss of exclusivity, 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. If any of our owned or in-licensed patents covering our product candidates or other technologies are narrowed, invalidated or found unenforceable, or if a court found that valid, enforceable patents held by third parties covered one or more of our product candidates or other technologies, our competitive position could be harmed or we could be required to incur significant expenses to protect, enforce or defend our rights. If we initiate lawsuits to protect, defend or enforce our patents, or litigate against third-party claims, such proceedings would be expensive and would divert the attention of our management and technical personnel, even if the eventual outcome is favorable to us. The degree of future protection for our intellectual property and other proprietary rights is uncertain, and we cannot ensure that:

- any of our patents, or any of our pending patent applications, if issued, or those of our licensors, will include claims having a scope sufficient to protect our product candidates and other technologies;
- any of our pending patent applications or those of our licensors may issue as patents;
- others will not or may not be able to make, use, offer to sell or sell products that are the same as or similar to our own but that are not covered by the claims of the patents that we own or license;
- we will be able to successfully commercialize our products on a substantial scale, if approved, before the relevant patents that we own or license expire;
- we were the first to make the inventions covered by each of the patents and pending patent applications that we own or license;
- we, our co-owners or our licensors were the first to file patent applications for the inventions;
- others will not develop similar or alternative products or technologies that do not infringe the patents we own or license;

- any of the patents we own or license will be found to ultimately be valid and enforceable;
- any patents issued to us or our licensors will provide a basis for an exclusive market for our commercially viable product candidates and other technologies or will provide us with any competitive advantages;
- a third party may not challenge the patents we own or license and, if challenged, a court would hold that such patents are valid, enforceable and infringed;
- we may develop or in-license additional proprietary technologies that are patentable;
- the patents of others will not have an adverse effect on our business;
- our competitors do not conduct research and development activities in countries where we do not have enforceable patent rights to prevent such activities and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we will develop additional proprietary technologies or product candidates that are separately patentable; or
- our development and commercialization activities, including our manufacturing processes, or products will not infringe upon the patents of our competitors or any other third parties, including any non-practicing entities or patent assertion entities.

In addition to patents, we also rely on confidential proprietary source codes, trade secrets and know-how. Although we have taken steps to protect the confidentiality of such proprietary source codes, trade secrets and know-how, including maintaining data security protocols and capabilities and entering into confidentiality agreements with third parties, and confidential information and assignment agreements with employees, consultants and advisors, there exists the potential that third parties may still somehow obtain this information or arrive at the same or similar information independently, which could reduce or eliminate our competitive advantages. Moreover, we may become subject to allegations that we directly or indirectly (through our employees, consultants, advisors or independent contractors that we may engage to assist us in developing our product candidates) have wrongfully or inadvertently disclosed, acquired or used trade secrets or other proprietary information of third parties.

We have or may have in the future collaborations to develop collaboration product candidates. Such collaboration product candidates are subject to at least the same risks as product candidates developed by ourselves, and they may be subject to additional risks associated with our collaborators' technologies. We may not fully control the development, manufacturing, or commercialization of our collaboration product candidates or our collaborators' activities. We and our collaborators may be unable to adequately obtain, maintain, protect, defend and/or enforce relevant intellectual property rights to protect the collaboration product candidates, and the development, manufacturing, or commercialization of our collaboration product candidates, by us or our collaborators or jointly, may infringe or otherwise violate intellectual property rights of third parties. We may be held responsible for part or all damages and costs in connection with the development, manufacture, or commercialization of such collaboration product candidates, and/or may be required to partially or fully defend or indemnify our collaborators in connection with the development, manufacture, or commercialization of our collaboration product candidates.

We may be forced to litigate to enforce or defend our intellectual property rights.

We may be forced to litigate to enforce or defend our intellectual property rights against infringement by competitors, and to protect our trade secrets and know-how against unauthorized use, but we may not be able to detect or prevent, alone or with our licensors and/or licensees, infringement, misappropriation or other violation of our intellectual property rights. In so doing, we may place our intellectual property at risk of being invalidated, held unenforceable or rendered limited or narrowed in scope such that we may not be able to adequately prevent the manufacture, sale or import of competitive products. In an infringement proceeding, a court may decide that a patent we own or license, or a patent we license in the future is invalid, unenforceable or not infringed, or may refuse to stop the other party from using the claimed invention at issue. Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Further, an adverse result in any litigation or other proceedings before government agencies such as the USPTO, may place pending applications at risk of non-issuance or burden them with material limitations in scope. Further, derivation proceedings, *ex parte* reexamination, inter partes review, post grant review and opposition proceedings initiated by third parties or brought by the USPTO or any foreign patent authority may be used to challenge the inventorship, ownership, claim scope or validity of our patents. Additionally, because of the substantial amount of discovery typically required in connection with intellectual property litigation, there is a risk that some of our confidential and proprietary information, trade secrets or know-how could be compromised by disclosure during this type of litigation. 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 value of the company. Such litigation or proceedings could substantially increase our operating losses, reduce the resources available for development activities or any future sales, marketing or distribution activities and distract

our personnel from their normal responsibilities. 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 and/or more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

Intellectual property rights of third parties could adversely affect our ability to develop or commercialize our product candidates, and we might be required to litigate or obtain licenses from third parties in order to develop or market our product candidates.

Our commercial success depends in part on our ability and the ability of any of our current or future partners to develop, manufacture, market, offer to sell, sell, import or otherwise exploit our product candidates and our technologies without infringing the intellectual proprietary rights of third parties. There is a substantial amount of litigation and patent office proceedings, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology, biopharmaceutical, pharmaceutical and high-tech industries, including patent infringement lawsuits, oppositions, *ex parte* reexaminations, post-grant review, inter partes review and interference proceedings before the USPTO and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing product candidates.

Third parties may assert that we are employing or have employed their proprietary technology without authorization. There may be third-party patents or patent applications that claim compositions, formulations, methods of manufacture or methods for use that cover or relate to our product candidates, their manufacture or uses. Because patent applications in most countries remain confidential for a period of time after they are filed (commonly, 18 months from their earliest priority date), it is possible that there are unpublished patent applications that may later issue with claims that our product candidates, or their manufacturing or uses, may be alleged to infringe. Because patent applications can take many years to issue, there may be pending patent applications which do not currently seem relevant, but may later result in issued patents that our product candidates, or their manufacturing or uses, may be alleged to infringe. In addition, third parties may file and obtain patents in the future and then allege that our technologies infringe these patents. Additionally, under U.S. patent law, a patent owner may seek a reissue within two years of issuance of a patent to broaden the scope of that patent's claims if certain legal requirements are met. As a result, patents that, at the time of issuance, do not appear relevant to our activities may later be broadened in a manner that could impact our business. There may be analogous processes for broadening the scope of patents in other jurisdictions as well. Further, patent owners may seek to amend claims in granted or issued patents or otherwise initiate proceedings at the USPTO, foreign patent agencies or courts to fix errors, deficiencies, etc. in their patents or during the prosecution, maintenance or defense of their patents so that claims that are unenforceable and/or not valid become enforceable and not invalid. We cannot guarantee that any of our or our licensors' or licensees' patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are or will be correct, complete or thorough, nor can we be certain that we or our licensors or our licensees have identified or will identify each and every third-party patent and pending patent application in the United States and abroad that is relevant to or necessary for the development, manufacture, and commercialization of our current and future products and product candidates in any jurisdiction. Our interpretation of the relevance or the scope of a patent or a pending patent application may be incorrect, which may negatively impact our ability to market our products. We or our licensors or our licensees may incorrectly determine that our products or product candidates are not covered by a third-party patent or may incorrectly predict whether a third-party's pending patent application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, and we or our licensors or our licensees may incorrectly conclude that a third-party patent is invalid and unenforceable or not infringed. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop, manufacture and market our products and product candidates. If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. As the number of competitors in the market grows and the number of patents issued in this area increases, the probability of patent infringement claims increases. Defense of infringement and other claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business.

Because our product candidates are still in developmental stages, and one or more features of the product candidates or related technologies such as their structures, manufacture, formulations or uses, may still change, we cannot be confident that we are aware of all third-party intellectual property that might be relevant to products that we eventually hope to commercialize. Various third-party competitors practice in relevant spaces, and may have issued patents, or patent applications that will issue as patents in the future, that will impede or preclude our ability to commercialize products. Furthermore, while U.S. patent laws provide a "safe harbor" to our clinical product candidates under 35 U.S.C. § 271(e)(1), which exempts from patent infringement activities related to pursuing FDA approval for a drug product, that exemption expires upon or around an NDA submission. Given the uncertainty of clinical trials, we cannot be certain of the timing of their completion and it is possible that we might want to submit an NDA at a time when one or more relevant third-party patents is in force. Thus, it is possible that at the time that we commercialize our product candidates, one or more third parties may have issued or later issue patent claims that cover our products or critical features of their production or uses. We may not be able to commercialize our products if patents issued to third parties or other third-party intellectual property rights cover,

or may be alleged to cover, our products or elements thereof, or their methods of manufacture or uses at the time that we seek to commercialize them. In such cases, we may not be in a position to develop or commercialize product candidates unless we successfully pursue litigation to nullify or invalidate the third-party intellectual property right concerned, successfully design around their claims, or enter into a license agreement with the intellectual property right holder(s). Such litigation or licenses could be costly or not available on commercially reasonable terms or timing or at all, and design-around could be prohibitively expensive or impossible.

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

- infringement and other intellectual property allegations, which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention and financial resources from our core business;
- substantial damages for infringement or other violation of third-party rights, which we may have to pay if a court decides that the product candidate or technology at issue infringes or otherwise violates the third-party's rights, and, if the court finds that the infringement or other violation was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees (and, in certain jurisdictions outside of the United States, we could be ordered to pay the patent owner's attorneys' fees even without such a finding);
- a court enjoining us from developing, manufacturing, importing, marketing or selling our product candidates, or from using our proprietary technologies, unless the relevant third party grants us an adequate license, which it is not required to do;
- even if a license is available from a third party, we may have to pay substantial royalties, upfront fees, milestones and other amounts and/or grant cross-licenses to intellectual property rights at terms that are not favorable to us, and a license may not be timely obtained; and
- redesigning our product candidates or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

Any of the foregoing could have a material adverse effect on our business, results of operations, financial condition and prospects.

Our ability to commercialize our product candidates in the United States and abroad may be adversely affected if we cannot successfully defend against infringement allegations or obtain a license on commercially reasonable terms to relevant third-party patents that cover our product candidates. Even if we have a strong defense and/or believe that third-party intellectual property allegations are without merit, there can be no assurance that a court would find in our favor on questions of infringement, validity, enforceability and/or priority. A court of competent jurisdiction could hold that these third-party patents are valid and enforceable and have been infringed, which could materially and adversely affect our ability to commercialize our product candidates or technologies covered by the asserted third-party patents. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is high, which requires us to present clear and convincing evidence as to the invalidity of any such U.S. patent claims, there is no assurance that a court of competent jurisdiction would invalidate the asserted claims of any such U.S. patent. Further, there is no assurance that courts or other administrative or judicial tribunals outside the United States would invalidate the claims of non-U.S. patents that may be asserted against our products and technology.

If we are found to infringe a third party's patent rights, and we are unsuccessful in demonstrating that any such patents are invalid or unenforceable, we could be required to pay damages and to obtain a license (which can involve royalty payments) from such third party to continue developing, manufacturing, marketing or selling our product candidates and our technologies. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain such a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to it, and it could require us to pay substantial licensing fees and/or make royalty, milestone and/or other payments. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, we may be unable to commercialize our product candidates or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business. We also could be temporarily or permanently forced, including by court order, to cease developing, manufacturing, and commercializing the infringing technology or product candidates. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a U.S. patent or other intellectual property right, and may not have to pay such damages outside the United States even if any infringement by our products or technology was not willful.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could

have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

Moreover, in recent years, individuals and groups that are non-practicing entities, commonly referred to as "patent trolls," have acquired patents and other intellectual property assets for the purpose of making claims of infringement in order to extract settlements. From time to time, we may receive threatening letters, notices or "invitations to license," or may be the subject of claims that our products and business operations infringe or violate the intellectual property rights of others. We may be forced to pay exorbitant settlement fees to settle such litigation and/or may face the negative consequences of infringement lawsuits by such patentees, such as injunctions against the commercialization of our products and technology and/or the distraction of our personnel from properly running our business due to the need to attend to such lawsuits.

Intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes the market price of our common shares to decline.

During any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motion, and other interim proceedings or developments in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our existing product candidates, approved products, programs, or intellectual property could be diminished. Accordingly, the market price of shares of our common stock may decline. Such announcements could also harm our reputation or the market for our future products, or discourage potential partners from entering into collaborations or business relationships with us, all of which could have a material adverse effect on our business, results of operations, financial condition and prospects.

Some of our in-licensed intellectual property rights have been developed through programs funded by the U.S. government and/or government agencies and we may in-license additional intellectual property rights that are developed through programs funded by the U.S. government and/or government agencies, and we may ourselves enter into arrangements involving government funding of certain programs and we make inventions as a result of such funding. Our intellectual property rights to inventions from programs utilizing government funding may be subject to the applicable provisions of the Bayh-Dole Act of 1980 (the "Bayh-Dole Act").

To the extent any of our current and future owned or in-licensed intellectual property is generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply. The U.S. government and/or government agencies have provided funding or other assistance in connection with the development of certain intellectual property rights licensed to us. In the future, we may license additional intellectual property rights in inventions supported by the U.S. government and/or government agencies. We may also enter into future arrangements involving government funding. If we make or first reduce to practice inventions as a result of such funding, our intellectual property rights to such inventions may be subject to the applicable provisions of the Bayh-Dole Act. Any exercise by the government of certain rights could harm our competitive position, business, financial condition, results of operations and growth prospects.

U.S. government rights in certain inventions supported by the U.S. government and/or government agencies include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for governmental purposes. In addition, the U.S. government has the right, under certain limited circumstances, to require us to grant exclusive, partially exclusive or non-exclusive licenses to any of these inventions to a third party if the government determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs or (iii) government action is necessary to meet requirements for public use under federal regulations, which are collectively referred to as march-in rights. The U.S. government will also have the right to take title to these inventions if we fail, or the applicable licensor fails, to disclose the invention to the government, elect title and file an application to register the intellectual property within specified time limits. In addition, the U.S. government may acquire title to these inventions in any country in which a patent application is not filed within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us, or the applicable licensor, to expend substantial resources.

In addition, the U.S. government requires that any products embodying an invention supported by the U.S. government funding or produced through the use of a subject invention supported by the U.S. government funding be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States. or that under the circumstances domestic manufacture is not commercially feasible. We may not be able to obtain a waiver of this preference for U.S. industry, and this preference may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. To the extent any of our owned or in-licensed future intellectual property is generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply. Certain government agencies may impose stricter or additional requirements beyond the Bayh-Dole Act in their funding agreements including more stringent requirements of manufacturing in the United States. If we are unable to comply with these

manufacturing requirements, we may experience a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

We may not be successful in obtaining or maintaining adequate intellectual property rights to product components and manufacturing processes for our development pipeline and to commercialize our product candidates.

At present, we have rights to certain intellectual property, through licenses from third parties and under patent filings that we own to develop our product candidates. Because our pipeline may involve additional product candidates that could require the use of proprietary rights held by third parties, the growth of our business could depend in part on our ability to acquire, in-license or use these proprietary rights. In addition, our product candidates may require specific pharmaceutical formulations to work effectively and efficiently, and these rights may be held by others. We may be unable to acquire or in-license intellectual property rights that may be necessary to permit us to implement our platform technologies or develop, manufacture or use our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us in obtaining access to the relevant third-party rights due to their size, cash resources and greater clinical development and commercialization capabilities. Further, we may be unable to negotiate a license within the specified time frame or under terms that are acceptable to us. If we are unable to do so, the third party may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our product candidate and enabling our competitors to compete with our product candidate.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment, or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights, our business, financial condition and prospects for growth could suffer.

We cannot ensure that pending claims in our and our licensors' pending patent applications will issue or that patents based on our or our licensors' patent applications will not be challenged and rendered invalid and/or unenforceable.

We have pending patent applications in the United States and/or foreign jurisdictions in our portfolio (owned or in-licensed) relating to our research programs and product candidates. However, we cannot predict:

- the scope of protection of any patent issuing based on our or our licensors' patent applications;
- whether the claims of any patent issuing based on our or our licensors' patent applications will provide adequate protection against competitors;
- whether or not third parties will find ways to challenge, narrow, invalidate or circumvent our or our licensors' patent rights;
- whether or not others will obtain patents claiming aspects similar to those covered by our or our licensors' patents, if issued, and patent applications;
- whether we or our licensors will need to initiate litigation or administrative proceedings to obtain, defend and/or enforce our patent rights which will be costly whether we win or lose; and/or
- whether the patent applications that we own or in-license will result in issued patents with claims that cover our product candidates or their manufacturing or uses.

We cannot be certain that the claims in our current or future patent applications directed to our product candidates, as well as technologies relating to our research programs, will be considered patentable by the USPTO or by patent offices in foreign countries. One aspect of the determination of patentability of our inventions depends on the scope and content of the "prior art," information that was or is deemed available to a person of ordinary skill in the relevant art prior to the priority date of the claimed invention. The biotechnology and pharmaceutical industries are intense, fast-moving and highly competitive. There may be prior art of which we are not aware that may affect the patentability of our patent claims or affect the validity or enforceability of an issued patent claim relevant to our business. There is no assurance that there is no prior art of which we are aware, but which we do not believe is relevant to our patent claims or business, which may, nonetheless, ultimately be found to limit our ability to obtain, maintain, defend and/or enforce patent rights, including those that protect us against third parties to make, use, sell, offer for sale or import our products that may be approved in the future, or to otherwise impair our competitive position. In some cases, prior art may prevent us from obtaining, maintaining, defending and/or enforcing patent rights that are necessary to protect our product candidates.

Even if the patents do issue based on our owned or in-licensed patent applications, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, revoked, invalidated or held unenforceable.

Furthermore, even if they are unchallenged, patents in our portfolio may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. If the breadth or strength of our intellectual property position with respect to our platform or product candidates is threatened, it could dissuade companies from collaborating with us to develop and threaten our ability to commercialize our product candidates. In the event of litigation or administrative proceedings, we cannot be certain that the claims in any of our owned or in-licensed current or future issued patents will be found not invalid and enforceable by courts or other tribunals in the United States or foreign countries. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our rights to develop and commercialize our product candidates are, and in the future, may be subject to the terms and conditions of licenses granted to us by others. If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties, or these agreements are terminated, or we otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

Certain aspects of some of our platform technologies and/or some of our product candidates utilize third-party technologies to which we have access through license or other agreements, and we may also enter into additional agreements with third parties in the future. Our current agreements with third parties impose, and may in the future impose additional, diligence, development and commercialization timelines, milestone payments, royalties, indemnification, insurance, non-competes or other obligations on us. If we fail to comply with our obligations to our licensors, collaborators or other third parties, our counterparties may have the right to terminate or take other actions under these agreements that are unfavorable to us. Termination of these agreements or reduction or elimination of our rights under these agreements may result in us having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology that are necessary for our business. In particular, we have a license agreement with the President and Fellows of Harvard College ("Harvard"), pursuant to which have obtained access to certain polypeptide technologies that can be useful for the development of one or more of our programs (the "Harvard License"). The intellectual property rights we in-licensed pursuant to the Harvard License include issued and/or pending patent filings that include claims that may generically cover the composition of matter, manufacturing and/or use of one or more of our current or future product candidates, including zolucatetide. Harvard may terminate the Harvard License under certain circumstances.

Our success will depend in part on the ability of our licensors to obtain, maintain, defend and enforce our licensed intellectual property rights including patent protection for our licensed intellectual property. To the extent that the licensors' inventions are made using the U.S. government support, such intellectual property rights are subject to provisions in the relevant agreements with the government and the Bayh-Dole Act. Further, certain patent filings relating to our product candidates may now or in the future be subject to step-in rights of certain of our licensors. We have limited or no control over our licensors' preparation, filing, obtaining, maintaining, defending or enforcing the licensed intellectual property rights, or their compliance with the provisions in their agreements with the U.S. government or other third parties. We have limited or no control over certain of our licensors', and may in the future have limited or no control of our other licensors', prosecution activities or use or licensing of any other intellectual property that may be related to our in-licensed intellectual property. Our licensors may not successfully prosecute the patent applications we license. Even if patents issue from these patent applications, our licensors may fail to obtain sufficient breadth of scope to protect our products and technologies, may fail to maintain these patents, may determine not to defend these patents when challenged, and may determine not to pursue litigation against other companies that are infringing these patents, or may pursue such litigation less aggressively than we would. If any of our licensors or licensees having rights to file, prosecute, maintain and defend our patent rights fail to conduct these activities for patents or patent applications protecting any of our product candidates, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors or other third parties from making, using or selling competing products. In addition, we may sublicense certain of our rights under various third-party licenses to our collaboration partners. Any impairment of these sublicensed rights could result in reduced revenues under our partnership, collaboration or licensing arrangement or result in termination of an agreement by one or more of our collaboration partners. In addition, intellectual property rights that we may in-license in the future may be sublicensed under intellectual property owned by third parties, in some cases through multiple tiers. The actions of our licensors may therefore affect our rights to use our sublicensed intellectual property, even if we are in compliance with all of the obligations under our license agreements. Should our licensors or any of the upstream licensors fail to comply with their obligations under the agreements pursuant to which they obtain the rights that are sublicensed to us, or should such agreements be terminated or amended, our ability to develop and commercialize our product candidates may be materially harmed.

We cannot be certain that activities by our licensors 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. Pursuant to the terms of the license agreements with our licensors, such licensors may have the right to control enforcement of our licensed patents or defense of any allegations asserting the invalidity or unenforceability of such patents and, even if we are permitted to pursue such enforcement or defense, we cannot ensure the cooperation of our licensors or, in some cases, other necessary parties, such as any co-owners of patents or other intellectual property from which we have not yet obtained a license or for which we obtained a license requiring consent or

cooperation of the owner for purposes of enforcement. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such allegations to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business. In addition, even when we have the right to control patent prosecution of licensed patents and patent applications, enforcement of licensed patents, or defense of allegations asserting the invalidity or unenforceability of those patents, we may still be adversely affected or prejudiced by actions or inactions of our licensors and their counsel that took place prior to or after assuming control.

Our current or future license agreements may not provide exclusive or sufficient rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our product candidates in the future. Some licenses granted to us may be subject to certain preexisting rights held by the licensors or certain third parties. As a result, we may not be able to prevent third parties from developing and commercializing competitive products in certain territories or fields.

In the event that our third-party licensors or other counterparties determine that, in spite of our efforts, we have breached a license agreement or have failed to meet certain obligations thereunder, it may elect to terminate the applicable agreement or, in some cases, one or more licenses under such agreement or otherwise restrict our rights under the agreement. Such termination or restriction of rights could result in us losing the ability to develop and commercialize product candidates and technology covered by the licensed intellectual property. In the event of such termination, or if the underlying patent rights under a third-party in-license or other agreement fail to provide the intended exclusivity, third parties may be able to seek regulatory approval of, and to market, products identical or substantially similar to ours and we may be required to cease the development and commercialization of our product candidates. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to allegations, regardless of their merit, that we are infringing or otherwise violating a licensor's rights. Any of these events could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

In addition, the agreements under which we license or otherwise acquire intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant patents, know-how and proprietary technology, or increase what we believe to be our financial or other obligations under the relevant agreement. Disputes may also arise between us and our licensors or other counterparties regarding intellectual property subject to a license agreement, including: the scope of rights granted under the agreement and other interpretation-related issues; whether and the extent to which our technology and processes are covered by intellectual property of the licensor that is not subject to the agreement; our right to sublicense patent and other rights to third parties under collaborative development relationships; our diligence obligations with respect to the use of the licensed or otherwise acquired technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations; and the inventorship and/or ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our collaboration partners.

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

We are generally also subject to all of the same risks with respect to protection of intellectual property that we license, as we are for intellectual property that we own, for example, those described below. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize products could suffer.

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

In addition to patent protection, we also seek to rely upon trade secret protection, data security protocols and capabilities, and non-disclosure agreements with our employees, consultants and third parties, to maintain our competitive position and to protect our confidential and proprietary source code, know-how and other information that is not patentable or processes for which patents are difficult to enforce, and any other elements of our product candidates and their discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. However, confidential information including trade secrets and know-how may be difficult to protect.

It is our policy to require our employees, corporate collaborators, outside scientific collaborators, CROs, CDMOs, consultants, advisors and other third parties to execute confidentiality agreements upon the commencement of employment, consulting or business relationships with us. However, we cannot guarantee that we have entered into agreements with each party that may have or have had access to our trade secret or proprietary technologies and processes. Despite our efforts, any of these parties may breach the agreements and we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that

competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. We may not be able to obtain adequate remedies for any such breaches.

In addition to contractual measures, we try to protect the confidential nature of our trade secret and proprietary information through other appropriate precautions, such as physical and technological security measures. However, trade secrets and know-how can be difficult to protect despite these precautions. Such measures may not, for example, in the case of misappropriation of trade secrets or know-how by an employee, former employee, or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee, former employee, or consultant from misappropriating our trade secrets or know-how and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully.

Enforcing a claim that a party wrongfully or illegally disclosed or misappropriated trade secrets or know-how can be difficult, expensive and time-consuming, and the outcome is unpredictable. Some courts inside and outside the United States are less willing or unwilling to protect trade secrets and know-how. In addition, trade secrets and know-how may be lawfully obtained or independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets or know-how, were to be disclosed or misappropriated, or if any such information were independently developed by a competitor, our competitive position could be harmed.

Certain former employees have obtained employment with companies or academic institutions that could be considered competitive with us and are operating their business in areas that are similar to ours, including in their business model, product design efforts, product development or formulation technology. This competition may be limited by contractual provisions; however, these contractual provisions may not be enforceable by us in the Commonwealth of Massachusetts or other jurisdictions. In addition, we may not be aware of such competitive employment arrangements until after our trade secrets or know-how has been disclosed to potentially competitive companies.

If we choose to go to court to enjoin a third party from using any of our trade secrets or know-how, we may incur substantial costs and/or we may ultimately not be successful. In addition, courts inside and outside the United States are sometimes less willing or unwilling to protect trade secrets or know-how. Even if we are successful, these types of lawsuits may consume, in addition to substantial costs, significant amounts of our time and other resources. We may also need to share our trade secret or proprietary know-how with current or future partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We may be subject to allegations that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties including alleged trade secrets of their former employers.

As is common in the biotechnology industry, we employ individuals, including certain of our key employees, and engage consultants and independent contractors. Many of our employees, consultants or independent contractors are or were previously employed at academic institutions or other biotechnology companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to allegations that we, or our employees, consultants or independent contractors, have inadvertently or otherwise used or disclosed intellectual property, including trade secrets, know-how or other proprietary information, of any of their former employers or other third parties. Litigation may be necessary to defend against these allegations. If we fail in defending against, or successfully defending against, any such allegations, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such allegations, litigation could result in substantial costs and be a distraction to management and other employees.

We may be subject to allegations challenging the inventorship or ownership of our patents and other intellectual property.

We may be subject to allegations that current or former employees, consultants, independent contractors, collaborators or other third parties have an ownership or other interest in our patents or other intellectual property. Ownership disputes may arise, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates and technology. Litigation may be necessary to defend against these and other allegations challenging inventorship or ownership. If we fail in defending against any such allegations, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse impact on our business. Even if we are successful in defending against such allegations, litigation could result in substantial costs and be a distraction to management and other employees.

In addition, while it is our policy to require our employees, consultants, and independent contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the inventorship and/or the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and applications will be due to be paid to the USPTO and various non-U.S. patent agencies in several stages over the lifetime of the patents or applications. We rely on our outside counsel or vendor to pay these fees due; however, we cannot guarantee that we will successfully pay these fees. The USPTO and various non-U.S. government patent agencies also require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. We are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our in-licensed intellectual property, and we cannot guarantee that they will do so. In an event of abandonment or lapse of a patent or patent application, our competitors might be able to enter the market and this circumstance would have a material adverse impact on our business. We cannot be sure that we or our licensors will be able to fully comply with these requirements, and we or our licensors may lose material patent protection as a result.

In addition, public health pandemics, geopolitical instability, natural disasters, or similar events may impair our and our licensors' ability to comply with these procedural, document submission, fee payment, and other requirements imposed by government patent agencies, which may materially and adversely affect our ability to obtain or maintain patent protection for our product candidates. There could also be delays at the USPTO caused by staffing cuts and other U.S. government actions as a result of the U.S. Department of Government Efficiency or other executive actions to reduce the size of the U.S. government.

The USPTO and various non-U.S. government agencies require compliance with certain foreign filing requirements during the patent application process. For example, 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 in other jurisdictions. 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 cases, for example in China and India, a foreign filing license cannot be obtained retroactively in accordance with the applicable rules. There are situations in which non-compliance can result in abandonment of a pending patent application or can be grounds for revoking or invalidating an issued patent and/or rendering an issued patent unenforceable, resulting in the loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the relevant markets with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations and prospects. We may also be dependent on our licensors to take the necessary actions to comply with these requirements with respect to our licensed intellectual property. We cannot ensure that our licensors will take such action, or timely take such action, in a manner sufficient to protect our rights.

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court.

If we or one of our collaboration partners were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate or technology is invalid and/or unenforceable. In patent litigation in the United States and other jurisdictions, 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 patent subject matter eligibility, novelty, non-obviousness, written description and/or enablement. 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 allegations before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include post- or pre-grant administrative proceedings, such as *ex parte* reexamination, inter partes review, post grant review, interference proceedings and equivalent proceedings in foreign jurisdictions (*e.g.*, opposition proceedings). Such proceedings could result in revocation or amendment of our patents in such a way that they no longer cover our product candidates or technology. 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 and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity and/or unenforceability of patent rights covering a product candidate or technology, we would lose at least part, and perhaps all, of the patent protection on our product candidate or technology. Such a loss of patent protection could have a material adverse impact on our business. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention, or decide that the other party's use of our patented technology falls within the safe harbor to patent infringement under 35 U.S.C. § 271(e)(1) or analogous laws outside the United States.

If we do not obtain sufficient patent term for our product candidates, our business may be materially harmed.

Patents have a limited term. The terms of individual patents depend upon the legal term for patents in the countries in which they are granted. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from the earliest non-provisional filing date, subject to patent term adjustments, extensions and disclaimers. Many foreign jurisdictions provide a similar 20-year nominal patent term, though many require payment of regular, often annual, annuities to maintain pendency of an application or viability of an issued patent. However, the actual protection afforded by a patent varies from country to country, and also depends upon many factors, including the type of patent, the scope of coverage, the availability of regulatory related extensions, the availability of extensions for patent office delays during the examination process, the availability of legal remedies in a particular country and the validity and enforceability of the patent, and whether a portion of the patent term has been terminally disclaimed based on other patents. These factors may emerge and change over the course of time, and accordingly, a patent's expiration date might change over time in unpredictable ways. Various extensions including patent term extension based on regulatory review and approval may be available, but the durations of such extensions, and the protections they afford, are limited in the United States and other countries and regions. Additional patent terms may be available through a patent term adjustment process in the United States, for delays caused by the USPTO during prosecution, which may be reduced by applicants' delays. Although various extensions or adjustments may be available, the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product candidate, we may face substantially increased competition from generics or biosimilars.

Depending upon the timing, duration and specifics of FDA regulatory approval of our product candidates, one or more patents issued from U.S. patent applications that we or a future licensor file may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Amendments") through patent term extension. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during the FDA regulatory review process based on the first regulatory approval for a particular drug. A maximum of one patent may be extended per FDA-approved drug as compensation for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of drug approval, and only those claims covering such approved drug product, an approved method for using it or a method for manufacturing it may be extended. Patent term extension may also be available in certain foreign countries upon regulatory approval of our product candidates.

Despite the possibility of an extension, we may not be granted an extension in the United States or another jurisdiction because of, for example, failure to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time or the scope of patent protection that is granted through the extension may be less than we requested or expected and may not be sufficient to protect all uses of our products.

If we are unable to obtain patent term extension, or the foreign equivalent, or the term of any such extension is less than we requested or expected or the scope is not sufficient, our competitors or other third-parties may obtain approval of competing drugs following our patent expiration, and our revenue could be reduced, possibly materially. Further, if this occurs, our competitors or other third-parties may take advantage of our investment in development and trials by referencing our clinical and nonclinical data and launch their drug earlier than might otherwise have been the case. Any of the foregoing could materially harm our business, financial condition, results of operations and growth prospects.

We will not seek to protect our intellectual property rights in all jurisdictions throughout the world, and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.

Filing, prosecuting, maintaining and defending patents covering our platform and product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some or all countries outside the United States can be less extensive than those in the United States. In addition, the laws of some countries do not protect intellectual property rights to the same extent as laws in the United States. Competitors may use our technologies and innovations in jurisdictions where we have not obtained patent protection to develop their own products and technologies and, further, may export otherwise infringing products or technologies to territories where we have patent protection, but where enforcement is not as strong as in the United States or Europe.

These products may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

In addition, we may decide to abandon patent applications before they are granted. The examination of each patent application is an independent proceeding. As a result, patent applications in the same family may issue as patents in some jurisdictions, such as in the United States, but may issue as patents with claims of different scope or may even not issue in other jurisdictions. Furthermore, the requirements for patentability differ in certain jurisdictions and countries. For example, some countries do not grant claims directed to methods of treatment or have additional restrictions on the scope of method of treatment claims compared to the United States. Accordingly, depending on the country, the scope of patent protection may vary for the same product candidate or technology. For costs or other reasons, we may choose not to file, prosecute, maintain, defend and/or enforce certain patent filings, including abandoning pending patent applications or issued patents.

While we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain protection efforts, and achieve successful protection, in all such markets. Additionally, the prosecution of patent applications can be a long process and patents may not be timely granted if ever granted, potentially delaying our ability to assert such patents against competitors. Accordingly, our efforts to protect our intellectual property rights in the United States and foreign countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our product candidates in all of our expected significant markets. If we encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business, the value of these rights may be diminished, and we may face additional competition.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws in the United States and Europe, and many companies have encountered significant difficulties in obtaining, defending or enforcing such rights in such jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor obtaining, defending, or enforcing patents, trade secrets and other intellectual property rights, which could make it difficult for us to stop the infringement of any patents we obtain, prevent misappropriation of our intellectual property or prevent the marketing of competing products by third parties in violation of our proprietary rights generally. Proceedings to enforce our patent rights in other jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put any patents we obtain at risk of being invalidated or interpreted narrowly, and put our patent applications at risk of not issuing as patents, and could result in the assertion by third parties of claims or rights 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. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant, or any, commercial advantage from the intellectual property that we develop or license.

Some countries also have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In those countries, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be materially impaired.

In Europe, a new unitary patent system took effect on June 1, 2023, which may significantly impact European patents, including those granted before the introduction of the new system. Under the new system, applicants can, upon grant of a European patent, opt for that patent to become a unitary patent which will be subject to the jurisdiction of a new unitary patent court (“UPC”). During the first seven years of the UPC’s existence, certain European patents granted before the implementation of the new system can be opted out of UPC jurisdiction, and validated as national patents in any one or more of the UPC countries. We may decide during this transition period to opt out 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. Patents that are under the jurisdiction of the UPC may be challenged in a single UPC-based revocation proceeding that, if successful, could invalidate the patent in all countries who are signatories to the UPC. The UPC may provide our competitors with a new forum to centrally revoke our European patents, and allow for the possibility of a competitor to obtain pan-European injunction. Further, because the UPC is a new court system and there is no precedent for the court’s laws, there is increased uncertainty regarding the outcome of any patent litigation. We are unable to predict what impact the new patent regime may have on our ability to exclude competitors in the European market.

If we are unable to obtain and enforce patents as needed in particular markets, our ability to exclude competitors in those markets may be reduced.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining, maintaining, defending and enforcing patents in the biotechnology industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States and in other major jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents, and may diminish our ability to protect our inventions and to obtain, maintain, enforce and defend our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our current or future owned and licensed patents.

The patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. Recent rulings from the U.S. Supreme Court and the Court of Appeals for the Federal Circuit have narrowed the scope of patent protection available in specified circumstances and weakened the rights of patent owners in specified situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our or our licensors' ability to obtain new patents and to maintain, defend and/or enforce our existing or future patents. The U.S. Supreme Court has ruled on several patent cases in recent years, narrowing the scope of patent protection available in certain circumstances or otherwise weakening the rights of patent owners. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the validity and enforceability of issued or future patents. Depending on future actions by the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our or our licensors' ability to obtain new patents in such counties and to maintain, defend and/or enforce our existing or further patents in such countries. We cannot predict how future decisions by the federal courts, the U.S. Congress, the USPTO and/or analogous courts and bodies outside the United States may impact the value of our patents. Changes in the patent laws of the United States and other jurisdictions might also adversely affect our business, financial condition, results of operations and prospects.

The USPTO has issued subject matter eligibility guidance instructing USPTO examiners on the ramifications of the Supreme Court rulings in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* and *Association for Molecular Pathology v. Myriad Genetics, Inc.*, and applied the *Myriad* ruling to natural products and principles including all naturally occurring molecules. In addition, the USPTO continues to provide updates to its guidance that may make it impossible for us to obtain similar patent claims in future patent applications. Currently, our patent portfolio contains claims of various types and scopes, including methods of medical treatment. The presence of varying types of claims in our patent portfolio may not eliminate our exposure to potential validity challenges alleging a lack of subject matter eligibility. Furthermore, U.S. Court of Appeals for the Federal Circuit has held that an inventor on a U.S. patent must be a natural person and not a machine or AI. As a result, AI systems, regardless of their sophistication, cannot be named as inventors or joint inventors on a patent application as they are not natural persons. The USPTO has recently issued inventorship guidance for AI-assisted inventions. Given that we use AI in certain aspects of our Helicon discovery platform, certain AI-assisted inventions may be deemed ineligible for patent protection if it is determined that there is not a sufficient level of human inventive contribution.

In the United States, the Leahy-Smith America Invents Act (the "Leahy-Smith Act") was signed into law on September 16, 2011. The Leahy-Smith Act included a number of significant changes to U.S. patent law. These included provisions that affect the way patent applications are prosecuted, redefine prior art and provide potentially more efficient and cost-effective avenues for competitors to challenge the validity of patents. The USPTO has promulgated regulations and developed procedures to govern administration of the Leahy-Smith Act. Many substantive changes to patent law associated with the Leahy-Smith Act has come into effect since March 16, 2013. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

An important change introduced by the Leahy-Smith Act is that, as of March 16, 2013, the United States transitioned to a "first-inventor-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. This requires us to be cognizant of the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to either: (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our patents or patent applications.

Among some of the other changes introduced by the Leahy-Smith Act are changes that limit where a patentee may file a patent infringement suit and new procedures providing opportunities for third parties to challenge any issued patent in the USPTO. These

new post grant challenges include post grant review and inter partes review proceedings before the Patent Trial and Appeal Board at the USPTO. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal court necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim unpatentable even though the same evidence would be insufficient to invalidate the claim if presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate patent claims that would not have been invalidated if challenged by the third party as a defendant in a district court action. The USPTO has made many changes and may make future changes to the rules of practice for implementing post-grant proceedings. These USPTO rules and changes thereto can impact the ability of third parties, and our ability, to challenge or defend U.S. patents before the USPTO.

Similarly, changes in patent law and regulations in other jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain, maintain, defend or enforce current and future patents in our portfolio.

Geopolitical actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of patent applications and the maintenance, enforcement or defense of issued patents. For example, the United States and foreign government actions related to Russia's invasion of Ukraine resulted in Russia issuing Decree No. 299 that effectively nullifies the enforcement of Russian patents owned by entities and individuals in "unfriendly" countries, including the United States.

Any trademarks we have obtained or may obtain may be infringed or otherwise violated or successfully challenged. If our trademarks and trade names are not adequately protected, or if we are unable to obtain desired trademarks or trade names, then we may not be able to build brand name recognition in our markets of interest and our business may be adversely affected.

We expect to utilize trademark protection for our products, product candidates and/or platform. Once we select new trademarks and apply to register them, our trademark applications may not be approved. During trademark registration proceedings in the United States and foreign jurisdictions, we may receive rejections. We are given an opportunity to respond to those rejections, but we may not be able to overcome such rejections and obtain sufficient, or any, trademark protection.

We have also not yet registered trademarks for any of our product candidates in any jurisdiction. Any trademark applications we file may be rejected and registered trademarks may not be obtained, maintained or enforced. If we do not successfully register our trademarks, we may encounter difficulty in enforcing, or be unable to enforce, our trademark rights against third parties, which could adversely affect our business and our ability to effectively compete in the marketplace.

In addition, any proprietary name we propose to use with any of our product candidate in the United States will need to be approved by the FDA, regardless of whether we have registered, or applied to register, the proposed proprietary name as a trademark. The FDA conducts a review of proposed proprietary names, including an evaluation of potential for confusion with other products' proprietary names, as part of the NDA review process. If the FDA 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 proprietary name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

In addition, our unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic, or determined to be infringing on, misappropriating or violating other marks. In the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademark registrations may not survive such proceedings. In the event that our trademarks are successfully challenged, we could be forced to rebrand our product candidates, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion.

Our competitors may also infringe or otherwise violate our trademarks and we may not have adequate resources to enforce our trademarks. We may not be able to protect our rights to our trademarks and trade names, which we need to build name recognition among potential collaborators or customers in our markets of interest. Any of the foregoing events may have a material adverse effect on our business.

Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement allegation asserted by the owner of a senior trademark. Over the long term, if we are unable to successfully register our trademarks and trade names and establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related

to trademarks, trade names, domain names or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations.

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. For example:

- our product candidates, if approved, may eventually become commercially available in generic or biosimilar product forms;
- others may be able to make similar molecules to our product candidates that are not covered by the claims of the patents that we license or own now or in the future;
- we, or current or future licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- we, or current or future licensors or collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or own;
- we, or current or future licensors or collaborators, may fail to meet our obligations to the U.S. government regarding any patents and patent applications funded by U.S. government grants;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing on our owned or licensed intellectual property rights;
- it is possible that our pending patent applications or those that we may own or license in the future will not lead to issued patents;
- it is possible that there are prior public disclosures that could invalidate our patents;
- it is possible that there are patent applications that may later issue with claims covering our product candidates or technology similar to ours;
- it is possible that our patents or patent applications omit individual(s) that should be listed as inventor(s) or include individual(s) that should not be listed as inventor(s), which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable or result in a change in ownership;
- issued patents that we own or in-license may be held invalid, unenforceable or narrowed in scope, including as a result of legal challenges;
- the claims of our issued patents or patent applications, if and when issued, may not cover our product candidates or narrowly cover them in such a way that competitors may be able to design around to avoid infringement allegations;
- the laws of foreign countries may not protect our proprietary rights or the proprietary rights of our current or future licensors or collaborators to the same extent as the laws of the United States;
- the inventors of our patents or patent applications may become involved with competitors, develop products or processes that are similar to or alternative to those claimed in our patent filings or become hostile to our patents or patent applications on which they are named as inventors, and might take action detrimental to our patent and other intellectual property rights;
- our competitors might conduct research and development activities in countries where we 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 have engaged in scientific collaborations in the past and we intend to continue to do so in the future, and our collaborators may develop adjacent or competing products that are outside the scope of our patents;
- we may not develop additional proprietary technologies that are patentable;
- the product candidates and technology we develop may be covered by third-party patents or other intellectual property rights;
- the patents of others may prohibit or otherwise harm our ability to conduct our business; or

- we may choose not to apply for a patent in order to maintain certain trade secrets, know-how, or other technology confidential, and a third party may subsequently commercialize such technology and/or apply for and obtain a patent covering such technology.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Risks Related to the Potential Commercialization of Our Pipeline

We have no sales, distribution or marketing experience, and may invest significant financial and management resources to establish these capabilities. If we are unable to establish such capabilities or enter into agreements with third parties to market and sell our future products, if approved, we may be unable to generate any revenues from product sales.

Given our stage of development as a company, we have no sales, distribution or marketing experience. To successfully commercialize any products that may result from our programs, we will need to develop sales and marketing capabilities in the United States, Europe and other regions, either on our own or with others. These efforts will require substantial additional resources, some or all of which may be incurred in advance of any approval of these product candidates. Any failure or delay in the development of our or third parties' internal sales, marketing, and distribution capabilities would adversely impact the commercialization of our product candidates.

Factors that may inhibit our efforts to commercialize our product candidates on our own include:

- inadequate funding;
- our inability to recruit and retain an adequate number of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade an adequate number of physicians to prescribe any future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage compared to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

We may enter into partnership, collaboration, and licensing arrangements with third parties to utilize their mature marketing and distribution capabilities, but we may be unable to enter into marketing agreements on favorable terms, if at all. If these third parties do not commit sufficient resources to commercialize our future products, if any, and we are unable to develop the necessary marketing capabilities on our own, we may be unable to generate sufficient product revenue to sustain our business. We may be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without a significant internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies. Our future product revenue may be lower than if we directly marketed or sold our product candidates, if approved. In addition, any revenue we receive will depend in whole or in part upon the efforts of these third parties, which may not be successful and are generally not within our control. If we are not successful in commercializing any approved products, our future product revenue will suffer and we may incur significant additional losses.

If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

The biopharmaceutical market is intensely competitive. If we are unable to compete effectively with existing drugs, new treatment methods and new technologies, we may be unable to successfully commercialize any drugs that we develop.

The biopharmaceutical market is intensely competitive and rapidly changing. Many large pharmaceutical and biotechnology companies, academic institutions, governmental agencies and other public and private research organizations, known and unknown, are pursuing the development of novel drugs for the same diseases that we are targeting or expect to target. Many of our competitors have:

- greater financial, technical and human resources than we have at every stage of the engineering, development, manufacture and commercialization of products;
- more extensive experience in nonclinical testing, conducting clinical trials, obtaining regulatory approvals and in manufacturing, marketing and selling products;
- product candidates that are based on previously tested or accepted technologies;

- products that have been approved or are in late stages of development; and
- collaborative arrangements in our target markets with leading companies and research institutions.

Accordingly, our competitors may be more successful than us in obtaining patent protection, regulatory exclusivities or FDA approval and commercialize products or achieve widespread market acceptance more rapidly than we do, which may impact future approvals or sales of our product candidates that receive regulatory approval. If the FDA approves the commercial sale of our product candidates, we will also be competing with respect to marketing capabilities and manufacturing efficiency. We expect competition among products will be based on product efficacy and safety, the timing and scope of regulatory approvals, availability of supply, marketing and sales capabilities, product price, reimbursement coverage by government and private third-party payors, regulatory exclusivities and patent position. Our profitability and financial position will suffer if our product candidates receives regulatory approval but cannot compete effectively in the marketplace.

In addition, our competitors may develop partnership, collaboration, and licensing arrangements with or receive funding from larger pharmaceutical or biotechnology companies, providing them with an advantage over us. Our competitors may also succeed in developing, acquiring or licensing technologies and drug products that are more effective or less costly than our product candidates, which could render our product candidates obsolete and noncompetitive. Our competitors may therefore be more successful in commercializing their products than we are, which could adversely affect our competitive position and business. Competitive products may make any products we develop obsolete or noncompetitive before we can recover the expenses of developing and commercializing our products, if approved.

We expect to face intense competition from drugs that have already been approved and accepted by the medical community for the treatment of the conditions for which we may develop products. We also expect to face competition from new drugs that enter the market. There are a number of drugs currently under development, which may become commercially available in the future, for the treatment of the conditions for which we are trying, or may in the future try, to develop products. These drugs may be more effective, safer, less expensive or marketed and sold more effectively, than any products we develop. In most cases, we do not currently plan to run head-to-head clinical trials evaluating our product candidates against the current standards of care, which may make it more challenging for our product candidates to compete against the current standards of care due to the lack of head-to-head clinical trial data.

If we successfully develop any product candidates, and obtain approval for them, we expect to face competition based on many different factors, including: the safety and effectiveness of our products relative to alternative therapies, if any; the ease with which our products can be administered and the extent to which patients accept relatively new routes of administration; the timing and scope of regulatory approvals for these product candidates; the availability and cost of manufacturing, marketing and sales capabilities; the price of any approved product; reimbursement coverage; and patent position.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites, as well as in acquiring technologies complementary to, or necessary for, our product candidates.

The commercial success of any current or future product candidate, if approved, will depend upon the degree of market acceptance by physicians, patients, third-party payors and others in the medical community.

Even with the requisite approvals, the commercial success of our products will depend in part on the medical community, patients and third-party or governmental payors, and our products in particular, as medically useful, cost-effective and safe. Furthermore, the method of administration of any of our products, if approved, could have an impact on commercial acceptance of any such products and ultimately the commercial success of such products. Furthermore, ethical, social and legal concerns about the application of AI to research and development of products could result in additional regulations restricting access to or otherwise limit demand for our products. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including: the potential efficacy and potential advantages over alternative treatments; the ability to offer our products, if approved, at competitive prices; the prevalence and severity of any side effects, including any limitations or warnings contained in a product's approved labeling; the prevalence and severity of any side effects resulting from checkpoint inhibitors or other drugs or therapies with which our products are administered; relative convenience and ease of administration; any restrictions on the use of our products, if approved, together with other medications; the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies; the strength of marketing and distribution support and timing of market introduction of competitive products; publicity concerning our products or competing products and treatments; and sufficient

third-party insurance coverage or reimbursement, and patients' willingness to pay out-of-pocket in the absence of third-party coverage or adequate reimbursement.

Even if a potential product displays a favorable efficacy and safety profile in nonclinical studies and clinical trials, market acceptance of the product will not be known until after it is launched. Our efforts to educate the medical community and third-party payors on the benefits of the products may require significant resources and may never be successful. Our efforts to educate the marketplace may require more resources than are required by the conventional technologies marketed by our competitors due to the complexity and uniqueness of our product candidates.

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

In addition, if any of our products are approved for marketing, we or a collaboration partner will be subject to significant regulatory obligations regarding the submission of safety and other post-marketing information and reports for such product, and will need to continue to comply (or ensure that our third-party providers comply) with current cGMP and GCPs for any clinical trials that we or a collaboration partner conduct post-approval. In addition, there is always the risk that we or a collaboration partner or Regulatory Authority might identify previously unknown problems with a product post-approval, such as adverse events of unanticipated severity or frequency. Compliance with these requirements is costly, and any such failure to comply or other issues with our product candidates identified post-approval could have a material adverse impact on our business, financial condition and results of operations.

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. Recent and ongoing changes in the United States' trade policy with foreign countries, including the continued uncertainty surrounding U.S. tariffs and potential retaliatory measures by foreign governments, may disrupt the global supply chain for biopharmaceutical products. For example, in April 2025, the United States imposed "reciprocal" tariffs, which were broad tariffs on imports from virtually all countries, with particularly high tariffs on imports from China. The U.S. Supreme Court invalidated these reciprocal tariffs on February 20, 2026. However, in July 2026, the United States imposed new tariffs ranging from approximately 10%-12.5% on virtually all imports to the United States. The United States has also imposed significantly higher tariffs applicable to certain imports in select industries, including certain pharmaceuticals. U.S. tariffs on many imports from China remain higher than those that apply to other U.S. trading partners. The United States also is investigating whether to impose additional broad-based tariffs, and has completed or is undertaking other investigations that could result in further product- or industry-specific tariffs. These historically elevated tariffs have resulted in other countries imposing additional tariffs on imports from the United States, and may result in more retaliatory tariffs. 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. The outcome of any current or future legal challenges to these new tariffs is presently unclear, and these tariffs may result in increased costs for raw materials and contract manufacturing services, reduced ability to source critical contract manufacturing organizations, and a delay in our development timelines.

We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the applicable foreign regulatory authority and may never receive such regulatory approval for any of 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 marketing 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. 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 are subject to export and import controls, economic sanctions and anti-corruption laws and regulations of the United States and other jurisdictions. We can face criminal liability and other serious consequences for violations of these laws and regulations, which can harm our business.

Because we plan to market our products, if approved, outside of the United States, our business is subject to risks associated with doing business outside of the United States including, an increase in our expenses, diversion of our management's attention from the acquisition or development of product candidates or forgoing profitable licensing opportunities in these geographies. Accordingly, our business and financial results in the future could be adversely affected due to a variety of factors, including: efforts to develop an international sales, marketing, and distribution organization; changes in a specific country's or region's political and cultural climate or economic condition; unexpected changes in foreign laws and regulatory requirements; difficulty of effective enforcement of contractual provisions in local jurisdictions; inadequate intellectual property protection in foreign countries; trade-protection measures, import or export licensing requirements such as Export Administration Regulations promulgated by the U.S. Department of Commerce and fines, penalties or suspension or revocation of export privileges; the effects of applicable foreign tax structures and potentially adverse tax consequences; and significant adverse changes in foreign currency exchange rates.

In addition to FDA and related regulatory requirements in the United States and abroad, we are subject to extensive additional federal, state and foreign anti-bribery regulations, which include the U.S. Foreign Corrupt Practices Act, U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the UK Bribery Act 2010 and similar laws in other countries outside of the United States. We are developing and implementing a corporate compliance program based on what we believe are current best practices in the biotechnology industry for companies similar to ours, but we cannot guarantee that we, our employees, our consultants or our third-party contractors are or will be in compliance with all federal, state and foreign regulations regarding bribery and corruption. Moreover, our collaboration partners and third-party contractors located outside the United States may have inadequate compliance programs or may fail to respect the laws and guidance of the territories in which they operate. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could also have an adverse effect on our business, financial condition and results of operations.

The insurance coverage and reimbursement status of newly approved products, including those in a new category of medicines, is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue.

The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford expensive treatments such as the products that we hope to develop and sell. Sales of our product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment in any of our products. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is: a covered benefit under its health plan; safe, effective and medically necessary; appropriate for the specific patient; cost-effective; and neither experimental nor investigational.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. The Centers for Medicare & Medicaid Services ("CMS"), an agency within the U.S. Department of Health and Human Services ("HHS"), determines whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private payors tend to follow CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for products.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for our product candidates that we commercialize and, if reimbursement is available, the level of reimbursement.

Outside the United States, certain countries, including a number of member states of the EU (the "Member States"), set prices and reimbursement for pharmaceutical products, or medicinal products, as they are commonly referred to in the EU, with limited participation from the marketing authorization holders. Reimbursement agencies in Europe may be more conservative than CMS. For example, a number of cancer drugs have been approved for reimbursement in the United States and have not been approved for

reimbursement in certain European countries. We cannot be sure that such prices and reimbursement will be acceptable to us or our collaboration partners. If the regulatory authorities in these foreign jurisdictions set prices or reimbursement levels that are not commercially attractive for us or our collaboration partners, our revenues from sales by us or our collaboration partners and the potential profitability of our products in those countries would be negatively affected. An increasing number of countries are taking initiatives to attempt to reduce large budget deficits by focusing cost-cutting efforts on pharmaceuticals for their state-run health care systems. These international price control efforts have impacted all regions of the world but have been most drastic in the European Union.

Additionally, the requirements governing product pricing vary widely from country to country. Some countries require approval of the sale price of a product before it can be marketed, while in others, the pricing review period begins after marketing or product licensing approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then may experience delays in the reimbursement approval of our product or be subject to price regulations that would delay our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenues we are able to generate from the sale of the product in that particular country. For example, the EU provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. A Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for our product candidates. Historically, products launched in the EU do not follow price structures of the United States and generally prices tend to be significantly lower.

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 level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates.

We expect to experience pricing pressures in connection with the sale of any of our product candidates, 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 surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

For more information on the laws and regulations that may impact coverage and reimbursement of our product candidates, see the sections of our Final Prospectus dated June 10, 2026 filed with the SEC titled, "*Business—Government Regulation—Coverage and Reimbursement*" and "*Business—Government Regulation—Current and Future U.S. Healthcare Reform.*"

Healthcare legislative reform discourse and potential or enacted measures may have a material adverse impact on our business and results of operations and legislative or political discussions surrounding the desire for and implementation of pricing reforms may adversely impact our business.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example, (i) changes to our manufacturing arrangements, (ii) additions or modifications to product labeling, (iii) the recall or discontinuation of our products or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

The containment of healthcare costs has become a priority of federal, state and foreign governments and the prices of products have been a focus in this effort. There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical products, limiting coverage and the amount of reimbursement for drugs and other medical products, government control and other changes to the healthcare system in the United States. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. For more information on the healthcare reform measures that may impact our business, see the section of our Final Prospectus dated June 10, 2026 filed with the SEC titled, "*Business—Government Regulation—Current and Future U.S. Healthcare Reform.*"

Most recently, on December 19, 2025, CMS released two proposed rules that would incorporate most-favored-nation pricing principles into federal reimbursement for prescription drugs: the Global Benchmark for Efficient Drug Pricing Model ("GLOBE") for Medicare Part B and the Guarding U.S. Medicare Against Rising Drug Costs Model ("GUARD") for Medicare Part D. On October 2,

2026, CMS published the final rule for GLOBE, which is scheduled to take effect on November 30, 2026. As finalized, GLOBE is a mandatory model under Section 1115A of the Social Security Act that, beginning January 1, 2027, with a performance period running from April 1, 2027 through March 31, 2032, would require manufacturers of certain single-source Part B drugs furnished in randomly selected geographic areas covering approximately 25% of Original Medicare Part B beneficiaries to pay rebates calculated by reference to international benchmark prices, in place of the existing Part B inflation rebate calculation. Relative to the proposed rule, CMS narrowed GLOBE's scope, including by excluding orphan-only drugs, plasma-derived products and certain cell and gene therapies, and CMS has stated that it intends to waive mandatory participation for any calendar quarter in which a manufacturer participates in the voluntary GENEROUS Model described below.

CMS has not yet finalized GUARD, which, as proposed, would apply a similar MFN-based rebate approach to qualifying Medicare Part D drugs, and we cannot predict whether or when GUARD will be finalized or whether it will include exclusions or waivers similar to those in GLOBE. On October 7, 2026, the Pharmaceutical Research and Manufacturers of America filed suit in the U.S. District Court for the District of Columbia challenging GLOBE as unlawful, beyond CMS's statutory authority and unconstitutional, and seeking injunctive relief. We cannot predict the outcome of this litigation or whether GLOBE will take effect on its current timeline. In addition, CMS has indicated that GLOBE's current design is a first-phase test and that the model could be expanded in the future, including on a nationwide basis, if applicable statutory criteria are met. Accordingly, GLOBE, GUARD or similar MFN-based models, as finalized, expanded or modified, could adversely affect the prices we or any collaborator may obtain for any approved product.

Additionally, in November 2025, CMS introduced the voluntary GENErating cost Reductions for U.S. Medicaid ("GENEROUS") Model, a voluntary MFN framework for manufacturers participating in the Medicaid Drug Rebate Program, in which a number of manufacturers have agreed to participate. Although participation is voluntary, the GENEROUS Model, together with GLOBE and GUARD, could impact the drug pricing landscape for manufacturers, including through its effect on the application of GLOBE and, potentially, GUARD

Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our revenue generated from the sale of any approved products. Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their commercial products, which has resulted in several Congressional inquiries and proposed and enacted state and federal legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for pharmaceutical products. The U.S. Congress has indicated that it will continue to seek new legislative measures to control drug costs.

In December 2021, Regulation No 2021/2282 on Health Technology Assessment ("HTA") amending Directive 2011/24/EU, was adopted in the EU. This Regulation, which entered into force in January 2022 and became applicable in January 2025, is intended to boost cooperation among Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. The Regulation will permit Member States to use common HTA tools, methodologies and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual Member States will continue to be responsible for assessing nonclinical (*e.g.*, economic, social, ethical) aspects of health technologies and making decisions on pricing and reimbursement.

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

If the market opportunities for our product candidates are smaller than we believe they are, our revenue may be adversely affected and our business may suffer.

The estimates of market opportunity and forecasts of market growth included in documents that we file with the SEC may prove to be smaller than we believe, and even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, or at all. Although we are initially focused on developing and commercializing zolucatetide for the treatment of desmoid tumors, we also plan to evaluate developing zolucatetide for the treatment of FAP, HCC and other rare solid tumors and cancer-related conditions. We expect this evaluation will take into account expected clinical timelines, regulatory feedback, costs and

the clinical data from our Phase 1/2 trial. For example, in October 2026, we announced the initiation of a dose-ranging clinical cohort evaluating zolucatetide in patients with FAP as part of our ongoing Phase 1/2 clinical trial of zolucatetide. In addition, an important area of focus of our research and product development activities is the development of treatments for severe rare genetic diseases. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on estimates and independent market research, industry and general publications obtained from third parties. Market opportunity estimates and growth forecasts included in this Quarterly Report and the other documents that we file with the SEC are subject to significant uncertainty and are based on assumptions and estimates. These estimates, which have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations and market research, may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these indications. Additionally, the potentially addressable patient population may not ultimately be amenable to treatment with our product candidate if we cannot achieve our intended dosing interval. Our market opportunity may also be limited by current and future products of our competitors that are already available in the market or may enter the market for such patients. If any of our estimates prove to be inaccurate, the market opportunity for our product candidates could be significantly diminished and have an adverse material impact on our business.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, and false claims laws. If we are unable to comply, or have not fully complied with such laws, we could face substantial penalties.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations will be directly, or indirectly through our prescribers, customers and purchasers, subject to various federal and state fraud and abuse laws and regulations that will impact, among other things, our proposed sales, marketing, and educational programs. The laws that will affect our operations include, but are not limited to the federal Anti-Kickback Statute, federal and state false claims laws, transparency requirements, price reporting requirements, and the other federal and state laws described in the section of the Prospectus titled, “Business—Government Regulation—Other Healthcare Laws.”

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities, including certain consulting agreements we have entered into with physicians who are paid, in part, in the form of stock or stock options could be subject to challenge under one or more such laws. If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, mandatory or discretionary exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the EU. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of Member States, such as the UK Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician’s employer, his or her competent professional organization or the regulatory authorities of the individual Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

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

We face an inherent risk of product liability exposure related to the testing of any of our current or future product candidates in clinical trials, and we may face an even greater risk if we commercialize any product candidate that we may develop. If we cannot successfully defend ourselves against allegations that our product candidates caused injuries, or we failed to warn of potential injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, allegations of liability may result in decreased demand for any product candidate that we may develop; loss of revenue; substantial monetary awards to patients, healthy volunteers or their children; significant time and costs to defend the related litigation; withdrawal of clinical trial participants; the inability to commercialize any product candidate(s) that we may develop; and injury to our reputation and significant negative media attention.

We carry product liability insurance which we believe to be sufficient in light of our current clinical programs; however, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If and when we obtain marketing approval for product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. On occasion, large judgments have been awarded in class action lawsuits based on drugs or medical treatments that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

Risks Related to Our Business Operations and Employee Matters

Our future success depends on our ability to retain key employees, consultants and advisors and to attract, retain and motivate qualified personnel.

Our ability to compete in the highly competitive biotechnology industry depends upon our ability to attract and retain highly qualified managerial, scientific, technical and medical personnel. We are highly dependent upon members of our management, including our Chief Executive Officer, as well as technology and scientific teams, many of whom have been instrumental for us and have substantial experience with developing therapies, identifying potential product candidates and building the technologies related to the development of our Helicon discovery platform and our pipeline. Each of the members of our management team, and all of our employees, including key technical personnel, scientists and clinicians, are employed "at will," meaning we or each officer or employee may terminate the employment relationship at any time. The loss of any of these persons' services may adversely impact the achievement of our research, development, financing and commercialization objectives. We currently do not have "key person" insurance on any of our employees. Many of our key employees, including members of our leadership team, have been with us for several years, and have a significant amount of fully vested stock options or other long-term equity incentives which may become valuable and will be publicly tradable upon expiration of the applicable lock-up period. We may not be able to retain these employees due to the competitive environment in the biotechnology industry, particularly in the greater Boston, Massachusetts region.

In addition, we rely on consultants, contractors and advisors, including scientific and clinical advisors, to assist us in formulating our research and development, regulatory approval and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. The loss of the services of one or more of our current employees or advisors might impede the achievement of our research, development, regulatory approval and commercialization objectives. In addition, we have flexibly added capability and capacity through the use of contractors. We may not be able to retain the services of such personnel, which might result in delays in the operation of our business.

Recruiting and retaining other qualified employees, consultants and advisors for our business, including scientific and technical personnel, also will be critical to our success. Competition for skilled personnel, including in AI, research, clinical operations, regulatory affairs, therapeutic area management and manufacturing, is intense and the turnover rate can be high. We may not be able to attract and retain personnel on favorable terms given the competition among numerous biotechnology companies and academic institutions for individuals with similar skill sets. In addition, adverse publicity, failure to succeed in nonclinical or clinical trials or applications for marketing approval may make it more challenging to recruit and retain qualified personnel. The inability to recruit, or loss of services of certain executives, key employees, consultants or advisors, may impede the progress of our research, development and commercialization objectives and have a material adverse impact on our business, financial condition, results of operations and prospects.

We expect to continue to expand our development and regulatory capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We have experienced significant growth since our inception in 2015. We expect continued growth in the number of our employees and the scope of our operations, particularly to continue our planned clinical operations, nonclinical and IND-enabling studies or studies approved by comparable foreign authorities, establish regulatory, quality, and manufacturing supply chain logistics and facility operations.

To manage our anticipated future growth, we will continue to seek to implement and improve our managerial, operational, and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the complexity in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

In addition, future growth imposes significant added responsibilities on members of management, including: identifying, recruiting, integrating, maintaining, and motivating new employees; managing our internal development efforts effectively, including the clinical and FDA, or comparable foreign regulatory authority, review process for zolucatetide and any current or future product candidates, while complying with our contractual obligations to third parties; and improving our operational, financial and management controls, reporting systems, and procedures.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors, and consultants to provide certain services, including strategic, financial, business development, and research and development services, as well as certain aspects of regulatory approval and manufacturing. There can be no assurance that the services of independent organizations, advisors, and consultants will continue to be available to us on a timely basis when needed or on reasonable terms, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants, CROs, CDMOs or contract manufacturing organizations ("CMOs") is compromised for any reason, our nonclinical or clinical trials may be extended, delayed, or terminated, and we may not be able to obtain regulatory approval of zolucatetide or any of our other current or future product candidates or otherwise advance our business. We cannot assure you that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new qualified employees and expanding our groups of consultants and contractors, we may experience delays or may not be able to successfully implement the tasks necessary to further develop and commercialize zolucatetide for desmoid tumors and any other rare tumors and any future product candidates we develop and, accordingly, we may not achieve our research, development, and commercialization goals.

Our information technology systems or our infrastructure may fail or experience security breaches and incidents that could adversely impact our business and operations and subject us to liability.

Our information technology systems and data are vulnerable to compromise or damage from cybersecurity attacks or accidents. We have experienced significant growth in the complexity of our data and the software tools that our hardware infrastructure supports. We rely significantly upon information technology systems and infrastructure owned and maintained by us or by third-party providers to generate, collect, store and transmit confidential and proprietary information and data (including but not limited to intellectual property, proprietary business information and personal information) and to operate our business. We also outsource elements of our operations to, and obtain products and services from, third-parties and engage in collaborations for drug design with third parties, each of which has or could have access to our confidential or proprietary information. Our employees on occasion travel to countries which are at elevated risk of cyber-intrusion, data theft and expropriation.

We deploy and operate an array of technical and procedural controls to reduce the risks to our information technology ("IT") systems, infrastructure and data and to work to maintain the availability, confidentiality and integrity of our data, and we expect to continue to incur significant costs on such detection and prevention efforts. While we continue to make investments to improve the protection of data and information technology, including in the hiring of qualified IT personnel, periodic cyber security awareness trainings, improvements to IT infrastructure and controls, and conduct regular testing of our systems, there can be no assurance that our efforts will prevent service interruptions or security breaches. Despite these measures, our information technology and other internal infrastructure systems face the risk of failures, interruptions, security breaches and incidents or other harm from various causes or sources, and third parties with whom we share confidential or proprietary information face similar risks and may experience similar events that materially impact us. These causes or sources include but are not limited to the following:

- service interruptions;
- system malfunctions;
- computer viruses and other malicious code;
- natural disasters and force majeure events;
- global political instability;
- warfare;
- cyber-intrusions by hostile nation-state actors;
- telecommunication and electrical failures;
- inadvertent or intentional actions by our employees or third-party providers; and
- cyber-attacks by malicious third parties, including the deployment of ransomware and malware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information.

With respect to cyber-attacks, the techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources, including outside groups and individuals with a range of motives (including industrial espionage) and expertise, such as organized crime affiliates, terrorist organizations or hostile foreign governments or agencies. These risks may be heightened in connection with geopolitical events such as the conflict between Russia and Ukraine. Technological developments, including advances in frontier artificial intelligence models, may increase the sophistication and speed of cybersecurity incidents and other malicious attacks that we experience. The costs to investigate and mitigate actual and suspected cybersecurity breaches and incidents could be significant. We may not be able to anticipate all types of security threats and implement preventive measures effective against all such threats. In addition, an increased amount of work is occurring remotely, including through the use of mobile devices. This could increase our cybersecurity risk, create data accessibility concerns and make us more susceptible to communication disruptions.

We have experienced, and we may continue to experience, cyber-attacks, security breaches and incidents and other system failures, although to our knowledge we have not experienced any material interruption or incident. The loss, corruption, unavailability of or damage to our data would interfere with and undermine the insights we draw from our Helicon discovery platform and could impair the integrity of our clinical trial data, leading to regulatory delays or the inability to get our product candidates approved. If we do not accurately predict and identify our infrastructure requirements and failures and timely enhance our infrastructure, or if our remediation efforts are not successful, it could result in a material disruption of our business operations and development programs, including the loss or unauthorized disclosure of our know-how, individuals' personal information or other proprietary or sensitive data. A security breach or incident that leads to unauthorized acquisition, disclosure or other processing of our intellectual property or other proprietary information could also affect our intellectual property rights and enable competitors to compete with us more effectively.

Likewise, as we rely on third parties such as CROs, contractors and consultants, including for the manufacture of our product candidates and for the conduct of our clinical trials, similar events relating to their systems and operations could also have a material adverse effect on our business and lead to regulatory agency actions. For example, the loss of clinical trial data from completed, ongoing or future clinical trials could result in delays in or denials of our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Any security compromise affecting us, our collaborators or our industry, whether real or perceived, could harm our reputation, erode confidence in the effectiveness of our security measures, and lead to regulatory scrutiny. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or systems, or inappropriate disclosure of confidential or proprietary or personal information, we could incur liability, our competitive position could be harmed, and the further development and commercialization of our product candidates could be delayed, result in substantial costs and distract management.

Failures, disruptions, security breaches and incidents, cyber-attacks and other harmful events impacting data processed or maintained in our business, or information technology systems or infrastructure used in our business, including those resulting in a loss of or damage to our information technology systems or infrastructure, or the loss of or inappropriate acquisition, disclosure or other processing of confidential, proprietary or personal information, or the perception any of these has occurred, could expose us to a risk of loss, enforcement measures, regulatory agency investigations, proceedings and other actions, penalties, fines, indemnification allegations, litigation, potential civil or criminal liability, collaborators' loss of confidence, damage to our reputation and other consequences, which could materially adversely affect our business and results of operations. While we maintain insurance coverage for certain expenses and liabilities related to failures or breaches of our information technology systems, it may not be adequate to cover all losses associated with such events. In addition, such insurance may not be available to us in the future on satisfactory terms or at all. Furthermore, if the information technology systems of third parties with whom we do business become subject to disruptions or security breaches or incidents, we may have insufficient recourse against them.

Interruptions in the availability of server systems or communications with internet or cloud-based services, or failure to maintain the security, confidentiality, accessibility or integrity of data stored on such systems, could harm our business.

We rely on third-party data centers and telecommunications solutions, including cloud infrastructure services such as Amazon Web Services, to host substantial portions of our Helicon discovery platform and to support our business operations. We have limited control over these cloud-based service or other third-party providers, although we attempt to reduce risk by minimizing reliance on any single third party or its operations. We have experienced, and expect we may in the future again experience system interruptions, outages or delays due to a variety of factors, including infrastructure changes, human or software errors, website hosting disruptions and capacity constraints. A prolonged service disruption affecting our cloud-based solutions could damage our reputation or otherwise materially harm our business.

Further, if the security measures of our third-party data center or cloud infrastructure providers are breached by cyber-attacks or other means and unauthorized access to our information technology systems or data occurs, it could result in interruptions to our operations and the loss of proprietary or confidential information, which could damage our reputation, cause us to incur substantial

costs, divert our resources from other tasks and subject us to significant legal and financial exposure and liabilities, any one of which could materially adversely affect our business, results of operations, and prospects. Such third-party providers may also be subject to natural disasters, global political instability, warfare, power losses, telecommunications failures or other disruptive events that could negatively affect our business and require us to incur significant costs to secure alternate cloud-based solutions. In addition, any changes in our third-party providers' service levels or features that we utilize or the termination of our agreements could also adversely affect our business.

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

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

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

We currently operate and plan to operate in a highly regulated industry and although we are not currently a party to any material proceedings or claims, we could in the future 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, employment and other allegations and legal proceedings which 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 such 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 and results of operations. 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 and cause reputational harm.

Employee litigation and unfavorable publicity could negatively affect our future business.

Our employees may, from time to time, bring lawsuits against us regarding injury, creating a hostile workplace, discrimination, wage and hour disputes, sexual harassment or other employment issues. In recent years there has been an increase in the number of discrimination and harassment allegations generally. Coupled with the expansion of social media platforms and similar devices that allow individuals access to a broad audience, these allegations have had a significant negative impact on some businesses. Certain companies that have faced employment- or harassment-related lawsuits have had to terminate management or other key personnel and have suffered reputational harm that has negatively impacted their business. If we were to face any employment-related allegations, our business could be negatively affected.

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

We do not carry insurance for all categories of risk that our business may encounter and insurance coverage is becoming increasingly expensive. We do not know if we will be able to maintain existing insurance with adequate levels of coverage in the future, and any liability insurance coverage we acquire in the future may not be sufficient to reimburse us for any expenses or losses

we may suffer. If we obtain marketing approval for any product candidates that we or our collaborators may develop, we intend to acquire insurance coverage to include the sale of commercial products, but we may be unable to obtain such insurance on commercially reasonable terms or in adequate amounts. The coverage or coverage limits currently maintained under our insurance policies may not be adequate. If our losses exceed our insurance coverage, our financial condition would be adversely affected. Clinical trials or regulatory approvals for any of our product candidates could be suspended, which could adversely affect our results of operations and business, including by preventing or limiting the development and commercialization of any product candidates that we or our collaborators may identify. Additionally, operating as a public company has made it more expensive for us to obtain directors and officers liability insurance. If we do not maintain adequate levels of directors' and officers' liability insurance, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors and in our leadership team.

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 and our current and future CDMOs 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. Our operations will involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also may produce hazardous waste products. We generally anticipate contracting with third parties for the disposal of these materials and wastes. We will not be able to eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from any use by us of 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.

Although we maintain general liability insurance as well as workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort allegations that may be asserted against us in connection with our storage or disposal of biological or hazardous materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Further, with respect to the operations of our current and any future CDMOs, it is possible that if they fail to operate in compliance with applicable environmental, health and safety laws and regulations or properly dispose of wastes associated with our products, we could be held liable for any resulting damages, suffer reputational harm or experience a disruption in the manufacture and supply of our product candidates. In addition, our supply chain may be adversely impacted if any of our CDMOs become subject to injunctions or other sanctions as a result of their non-compliance with environmental, health and safety laws and regulations.

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

Natural disasters could severely disrupt our operations, and have a material adverse impact on our business, results of operations, financial condition and prospects. If a natural disaster, power outage, cybersecurity attack or other force majeure event occurred that prevented us from using all or a significant portion of our headquarters, damaged critical infrastructure, such as the manufacturing facilities of our CDMOs, limited our ability to access or use our Helicon discovery platform 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 have currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. Cybersecurity liability insurance is difficult to obtain and may not cover any damages we would sustain based on any breach of our computer security protocols or other cybersecurity attack. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse impact on our business.

Risks Related to Ownership of Our Common Stock

The price of our common stock may be volatile and fluctuate substantially, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations.

Our stock price is likely to be volatile. The stock market in general, and the market for biotechnology companies in particular, has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price for our common stock may be influenced by many factors, including: the commencement, enrollment, completion or results of nonclinical and clinical trials of our product candidates or those of our competitors; the success of competitive products or technologies; commencement or termination of partnership, collaboration, and licensing arrangements; regulatory or legal developments in the United States and other countries; developments or disputes concerning patent applications, issued patents or other proprietary rights; significant lawsuits, including patent or stockholder litigation; the recruitment or departure of key personnel; the level of expenses related to any of our product candidates or clinical development programs; the results of our efforts to discover, develop, acquire or in-license additional product candidates; actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts; variations in our financial results or those of companies that are perceived to be similar to us; changes in the structure of healthcare payment systems; market conditions in the biotechnology and high-tech sectors, including high interest rates and borrowing costs; general economic, industry and market conditions; and the numerous product candidates in our pipeline, the development of which could each generate news or significant adverse events that could impact financial results or recommendations by securities analysts.

If our quarterly or annual results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly or annual fluctuations in our results may, in turn, cause the price of our stock to fluctuate substantially. We believe that period-to-period comparisons of our results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

In the past, following periods of volatility in the market price of a company's securities, securities class-action litigation often has been instituted against that company. Such litigation, if instituted against us, could cause us to incur substantial costs to defend such allegations and divert management's attention and resources, which could seriously harm our business, financial condition, results of operations and prospects.

We may not be able to satisfy listing requirements of the Nasdaq Global Select Market ("Nasdaq") or maintain a listing of our common stock on Nasdaq.

We must meet certain financial and liquidity criteria to maintain our common stock's listing on Nasdaq. If we fail to meet any of Nasdaq's listing standards, our common stock may be delisted. In addition, our board of directors may determine that the cost of maintaining our listing on a national securities exchange outweighs the benefits of such listing. The delisting of our common stock from Nasdaq could materially impair our stockholders' ability to buy and sell our common stock and could have an adverse effect on the market price of, and the efficiency of the trading market for, our common stock. The delisting of our common stock could significantly impair our ability to raise capital and the value of your investment.

Sales of a substantial number of shares of our common stock in the public market could cause our common stock price to fall.

Our common stock price could decline as a result of sales of a large number of shares of common stock or the perception that these sales could occur. These sales, or the possibility that these sales may occur, might also make it more difficult for us to sell equity securities in the future at a time and price that we deem appropriate.

As of September 30, 2026, we have 123,657,716 shares of common stock and non-voting common stock outstanding. Of these shares, the 38,525,000 shares sold in our IPO may be resold in the public market immediately. The resale of 68.8% shares of our outstanding common stock is currently restricted under securities laws or other agreements, but will be able to be sold after the expiration of the lock-up period in December 2026 and termination of restrictions under securities laws.

Moreover, holders of approximately 78,158,737 shares of our common stock and 1,581,210 shares of our non-voting common stock, or approximately 64.5% of our outstanding shares of capital stock, have rights, subject to some conditions, to require us to file registration statements covering the sale of their shares (or, in the case of the non-voting common stock, the voting common stock to be received upon conversion of the non-voting common stock) or to include their shares in registration statements that we may file for ourselves or our other stockholders. We have also registered all shares of common stock that we may issue under our equity compensation plans or that are issuable upon exercise of outstanding options. These shares will be able to be sold in the public market upon issuance and once vested, subject to volume limitations applicable to affiliates and lock-up agreements. If any of these additional shares are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

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

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

We may seek additional capital through public or private equity or debt financings, government or other third-party grants, asset sales, royalty financings, partnership, collaboration, and licensing arrangements, or a combination of these approaches. To the extent that we raise additional capital through the sale of stock or convertible or exchangeable debt securities, warrants or other similar equity securities, our stockholders' ownership interest could be diluted and the terms may include liquidation or other preferences that adversely affect our stockholders' rights as common stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and could involve restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through collaborations and alliances and licensing arrangements with third parties or through asset sales, we may have to relinquish valuable rights to our technologies or product candidates or grant licenses on terms unfavorable to us.

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

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

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Our executive officers, directors, five percent stockholders and their affiliates beneficially own approximately 41.0% of our outstanding common stock and non-voting common stock. As a result, these stockholders, acting together, may be able to exert significant influence over matters such as elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders.

Some of these persons or entities may have interests different than other stockholders. For example, because many of these stockholders purchased their shares at prices substantially below the current market price of our common stock and have held their shares for a longer period, they may be more interested in selling our company to an acquirer than other investors, or they may want us to pursue strategies that deviate from the interests of other stockholders. The significant concentration of ownership may also adversely affect the trading price of our common stock due to investors' perception that it may create conflicts of interest.

In addition, certain of our stockholders hold non-voting common stock that is convertible at the stockholder's discretion into common stock, subject to certain restrictions. To the extent holders of our non-voting common stock exercise their option to make this conversion, the relative voting power of such stockholder will increase and the relative voting power of all other holders of common stock will decrease, which may limit your ability to influence matters subject to stockholder approval.

We have broad discretion in the use of our cash and cash equivalents, including the net proceeds from our IPO and concurrent private placement, and may not use them effectively.

Our management has broad discretion in the application of our cash and cash equivalents, including the net proceeds from our IPO and concurrent private placement, and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply our funds effectively could result in financial losses that could have a material adverse impact on our business, cause the price of our common stock to decline, and delay the development of our product candidates. Pending their use, we may invest our cash and cash equivalents, including the net proceeds from our IPO and concurrent private placement, in a manner that does not produce income or that loses value.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders or remove our current management.

Provisions in our seventh amended and restated certificate of incorporation and amended and restated bylaws may significantly reduce the value of our shares to a potential acquiror or make it difficult for a third party to acquire, or attempt to acquire, control of our company, even if a change of control was considered favorable by certain stockholders. For example, our board of directors has the authority to issue up to 10,000,000 shares of preferred stock and may fix the price, rights, preferences, privileges and restrictions of the preferred stock without any further vote or action by our stockholders. The issuance of shares of preferred stock may delay or prevent a change of control transaction. As a result, the market price of our common stock and the voting and other rights of our stockholders may be adversely affected. The issuance of shares of preferred stock may result in the loss of voting control to other stockholders.

Our seventh amended and restated certificate of incorporation and our amended and restated bylaws contain other provisions that could have an anti-takeover effect, including:

- only one of our three classes of directors are elected each year;
- stockholders are not entitled to remove directors other than by a two-thirds vote and only for cause;
- stockholders are not permitted to take actions by written consent;
- stockholders cannot call a special meeting of stockholders; and
- stockholders must give advance notice to nominate directors or submit proposals for consideration at stockholder meetings.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law ("DGCL"), which regulates corporate acquisitions by prohibiting Delaware corporations from engaging in specified business combinations with particular stockholders of those companies. These provisions could discourage potential acquisition proposals and could delay or prevent a change of control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in our stockholders' best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

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

We do not anticipate paying any cash dividends on our capital stock in the foreseeable future.

We do not currently intend to declare or pay cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends.

As a result, capital appreciation, if any, of our common stock will be the sole source of gain for our stockholders for the foreseeable future.

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

Our amended and restated bylaws provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any state law claims for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of, or a claim based on, fiduciary duty owed by any of our current or former directors, officers, and employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL, our certificate of incorporation or our bylaws (including the interpretation, validity or enforceability thereof) or (iv) any action asserting a claim that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery of the State of Delaware having personal jurisdiction over the indispensable parties named as defendants therein (the "Delaware Forum Provision"). The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act or the Securities Exchange Act of 1934, as amended (the "Exchange Act"). 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. 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 bylaws further provide that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the sole and exclusive forum for resolving any complaint asserting a cause or causes of action arising under the Securities Act (the "Federal Forum Provision"). In addition, our amended and restated bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the foregoing provisions; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

The Delaware Forum Provision and the Federal Forum Provision in our amended and restated bylaws may impose additional litigation costs on stockholders in pursuing any such claims. Additionally, the forum selection clauses in our amended and restated bylaws may limit our stockholders' ability to bring a claim in a forum that they find favorable for disputes with us or our directors, officers, or employees, which may discourage such lawsuits against us and our directors, officers, and employees even though an action, if successful, might benefit our stockholders. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court were "facially valid" under Delaware law, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the federal district courts of the United States may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

General Risk Factors

We incur increased costs as a result of operating as a public company, and our management is and will be required to devote substantial time to new compliance initiatives. We are subject to financial reporting and other requirements for which our accounting and other management systems and resources may not be adequately prepared.

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the federal securities laws, including the Sarbanes-Oxley Act and rules subsequently implemented by the SEC and Nasdaq have imposed various requirements on public companies, including requirements to file annual, quarterly and event driven reports with respect to our business and financial condition, and to establish and maintain effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance. We may not be able to produce reliable financial statements or file these financial statements as part of a periodic report in a timely manner with the SEC or comply with the Nasdaq listing requirements. In addition, we could make errors in our financial statements that could require us to restate our financial statements.

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

We are an "emerging growth company" ("EGC"), as defined in the JOBS Act. We will remain an EGC until the earlier of: (i) the last day of the fiscal year in which we have total annual gross revenues of $1.235 billion or more; (ii) the last day of the fiscal year following the fifth anniversary of the date of the completion of our IPO; (iii) the date on which we have issued more than $1.0 billion in non-convertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC. For so long as we remain an EGC, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include: not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act ("Section 404"); not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements; reduced disclosure obligations regarding executive compensation; and exemptions from the requirements of holding a non-binding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We may choose to take advantage of some, but not all, of the available exemptions. We have taken advantage of reduced reporting burdens in this Quarterly Report. We cannot predict whether investors will find our common stock less attractive if we rely

on certain or all of 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.

In addition, the JOBS Act provides that an EGC may take advantage of an extended transition period for complying with new or revised accounting standards. This allows an EGC to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, therefore, while we are an EGC we may not be subject to new or revised accounting standards at the same time that they become applicable to other public companies that are not EGCs.

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

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

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

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

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

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

Our future ability to utilize our NOL carryforwards and certain other tax attributes may be limited.

Since our inception, we have incurred losses and we may never achieve profitability. As of December 31, 2025, we had U.S. federal NOL carryforwards of $357.9 million (of which $348.9 million can be carried forward indefinitely and the remainder of which begins to expire in 2036) and state NOL carryforwards of $347.4 million (of which $2.7 million can be carried forward indefinitely and the remainder of which begin to expire in 2036). We also had U.S. federal research and development tax credit carryforwards of $17.2 million available to offset future U.S. federal income taxes, which begin to expire in 2030. As of December 31, 2025, we had state tax credit carryforwards of $7.7 million which begin to expire in 2030. To the extent that we continue to generate taxable losses, under current law, our unused U.S. federal NOLs may be carried forward to offset a portion of future taxable income, if any. Additionally, we continue to generate business tax credits, including research and development tax credits, which generally may be carried forward to offset a portion of future taxable income, if any, subject to expiration of such credit carryforwards. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "Code"), if a corporation undergoes an "ownership change," generally defined as one or more shareholders who own at least five percent of the corporation's equity increasing their equity ownership in the aggregate by more than 50 percentage points (by value) over a three-year period, the corporation's ability to use its pre-change NOLs and other pre-change tax attributes (such as research and development tax credits) to offset its post-change income or taxes may be limited. Similar rules may apply under state tax laws. We may experience ownership changes in the future as a result of shifts in our stock ownership, some of which are outside of our control. As a result, if we earn net taxable income, our ability to use

our pre-change NOLs or other pre-change tax attributes to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. There is a risk that due to changes under the tax law, regulatory changes or other unforeseen reasons, our existing NOLs or business tax credits could expire or otherwise be unavailable to offset future income tax liabilities. At the state level, there may also be periods during which the use of NOLs or business tax credits is suspended or otherwise limited, which could accelerate or permanently increase state taxes. For these reasons, we may not be able to realize a tax benefit from the use of our NOLs or tax credits, even if we attain profitability.

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

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service (the "IRS") and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect our business and our financial condition. In recent years, many such changes have been made and changes are likely to continue to occur in the future. We cannot predict whether, when, in what form or with what effective dates, tax laws, regulations and rulings may be enacted, promulgated or decided or whether they could increase our tax liability or require changes in the manner in which we operate in order to minimize increases in our tax liability. Future changes in tax law could have a material adverse effect on our business, cash flow, financial condition or results of operations.

We and our service providers are subject to a variety of stringent and evolving privacy and data security laws, regulations and rules, contractual obligations, industry standards, policies and other obligations related to privacy and data security. Any actual or perceived failure to comply with such obligations could expose us to significant fines or other penalties and otherwise harm our business and operations.

In the ordinary course of our business, we and the third parties upon which we rely collect, receive, store or otherwise process personal data, including information we may collect about participants in our clinical trials. Our data processing activities subject us to numerous, evolving privacy and data security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements and other obligations relating to privacy and data security.

The legislative and regulatory framework for the processing of personal data worldwide is rapidly evolving in a manner that is increasingly stringent and, globally, this legal and regulatory framework is likely to remain uncertain for the foreseeable future. We must devote significant resources to understanding and complying with the changing landscape in this area. Each law is also subject to various interpretations by courts and Regulatory Authorities, creating additional uncertainty, and we may fail to comply with the evolving data protection laws, which may expose us to risk of enforcement actions taken by authorities, private rights of action in some jurisdictions and potential significant penalties if we are found to be non-compliant. Some of these laws and regulations also carry the possibility of criminal sanctions.

In the United States, numerous federal, state and local laws and regulations, including federal health information privacy laws, state information security and data breach notification laws, federal consumer protection laws (*e.g.*, Section 5 of the Federal Trade Commission Act), state consumer protection and privacy laws and other similar laws (*e.g.*, wiretapping and communications interception laws) govern the processing of health-related and other personal data. At the state level, 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 individuals certain rights concerning their personal data. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. While existing state comprehensive privacy laws exempt some data processed in the context of clinical trials, these developments may further complicate compliance efforts and increase legal risk and compliance costs for us and the third parties upon whom we rely.

Additionally, we may be subject to new laws governing the privacy of consumer health data. These various privacy and data security laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products. Regulators and legislators in the United States are increasingly scrutinizing and restricting certain personal data transfers and transactions involving foreign countries. For example, the Biden Administration's executive order Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern as implemented by the Department of Justice's final rule issued in December 2024, effective April 8, 2025, prohibits data brokerage transactions involving certain sensitive personal data categories, including health data, genetic data and biospecimens, to certain countries of concern, including China. The final rule also restricts certain investment agreements, employment agreements and vendor agreements involving such data and countries of concern, absent specified cybersecurity controls. The final rule does not exempt key-coded or otherwise anonymized, pseudonymized, de-identified or encrypted data. Actual or alleged violations of the final rule may be punishable by criminal and/or civil sanctions and may result in exclusion from participation in federal and state programs.

Outside the United States, an increasing number of laws, regulations and industry standards may govern privacy, data security and the transfer of personal data between jurisdictions. For example, the EU's General Data Protection Regulation ("EU GDPR") and the United Kingdom's General Data Protection Regulation ("UK GDPR" and, together with the EU GDPR, "GDPR") impose strict

requirements for processing personal data including relating to processing of sensitive data (such as health data), ensuring there is a legal basis or condition to justify the processing of personal data, where required requirements relating to obtaining consent of individuals, disclosures about how personal data is to be used, limitations on retention of information, implementing safeguards to protect the security and confidentiality of personal data, where required providing notification of data breaches, maintaining records of processing activities and documenting data protection impact assessments where there is high risk processing and taking certain measures when engaging third party processors. Under GDPR, companies may face temporary or definitive bans on data processing and other corrective activities, fines of up to €20.0 million (£17.5 million GBP) or 4% of annual global revenues, whichever is greater, and 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. Non-compliance could also result in a material adverse effect on our business, financial position and results of operations.

In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area ("EEA") and the United Kingdom ("UK") have significantly restricted the transfer of personal data to the United States and other countries. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA's standard contractual clauses, the UK's International Data Transfer Agreement / Addendum and the EU-U.S. Data Privacy Framework ("Framework") and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States (or other countries), or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants and activities activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

Although the UK is regarded as a third country under the EU GDPR, the European Commission has adopted an adequacy decision in favor of the UK, a decision recognizing the UK as providing adequate protection under the EU GDPR and enabling data transfers from Member States to the UK without additional safeguards. The UK adequacy decision was renewed in December 2025 and will automatically expire in December 2031. The EU GDPR and the UK GDPR currently impose substantially similar obligations. However, the European Commission retains the authority to monitor developments in UK law, including implementation of the Data (Use and Access) Act 2025, and may amend, suspend or repeal the adequacy decisions if it determines that the UK no longer ensures an essentially equivalent level of protection. Any such action, or a successful legal challenge to the adequacy decisions could lead to additional compliance costs and could increase our overall risk.

Additionally in the EEA, the NIS 2 Directive ("NIS 2") is replacing the cybersecurity legal framework under the current NIS framework, aiming to ensure a high level of cybersecurity in the region. NIS 2 brings new medium and large organizations providing services in the EEA within scope of the legal framework. It extends to additional sectors and expands the list of in-scope healthcare organizations, including to certain providers engaged in research and development of medicinal products. The new regime imposes direct obligations on management in respect of an in-scope organization's compliance with NIS 2, requires covered organizations to put in place certain cyber risk management measures, strengthens incident reporting requirements and provides supervisory authorities with greater oversight. The majority of obligations will come into force when national legislation implementing NIS 2 becomes effective in the relevant Member State. Member States had until October 17, 2024 to transpose NIS 2 into national legislation, although many countries have still not completed the transposition. As such, the cybersecurity regulatory landscape in the EEA is currently fragmented and uncertain. To the extent we are subject to NIS 2, we will require additional investment of our resources in compliance programs. Under NIS 2 companies may be subject to administrative fines of up to the higher amount of €10.0 million or 2% of worldwide turnover.

In addition to privacy and data 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 privacy and data security, and our efforts to comply with such obligations may not be successful. We publish privacy policies and other statements, such as compliance with certain certifications or self-regulatory principles, regarding privacy and data security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Obligations related to privacy and data security 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 and 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 in our efforts to comply with our privacy and data security obligations. Moreover, despite our efforts, our personnel or third parties on whom we rely, including CROs supporting our clinical trials, clinical trial sites with whom we have contracted and other third parties supporting our clinical trials, may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with applicable privacy and data 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 on processing personal data; and 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 significant 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, financial condition, results of operations and growth prospects, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including, as relevant, clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

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

Our results of operations could be adversely affected by general conditions in the global economy and financial markets. The global economy and financial markets have experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, rising inflation, uncertainty from changes in tariff policies, fluctuating interest rates, declines in economic growth, global supply chain disruptions and uncertainty about economic stability. The global economy and financial markets may also be adversely affected by the current or anticipated impact of military conflict, terrorism or other geopolitical events, including the ongoing wars in Ukraine and the Middle East, and the increasingly strained relationship between the United States and China. Sanctions imposed by the United States and other countries in response to such conflicts may adversely impact the financial markets and the global economy, and the economic countermeasures by the affected countries or others could exacerbate market and economic instability.

There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. A severe or prolonged economic downturn could result in a variety of risks to our business, including weakened demand for any product candidates or products we may develop and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. If the equity and credit markets deteriorate, it may make any necessary equity or debt financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could impair our ability to achieve our growth strategy, could harm our financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that our current or future service providers, manufacturers or other collaborators may not survive such difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget. We cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

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

(a) Recent Sales of Unregistered Equity Securities

None.

(b) Use of Proceeds from Initial Public Offering and Concurrent Private Placement

On June 9, 2026, our Registration Statement on Form S-1 (No. 333-296032) for our IPO was declared effective by the SEC, pursuant to which we issued and sold an aggregate of 38,525,000 shares of common stock (inclusive of 5,025,000 shares of common stock sold pursuant to the underwriters' exercise of their option to purchase additional shares) at a public offering price of $20.00 per share for aggregate gross proceeds of $770.5 million and aggregate net cash proceeds of $712.9 million, after deducting approximately $57.6 million underwriting discounts and commissions and other offering costs. Concurrently with the IPO, we also completed a private placement, in which we issued and sold to Regeneron Pharmaceuticals, Inc. an aggregate of 4,166,666 shares of our common stock at a per share price of $18.00, equal to 90% of the IPO price. The aggregate cash purchase price of the private placement shares was $75.0 million, resulting in aggregate net cash proceeds of $75.0 million.

Our IPO and concurrent private placement closed on June 11, 2026. Leerink Partners, LLC, BofA Securities, Inc., Evercore Group L.L.C. and Guggenheim Securities, LLC acted as active bookrunning managers for the offering. LifeSci Capital LLC acted as a passive bookrunning manager for the offering.

None of the expenses associated with our IPO were paid to directors, officers, persons owning 10% or more of any class of equity securities, or to our affiliates.

There has been no material change in the planned use of proceeds from our initial public offering and concurrent private placement as described in our final prospectus dated June 9, 2026 filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended.

(c) Issuer Repurchases of Securities

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

(a) None.

(b) None.

(c) During the three months ended September 30, 2026, the following officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted “Rule 10b5-1 trading arrangement” as defined in Item 408(c) of Regulation S-K.

On September 11, 2026, Teresa Jurgensen, our EVP, General Counsel, adopted a trading plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act. The trading plan provides for the sale of up to 38,500 shares of our common stock issuable upon exercise of outstanding vested stock options and expires on August 31, 2027, subject to early termination in accordance with the terms of the plan.

On September 11, 2026, Thomas Kotarakos, our Chief Financial Officer, adopted a trading plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act. The trading plan provides for the sale of up to 45,000 shares of our common stock issuable upon exercise of outstanding vested stock options and expires on August 31, 2027, subject to early termination in accordance with the terms of the plan.

On September 14, 2026, Rohin Mhatre, our Chief Technical Operations Officer, adopted a trading plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act. The trading plan provides for the sale of up to 53,590 shares of our common stock issuable upon exercise of outstanding vested stock options and expires on September 30, 2027, subject to early termination in accordance with the terms of the plan.

Except as described above, none of our other directors or officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted or terminated a "10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement" (as defined in Item 408(c) of Regulation S-K) during the three months ended September 30, 2026.

Item 6. Exhibits.

Exhibit Number	Description
3.1	Seventh Amended and Restated Certificate of Incorporation of Parabilis Medicines, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on June 11, 2026).
3.2	Amended and Restated Bylaws of Parabilis Medicines, Inc. (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed on June 11, 2026).
4.1	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1 (File No. 333-296032) filed on June 9, 2026).
4.2+	Sixth Amended and Restated Investors' Rights Agreement, by and among the Registrant and certain of its stockholders, dated as of January 6, 2026 (incorporated by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-1 (File No. 333-296032) filed on June 9, 2026).
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

** The certifications furnished in Exhibit 32.1 and 32.2 hereto are deemed to be furnished with this Quarterly Report on Form 10-Q and will not be deemed to be "filed" for purposes of Section 18 of the Exchange Act, except to the extent that the Registrant specifically incorporates it by reference.

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

SIGNATURES

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

Parabilis Medicines, Inc.

Date: November 12, 2026

By: /s/ Mathai Mammen, M.D., Ph.D.
Mathai Mammen, M.D., Ph.D.
Chairman, Chief Executive Officer and President

Date: November 12, 2026

By: /s/ Thomas Kotarakos
Thomas Kotarakos
Chief Financial Officer

Exhibit 31.1

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

I, Mathai Mammen, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Parabilis Medicines, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);
   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer 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 12, 2026 /s/Mathai Mammen, M.D., Ph.D.

Mathai Mammen, M.D., Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, Thomas Kotarakos, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Parabilis Medicines, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);
   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer 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 12, 2026 /s/Thomas Kotarakos

Thomas Kotarakos
Chief Financial Officer
(Principal Financial Officer and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Parabilis Medicines, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: November 12, 2026

By: /s/Mathai Mammen, M.D., Ph.D.
Mathai Mammen, M.D., Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Parabilis Medicines, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: November 12, 2026

By: /s/Thomas Kotarakos

Thomas Kotarakos
Chief Financial Officer
(Principal Financial Officer and Accounting Officer)