UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 10-Q

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

For the quarterly period ended June 30, 2025

☐ **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: 001-39303

PLIANT THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**47-4272481**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
331 Oyster Point Blvd., South San Francisco, CA	**94080**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (650) 481-6770

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol	Name of Each Exchange on which Registered
Common Stock, par value $0.0001 per share	PLRX	The Nasdaq Stock Market LLC
Series A Junior Participating Preferred Purchase Rights	N/A	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 August 1, 2025, the registrant had 61,388,154 shares of common stock, $0.0001 par value per share, outstanding.

Table of Contents

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, or this Report, contains forward-looking statements that involve risks, uncertainties, and assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. The statements contained in this Report that are not purely historical are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Forward-looking statements are often identified by the use of words such as, but not limited to, "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of those terms, and similar expressions that convey uncertainty of future events or outcomes. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. Forward-looking statements in this Report include, but are not limited to, statements about:

- Our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- The success, cost and timing of our product development activities and preclinical and clinical trials of our product candidates;
- Our plans to initiate, recruit and enroll patients in, and conduct our clinical trials at the pace that we project;
- Our plans and strategy to obtain and maintain regulatory approvals of our product candidates;
- Our plans and strategy to obtain funding for our operations, including funding necessary to complete further development and, upon successful development, if approved, commercialize any of our product candidates;
- The effect and impact of new, existing and proposed laws and regulations;
- The potential benefit of orphan drug and Fast Track designations for any of our product candidates;
- Our ability to compete with companies currently marketing or engaged in the development of treatments for fibrosis;
- Our plans and strategy regarding obtaining and maintaining intellectual property protection for our product candidates and the duration of such protection;
- Our plans and strategy regarding the manufacture of our product candidates for clinical trials and for commercial use, if approved;
- Our dependence on future collaborators for developing, obtaining regulatory approval for and commercializing product candidates in the collaboration;
- Our receipt and timing of any milestone payments or royalties under any future research collaboration or license agreements or arrangements;
- Our plans and strategy regarding the commercialization of any products that are approved for marketing and our ability to establish adequate pricing in the U.S. and international markets;
- The size and growth potential of the markets for our product candidates, and our ability to serve those markets, either alone or in combination with others;
- The anticipated timing and cost savings of, and estimated expenses associated with, our recently announced restructuring and workforce reduction;
- Our ability to attract and retain qualified employees and key personnel;
- Our expectations regarding government and third-party payor coverage and reimbursement; and
- Our expectations of obtaining a positive health technology assessment recommending our products.

These statements are based on the beliefs and assumptions of our management, which are in turn based on information currently available to management. Such forward-looking statements are subject to risks, uncertainties and other important factors that could cause actual results and the timing of certain events to differ materially from future results and timing expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section entitled "Risk Factors" included under Part II, Item 1A in this Report. Furthermore, such forward-looking statements speak only as of the date of this Report. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

SUMMARY OF RISKS ASSOCIATED WITH OUR BUSINESS

Our business involves significant risks, some of which are summarized below. The summary risk factors listed below should be read together with the text of the full risk factors discussed in "Part II, Item 1A - Risk Factors" in this Report. You should carefully consider the risks described below, as well as the other information in this Report, including our financial statements and the related notes and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” as well as in other documents that we file with the Securities and Exchange Commission, or the SEC. The occurrence of any of the events or developments described in this Report could have a material adverse effect on our business, financial condition, results of operations, growth prospects and stock price. In such an event, the market price of our common stock could decline. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations and the market price of our common stock.

Risks Related to Our Financial Position and Need for Additional Capital

- We have incurred significant net losses since inception, and we expect to continue to incur significant net losses for the foreseeable future.
- We will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs, future commercialization efforts or other operations.

Risks Related to Research and Development and the Biopharmaceutical Industry

- We have a limited operating history, which may make it difficult to evaluate our prospects and likelihood of success.
- Our business is highly dependent on the success of our product candidates that we advance into the clinic. All of our product candidates will require significant additional preclinical and clinical development before we may be able to seek regulatory approval for and launch a product commercially.
- Our approach to drug discovery and development in the area of fibrotic diseases is unproven and may not result in marketable products
- Clinical development involves a lengthy, complex, and expensive process, with an uncertain outcome to support either a marketing authorization or positive pricing and reimbursement decisions.
- We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- We may fail to obtain and maintain certain regulatory exclusivities and orphan designations in some jurisdictions and therefore fail to secure orphan exclusivity or other exclusivity extensions in those jurisdictions.
- Our ongoing and future clinical trials may reveal significant adverse events or unexpected drug-drug interactions not seen in our preclinical studies and may result in a safety profile that could delay or prevent regulatory approval or market acceptance of any of our product candidates.
- If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- We face substantial competition, which may result in others discovering, developing, or commercializing products before or more successfully than us.
- We may fail to secure an appropriate reimbursement price or a positive health technology assessment.

Risks Related to Our Intellectual Property

- Our success depends in part on our ability to obtain patent term extensions and to protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.
- Our future collaborators may assert ownership or commercial rights to inventions they develop from research we support, or that we develop from our use of the tissue samples or other biological materials which they provide to us, or otherwise arising from such collaboration.

Risks Related to Our Reliance on Third Parties

- We rely on third parties to conduct certain aspects of our preclinical studies and clinical trials and for tissue samples and other materials required for our research and development activities.

- We rely on single-source third party suppliers located in foreign jurisdictions, including China, to manufacture our drug candidates. An interruption in this supply, caused by a business interruption or geopolitical events, could materially disrupt our research and development activities.
- If we are unable to enter into new collaborations, or if these collaborations are not successful, our business could be adversely affected.

Risks Related to Managing Our Business and Operations

- Our loss of key management personnel, or our failure to recruit additional highly skilled personnel, will impair our ability to develop current product candidates or identify and develop new product candidates, could result in loss of markets or market share and could make us less competitive.

Item 1. Condensed Financial Statements.

Pliant Therapeutics, Inc.
Condensed Balance Sheets
(Unaudited)
(In thousands, except number of shares and per share amounts)

	June 30, 2025	*December 31, 2024
Assets		
Current assets		
Cash and cash equivalents	$ 86,820	$ 71,188
Short-term investments	176,053	284,536
Prepaid expenses and other current assets (Note 5)	4,571	6,540
Total current assets	267,444	362,264
Property and equipment, net (Note 4)	4,892	5,525
Operating lease right-of-use assets (Note 15)	25,615	27,243
Restricted cash	1,482	1,482
Other non-current assets	391	435
Total assets	$ 299,824	$ 396,949
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 1,384	$ 5,960
Accrued research and development	10,790	14,363
Accrued liabilities (Note 6)	7,192	12,353
Operating lease liabilities, current (Note 15)	1,225	542
Total current liabilities	20,591	33,218
Operating lease liabilities, non-current (Note 15)	28,791	29,439
Long-term debt (Note 7)	30,360	30,211
Total liabilities	79,742	92,868
Commitments and Contingencies (Note 14)		
Stockholders' equity		
Preferred stock, $0.0001 par value per share; 10,000,000 shares authorized at June 30, 2025 and December 31, 2024, 300,000 shares designated as Series A Junior Participating Preferred Stock at June 30, 2025 and none designated as Series A Junior Participating Preferred Stock at December 31, 2024; and none issued or outstanding at June 30, 2025 and December 31, 2024 (Note 8 and 10)	—	—
Common stock, $0.0001 par value per share; 300,000,000 shares authorized at June 30, 2025 and December 31, 2024; and 61,386,183 and 60,860,838 shares issued and outstanding at June 30, 2025 and December 31, 2024, respectively; (Note 9)	6	6
Additional paid-in capital	1,029,595	1,013,806
Accumulated deficit	(809,518)	(710,052)
Accumulated other comprehensive (loss) gain	(1)	321
Total stockholders' equity	220,082	304,081
Total liabilities and stockholders' equity	$ 299,824	$ 396,949

* The condensed balance sheet as of December 31, 2024 has been derived from the audited financial statements as of that date.

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

Pliant Therapeutics, Inc.
Condensed Statements of Operations and Comprehensive Loss
(Unaudited)
(In thousands, except number of shares and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	**2024**	**2025**	**2024**
Operating expenses:				
Research and development	$ (32,198)	$ (45,617)	(75,634)	(82,763)
General and administrative	(13,394)	(15,022)	(28,893)	(30,268)
Total operating expenses	(45,592)	(60,639)	(104,527)	(113,031)
Loss from operations	(45,592)	(60,639)	(104,527)	(113,031)
Interest and other income (expense), net	3,101	5,653	6,669	11,535
Interest expense	(809)	(868)	(1,608)	(1,313)
Net loss	$ (43,300)	$ (55,854)	$ (99,466)	$ (102,809)
Net loss per share - basic and diluted	$ (0.71)	$ (0.92)	$ (1.62)	$ (1.71)
Shares used in computing net loss per share - basic and diluted	61,386,183	60,382,796	61,304,881	60,281,859
Comprehensive loss:				
Net loss	$ (43,300)	$ (55,854)	$ (99,466)	$ (102,809)
Net unrealized loss on short-term investments	(160)	(128)	(322)	(962)
Total other comprehensive loss	(160)	(128)	(322)	(962)
Comprehensive loss	$ (43,460)	$ (55,982)	$ (99,788)	$ (103,771)

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

Pliant Therapeutics, Inc.
Condensed Statements of Stockholders' Equity
(Unaudited)
(In thousands, except number of shares and per share amounts)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Gain/(Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2024	60,860,838	$ 6	$ 1,013,806	$ 321	$ (710,052)	$ 304,081
Issuance of common stock under benefit plans	525,345	—	498	—	—	498
Stock-based compensation expense	—	—	8,913	—	—	8,913
Net unrealized loss on short-term investments	—	—	—	(162)	—	(162)
Net loss	—	—	—	—	(56,166)	(56,166)
Balance at March 31, 2025	61,386,183	$ 6	$ 1,023,217	$ 159	$ (766,218)	$ 257,164
Issuance of common stock under benefit plans	—	—	—	—	—	—
Stock-based compensation expense	—	—	6,378	—	—	6,378
Net unrealized loss on short-term investments	—	—	—	(160)	—	(160)
Net loss	—	—	—	—	(43,300)	(43,300)
Balance at June 30, 2025	61,386,183	$ 6	$ 1,029,595	$ (1)	$ (809,518)	$ 220,082

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

Pliant Therapeutics, Inc.
Condensed Statements of Stockholders' Equity
(Unaudited)
(In thousands, except number of shares and per share amounts)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2023	59,921,002	$ 6	$ 972,973	$ 345	$ (499,748)	$ 473,576
Issuance of common stock under benefit plans	397,540	—	1,879	—	—	1,879
Stock-based compensation expense	—	—	9,666	—	—	9,666
Net unrealized loss on short-term investments	—	—	—	(834)	—	(834)
Net loss	—	—	—	—	(46,955)	(46,955)
Balance at March 31, 2024	60,318,542	$ 6	$ 984,518	$ (489)	$ (546,703)	$ 437,332
Issuance of common stock under benefit plans	106,602	—	684	—	—	684
Stock-based compensation expense	—	—	10,644	—	—	10,644
Net unrealized loss on short-term investments	—	—	—	(128)	—	(128)
Net loss	—	—	—	—	(55,854)	(55,854)
Balance at June 30, 2024	60,425,144	$ 6	$ 995,846	$ (617)	$ (602,557)	$ 392,678

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

Pliant Therapeutics, Inc.
Condensed Statements of Cash Flows
(Unaudited)

(In thousands)	Six Months Ended June 30, 2025	2024
Cash flows from operating activities		
Net loss	$ (99,466)	$ (102,809)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	895	1,135
Stock-based compensation expense	15,291	20,310
Non-cash operating lease expense	1,628	1,831
Net amortization (accretion) on short-term investments and debt	3,339	944
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	1,970	313
Other non-current assets	43	(45)
Accounts payable	(4,580)	(1,369)
Accrued liabilities	(8,622)	4,767
Operating lease liabilities	35	(645)
Net cash used in operating activities	(89,467)	(75,568)
Cash flows from investing activities		
Purchase of short-term investments	(65,756)	(100,897)
Maturity of short-term investments	170,731	173,888
Purchase of property and equipment	(374)	(2,743)
Net cash provided by investing activities	104,601	70,248
Cash flows from financing activities		
Proceeds from issuances of common stock under benefit plans	498	2,563
Proceeds from term loan, net of issuance costs	—	19,909
Net cash provided by financing activities	498	22,472
Net increase in cash and cash equivalents	15,632	17,152
Cash and cash equivalents and restricted cash at beginning of period	72,670	64,716
Cash, cash equivalents and restricted cash at end of period	$ 88,302	$ 81,868
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ 1,457	$ 1,039
Reconciliation of cash, cash equivalents, and restricted cash reported in the balance sheets		
Cash and cash equivalents	$ 86,820	$ 80,386
Restricted cash	1,482	1,482
Total cash, cash equivalents, and restricted cash	$ 88,302	$ 81,868
Supplemental disclosures of noncash investing and financing activities:		
Net unrealized gain on short-term investments	$ (322)	$ (962)
Purchase of property and equipment in accounts payable and accrued liabilities	$ 112	$ 220
Supplemental disclosures of cash flow information related to leases:		
Right-of-use assets obtained in exchange for new operating lease liabilities	$ —	$ 29,779

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

Pliant Therapeutics, Inc.
Notes to Condensed Financial Statements
(Unaudited)

1. Organization and Description of Business

Pliant Therapeutics, Inc. (the "Company" or "Pliant" or "we" or "our" or "us") is a clinical-stage biopharmaceutical company focused on discovering and developing integrin-based therapeutics. The Company is located in South San Francisco, California, and was incorporated in the state of Delaware in June 2015.

Bexotegrast in Idiopathic Pulmonary Fibrosis (IPF)

In March 2025, we announced that we were discontinuing the BEACON-IPF Phase 2b trial following a prespecified data review and recommendation by the trial's independent Data Safety Monitoring Board ("DSMB"), as well as a secondary review and recommendation by an outside expert panel, due to an imbalance in safety events between the treatment and placebo groups. In June 2025, we announced that we were discontinuing the development of bexotegrast in IPF as the results of BEACON-IPF demonstrated an unfavorable risk-benefit profile.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited interim condensed financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP") and follow the requirements of the Securities and Exchange Commission ("SEC"), for interim financial reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by U.S. GAAP have been condensed or omitted, and accordingly the unaudited interim condensed financial statements do not include all of the information and notes required by U.S. GAAP for complete financial statements. These unaudited interim condensed financial statements have been prepared on the same basis as our annual financial statements and, in the opinion of management, reflect all adjustments (consisting only of normal recurring adjustments) that are necessary for a fair presentation of the Company's financial information. The results of operations for the three and six months ended June 30, 2025 are not necessarily indicative of the results to be expected for the year ending December 31, 2025 or for any other interim period or for any other future year.

The financial information included herein should be read in conjunction with the audited financial statements and related notes in the Company's Annual Report on Form 10-K for the year ended December 31, 2024, filed with the SEC on March 3, 2025 (the "2024 10-K").

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, and expenses as well as the disclosure of contingent assets and liabilities as of and during the reporting period. The Company bases its estimates and assumptions on historical experience when available and on various factors that it believes to be reasonable under the circumstances. Significant estimates and assumptions reflected in these financial statements include, but are not limited to, stock-based compensation expense, operating lease right-of-use ("ROU") assets and liabilities, accruals and prepayments for research and development costs, income taxes and uncertain tax positions. The Company assesses estimates on an ongoing basis, however, actual results could materially differ from those estimates.

Significant Accounting Policies

There have been no significant changes to the accounting policies during the three and six months ended June 30, 2025, as compared to the significant accounting policies described in Note 2 of the "Notes to the Financial Statements" in the Company's audited financial statements included in its 2024 10-K.

Accounting Pronouncements Not Yet Adopted

In December 2023, the Financial Accounting Standards Board ("FASB") issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures. ASU 2023-09 requires disclosure of additional categories of information about federal, state and foreign income taxes in the rate reconciliation table and more details about the reconciling items in some categories if items meet a quantitative threshold. The ASU requires entities to disclose income taxes paid, net of refunds, disaggregated by federal (national), state and foreign taxes for annual periods and to disaggregate the information by jurisdiction based on a quantitative threshold. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024 on a prospective basis and retrospective application is permitted. The Company is currently evaluating the impact of this standard on its disclosures and will adopt the ASU for its Annual Report on Form 10-K for the year ended December 31, 2025.

In November 2024, the FASB issued ASU 2024-03 "Disaggregation of Income Statement Expenses," which aims to improve the disclosures about a public business entity's expenses and address requests from investors for more detailed

information about the types of expenses in commonly presented expense captions. The guidance is effective for the Company's annual periods beginning in 2027 and interim periods beginning in the first quarter of fiscal year 2028. The Company is currently evaluating the impact of the new guidance on its disclosures.

3. Financial Instruments

The Company's short-term investments consist of U.S. Treasury securities, U.S. Government agency securities and highly rated, investment-grade corporate debt securities with original maturities beyond three months at the date of purchase. The Company has classified and accounted for its short-term investments as available-for-sale securities as the Company may sell these securities at any time for reasons including, but not limited to, managing liquidity, credit risk, duration and asset allocation and such investments represent cash available for current operations. As a result, short-term investments may include securities with maturities beyond twelve months that are classified within current assets in the condensed balance sheets. The Company's short-term investments classified as available-for-sale are carried at fair market value with unrealized gains or losses recognized in the statements of operations and comprehensive loss.

The Company's cash equivalent Money Market Funds are classified as Level 1 in the fair value hierarchy because they are valued using quoted active market prices. The fair value of the Company's U.S. Treasury securities, U.S. Government agency securities and corporate debt securities are classified as Level 2 because they are valued using observable inputs to quoted market prices other than Level 1 prices, benchmark yields, reported trades, broker/dealer quotes or alternative pricing sources with reasonable levels of price transparency and include U.S. Government agency securities, U.S. Treasury securities and corporate debt securities.

There were no assets or liabilities recorded at fair value to the condensed balance sheets using Level 3 inputs as of June 30, 2025 and as of December 31, 2024.

The following tables show the Company's short-term investments and cash equivalents by significant investment category as of June 30, 2025 and December 31, 2024 (in thousands):

		As of June 30, 2025				As of December 31, 2024			
		Adjusted Cost	Unrealized Gains	Unrealized Losses	Market Value	Adjusted Cost	Unrealized Gains	Unrealized Losses	Market Value
Money Market Funds	Level 1	$ 67,627	$ —	$ (4)	$ 67,623	$ 54,825	$ —	$ —	$ 54,825
U.S. Treasury securities	Level 2	2,473	—	—	2,473	9,968	7	—	9,975
U.S. Government agency securities	Level 2	45,156	34	—	45,190	77,769	235	—	78,004
Corporate debt securities	Level 2	133,414	13	(44)	133,383	196,479	160	(82)	196,557
Total financial assets		$ 248,670	$ 47	$ (48)	$ 248,669	$ 339,041	$ 402	$ (82)	$ 339,361

	As of June 30, 2025				As of December 31, 2024			
	Adjusted Cost	Unrealized Gains	Unrealized Losses	Market Value	Adjusted Cost	Unrealized Gains	Unrealized Losses	Market Value
Classified as:								
Cash equivalents	$ 72,620	$ —	$ (4)	$ 72,616	$ 54,825	$ —	$ —	$ 54,825
Short-term investments	176,050	47	(44)	176,053	284,216	402	(82)	284,536
Total	$ 248,670	$ 47	$ (48)	$ 248,669	$ 339,041	$ 402	$ (82)	$ 339,361

There were no liabilities measured at fair value on a recurring basis as of June 30, 2025 and December 31, 2024. The Company evaluates transfers between levels at the end of each reporting period and there have been no transfers between fair value measurement levels during the six months ended June 30, 2025. In addition, there were no assets or liabilities measured at fair value on a non-recurring basis as of June 30, 2025 and December 31, 2024.

The Company records interest income, accretion income and amortization expense on short-term investments to interest and other income (expense), net in its condensed statement of operations and comprehensive loss.

4. Property and Equipment, net

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

	As of June 30, 2025	As of December 31, 2024
Laboratory equipment	$ 11,349	$ 10,988
Leasehold improvements	2,156	2,118
Furniture and fixtures	1,831	1,775
Computer equipment and software	1,105	1,105
Construction-in-progress	153	346
Total property and equipment, gross	16,594	16,332
Less: Accumulated depreciation	(11,702)	(10,807)
Total property and equipment, net	$ 4,892	$ 5,525

Depreciation expense was $0.4 million and $0.9 million for the three and six months ended June 30, 2025, respectively, and $0.6 million and $1.1 million for the three and six months ended June 30, 2024, respectively.

5. Prepaid Expenses and Other Current Assets

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

	As of June 30, 2025	As of December 31, 2024
Prepaid licenses	$ 1,685	$ 1,097
Interest receivable	1,535	2,302
Prepaid research and development	996	2,101
Prepaid insurance	280	877
Other	75	163
Total prepaid expenses and other current assets	$ 4,571	$ 6,540

6. Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	As of June 30, 2025	As of December 31, 2024
Accrued compensation and benefits	$ 6,233	$ 11,154
Other accrued liabilities	959	1,199
Total accrued liabilities	$ 7,192	$ 12,353

Accrued compensation and benefits consist primarily of accrued bonuses and accrued vacation.

7. Long-term Debt

In March 2024 we entered into an Amended and Restated Loan and Security Agreement (the "Amended Loan Agreement") with Oxford Finance LLC (the “Lender” or “Oxford”) and drew an additional Term Loan (as defined below) of $20.0 million. While the Amended Loan Agreement upsized our existing Term Loan facility to a total size of $150.0 million aggregate principal amount (the "Term Loans"), the availability of additional Term Loans is contingent upon the continued development of bexotegrast in IPF, and therefore, we do not expect to have access to additional borrowing under the Amended Loan Agreement. See Note 7 of the "Notes to the Financial Statements" in the Company's audited financial statements included in the 2024 10-K for more information.

The principal amount outstanding under the Term Loans will accrue interest at a floating per annum rate equal to (i) the greater of (a) 1-month term Chicago Mercantile Exchange (“CME”) Term Secured Overnight Financing Rate (“SOFR”) on the last business day of the month that immediately precedes the month in which the interest will accrue and (b) three and one-half percent (3.50%) plus (ii) five and one-quarter percent (5.25%), subject to an agreed upon floor of 8.75%. Beginning on July 1, 2028, the Company is required to repay the Term Loans in consecutive equal monthly payments of principal, together with

applicable interest, in arrears. Interest on the Term Loans is paid on a monthly basis. All unpaid principal and accrued and unpaid interest with respect to each Term Loan will be due and payable in full on March 1, 2029. Accrued interest as of June 30, 2025 and December 31, 2024 is included in other accrued liabilities.

The Company will be required to make a final payment of 5.50% of the original principal amount of the Term Loans that were drawn, payable at maturity or upon any earlier acceleration or prepayment of the Term Loans. The Company may prepay the Term Loans in whole or in part, subject to a prepayment fee equal to (i) if prepaid on or before the first anniversary date of the funding date of such Term Loan, 3.00% of the principal amount of the applicable Term Loan prepaid, (ii) if prepaid after the first anniversary and on or before the second anniversary of the funding date of such Term Loan, 2.00% of the principal amount of the applicable Term Loan prepaid, and (iii) if prepaid after the second anniversary and on or before the third anniversary of the funding date of such Term Loan prepaid, 1.00% of the principal amount of the applicable Term Loan prepaid.

The Amended Loan Agreement contains representations and warranties, affirmative, and negative covenants, and events of default that are customary for loans of this type. The occurrence of an event of default could result in the acceleration of the obligations under the Amended Loan Agreement, termination of the Term Loan commitments and the right by the Lender to foreclose on the collateral securing the obligations. During the existence of an event of default, the Term Loans would accrue interest at a rate per annum equal to 5.00% above the otherwise applicable interest rate.

The estimated fair value of the Term Loans as of June 30, 2025 was measured using Level 3 inputs and approximates the carrying value recorded to the balance sheet. The effective interest rate for the Term Loan is 10.61% for the three and six months ended June 30, 2025 and 11.60% and 11.79% for the three and six months ended June 30, 2024, respectively. Interest expense during the three and six months ended June 30, 2025 was $0.8 million and $1.6 million, respectively and during the three and six months ended June 30, 2024 was $0.9 million and $1.3 million, respectively.

Future maturities of debt as of June 30, 2025 are as follows (in thousands):

	As of June 30, 2025
2028	$ 20,000
2029	10,000
Thereafter	—
Total payments	30,000
Less: unamortized debt issuance costs	(149)
Accretion of final payment	509
Total	$ 30,360

8. Preferred Stock

Under the Company's Amended and Restated Certificate of Incorporation, the Company is authorized to issue two classes of shares: preferred stock and common stock. The preferred stock may be issued in series, and the Company's board of directors is authorized to determine the rights, preferences, and terms of each series. These rights, preferences and terms could include dividend rights, conversion rights, voting rights, terms of redemptions, liquidation preferences and sinking fund terms. As of June 30, 2025 and December 31, 2024, the Company was authorized to issue 10,000,000 shares of preferred stock and there was no outstanding preferred stock as of June 30, 2025 and December 31, 2024.

9. Common Stock

As of June 30, 2025 and December 31, 2024, the Company was authorized to issue 300,000,000 shares of common stock at a par value of $0.0001 per share. The Common Stock has the following rights and privileges:

Voting

The holders of shares of common stock are entitled to one vote for each share of common stock held at any meeting of stockholders and at the time of any written action in lieu of a meeting.

Dividends

The holders of shares of common stock are entitled to receive dividends, when declared by the Company's board of directors. Cash dividends may not be declared or paid to holders of shares of common stock until all unpaid dividends on preferred stock have been paid in accordance with their terms. No dividends have been declared or paid by the Company since its inception. The terms of the Amended Loan Agreement restrict our ability to declare and pay dividends.

Liquidation

Subject to the preferential rights of holders of preferred stock then outstanding, the holders of shares of common stock are entitled to share ratably in the Company's remaining assets available for distribution to its stockholders in the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company.

Shares reserved for future issuance

	As of June 30, 2025	As of December 31, 2024
Outstanding stock option awards	9,037,076	8,300,804
Vesting of RSUs	1,060,650	932,634
Shares of common stock available for future grants under the 2020 Stock Option and Incentive Plan	6,050,630	4,212,229
Shares of common stock available for future issuance under the 2020 Employee Stock Purchase Plan	1,753,367	1,294,745
Shares of common stock available for future grants under the 2022 Inducement Plan	1,425,000	1,460,000
Total shares reserved for future issuance	19,326,723	16,200,412

10. Stockholder Rights Agreement

On March 12, 2025, the Company's board of directors adopted a stockholder rights agreement and declared a dividend of one right (each, a "Right") for each outstanding share of our common stock to stockholders of record at the close of business on March 25, 2025. Each Right entitles its holder, subject to the terms of the Rights Agreement (as defined below), to purchase from the Company one one-thousandth of a share of Series A Junior Participating Preferred Stock, par value $0.0001 per share, of the Company at an exercise price of $12.64 per Right, subject to adjustment. The description and terms of the Rights are set forth in a Rights Agreement, dated as of March 12, 2025 (the "Rights Agreement"), by and between the Company and Computershare Trust Company, N.A., a federally chartered trust company, as rights agent. Subject to certain exceptions, Rights become exercisable and trade separately from our common stock only upon the earlier of (i) the close of business on the tenth business day following the public announcement of an Acquiring Person (as defined in the Rights Agreement) beneficially owning 20%, when referring to a passive investor, and 10%, when referring to a person that is not a passive investor, or more of our common stock, and (ii) the close of business on the tenth business day after the commencement of a tender offer or exchange offer that, if consummated, would result in a person or group becoming an Acquiring Person. The Rights will expire on March 11, 2026, unless such Rights are earlier redeemed, exchanged or terminated, as provided in the Rights Agreement.

The Rights Agreement is intended to reduce the likelihood that any entity, person or group is able to gain control of the Company through open market accumulation without paying all stockholders an appropriate control premium or providing the board of directors sufficient opportunity to make informed judgments and take actions that are in the best interests of the Company and all stockholders. The Rights Agreement is not intended to interfere with any merger or other business combination approved by the board of directors.

11. Equity Incentive Plans and Stock-Based Compensation

In 2015, the Company's board of directors adopted the 2015 Equity Incentive Plan, as amended in 2018, 2019 and 2020 (the "2015 Plan"), which provided for the grant of incentive stock options, nonqualified stock options or other awards including stock appreciation rights and restricted stock awards to the Company's employees, officers, directors, advisors, and consultants. In May 2020, the board of directors adopted the 2020 Stock Option and Incentive Plan (the "2020 Plan") and suspended the 2015 Plan. Awards outstanding under either the 2015 Plan or 2020 Plan that are cancelled, expire or otherwise terminated subsequent to May 2020 will become available for issuance as common stock under the 2020 Plan. Additionally, the 2020 Plan is subject to automatic increases on January 1 of each year beginning January 1, 2021. The number of shares added each January 1 will be equal to the lesser of: (i) 5% of the outstanding shares on the immediately preceding December 31 or (ii) such amount as determined by the compensation committee of the board of directors.

The 2020 Plan provides for the grant of incentive stock options, nonqualified stock options or other awards including stock appreciation rights, restricted stock awards and restricted stock units to the Company's employees, officers, directors, advisors and consultants.

In 2022, the board of directors adopted the 2022 Inducement Plan ("Inducement Plan"), under which the Company may grant nonqualified stock options or other awards including stock appreciation rights and restricted stock awards.

Options under the 2020 Plan and Inducement Plan may be granted for periods of up to 10 years and at prices no less than the market price of the Company's common stock on the date of grant, provided, however, that the exercise price of an incentive stock option granted to a 10% shareholder shall not be less than 110% of the fair value of the shares on the date of grant and the option is not exercisable after the expiration of five years from the date of grant.

Incentive Stock Options and Nonqualified Stock Options

Stock options issued under either the 2015 Plan, the 2020 Plan or the Inducement Plan generally vest over four years and expire ten years from the date of grant. Certain options provide for accelerated vesting if there is a change in control, as defined in the respective plans.

The Company used Black-Scholes option pricing model to estimate stock-based compensation expense for stock option awards with the following assumptions:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Expected volatility	88.02% - 89.30%	85.58% - 86.46%	86.82% - 89.30%	85.28% - 86.46%
Risk-free interest rate	3.98% - 4.12%	4.17% - 4.60%	3.98% - 4.45%	4.04% - 4.60%
Expected dividend	—	—	—	—
Expected term (in years)	5.34 - 6.07	5.31 - 6.08	5.34 - 6.08	5.31 - 6.08
Underlying common stock fair value	$1.37 - $1.61	$11.51 - $15.36	$1.37 - $12.63	$11.51 - $17.44

A summary of option activity under the 2015 Plan and the 2020 Plan is as follows:

	Number of Options	Weighted-Average Exercise Price per Share	Weighted-Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2024	8,300,804	$ 17.23	7.49	$ 13,769
Granted	2,271,680	$ 9.68		
Exercised	(4,921)	$ 12.18		
Forfeited	(1,530,487)	$ 14.88		
Outstanding as of June 30, 2025	9,037,076	$ 15.73	6.78	$ —
Exercisable as of June 30, 2025	5,613,168	$ 16.74	5.50	$ —
Vested and expected to vest as of June 30, 2025	9,037,076	$ 15.73	6.78	$ —

As of June 30, 2025, there were $33.7 million of unrecognized compensation costs that are expected to be recognized over the weighted-average period of 2.6 years related to stock options. Aggregate intrinsic value represents the difference between the fair value of the underlying common stock and the exercise price as of June 30, 2025.

Restricted Stock Units

The service-based condition for restricted stock units (“RSUs”) is generally satisfied over three years.

	Restricted Stock Units	Weighted Average Grant Date Fair Value
Unvested and outstanding as of December 31, 2024	932,634	$ 24.28
Granted	840,341	$ 10.67
Released	(370,437)	$ 26.09
Forfeited	(341,888)	$ 14.64
Unvested and outstanding as of June 30, 2025	1,060,650	$ 15.97

As of June 30, 2025, the Company had $12.4 million of unrecognized stock-based compensation expense related to outstanding RSUs expected to be recognized over a weighted-average period of 2.0 years.

Performance-Based Restricted Stock Units

Performance-based restricted stock units (“PSUs”) were granted in 2022 and vested upon the achievement of market and performance conditions. Market conditions include the Company's total shareholder return (“TSR”) relative to the Nasdaq Biotechnology Index over the term of the award ending on June 30, 2024. Additionally, the number of shares of common stock issuable upon vesting ranged from 0% to 200% of the PSUs based on achievement of certain targets.

The fair value of the TSR PSUs were derived from a Monte Carlo simulation model that used the following key assumptions:

Valuation date share price	$	17.57
Award term (years)		1.92
Volatility		70.62 %
Correlation coefficient		0.3508
Average peer group volatility		79.69 %
Average peer group correlation coefficient		0.4397
Risk-free interest rate		2.84 %

The measurement period for the PSUs associated with TSR concluded on the last trading day of the second quarter 2024 and in July 2024, upon certification of the TSR results by the compensation committee of the board of directors, the award recipients vested in a total of 155,292 shares of common stock, representing 55% achievement. Such 155,292 shares of common stock were issued to award recipients as of September 30, 2024. There were no outstanding PSUs as of June 30, 2025.

2020 Employee Stock Purchase Plan

In June 2020, the Company adopted the Company's 2020 Employee Stock Purchase Plan (the "2020 ESPP"). The 2020 ESPP provides that the number of shares reserved and available for issuance will automatically increase on January 1 of each calendar year, beginning January 1, 2021, by the least of (1) 1.0% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year, (2) 700,000 shares or (3) such lesser amount as determined by the administrator of the 2020 ESPP, which is the compensation committee of the board of directors of the Company.

Under the 2020 ESPP, eligible employees may purchase shares of our common stock through payroll deductions that cannot exceed 15% of each employee's salary. The 2020 ESPP provides for a six-month offering period. At the end of the purchase period, eligible employees are permitted to purchase shares of common stock at the lower of 85% of the fair market value at the beginning of the offering period or 85% of the fair market value at the end of the purchase period, subject to tax limitations on the total value of the purchase. The 2020 ESPP is considered a compensatory plan, and the Company recorded $0.1 million in stock-based compensation expense for both the three and six months ended June 30, 2025, and $0.1 million and $0.3 million for the three and six months ended June 30, 2024, respectively. During the three and six months ended June 30, 2025, 0 and 149,987 shares of common stock were issued respectively under the 2020 ESPP with 1,753,367 shares remaining available for issuance under the 2020 ESPP. The Company used Black-Scholes option pricing model to estimate stock-based compensation expense for the 2020 ESPP with the following assumptions:

	Three and Six Months Ended June 30,	
	2025	2024
Risk-free interest rate	4.29%	5.27%
Expected term of options (in years)	0.50	0.50
Expected stock price volatility	208.00%	63.92%
Expected dividends	—	—

Stock-Based Compensation Expense

The following table presents the components and classification of stock-based compensation expense for the Company's stock-based awards for the three and six months ended June 30, 2025 and 2024 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Stock options and ESPP	$ 4,406	$ 6,287	$ 10,367	12,645
Restricted stock units	1,976	3,314	4,927	6,560
Performance-based restricted stock units	—	1,043	—	1,105
Total stock-based compensation expense	$ 6,382	$ 10,644	$ 15,294	$ 20,310
Research and development expenses	$ 1,935	$ 4,102	$ 5,637	$ 7,172
General and administrative expenses	$ 4,447	$ 6,542	$ 9,657	$ 13,138

12. Income Taxes

For the three and six months ended June 30, 2025 and 2024, the Company did not record an income tax provision. The Company will continue to maintain a 100% valuation allowance on total deferred tax assets. The Company believes it is more likely than not that the related deferred tax asset will not be realized. As a result, the Company's effective tax rate will remain at 0% because there are no estimated or discrete items that would impact the tax provision.

On July 4, 2025, the One Big Beautiful Bill Act, or OBBBA, was enacted in the United States, which includes significant changes to federal tax law and other regulatory provisions that may impact the Company. We are currently evaluating the impact of the OBBBA on our financial condition and results of operations.

13. Segments

The Company operates and manages its business as one reportable and operating segment, which is the business of developing and commercializing novel therapies for patients. The Company's chief executive officer, who is the chief operating decision maker ("CODM"), reviews financial information on an aggregate basis for allocating and evaluating financial performance. The Company defines its segments based on the way in which internally reported financial information is regularly reviewed by the CODM to analyze financial performance, make decisions, and allocate resources. The CODM assesses performance for the segment and decides how to allocate resources based on net loss which is also reported on the Statement of Operations and Comprehensive Loss as consolidated net loss.

All long-lived assets are maintained in the United States of America.

Our CODM is regularly provided with more detailed expense information than what is included in our Statement of Operations and Comprehensive Loss. The table below shows a reconciliation of the Company's net loss, including the significant expense categories regularly provided to and reviewed by the CODM, as computed under U.S. GAAP to the Company's total net loss in the statements of operations (in thousands).

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Operating expenses:				
Bexotegrast - clinical trial and third party contracting costs	13,359	26,360	34,948	43,57
Employee-related expenses - research and development (excluding stock-based compensation)	10,344	8,381	20,830	17,51
General and administrative costs (excluding stock-based compensation)	8,947	8,476	19,236	17,12
Other segment items	12,942	17,422	29,513	34,80
Segment loss	45,592	60,639	104,527	113,03
Reconciliation of segment loss				
Interest and other (income) expense, net	(3,101)	(5,653)	(6,669)	(11,53
Interest expense	809	868	1,608	1,31
Net loss	$ 43,300	$ 55,854	$ 99,466	$ 102,80

Other segment items include total stock-based compensation and research and development costs related to other pipeline programs and other non-program costs (excluding employee-related expenses).

14. Commitments and Contingencies

Purchase Commitments

The Company has contractual arrangements with research and development organizations and suppliers; however, these contracts are generally cancellable on 30 days' notice and the obligations under these contracts are largely based on services performed.

15. Leases

On September 28, 2023, the Company entered into a lease agreement with HCP BTC, LLC, a Delaware limited liability company ("the Landlord") for premises consisting of approximately 100,904 square feet of office and laboratory space located at Oyster Point Blvd, South San Francisco, California (the "Oyster Point Lease"), which is being used as a single unified Company headquarters. The lease term of approximately seven years started in the second quarter of 2024 when the Landlord substantially completed tenant improvements and may be extended for a period of eight years at the then prevailing market rates for a comparable property. Future lease payments are approximately $40.5 million which represent the non-cancellable periods of the lease. We excluded extension options that are not reasonably certain to be exercised from our lease terms. Our lease payments consist primarily of fixed rental payments for the right to use the underlying leased assets over the lease term. Our lease agreement provides us the right to sublet the premises, subject to approval by the Landlord. Additionally, the Company provided a letter of credit to the Landlord in the amount of $1.4 million in connection with the Oyster Point Lease, which is classified as restricted cash as of June 30, 2025.

Though the Oyster Point Lease is accounted for as a single contract, the office space was occupied in March 2024 while the laboratory space was occupied in June 2024. Accordingly, the Company measured and allocated consideration to each lease component. Upon commencement of each lease component the Company recognized an aggregate right-of-use asset ("ROU") and lease liability of $23.7 million and $6.1 million during the quarters ended March 31, 2024 and June 30, 2024, respectively.

The undiscounted future non-cancellable lease payments of the Company's operating lease liability as of June 30, 2025 were as follows (in thousands):

		Operating Lease
2025 (remainder of the year)		1,940
2026		4,406
2027		5,898
2028		7,468
2029 and thereafter		20,822
Total undiscounted lease payments	$	40,534
Less: Present value discount		(10,518)
Total discounted lease payments	$	30,016
Total current operating lease liabilities	$	1,225
Total non-current operating lease liabilities	$	28,791
Total lease liability	$	30,016

The weighted-average remaining lease terms and discount rates related to the Company's operating leases were as follows:

	Six Months Ended June 30,	
	2025	2024
Weighted-average remaining lease term (in years)	6.0	6.9
Weighted-average discount rate	9.3%	9.3%

Variable lease costs comprise primarily of the Company's proportionate share of operating expenses, property taxes, and insurance. Short-term lease expense and variable lease payments recorded in operating expenses were immaterial for the three and six months ended June 30, 2025 and 2024. Lease expenses for each of the three and six months ended June 30, 2025 and 2024 are as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Operating lease costs	$ 1,505	$ 1,625	$ 3,011	$ 2,597
Other variable costs	522	280	952	445
Total expense	$ 2,027	$ 1,905	$ 3,963	$ 3,042

16. Defined Contribution Plan

The Company sponsors a defined contribution plan under Section 401(k) of the Internal Revenue Code covering substantially all full-time U.S. employees. Employee contributions are voluntary and are determined on an individual basis subject to the maximum allowable under federal tax regulations. The Company made contributions to the plan of $0.3 million and $1.0 million for the three and six months ended June 30, 2025 and $0.5 million and $0.8 million for the three and six months ended June 30, 2024.

17. Net Loss Per Share Attributable to Common Stockholders

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

	Six Months Ended June 30,	
	2025	**2024**
Options to purchase common stock	9,037,076	8,230,237
Restricted stock units	1,060,650	1,180,746
Performance-based restricted stock units*	—	155,292
Total	10,097,726	9,566,275

*Represents TSR based PSUs outstanding based on level of achievement of 55% as measured on June 30, 2024

18. Restructuring of Operations

On May 1, 2025, we announced a reduction in workforce that impacted approximately 45% of our then-current employees. We expect the total cost of the current restructuring plan, which was largely completed as of June 30, 2025, to be approximately $3.8 million. For the three and six months ended June 30, 2025, one-time termination benefits totaling $2.7 million was recorded to research and development expenses and $1.0 million was recorded to general and administrative expenses. As of June 30, 2025, we have paid $3.2 million in termination benefits and an accrual of $0.5 million is recorded within Accrued Liabilities on the condensed consolidated balance sheets.

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

The following discussion and analysis should be read in conjunction with our condensed financial statements and related notes appearing elsewhere in this Report, as well as our audited financial statements and related notes included in our 2024 10-K. This discussion and analysis contains forward-looking statements based upon current beliefs, plans and expectations that involve risks, uncertainties and assumptions, such as statements regarding our plans, objectives, expectations, intention, beliefs and projections. Our actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth in the section titled "Risk Factors" under Part II, Item 1A of this Report and under Part I, Item 1A of our 2024 10-K. In some cases, you can identify forward-looking statements by terminology such as "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potentially," "predict," "should," "will" or the negative of these terms or other similar expressions.

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

Overview

We are a clinical-stage biopharmaceutical company focused on discovering and developing integrin-based therapeutics. We have applied our deep understanding of fibrosis biology, along with our medicinal chemistry and translational medicine expertise to develop a set of proprietary tools designed to discover and de-risk product candidates quickly and efficiently.

In June 2025, we announced that we were discontinuing the development of bexotegrast in IPF as the results of our global Phase 2b/3 trial, BEACON-IPF, demonstrated an unfavorable risk-benefit profile.

In January 2023, we received United States Food and Drug Administration, or FDA, clearance of an investigational new drug application, or IND, for PLN-101095, a small molecule, dual selective inhibitor of integrins αvβ8 and αvβ1 for the treatment of solid tumors that are resistant to immune checkpoint inhibitors. We are currently enrolling the fifth of five potential dose cohorts in a Phase 1 open-label dose-escalation trial of PLN-101095 as monotherapy and in combination with pembrolizumab in patients with solid tumors that are resistant to immune checkpoint inhibitors.

Our Phase 1-ready program PLN-101325, is in development for treatment of muscular dystrophies, including Duchenne muscular dystrophy. PLN-101325 is a monoclonal antibody designed to act as an allosteric agonist of integrin α7β1. PLN-101325 has received a clinical trial approval (CTA) in Australia.

Second Quarter and Recent Developments

Bexotegrast

- **Bexotegrast development in idiopathic pulmonary fibrosis (IPF) discontinued.** Following an analysis of the full safety and efficacy data from the BEACON-IPF Phase 2b/3 clinical trial, the Company has discontinued development of bexotegrast in idiopathic pulmonary fibrosis (IPF). While bexotegrast-treated patients demonstrated early signs of efficacy, the drug was shown to have an unfavorable risk-benefit profile based on IPF-related adverse events. Full results from BEACON-IPF will be submitted for future publication.

Oncology Program

- **Phase 1 trial of PLN-101095 in solid tumors continues to enroll.** PLN-101095 is an oral, small molecule, dual selective inhibitor of αvβ8 and αvβ1 integrins designed to block TGF-β activation in the tumor microenvironment. The Phase 1 open-label, dose-escalation trial of PLN-101095 trial as monotherapy and in combination with pembrolizumab is in patients with solid tumors that are resistant to immune checkpoint inhibitors. The trial is currently dosing the fifth of five planned dose cohorts, evaluating PLN-101095 at 2000 mg administered twice daily (BID). Initial data from the two highest dose cohorts of the trial is expected by the end of 2025.

Corporate Highlights

- In May, the Company announced a strategic restructuring of its workforce and other cost saving actions intended to extend its cash runway. By the end of the second quarter, the restructuring was largely complete.

Since inception, we have had significant operating losses. Our net loss was $43.3 million and $55.9 million for the three months ended June 30, 2025 and 2024, respectively. Our net loss for the six months ended June 30, 2025 and 2024 was $99.5 million and $102.8 million, respectively. As of June 30, 2025, we had an accumulated deficit of $809.5 million and cash, cash equivalents, and short-term investments of $264.4 million. We expect to continue to incur net losses for the foreseeable future as we:

- perform research and development activities to identify and develop product candidates;
- advance product candidates into and through clinical development;
- require the manufacture of supplies to support research and development, preclinical studies and clinical trials;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- maintain, expand and protect our intellectual property portfolio; and
- invest in or in-license other technologies or product candidates.

Components of Operations

Operating Expenses

Research and Development

Our research and development expenses consist of expenses incurred in connection with the development of our product candidates. Research and development expenses include:

- employee-related expenses, which include salaries, benefits and stock-based compensation for our research and development personnel;
- expenses incurred under agreements with third-party contract organizations for pre-clinical studies, clinical trials and consultants that conduct research and development activities on our behalf;
- costs associated with the manufacture of supplies to support research and development, preclinical studies and clinical trials;
- depreciation of laboratory equipment and costs of equipment and supplies;
- facilities expenses, which include expenses for rent and other facility related costs; and
- other expenses and other allocations associated with research and development.

The following table summarizes our research and development expenses for the three months ended June 30, 2025 and 2024 (in thousands):

	Three Months Ended June 30,		
	2025	2024	$ Change
Employee related expenses	$ 12,279	$ 12,469	$ (190)
Outside and consulting services for preclinical studies and research and development activities by third-party contract organizations	4,087	3,838	249
Clinical trials expenses	11,291	24,195	(12,904)
Depreciation of lab equipment and costs of equipment and supplies	1,291	1,291	—
Facilities expenses	1,742	1,921	(179)
Other expenses and other allocations	1,508	1,903	(395)
Total research and development expenses	$ 32,198	$ 45,617	$ (13,419)

We expense all research and development costs in the periods in which they are incurred. We do not allocate our internal costs by product candidates or by preclinical programs as these are in early stages of clinical trials or development, and any such allocation would involve significant estimates and judgments and, accordingly, would be imprecise. Where appropriate, we allocate our third-party research and development expense by product candidate or preclinical program. These expenses primarily relate to outside consultants, clinical research organizations and contract manufacturing organization. When we refer to the research and development expenses associated with a specific product candidate or preclinical program, these refer exclusively to the allocated third-party expenses associated with that product candidate.

Due to discontinuing development of bexotegrast in IPF, we expect research and development expenses to decrease in the near term as we have re-prioritized our development of product candidates that are in earlier, less capital-intensive stages of development. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming, and the successful development of our product candidates is highly uncertain. As a result, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates.

General and Administrative

Our general and administrative expenses consist primarily of salaries, benefits and stock-based compensation for our general and administrative personnel, allocated facilities costs, insurance and other expenses for outside professional services, including legal, marketing, investor relations, human resource and accounting services. We expect general and administrative expenses to remain relatively consistent for the foreseeable future. In addition, if we obtain regulatory approval for any of our product candidates and do not enter into a third-party commercialization collaboration, we expect to incur significant expenses related to building a sales and marketing team to support product sales, marketing and distribution activities.

Interest and Other Income (Expense), net

Our interest and other income (expense), net consists of interest, accretion income and amortization expense on cash, cash equivalents, and short-term investments, and realized gains and losses on short-term investments.

Interest Expense

Our interest expense is derived from a term loan executed under the Oxford Loan Agreement that we entered into in May 2022 and amended in March 2024 (the "Amended Loan Agreement"). Borrowings under the Amended Loan Agreement bear interest at a rate per annum equal to 1-month term SOFR plus 5.25%, subject to an agreed upon floor of 8.75%.

Financial Operations Overview

Comparison of the three months ended June 30, 2025 and 2024 (in thousands)

	Three Months Ended June 30,		
	2025	**2024**	**$ Change**
Operating expenses:			
Research and development	$ (32,198)	$ (45,617)	$ 13,419
General and administrative	(13,394)	(15,022)	1,628
Total operating expenses	(45,592)	(60,639)	15,047
Loss from operations	(45,592)	(60,639)	15,047
Interest and other income (expense), net	3,101	5,653	(2,552)
Interest expense	(809)	(868)	59
Net loss	$ (43,300)	$ (55,854)	$ 12,554

Research and development expenses

The following table summarizes our research and development expenses for the three months ended June 30, 2025 and 2024 (in thousands):

	Three Months Ended June 30,		
	2025	**2024**	**$ Change**
Program-specific external expenses:			
Bexotegrast - clinical trial and third party contracting costs	$13,359	$26,360	$ (13,001)
Other pipeline programs - clinical trial and third party contracting costs	2,019	1,673	346
Total program-specific external expenses	15,378	28,033	$ (12,655)
Unallocated internal expenses			
Employee-related expenses	12,279	12,469	$ (190)
Depreciation of lab equipment and costs of equipment and supplies	1,291	1,291	—
Facilities expenses	1,742	1,921	$ (179)
Other expenses and other allocations	1,508	1,903	(395)
Total unallocated internal expenses	16,820	17,584	$ (764)
Total research and development expenses	$ 32,198	$ 45,617	$ (13,419)

Research and development expenses for the three months ended June 30, 2025 decreased $13.4 million, primarily due to the discontinuation of BEACON-IPF and lower employee-related expenses, driven by a reduction in headcount resulting from our restructuring initiated May 1, 2025.

General and Administrative Expenses

General and administrative expenses for the three months ended June 30, 2025 decreased $1.6 million, primarily due to a decrease in employee related costs driven by the reduction in workforce and associated reversal of expense for unvested, forfeited stock awards.

We currently expect general and administrative expenses to decrease in the near-term in response to the reduction in workforce then remain relatively consistent for the foreseeable future.

Interest and Other Income (Expense), Net

Interest and other income (expense), net decreased $2.6 million due to lower investment balances due to continued funding of operating activities.

Interest Expense

Interest expense for the three months ended June 30, 2025 decreased $0.1 million due to changing interest rates associated with the Amended Loan Agreement.

Comparison of the six months ended June 30, 2025 and 2024 (in thousands)

	Six Months Ended June 30,		
	2025	**2024**	**$ Change**
Operating Expenses:			
Research and development	(75,634)	(82,763)	7,129
General and administrative	(28,893)	(30,268)	1,375
Total operating expenses	(104,527)	(113,031)	8,504
Loss from operations	(104,527)	(113,031)	8,504
Interest and other income (expense), net	6,669	11,535	(4,866)
Interest expense	(1,608)	(1,313)	(295)
Net income or loss	(99,466)	(102,809)	3,343

Research and development expenses

The following table summarizes our research and development expenses for the six months ended June 30, 2025 and 2024 (in thousands):

	Six Months Ended June 30,		
	2025	**2024**	**$ Change**
Program-specific external expenses:			
Bexotegrast - clinical trial and third party contracting costs	34,948	43,577	$ (8,629)
Other pipeline programs - clinical trial and third party contracting costs	4,403	3,899	$ 504
Total program-specific external expenses	39,351	47,476	$ (8,125)
Unallocated internal expenses			
Employee-related expenses	26,467	24,687	$ 1,780
Depreciation of lab equipment and costs of equipment and supplies	2,684	2,978	$ (294)
Facilities expenses	3,619	3,574	$ 45
Other expenses and other allocations	3,513	4,048	$ (535)
Total unallocated internal expenses	36,283	35,287	$ 996
Total research and development expenses	75,634	82,763	$ (7,129)

Research and development expenses for the six months ended June 30, 2025 decreased $7.1 million, primarily due to the discontinuation of BEACON-IPF.

General and Administrative Expenses

General and administrative expenses for the six months ended June 30, 2025 decreased $1.4 million, primarily attributable to decreased employee-related costs, driven by our restructuring of operations.

We expect our general and administrative expenses to remain relatively consistent for the foreseeable future.

Interest and Other Income (Expense), net

Interest and other income (expense), net decreased $4.9 million, attributable to lower investment balances due to continued funding of operating activities.

Interest Expenses

Interest expense for the six months ended June 30, 2025 increased $0.3 million due to additional borrowings under the Amended Loan Agreement.

Liquidity and Capital Resources

Overview

As of June 30, 2025, we had $264.4 million of cash, cash equivalents and short-term investments. Our short-term investments consist of U.S. Treasury securities, U.S. Government agency securities and highly rated, investment-grade corporate debt securities.

In March 2024, we entered into an Amended Loan Agreement with Oxford Finance LLC (or the “Lender” or “Oxford”) which upsized our existing Term Loan facility to a total size of $150.0 million aggregate principal amount (the "Term Loans"). Pursuant to the Amended Loan Agreement, we drew an additional Term Loan of $20.0 million and given the discontinuation of development of bexotegrast in IPF, we do not expect to have access to additional borrowing under the Oxford Agreement. See Note 7 to the Notes to our 2024 Form 10-K for more information.

During the third quarter of 2021, we entered into a Controlled Equity Offering^{SM} Sales Agreement (the “Sales Agreement”) with Cantor Fitzgerald & Co., as sales agent, pursuant to which we may issue and sell shares of common stock in an "at-the-market" offering. In March 2023, we filed a prospectus registering the offer and sale of up to $150.0 million of shares of common stock from time to time pursuant to the Sales Agreement. As of the date of this Report, we have not issued any shares pursuant to any at-the-market offerings, including pursuant to the Sales Agreement, but may do so at a future date.

We believe that our existing capital resources will be sufficient to fund our anticipated operating expenses and capital expenditure requirements for the next 12 months and beyond. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Further, our operating plan may change, and we may need additional funds to meet operational needs and capital requirements for product development and commercialization sooner than planned.

Funding Requirements

Our primary use of cash is to fund operating expenses, primarily research and development expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable, accrued expenses and prepaid expenses.

Our future funding requirements will depend on many factors, including the following:

- the initiation, progress, timing, costs and results of preclinical studies and clinical trials for our product candidates;
- the clinical development plans we establish for these product candidates;
- the timelines of our clinical trials and the overall costs to conduct and complete the clinical trials, which may be impacted by health epidemics and pandemics, such as COVID-19;
- the number and characteristics of product candidates that we develop;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, and other comparable foreign regulatory authorities including but not limited to the European Medicines Agency (EMA) and the U.K. Medicines and Healthcare products Regulatory Agency (MHRA);
- whether we enter into any collaboration agreements and the terms of any such agreements;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;

- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us or our product candidates;
- the effect of competing technological and market developments;
- the cost and timing of completion of commercial-scale outsourced manufacturing activities;
- the cost and timing of achieving favorable pricing and reimbursement agreements with the pricing authorities in each market of interest, including of securing a positive recommendation after undergoing a health technology assessment by health technology authorities;
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own; and
- the cost of operating as a public company.

Further, our operating plan may change, and we may need additional funds to meet operational needs and capital requirements for clinical trials and other research and development expenditures. If we need to raise additional capital to fund our operations, funding may not be available to us on acceptable terms, or at all. In addition, the discontinuation of our development of bexotegrast in IPF may intensify the risk that we will be unable to access capital on favorable terms, or at all, as and when needed. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of or suspend one or more of our preclinical studies, clinical trials, research and development programs or commercialization efforts. We may seek to raise any necessary additional capital through a combination of public or private equity offerings, debt financings, collaborations and other licensing arrangements. If we raise additional capital through debt financing, we 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 through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us.

Cash Flows

Comparison of the six months ended June 30, 2025 and 2024

The following summarizes our cash flows for the periods indicated (in thousands):

	Six Months Ended June 30,	
	2025	**2024**
Net cash used in operating activities	$ (89,467)	$ (75,568)
Net cash provided by investing activities	104,601	70,248
Net cash provided by financing activities	498	22,472
Net increase in cash and cash equivalents	$ 15,632	$ 17,152

Cash Used in Operating Activities

Net cash used in operating activities increased $13.9 million, primarily due to settling payables and accrued expenses relating to the bexotegrast program including close-out activities for the BEACON-IPF study.

Cash Provided by Investing Activities

Net cash provided by investing activities increased over the same period of the prior year as maturities of marketable securities exceeded related purchases during the six months ended June 30, 2025.

Cash Provided by Financing Activities

Net cash provided by financing activities decreased $22.0 million, primarily due to additional Term Loans entered into during the six months ended June 30, 2024 associated with the Amended Loan Agreement as well as decreased proceeds from the issuance of common stock under benefit plans during the six months ended June 30,2025.

Contractual Obligations and Other Commitments

At June 30, 2025, we have a non-cancelable operating lease for office and laboratory space for a period of seven years through March 31, 2031. Refer to Note 14 and Note 15 to our financial statements appearing elsewhere in this Report for a discussion of material obligations and commitments.

Off-Balance Sheet Arrangements

During the periods presented, we did not have, nor do we currently have, any off-balance sheet arrangements or holdings in any variable interest entities.

Critical Accounting Polices and Estimates

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

There have been no material changes to our critical accounting policies and estimates from those described in "Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our 2024 10-K.

Recent Accounting Pronouncements

See Note 2 to the Notes to Condensed Unaudited Financial Statements of this Report for more information.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

The primary objectives of our investment activities are to ensure liquidity and to preserve capital. We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities. We had cash and cash equivalents, restricted cash and short-term investments of $264.4 million as of June 30, 2025 which consisted of bank deposits, highly liquid money market funds and short-term investments in U.S. treasury securities, U.S. government agency securities and corporate debt securities. Under the Amended Loan Agreement, we had a $30.0 million term loan outstanding as of June 30, 2025 which is subject to the movement in interest rates. Due to the short-term maturities of our cash equivalents and short-term investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash equivalents or short-term investments.

To minimize the risk, we maintain our portfolio of cash equivalents and short-term investments in institutional market funds that are composed of U.S. Treasury and U.S. Treasury-backed repurchase agreements or short-term U.S. Treasury securities, U.S. Government agency securities and highly rated, investment-grade corporate debt securities. We do not believe that inflation, interest rate changes, or exchange rate fluctuations had a significant impact on our results of operations for any periods presented herein. A hypothetical 10% change in interest rates during the periods presented would not have had a material impact on our condensed financial statements.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As of June 30, 2025, management, with the participation of our Chief Executive Officer and Chief Financial Officer, performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Our disclosure controls and procedures 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, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosures.

Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of June 30, 2025, the design and operation of our disclosure controls and procedures were effective at a reasonable assurance level.

Changes in Internal Control over Financial Reporting

There was no change in our internal controls over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) under the Exchange Act that occurred during the quarter ended June 30, 2025 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

As of the date of this filing, we are not party to any material legal matters or claims. We may become party to legal matters and claims arising in the ordinary course of business. We cannot predict the outcome of any such legal matters or claims, and despite the potential outcomes, the existence thereof may have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 1A. Risk Factors.

Our business faces significant risks. If any of the events or circumstances described in the following risks actually occurs, our business may suffer, the trading price of our common stock could decline and our financial condition or results of operations could be harmed. These risks should be read in conjunction with the other information set forth in this Report. The risks and uncertainties described below are not the only ones facing us. There may be additional risks faced by our business. Other events that we do not currently anticipate or that we currently deem immaterial also may adversely affect our financial condition or results of operations.

RISK FACTORS

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant net losses since inception and we expect to continue to incur significant net losses for the foreseeable future.

We have incurred significant net losses since our inception and have financed our operations principally through equity and debt financing and our prior collaboration with Novartis. We continue to incur significant research and development and other expenses related to our ongoing operations. Our net loss was $43.3 million and $55.9 million for the three months ended June 30, 2025 and 2024, respectively. Our net loss for the six months ended June 30, 2025 and 2024 was $99.5 million and $102.8 million, respectively. As of June 30, 2025, we had an accumulated deficit of $809.5 million. We have devoted substantially all of our resources and efforts to research and development, and we expect that it will be at least several years, if ever, before we generate revenue from product sales. Even if we receive marketing approval for and commercialize one or more of our product candidates, we expect that we will continue to incur substantial research and development and other expenses in order to further develop and, if approved, market additional potential product candidates.

We expect to continue to incur significant losses for the foreseeable future as we:

- advance our product candidates through clinical development, and, if successful, later-stage clinical trials;
- discover and develop new product candidates;
- advance our preclinical development programs into clinical development;
- further develop manufacturing processes and manufacture our product candidates;
- experience delays or interruptions to preclinical studies, clinical trials, our receipt of services from our third-party service providers on whom we rely, or our supply chain due to the effects of health epidemics and pandemics, such as COVID-19;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- commercialize our current product candidates and any future product candidates, if approved;
- increase the amount of research and development activities to identify and develop product candidates;
- hire additional clinical development, quality control, scientific and management personnel;
- establish a sales, marketing, medical affairs and distribution infrastructure to commercialize any products for which we may obtain marketing approval and intend to commercialize on our own or jointly with third parties;
- maintain, expand and protect our intellectual property portfolio;
- invest in or in-license other technologies or product candidates; and
- continue to build out our organization to engage in such activities.

To become and remain profitable, we must develop and eventually commercialize products with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials, obtaining marketing approval for product candidates, manufacturing, marketing, and selling products for which we may obtain marketing approval and satisfying any post-marketing requirements. We may never succeed in any or all of these activities and, even if we do, we may never generate revenue that is significant enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to

become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business, or continue our operations.

We will require substantial additional capital to fund our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs, future commercialization efforts or other operations.

Developing biopharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive, and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception. We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct clinical trials of our current product candidates and any future product candidates that we may develop, seek regulatory approvals for our product candidates and to launch and commercialize any products for which we receive regulatory approval. Accordingly, we will need to obtain substantial additional funding in order to maintain our continuing operations, and such funding may be more difficult to obtain given the discontinuation of the BEACON-IPF trial and our development of bexotegrast in idiopathic pulmonary fibrosis (IPF). If we are unable to raise capital when needed or on acceptable terms, we may be forced to delay, reduce, or eliminate one or more of our research and drug development programs or future commercialization efforts.

As of June 30, 2025, we had approximately $264.4 million in cash, cash equivalents, restricted cash and short-term investments. Based on our current operating plan, we believe that our existing cash, cash equivalents and short-term investments will be sufficient to fund our anticipated operating expenses and capital expenditure requirements for the next 12 months and beyond. However, our future capital requirements and the period for which our existing resources will support our operations may vary significantly from what we expect, and we will in any event require additional capital in order to complete clinical development of any of our current programs. Our monthly spending levels will vary based on new and ongoing development and corporate activities. Because the length of time and activities associated with development of our product candidates is highly uncertain, we are unable to estimate the actual funds we will require for 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 initiation, progress, timing, costs and results of preclinical studies and clinical trials for our product candidates;
- the clinical development plans we establish for these product candidates;
- the timelines of our clinical trials and the overall costs to conduct and complete the clinical trials, including any increased costs due to disruptions caused by marketplace conditions, including the effects of health epidemics and pandemics, such as COVID-19, or other geopolitical conditions;
- the cost and capital commitments required for developing manufacturing processes for our product candidates and manufacturing our product candidates at clinical and commercial scales;
- the number and characteristics of product candidates that we develop;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA and other comparable foreign regulatory authorities;
- whether we are able to enter into future collaboration agreements and the terms of any such agreements;
- the ability to and timing of achieving a favorable pricing and reimbursement decision by the pricing authorities in the markets of interest;
- the ability to secure a position recommendation following the health technology assessment by the health technology bodies in the relevant market;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us or our product candidates;
- the effect of competing technological and market developments;
- the cost and timing of completion of commercial-scale outsourced manufacturing activities; and
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own.

We have borrowed and in the future may borrow additional capital from institutional and commercial banking sources to fund future growth or potentially pursuant to new arrangements with different lenders. We have borrowed capital under our

Amended and Restated Loan and Security Agreement with Oxford Finance LLC, or Amended Loan Agreement. Following our discontinuation of BEACON-IPF, we do not expect to be eligible to borrow additional term loans under the Amended Loan Agreement, given that the availability of two term loans is subject to the satisfaction of certain conditions related to the BEACON-IPF clinical trial and the availability of the third term loan is at the sole discretion of the lender. In addition, we expect to continue to opportunistically seek access to the equity capital markets to support our development efforts and operations. However, we cannot be certain that additional funding will be available on acceptable terms, or at all, and such availability may be limited in the future given the discontinuation of our development of bexotegrast in IPF. Until we can generate sufficient revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements. If we raise additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Further, to the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, your ownership interest will be diluted. In addition, any debt financing may subject us to fixed payment obligations and 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 through marketing and distribution arrangements or other collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish certain valuable intellectual property or other rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. We also may be required to seek collaborators for any of our product candidates at an earlier stage than otherwise would be desirable or relinquish our rights to product candidates or technologies that we otherwise would seek to develop or commercialize ourselves. Market volatility resulting from challenging financial markets factors, including the effects of health epidemics and pandemics, such as the COVID-19 pandemic, could also adversely impact our ability to access capital as and when needed. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates 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 and cause the price of our common stock to decline.

Covenants and other provisions in the Amended Loan Agreement restrict our business and operations in many ways, and if we do not effectively manage our covenants, our financial conditions and results of operations could be adversely affected. In addition, our operations may not provide sufficient cash to meet the repayment obligations of our debt incurred under the Amended Loan Agreement.

Pursuant to the Amended Loan Agreement, Oxford has been granted a security interest in substantially all of our assets, excluding intellectual property (but including the right to payments and proceeds of intellectual property, with such exclusion of intellectual property subject to change pursuant to the terms of the Amended Loan Agreement), and a negative pledge on substantially all of our intellectual property, subject to customary exceptions. If an event of default occurs under the Amended Loan Agreement, Oxford may foreclose on its security interest and liquidate some or all of these assets, which would harm our business, financial condition and results of operations.

In the event of a default in connection with our bankruptcy, insolvency, liquidation, or reorganization, Oxford would have a prior right to substantially all of our assets to the exclusion of our general unsecured creditors. Only after satisfying the claims of Oxford and any unsecured creditors would any amount be available for our equity holders.

The pledge of these assets and other restrictions imposed in the Amended Loan Agreement may limit our flexibility in raising capital for other purposes. Because substantially all of our assets are pledged to secure the Amended Loan Agreement obligations, our ability to incur additional indebtedness or to sell or dispose of assets to raise capital may be impaired, which could have an adverse effect on our financial flexibility.

In addition, if we are unable to comply with certain financial and operating restrictions in the Amended Loan Agreement, we may be limited in our business activities and access to credit or may default under the Amended Loan Agreement. Provisions in the Amended Loan Agreement impose certain restrictions or require prior approval on our ability, and the ability of certain of our subsidiaries to, among other things:

- Incur additional debt;
- Make certain investments and acquisitions;
- Guarantee the indebtedness of others or our subsidiaries;
- Create liens or encumbrances;
- Engage in new lines of business;
- Enter into transactions with affiliates;
- Pay cash dividends and make distributions;

- Redeem or repurchase capital shares;
- Sell, lease or transfer certain parts of our business or property, including equity interests of our subsidiaries;
- Prepay other indebtedness; and
- Acquire new companies and merge or consolidate.

The Amended Loan Agreement also contains other customary covenants. We may not be able to comply with these covenants in the future. Our failure to comply with these covenants may result in the declaration of an event of default, which, if not cured or waived, may result in the acceleration of the maturity of indebtedness outstanding under the Amended Loan Agreement and would require us to pay all amounts outstanding. If the maturity of our indebtedness is accelerated, we may not have sufficient funds then available for repayment or we may not have the ability to borrow or obtain sufficient funds to replace the accelerated indebtedness on terms acceptable to us or at all. Our failure to repay our obligations under the Amended Loan Agreement would result in Oxford foreclosing on all or a portion of our assets, which could force us to curtail or cease our operations.

The amount of our future losses is uncertain and our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

Our quarterly and annual operating results may fluctuate significantly in the future due to a variety of factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and success or failure of clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- our ability to successfully recruit and retain subjects for clinical trials, and any delays caused by difficulties in such efforts;
- our ability to obtain marketing approval for our product candidates, and the timing and scope of any such approvals we may receive;
- the timing and cost of, and level of investment in, research and development activities relating to our product candidates, which may change from time to time;
- the cost of manufacturing our product candidates, which may vary depending on the difficulty of manufacture, quantity of production and the terms of our agreements with manufacturers;
- our ability to attract, hire and retain qualified personnel;
- expenditures that we will or may incur to develop our product candidates;
- the level of demand for our product candidates should they receive approval, which may vary significantly;
- the risk/benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future therapeutics that compete with our product candidates;
- general market conditions or extraordinary external events, such as recessions, inflationary and labor market pressures, changes in domestic policies, volatility and uncertainty, as well as potential volatility in the global trade markets or interest rates;
- the changing and volatile U.S. and global economic and political environments; and
- future accounting pronouncements or changes in our accounting policies.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide.

Risks Related to Research and Development and the Biopharmaceutical Industry

We have a limited operating history, which may make it difficult to evaluate our prospects and likelihood of success.

We have no products approved for commercial sale and have not generated any revenue from product sales to date. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, establishing our intellectual property portfolio and performing research and development of our product candidates and our technology related to transforming growth factor beta, or TGF-β, signaling and integrin biology, medicinal chemistry, translational screening technologies, and clinical insights to discover and develop novel therapies for the treatment of fibrosis. Our approach to the discovery and development of product candidates is unproven, and we do not know whether we will be able to develop any products of commercial value. We have not yet demonstrated the ability to progress any product candidate through clinical trials, obtain regulatory approval, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. In June 2025, we announced that we were discontinuing our development of bexotegrast in IPF. In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by early-stage biopharmaceutical companies in rapidly evolving fields. Consequently, we expect our operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control, and predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing drug products.

Our business is highly dependent on the success of the product candidates that we advance into the clinic. Our product candidates will require significant additional development before we may be able to seek regulatory approval for and launch a product commercially.

We are currently conducting a Phase 1 clinical trial of PLN-101095 in solid tumors, and PLN-101325 development for treatment of muscular dystrophies is Phase-1 ready. We have no products that are approved for commercial sale and may never be able to develop marketable products. If any of our product candidates encounter safety or efficacy problems, development delays, regulatory issues or other problems, our development plans and business would be significantly harmed. In that regard, in March 2025, we announced that we were discontinuing the BEACON-IPF Phase 2b trial following a prespecified data review and recommendation by the trial's independent DSMB, as well as a secondary review and recommendation by an outside expert panel. Subsequently, in June 2025, we announced we were discontinuing the development of bexotegrast in IPF.

Before we can generate any revenue from sales of any of our product candidates, we must undergo additional preclinical and clinical development, regulatory review, and approval in one or more jurisdictions. In addition, if one or more of our product candidates are approved, we must ensure access to sufficient commercial manufacturing capacity and conduct significant marketing efforts in connection with any commercial launch. These efforts will require substantial investment, and we may not have the financial resources to continue development of our product candidates.

We may experience setbacks that could delay or prevent regulatory approval of, or the extent of regulatory protection or our ability to commercialize, our product candidates, including:

- negative or inconclusive results from our preclinical studies or clinical trials or the clinical trials of others for product candidates similar to ours, leading to a decision or requirement to conduct additional preclinical testing or clinical trials or abandon a program;
- product-related side effects experienced by subjects in our clinical trials or by individuals using drugs or therapeutics similar to our product candidates;
- delays in submitting investigational new drug (IND) applications or comparable foreign applications or delays or failure in obtaining the necessary approvals from regulators to commence a clinical trial, or a suspension or termination of a clinical trial once commenced;
- conditions imposed by the FDA or comparable foreign authorities regarding the scope or design of our clinical trials;
- delays in enrolling subjects in clinical trials, including due to operational challenges, competition with other clinical trials or the effects of health epidemics and pandemics, such as the COVID-19 pandemic;
- high drop-out rates or screening failures of subjects from clinical trials;
- inadequate supply or quality of product candidates or other materials necessary for the conduct of our clinical trials;
- challenges manufacturing our product candidates to regulatory requirements in a cost effective manner;
- greater than anticipated clinical trial costs;
- inability to compete with other therapies;
- failure to secure or maintain orphan designation in some jurisdictions;

- poor efficacy of our product candidates during clinical trials;
- unfavorable FDA or other regulatory agency inspection and review of a clinical trial site;
- failure of our third-party contractors or investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner, or at all;
- delays and changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our technology in particular; or
- varying interpretations of data by the FDA and similar foreign regulatory agencies.

We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and our manufacturing, marketing, distribution and sales efforts or that of any future collaborator.

Our approach to drug discovery and development in the area of fibrotic diseases, with an initial focus on tissue-specific integrin modulation and TGF-β signaling inhibition, is unproven and may not result in marketable products.

Our approach to discover and develop targeted treatments for fibrosis focuses on the antagonism of tissue-specific TGF-β signaling through the inhibition of integrins known to mediate the release of activated TGF-β in fibrotic tissue. However, this mechanism has not been definitively proven to successfully treat fibrosis. Targeting integrins to treat fibrosis is a novel approach in a rapidly developing field, and there can be no assurance that we will not experience currently unknown problems or delays in developing our product candidates, that such problems or delays will not result in unanticipated costs, or that any such development problems can be solved. As a result, we may never succeed in developing a marketable product to treat fibrosis.

Clinical development involves a lengthy, complex, and expensive process, with an uncertain outcome.

To obtain the requisite regulatory approvals to commercialize any product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe and effective in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. In particular, the general approach for FDA approval of a new drug is dispositive data from two well-controlled, Phase 3 clinical trials of the relevant drug in the relevant patient population. Phase 3 clinical trials typically involve hundreds of patients, have significant costs and take years to complete. A product candidate can fail at any stage of testing, even after observing promising signals of activity in earlier preclinical studies or earlier stage clinical trials. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. For example, in March 2025, we announced that we were discontinuing the BEACON-IPF Phase 2b trial following a prespecified data review and recommendation by the trial's independent DSMB, as well as a secondary review and recommendation by an outside expert panel, and subsequently announced in June 2025 that we were discontinuing development of bexotegrast in IPF. In addition, initial success in clinical trials may not be indicative of results obtained when such trials are completed. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. A large number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials or divergent conclusions by the FDA, other regulatory agencies, IRBs, DSMBs or others in connection with such findings.

Most product candidates that commence clinical trials are never approved as products and there can be no assurance that any of our future clinical trials will ultimately be successful or support further clinical development of any of our product candidates. Product candidates that appear promising in the early phases of development may fail to reach the market for several reasons, including:

- preclinical studies or clinical trials may show the product candidates to be less effective than expected (e.g., a clinical trial could fail to meet its primary endpoint(s)) or to have unacceptable side effects or toxicities;
- failure to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful;
- failure to receive the necessary regulatory approvals;
- development of competing products in the same disease state;
- manufacturing costs, formulation issues, pricing or reimbursement issues, or other factors that make a product candidate uneconomical;
- failure or inability to perform by our third-party vendors, including vendors in foreign jurisdictions including China; and

- the proprietary rights of others and their competing products and technologies that may prevent one of our product candidates from being commercialized.

In addition, differences in trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. Further, as we rely on novel technologies including sophisticated imaging technologies to generate data relating to our clinical endpoints, there is an increased risk that we may not properly measure, analyze or interpret this data. Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval of their products. Additionally, some of our trials are open label studies, 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 typically, open label clinical trials test only the investigational product candidate and sometimes 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. 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. Therefore, it is possible that positive results observed in open label trials will not be replicated in later placebo-controlled trials.

In addition, the standards that the FDA and comparable foreign regulatory authorities use when regulating us require judgment and can change, which makes it difficult to predict with certainty how they will be applied. Although we are initially focusing our efforts on development of small molecule drug products, we are also commencing the development of biological products, including a potential candidate for muscular dystrophies, which could make us subject to additional regulatory requirements. Any analysis we perform of data from preclinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We may also encounter unexpected delays or increased costs due to new government regulations or changes in regulatory policy as a result of judicial challenges. Examples of such regulations and changes include future legislation or administrative action, or changes in FDA policy during the period of product development and FDA regulatory review. It is impossible to predict whether legislative changes will be enacted, or whether FDA or foreign regulations, guidance or interpretations will be changed, or what the impact of such changes, if any, may be. The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support approval. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain approval of any product candidates that we develop.

We must comply with numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, and if approved for marketing, pricing and third-party reimbursement. The foreign regulatory approval process varies among countries and may include all of the risks associated with FDA approval described above as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval. Approval by the FDA does not ensure approval by regulatory authorities outside the United States and vice versa.

Successful completion of clinical trials is a prerequisite to submitting a marketing application to the FDA and similar marketing applications to comparable foreign regulatory authorities, for each product candidate and, consequently, the ultimate approval and commercial marketing of any product candidates. We may experience negative or inconclusive results, which may result in our deciding, or our being required by regulators, to conduct additional clinical studies or trials or abandon some or all of our product development programs, which could have a material adverse effect on our business.

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

We may experience delays in initiating or completing clinical trials. We also may experience numerous unforeseen events during, or as a result of, any future clinical trials that could delay or prevent our ability to receive marketing approval or commercialize any product candidates, including:

- regulators, 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;
- the FDA or other comparable regulatory authorities may disagree with our clinical trial design, including with respect to dosing levels and dose selection administered in our planned clinical trials, which may delay or prevent us from initiating our clinical trials with our originally intended trial design or impact our ability to demonstrate favorable safety or efficacy traits;

- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective contract research organizations, or CROs, which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- the number of subjects required for clinical trials of any product candidates may be larger than we anticipate or subjects may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;
- we may experience delays or interruptions to our manufacturing supply chain, or we could suffer delays in reaching, or we may fail to reach, agreement on acceptable terms with third-party service providers on whom we rely;
- additional delays and interruptions to our clinical trials could extend the duration of the trials and increase the overall costs to finish the trials as our fixed costs are not substantially reduced during delays;
- we may elect to, or regulators, IRBs, DSMBs, or ethics committees may require that we or our investigators suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- we may not have the financial resources available to begin and complete the planned trials, or the cost of clinical trials of any product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate to initiate or complete a given clinical trial; and
- the FDA or other comparable foreign 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.

Our product development costs will increase if we experience additional delays in clinical testing or in obtaining marketing approvals. We do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. If we do not achieve our product development goals in the timeframes we announce and expect, the approval and commercialization of our product candidates may be delayed or prevented entirely. In addition, significant clinical trial delays could shorten any periods during which we may have the exclusive right to commercialize our product candidates and may allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates and harming our business and results of operations. Any delays in our clinical development programs may harm our business, financial condition, and results of operations significantly.

Our ongoing and future clinical trials may reveal significant adverse events or unexpected drug-drug interactions not seen in our preclinical studies and may result in a safety profile that could delay or prevent regulatory approval or market acceptance of any of our product candidates.

If significant adverse events or other side effects are observed in any of our ongoing or future clinical trials, we may have difficulty recruiting patients to our clinical trials, patients may drop out of our trials, or we may be required to abandon the trials or our development efforts altogether. In March 2025, we announced that we were discontinuing the BEACON-IPF Phase 2b trial following a prespecified data review and recommendation by the trial's independent DSMB, as well as a secondary review and recommendation by an outside expert panel due to an imbalance in safety events between treatment and placebo groups. We subsequently announced in June 2025 that we were discontinuing development of bexotegrast in IPF. We may also encounter unexpected drug-drug interactions in our ongoing or planned trials, and may be required to further test our candidates, including additional drug-drug interaction studies, which may be expensive, time consuming and result in delays to our programs.

Some potential therapeutics developed in the biopharmaceutical industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance of the approved product due to its tolerability versus other therapies.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. The enrollment of patients depends on many factors, including:

- the patient eligibility and exclusion criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints and the process for identifying patients;
- the willingness or availability of patients to participate in our trials;
- the proximity of patients to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating or other studies enrolling for similar diseases;
- the availability of competing commercially available therapies and other competing product candidates' clinical trials;
- our ability to obtain and maintain patient informed consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

Our clinical trials compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. 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 will reduce the number of patients who are available for our clinical trials in such clinical trial site.

Additionally, the FDA may modify or enhance trial requirements, which may affect enrollment. For example, in August 2023, the FDA published a guidance document, "Informed Consent, Guidance for IRBs, Clinical Investigators, and Sponsors," which supersedes past guidance and finalizes draft guidance on informed consent. Further, in December 2023, the FDA published a final rule, "Institutional Review Board Waiver or Alteration of Informed Consent for Minimal Risk Clinical Investigations," which allows exceptions from informed consent requirements when a clinical investigation poses no more than minimal risk to the human subject and includes appropriate safeguards to protect the rights, safety, and welfare of human subjects. The FDA's new guidance and rulemaking present evolving requirements for informed consent which may affect recruitment and retention of patients in clinical trials. Effects on recruitment and retention of patients may hinder or delay a clinical trial and could cause a significant setback to an applicable program.

The design or execution of our ongoing and future clinical trials may not support marketing approval.

The design or execution of a clinical trial can determine whether its results will support marketing approval, and flaws in the design or execution of a clinical trial may not become apparent until the clinical trial is well advanced.

Additionally, in some instances, there can be significant variability in safety or efficacy results between different trials with the same product candidate due to numerous factors, including differences in trial protocols, size and type of the patient populations, variable adherence to the dosing regimen or other protocol requirements and the rate of dropout among clinical trial participants. We do not know whether any clinical trials we conduct will demonstrate consistent or adequate efficacy and safety to obtain marketing approval to market our product candidates. For example, in March 2025, we announced that we were discontinuing the BEACON-IPF Phase 2b trial following a prespecified data review and recommendation by the trial's independent DSMB, as well as a secondary review and recommendation by an outside expert panel. We subsequently announced in June 2025 that we were discontinuing our development of bexotegrast in IPF.

Further, the FDA and comparable foreign regulatory authorities have substantial discretion in the approval process and in determining when or whether marketing approval will be obtained for any of our product candidates. Our product candidates may not be approved even if they achieve their primary endpoints in future Phase 3 clinical trials or registrational trials. The FDA or comparable foreign regulatory authorities may disagree with our trial designs and our interpretation of data from preclinical studies or clinical trials. Moreover, clinical data are often susceptible to varying interpretations and analyses, including by the FDA, comparable foreign regulatory authorities, IRBs or DSMBs interpreting such data. Further, requirements regarding clinical trial data may evolve. In June 2023, the FDA published draft guidance, which seeks to unify standards for clinical trial data for International Council for Harmonisation of Technical Requirements of Pharmaceuticals for Human Use, or ICH member countries and regions. Changes to data requirements may cause the FDA or comparable foreign regulatory authorities to disagree with data from preclinical studies or clinical trials, and may require further studies.

In addition, any of these regulatory authorities may change requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a pivotal Phase 3 or registrational clinical trial. Further, any of these regulatory authorities may also approve a product candidate for fewer or more limited indications than we request or may grant approval contingent on the performance of costly post-marketing clinical trials. The FDA or comparable foreign regulatory authorities may not approve the labeling claims that we believe would be necessary or desirable for the successful commercialization of our product candidates, if approved.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our future clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

We may be unable to obtain and maintain orphan drug designation for our product candidates and, even if we obtain such designation, we may not be able to realize the benefits of such designation, including potential marketing exclusivity of our product candidates, if approved.

Regulatory authorities in some jurisdictions, including the United States and other major markets, may designate drugs intended to treat conditions or diseases affecting relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, the FDA may designate a product candidate as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as having a patient population of fewer than 200,000 individuals 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 order to obtain orphan designation in the European Economic Area (EEA) and the U.K., the product must fulfill certain challenging criteria. Under Article 3 of Regulation (EC) 141/2000 in the EU, and Regulation 50G of the Human Medicines Regulation 2012 in the U.K., a medicinal product may be designated as an orphan medicinal product if it meets the following criteria: (1) such product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either the prevalence of such condition must not be more than five in 10,000 persons in the territory of the EU or U.K. (as applicable) when the application is made, or without the benefits derived from orphan status, it must be unlikely that the marketing of the medicine would generate sufficient return in the EU or U.K. to justify the investment needed for its development; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU or U.K. or if such a method exists, the product will be of significant benefit to those affected by the condition, as defined in Regulation (EC) 847/2000. In the EEA, the grant of the orphan designation does not mean that the product will be granted orphan status at the time it is assessed in parallel with the application for a marketing authorization. The authorities reassess then whether the product still fulfills the criteria for orphan status.

Should we seek orphan drug designation for one or more of our future product candidates, we may be unable to obtain and maintain such designation. Even if we obtain such designation, the designation of any of our product candidates as an orphan drug does not mean that any regulatory agency will accelerate regulatory review of, or ultimately approve, that product candidate, nor does it limit the ability of any regulatory agency to grant orphan drug designation to product candidates of other companies that treat the same indications as our product candidates.

Generally, if a product candidate with an orphan drug designation receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or foreign regulatory authorities from approving another marketing application for a product that constitutes a similar medicinal product treating the same indication for that marketing exclusivity period, except in limited circumstances. The applicable period is seven years in the United States and ten years in the EEA. The ten-year period of market exclusivity in the EEA can be extended by a further two years if the product qualifies for a pediatric extension, but can be reduced to a period of six years if the orphan designation criteria are no longer met after the fifth year. Orphan drug exclusivity may be revoked if any regulatory agency determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of patients with the rare disease or condition. On April 26, 2023, the European Commission adopted a proposal for a new Regulation set to replace Regulation (EC) No 726/2004 and a new Directive replacing Directive 2001/83 on the Community Code relating to medicinal products for human use. On June 4, 2025, the Council of the EU adopted its position on the European Commission's proposed reforms and will enter into negotiations with the European Parliament to reach an agreement on the reforms. If made into law, the proposals will revise and replace the existing general pharmaceutical legislation and may make it more difficult to obtain orphan designation in the EEA.

Even if we obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the product candidate from competition because different drugs with different active moieties can be approved for the same condition in the United States or EEA. Even after an orphan drug is approved, the FDA or EMA, as applicable, may subsequently approve another drug with the same active moiety for the same condition if the FDA concludes that the latter drug is not a similar medicinal product or is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

In addition, Congress is considering updates to the orphan drug provisions of the Food, Drug, and Cosmetic Act, or FDCA, in response to a recent decision by the U.S. Court of Appeals for the Eleventh Circuit. Any changes to the orphan drug provisions could change our opportunities for, or likelihood of success in obtaining, orphan drug exclusivity and would materially adversely affect our business, results of operations, financial condition and prospects.

A Fast Track designation by the FDA, even if granted for current or future product candidates, may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that our product candidates will receive marketing approval.

We may seek Fast Track designation for one or more of our future product candidates. If a drug product is intended for the treatment of a serious or life-threatening disease or condition and it demonstrates the potential to address unmet medical needs for such a disease or condition, the drug sponsor may apply for FDA Fast Track designation for a particular indication. We may seek Fast Track designation for our product candidates, but there is no assurance that the FDA will grant this designation to any of our proposed product candidates. Marketing applications submitted by sponsors of products in Fast Track development may qualify for priority review under the policies and procedures offered by the FDA, but the Fast Track designation does not assure any such qualification or ultimate marketing licensure by the FDA. The FDA has broad discretion whether or not to grant Fast Track 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. Even if we do receive Fast Track designation, we may not experience a faster development process, review or licensure compared to conventional FDA procedures or pathways and receiving a Fast Track designation does not provide assurance of ultimate FDA licensure. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. In addition, the FDA may withdraw any Fast Track designation at any time.

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

As product candidates progress through preclinical to late-stage clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield, manufacturing batch size, minimize costs and achieve consistent quality and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commercialize our product candidates and generate revenue.

In addition, there are risks associated with large scale manufacturing for clinical trials or commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, compliance with good manufacturing practices, lot consistency and timely availability of raw materials. Even if we obtain marketing approval for any of our product candidates, there is no assurance that our manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other comparable foreign regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential commercial launch of the product or to meet potential future demand. Additionally, if we advance a biological candidate into IND-enabling studies, the manufacturing processes for biological products is more complex and expensive than with small molecule products and additional manufacturing suppliers may be needed to manufacture clinical supplies for these programs. If our manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

We may not be successful in our efforts to identify or discover additional product candidates in the future.

Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including:

- our inability to design such product candidates with the pharmacological properties that we desire or attractive pharmacokinetics; or
- potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be medicines that will receive marketing approval and achieve market acceptance.

Research programs to identify new product candidates require substantial technical, financial, and human resources. If we are unable to identify suitable compounds for preclinical and clinical development, we will not be able to obtain product revenue in future periods, which likely would result in significant harm to our financial position and adversely impact our stock price.

Due to our limited resources and access to capital, we must make decisions on the allocation of resources to certain programs and product candidates; these decisions may prove to be wrong and may adversely affect our business.

We have limited financial and human resources and intend to initially focus on research programs and product candidates for a limited set of indications. As a result, we may forgo or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. In addition, we seek to accelerate our development timelines, including by initiating certain clinical trials of our product candidates before earlier-stage studies have been completed. This approach may cause us to commit significant resources to prepare for and conduct later-stage trials for one or more product candidates that subsequently fail earlier-stage clinical testing. Therefore, our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities or expend resources on product candidates that are not viable.

There can be no assurance that we will ever be able to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, which could materially adversely affect our future growth and prospects. We may focus our efforts and resources on potential product candidates or other potential programs that ultimately prove to be unsuccessful.

If product liability lawsuits are brought against us, we may incur substantial financial or other liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability as a result of testing any of our product candidates in clinical trials and will face an even greater risk if we commercialize any products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical trials, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- inability to bring a product candidate to the market;
- decreased demand for our products;
- injury to our reputation;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- initiation of investigations by regulators;
- fines, injunctions or criminal penalties;
- costs to defend the related litigation;
- diversion of management's time and our resources;
- substantial monetary awards to trial participants;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any product candidate, if approved; and
- decline in our share price.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We will need to obtain additional insurance for clinical trials as product candidates continue clinical development and as additional product candidates may enter the clinic. However, we may be unable to obtain, or may obtain on unfavorable terms, clinical trial insurance in amounts adequate to cover any liabilities from any of our clinical trials. Our insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

We face substantial competition, which may result in others discovering, developing, or commercializing products before or more successfully than us.

The development and commercialization of new drug products is highly competitive. We may face competition with respect to any product candidates that we seek to develop or commercialize in the future from major biopharmaceutical companies, specialty biopharmaceutical companies, and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization.

There are a number of biopharmaceutical and biotechnology companies that are currently pursuing the development of products for the treatment of fibrosis. Companies that we are aware of that are targeting the treatment of various fibrosis indications through inhibiting various parts of the TGF-β pathway include companies with significant financial resources such as AbbVie Inc., AstraZeneca plc, Bristol Myers Squibb Co., Corbus Pharmaceutical, Merck & Co., Inc., Eli Lilly & Company, Novartis AG, Scholar Rock, Inc., and Takeda Pharmaceutical Company.

Many of our current or potential competitors, either alone or with their strategic partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do.

Mergers and acquisitions in the biopharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, more convenient or less expensive than any products that we may develop. Furthermore, products currently approved for other indications could be discovered to be effective treatments of fibrosis as well, which could give such products significant regulatory and market timing advantages over product candidates that we may identify. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, products or technologies developed by our competitors may render our potential product candidates uneconomical or obsolete and we may not be successful in marketing any product candidates we may develop against competitors. The availability of competitive products could limit the demand, and the price we are able to charge, for any products that we may develop and commercialize.

The biopharmaceutical industry is subject to extensive regulatory obligations and policies that may be subject to significant and abrupt change, including due to judicial challenges, election cycles, and resulting regulatory updates and changes in policy priorities.

In June 2024, the U.S. Supreme Court issued an opinion holding that courts reviewing agency action pursuant to the Administrative Procedure Act (APA) "must exercise their independent judgment" and "may not defer to an agency interpretation of the law simply because a statute is ambiguous." The decision will have a significant impact on how lower courts evaluate challenges to agency interpretations of law, including those by the FDA, the U.S. Department of Health and Human Services (HHS), the Centers for Medicare and Medicaid Services (CMS) and other agencies with significant oversight of the biopharmaceutical industry. The new framework may increase both the frequency of such challenges and their odds of success by eliminating one way in which the government previously prevailed in such cases. As a result, significant regulatory policies may be subject to increased litigation and judicial scrutiny.

In addition, federal agency priorities, leadership, policies, rulemaking, communications, spending, and staffing may be significantly impacted by election cycles. For example, the current U.S. presidential administration has committed to significantly reduce government spending through cuts to federal healthcare programs and reductions in the workforces of key government agencies, such as HHS, FDA, and CMS. Efforts by the current administration to further limit federal agency budgets may result in reduced agency workforces and/or changes in agency operations, which may lead to slower response times and longer review periods, potentially affecting our ability to progress development of our product candidates or obtain regulatory approval for our product candidates.

Risks Related to Marketing, Reimbursement, Healthcare Regulations and Ongoing Regulatory Compliance

Even if a product candidate we develop receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

Even if any product candidate we develop receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients and third-party payors. In addition, the availability of coverage by third-party payors may be affected by existing and future healthcare reform measures designed to reduce the cost of health care. If the product candidates we develop do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable.

The degree of market acceptance of any product candidate, if approved for commercial sale, will depend on a number of factors, including:

- efficacy and potential advantages compared to alternative treatments;
- the ability to offer our products, if approved, for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the recommendations with respect to our product candidates in guidelines published by various scientific organizations applicable to us and our product candidates;
- positive health technology assessment (HTA) in jurisdictions where required;
- the strength of marketing and distribution support;
- the ability to obtain sufficient third-party coverage and adequate reimbursement and a positive recommendation by health technology bodies; and
- the prevalence and severity of any side effects.

If government and other third-party payors do not provide coverage and adequate reimbursement levels for any products we commercialize, market acceptance and commercial success would be reduced.

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

Significant uncertainty exists as to the coverage and reimbursement status of any products for which we may obtain regulatory approval. In the United States, sales of any products for which we may receive regulatory marketing approval will depend, in part, on the availability of coverage and adequacy of reimbursement from third-party payors. Third-party payors include government authorities such as Medicare, Medicaid, TRICARE, and the Veterans Administration, managed care providers, private health insurers, and other organizations. Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors are critical to new product acceptance. Patients are unlikely to use our product candidates unless coverage is provided, and reimbursement is adequate to cover a significant portion of the cost. We cannot be sure that coverage and adequate reimbursement will be available for any product that we may develop and, if reimbursement is available, what the level of reimbursement will be.

Government authorities and other third-party payors 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 as well as foreign jurisdictions, no uniform policy of coverage and reimbursement for products exists among third-party payors.

Coverage and reimbursement for products may vary depending on the payor, the insurance plan, and other factors. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to

achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of product candidates, once approved. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates, if approved.

A primary trend in the United States and European health care industries is toward cost containment, as legislative bodies, government authorities, third-party payors, and others have attempted to control costs by limiting coverage, pricing and the amount of reimbursement available for certain treatments. Such third-party payors, including Medicare, may question the coverage of, and challenge or seek to lower the prices charged for, medical products, and many third-party payors limit coverage and reimbursement for newly approved health care products. Moreover, reimbursement, if available, may vary according to the use of the product and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost products and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors or by future laws, regulations, or guidance seeking to limit prescription drug prices. If we are unable to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop, or if net prices are reduced by mandatory discounts or rebates, there could be a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Changes to current healthcare laws and state and federal healthcare reform measures that may be adopted in the future that impact coverage and reimbursement for drug or biologic products may result in additional payment reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used. For additional details regarding healthcare reform measures, see the discussion in the risk factor under the heading "Ongoing healthcare legislative and regulatory reform measures may have a material adverse effect on our business and results of operations."

Even if we obtain FDA approval of any of our product candidates, we may never obtain approval or commercialize such products outside of the United States, which would limit our ability to realize their full market potential.

In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approvals could result in significant delays, difficulties, and costs for us and may require additional preclinical studies or clinical trials which would 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. Satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. 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, our ability to realize the full market potential of our products will be harmed.

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

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

commercializing our products, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses.

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

Healthcare providers, physicians, third-party payors, and other potential referral sources in the United States and elsewhere play a primary role in the distribution, recommendation and prescription of biopharmaceutical products. Arrangements with third-party payors and customers can expose biopharmaceutical manufacturers to broadly applicable fraud and abuse and other healthcare laws and regulations, as detailed in Part I, Item 1 - Business - Government Regulation - Other Healthcare Laws of the 2024 Form 10-K. In particular, the research of our product candidates, as well as the promotion, sales and marketing of healthcare items and services, and certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs, remuneration provided to health care professionals and their affiliates, charitable donations, interactions with entities excluded from participation in government healthcare programs, and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials.

The distribution of biopharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of biopharmaceutical products.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment. Ensuring business arrangements comply with applicable healthcare laws can be time- and resource-consuming.

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

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

If any of our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, pharmacovigilance, 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 current Good Manufacturing Practice, or cGMP, and GCP requirements for any clinical trials that we conduct post-approval.

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

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a risk evaluation and mitigation strategies, or REMS, program as a condition of approval

of our product candidates, which could entail requirements for long-term patient follow-up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, we will have to comply with requirements including submissions of safety and other post-marketing information and reports and registration.

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

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

The FDA strictly regulates marketing, labeling, advertising, and promotion of products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. However, companies may share truthful and not misleading information that is not inconsistent with the labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses and a company that is found to have improperly promoted off-label uses may be subject to significant liability. The policies of the FDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

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

In the United States and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our ability to profitably sell any product candidates for which we obtain marketing approval or licensure. Changes in regulations, statutes or the interpretation of existing regulations governing the regulatory approval or licensure, manufacture, and marketing of regulated products or the pricing, coverage and reimbursement thereof could impact our business in the future by resulting in, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; (iv) more rigorous coverage criteria or additional downward pressure on the price that we receive for product candidates for which we obtain marketing approval; or (v) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs, as detailed in Part I, Item 1 – Business – Government Regulation – Current and Future Healthcare Reform Legislation of the 2024 Form 10-K. For example, in August 2022, former President Biden signed into law the Inflation Reduction Act, or IRA, which implements substantial changes to the Medicare program, including drug pricing reforms and changes to the Medicare Part D benefit design.

Among other reforms, the IRA imposes inflation rebates on drug manufacturers for products reimbursed under Medicare Parts B and D if the prices of those products increase faster than inflation; implements changes to the Medicare Part D benefit that, beginning in 2025, will cap patient annual out-of-pocket spending at $2,000, while imposing new discount obligations for pharmaceutical manufacturers and payors; and, beginning in 2026, establishes a “maximum fair price” for a fixed number of

high spend pharmaceutical and biological products that are selected by CMS and covered under Medicare Parts B and D following a price negotiation process with the agency. Under the current statute, for a drug product to be considered a qualifying single source drug that may be selected by CMS for price negotiation under the "maximum fair price" program, at least seven years must have elapsed since the biological product was licensed by the FDA. For a biological product to be considered a qualifying single source drug that may be selected by CMS for price negotiation, at least eleven years must have elapsed since the biological product was licensed by the FDA. However, the current administration has expressed interest in working with Congress to align the treatment of small molecule prescription drugs with that of biological products.

When originally enacted, the IRA explicitly excluded from price negotiation orphan drugs designated for only one rare disease or condition and for which the only active approved indication is for such disease or condition. However, the One Big Beautiful Bill Act signed into law on July 4, 2025 amended the applicable statute to broaden the orphan drug exclusion such that products with more than one orphan designation and more than one approved indication will remain exempt from price negotiations, so long as each approved indication is for a rare disease or condition.

Since its enactment, the CMS has taken steps to implement various drug pricing provisions of the IRA. This includes, without limitation, releasing the negotiated maximum prices, which will be effective in 2026, for the first ten drugs that were subject to the IRA's negotiation process, releasing quarterly lists of Medicare Part B products that are subject to adjusted coinsurance rates based on the inflationary rebate provisions of the IRA, and announcing a list of 15 additional drugs that will be subject to price negotiations during 2025. While it remains to be seen how the drug pricing provisions imposed by the IRA will affect the broader pharmaceutical industry (including orphan drug or small molecule development), several pharmaceutical manufacturers and other industry stakeholders have challenged the law, including through lawsuits brought against the HHS, the Secretary of HHS, CMS, and the CMS Administrator challenging the constitutionality and administrative implementation of the IRA's drug price negotiation provisions. We cannot predict whether the IRA, or any of its component parts, will be overturned, repealed, replaced, or amended nor can we predict the likelihood, nature, or extent of other health reform initiatives that may arise from future legislation and/or executive or administrative action. However, we expect these initiatives to increase pressure on drug pricing. Further, certain broader legislation that is not targeted to the healthcare industry may nonetheless adversely affect our profitability. Moreover, the healthcare regulatory landscape can also be affected by election cycles and any resulting changes in healthcare policy priorities. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

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

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

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, or if global health concerns 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 to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Drug marketing and reimbursement regulations may materially affect our ability to market and secure reimbursement for our products.

We intend to seek approval to market our product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the EU, the pricing of drugs is subject to governmental control and other market regulations which could put pressure on the pricing and usage of our product candidates. As of January 2025, Regulation No 2021/2282 on Health Technology Assessment (HTA Regulation) is applicable in the EU. The HTA Regulation intends to foster cooperation among EU member states in assessing health technologies and provide the

basis for cooperation at EU level for joint clinical assessments. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. Furthermore, in many European countries (including the U.K.), effective access to the market depends on whether the product obtains a positive recommendation from the relevant health technology assessment body. In addition, market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our product candidates and may be affected by existing and future health care reform measures.

Much like the federal Anti-Kickback Statute prohibition in the United States, the provision of benefits or advantages to induce or reward improper performance generally to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the EU. The provision of benefits or advantages to induce or reward improper performance generally is governed by the national anti-bribery laws of EU Member States, and in respect of the U.K. (which is no longer a member of the EU), the Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment. EU Directive 2001/83/EC, which is the EU Directive governing medicinal products for human use, further provides that, where medicinal products are being promoted to persons qualified to prescribe, recommend, use, procure or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy. This provision has been transposed into the Human Medicines Regulations 2012 and so remains applicable in the U.K. despite its departure from the EU.

Payments made to physicians in certain EU Member States and more generally throughout Europe (including the U.K.) and other countries must be publicly disclosed under applicable transparency provisions. 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 and/or the regulatory authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

In addition, in most foreign countries, including those within the EEA, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement are the prerogative of the Member States and vary widely from country to 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. Reference pricing used by various EU Member States and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. 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. In some countries, we may be required to conduct a clinical study or other studies that compare the cost-effectiveness of any of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. There can be no assurance that any country that has price controls or reimbursement limitations for biopharmaceutical products will allow or maintain favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the EU do not follow price structures of the United States and generally prices tend to be significantly lower. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of our products is unavailable or limited in scope or amount, our revenues from sales and the potential profitability of any of our product candidates in those countries would be negatively affected.

Additional laws and regulations governing international operations could negatively impact or restrict our operations.

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

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

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information products classified for national security purposes, as well as certain products, technology and technical data relating to those products. If we expand our presence outside of the United States, it

will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

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

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

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

Risks Related to Our Intellectual Property

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

Our business will depend in large part on obtaining and maintaining patent, IP regulatory rights (such as data exclusivity, marketing exclusivity and patent extensions) trademark and trade secret protection of our proprietary technologies and our product candidates, their respective components, synthetic intermediates, formulations, combination therapies, methods used to manufacture them and methods of treatment, as well as successfully defending these patents against third-party challenges. Our ability to stop unauthorized third parties from making, using, selling, offering to sell or importing our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents that cover these activities and whether a court would issue an injunctive remedy. If we are unable to secure and maintain patent protection for any product or technology we develop, or if the scope of the patent protection secured is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to commercialize any product candidates we may develop may be adversely affected.

The patenting process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, we may not pursue, obtain, or maintain patent protection in all relevant markets. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties and are reliant on our licensors or licensees.

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

We cannot be certain that we were the first to file any patent application related to our technology, including our product candidates, and, if we were not, we may be precluded from obtaining patent protection for our technology, including our product candidates.

We cannot be certain that we were the first to invent the inventions covered by pending patent applications and, if we are not, we may be subject to priority disputes. Furthermore, for United States applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third-party or instituted by the United

States Patent and Trademark Office, or USPTO, to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. Similarly, for United States applications in which at least one claim is not entitled to a priority date before March 16, 2013, derivation proceedings can be instituted to determine whether the subject matter of a patent claim was derived from a prior inventor's disclosure.

We may be required to disclaim part or all of the term of certain patents or all of the term of certain patent applications. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent or patent application claim. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. No assurance can be given that if challenged, our patents would be declared by a court to be valid or enforceable or that even if found valid and enforceable, would adequately protect our product candidates, or would be found by a court to be infringed by a competitor's technology or product. We may analyze patents or patent applications of our competitors that we believe are relevant to our activities and consider that we are free to operate in relation to our product candidates, but our competitors may obtain issued claims, including in patents we consider to be unrelated, which block our efforts or may potentially result in our product candidates or our activities infringing such claims. The possibility exists that others will develop products which have the same effect as our products on an independent basis which do not infringe our patents or other intellectual property rights or will design around the claims of patents that may issue that cover our products.

Recent or future patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. Under the Leahy-Smith America Invents Act, or America Invents Act, enacted in 2013, the United States moved from a "first to invent" to a "first-to-file" system. Under a "first-to-file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. The America Invents Act includes a number of other significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted, redefine prior art and establish a new post-grant review system. The America Invents 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 and financial condition.

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

- others may be able to make or use compounds that are similar to the compositions of our product candidates but that are not covered by the claims of our patents or those of our licensors;
- we or our licensors, as the case may be, may fail to meet our obligations to the U.S. government in regards to any in-licensed patents and patent applications funded by U.S. government grants, leading to the loss of patent rights;
- we or our licensors, as the case may be, might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that our pending patent applications will not result in issued patents;
- we may not be able to extend the patent term in some jurisdictions;
- it is possible that there are prior public disclosures that could invalidate our or our licensors' patents, as the case may be, or parts of our or their patents;
- it is possible that others may circumvent our owned or in-licensed patents or regulatory intellectual property rights such as our data protection, orphan market exclusivity and others;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products or technology similar to ours;
- the laws of foreign countries may not protect our or our licensors', as the case may be, proprietary rights to the same extent as the laws of the United States;
- the claims of our owned or in-licensed issued patents or patent applications, if and when issued, may not cover our product candidates;
- our owned or in-licensed issued patents may not provide us with any competitive advantages, may be narrowed in scope, or be held invalid or unenforceable as a result of legal challenges by third parties;

- the inventors of our owned or in-licensed patents or patent applications may become involved with competitors, develop products or processes which design around our patents, or become hostile to us or the patents or patent applications on which they are named as inventors;
- it is possible that our owned or in-licensed patents or patent applications omit individual(s) that should be listed as inventor(s) or include individual(s) that should not be listed as inventor(s), which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable;
- we have engaged in scientific collaborations in the past and will continue to do so in the future. Such collaborators may develop adjacent or competing products to ours that are outside the scope of our patents;
- we may not develop additional proprietary technologies for which we can obtain patent protection;
- it is possible that product candidates or diagnostic tests we develop may be covered by third parties' patents or other exclusive rights; or
- the patents of others may have an adverse effect on our business.

We may enter into license or other collaboration agreements that may impose certain obligations on us. If we fail to comply with our obligations under such agreements with third parties, we could lose license rights that may be important to our future business.

In connection with our efforts to expand our pipeline of product candidates, we may enter into certain licenses or other collaboration agreements pertaining to the in-license of rights to additional candidates. Such agreements may impose various diligence, milestone payment, royalty, insurance, or other obligations on us, subject to antitrust law restrictions. If we fail to comply with these obligations, our licensor or collaboration partners may have the right to terminate the relevant agreement, in which event we would not be able to develop or market the products covered by such licensed intellectual property.

Moreover, disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our product candidates, technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

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

In addition, we may have limited control over the maintenance and prosecution of these in-licensed patents and patent applications, or any other intellectual property that may be related to our in-licensed intellectual property. For example, we cannot be certain that such activities by any future licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We have limited control over the manner in which our licensors initiate an infringement proceeding against a third-party infringer of the intellectual property rights or defend certain of the intellectual property that is licensed to us. It is possible that the licensors' infringement proceeding, or defense activities may be less vigorous than had we conducted them ourselves.

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

In addition to patent protection, we rely heavily upon know-how and trade secret protection, as well as non-disclosure agreements and invention assignment agreements with our employees, consultants and third parties, to protect our confidential and proprietary information, especially where we do not believe patent protection is appropriate or obtainable. In addition to

contractual measures, we try to protect the confidential nature of our proprietary information using physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee or third-party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets 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 illegally disclosed or misappropriated a trade secret can be difficult, expensive, and time consuming, and the outcome is unpredictable. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. For example, our clinical development strategy includes the testing of live tissue samples, and our techniques for preserving and testing these samples are proprietary and confidential. If one or more third parties obtain or are otherwise able to replicate these techniques, an important feature and differentiator of our clinical development strategy will become available to potential competitors. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our competitive position could be harmed.

In addition, courts outside the United States are sometimes less willing to protect trade secrets. If we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology.

Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed by or made known to the individual or entity during the course of the party's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary technology by third parties. We have also adopted policies and conduct training that provides guidance on our expectations, and our advice for best practices, in protecting our trade secrets.

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

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

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

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

- if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights for our products and any license that is available may be non-exclusive, which could result in our competitors gaining access to the same intellectual property; and
- redesigning our product candidates or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition, and prospects. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure.

Our collaborators may assert ownership or commercial rights to inventions they develop from research we support or that we develop from our use of the tissue samples or other biological materials, which they provide to us, or otherwise arising from the collaboration.

We collaborate with several institutions, universities, medical centers, physicians, and researchers in scientific matters and expect to continue to enter into additional collaboration agreements. In certain cases, we do not have written agreements with these collaborators, or the written agreements we have do not cover intellectual property rights. Also, we rely on numerous third parties to provide us with tissue samples and biological materials that we use to conduct our research activities and develop our product candidates. If we cannot successfully negotiate sufficient ownership and commercial rights to any inventions that result from our use of a third-party collaborator's materials, or if disputes arise with respect to the intellectual property developed with the use of a collaborator's samples, or data developed in a collaborator's study, we may be limited in our ability to capitalize on the market potential of these inventions or developments.

Third parties may assert that we are employing their proprietary technology without authorization.

There may be third-party patents of which we are currently unaware with claims to compositions of matter, materials, formulations, methods of manufacture or methods for treatment that encompass the composition, use or manufacture of our product candidates. There may be currently pending patent applications of which we are currently unaware which may later result in issued patents that our product candidates or their use or manufacture may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patent were held by a court of competent jurisdiction to cover our product candidates, intermediates used in the manufacture of our product candidates or our materials generally, aspects of our formulations or methods of use, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business. Even if we obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

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

Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.

As is common in the biotechnology and biopharmaceutical industries, we employ individuals who were previously employed at universities or other biotechnology or biopharmaceutical companies, including our competitors or potential

competitors. Although no claims against us are currently pending, and although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property related proceedings could adversely affect our ability to compete in the marketplace.

We may not be successful in obtaining or maintaining necessary rights to develop any future product candidates on acceptable terms.

Because our programs may involve product candidates that may require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights.

Our product candidates may also require specific formulations to work effectively and efficiently, and these rights may be held by others. We may develop products containing our compounds and pre-existing biopharmaceutical compounds. We may be unable to acquire or in-license any compositions, methods of use, processes, or other third-party intellectual property rights from third parties that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm our business. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

Additionally, we sometimes collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. In certain cases, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of such program and our business and financial condition could suffer.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and companies, which may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire.

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

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

We may choose to challenge the patentability of claims in a third party's U.S. patent by requesting that the USPTO review the patent claims in an ex-parte re-examination, inter partes review or post-grant review proceedings. These proceedings are expensive and may consume our time or other resources. We may choose to challenge a third party's patent in patent opposition proceedings in the European Patent Office, or EPO, or other foreign patent office.

The costs of these opposition proceedings could be substantial and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO or other patent office then we may be exposed to litigation by a third party alleging that the patent may be infringed by our product candidates or proprietary technologies.

In addition, because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our owned and in-licensed issued patents or our pending applications, or that we or, if applicable, a licensor were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering our products or technology similar to ours. Any such patent application may have priority over our owned and in-licensed patent applications or patents, which could require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to those owned by or in-licensed to us, we or, in the case of in-licensed technology, the licensor may have to participate in an interference or derivation proceeding declared by the USPTO to determine priority of invention in the United States. If we or one of our licensors is a party to an interference or derivation proceeding involving a U.S. patent application on inventions owned by or in-licensed to us, we may incur substantial costs, divert management's time and expend other resources, even if we are successful.

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

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

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

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent application process and following the issuance of a patent. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In certain circumstances, even inadvertent noncompliance events may permanently and irrevocably jeopardize patent rights. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

Any patents covering our product candidates could be found invalid or unenforceable if challenged in court or the USPTO (or foreign patent offices).

If we or one of our licensors 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, as applicable, is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, inter partes review, post grant review, and equivalent proceedings in

foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, or if we are otherwise unable to adequately protect our rights, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and product candidates.

Our earliest patents may expire before, or soon after, our first product achieves marketing approval in the United States or foreign jurisdictions. Upon the expiration of our current patents, we may lose the right to exclude others from practicing these inventions. The expiration of these patents could also have a similar material adverse effect on our business, results of operations, financial condition and prospects. We own pending patent applications covering our proprietary technologies or our product candidates that if issued as patents are expected to expire from 2037 through 2045, without taking into account any possible patent term adjustments or extensions. However, we cannot be assured that the USPTO, EPO or other relevant foreign patent offices will grant any of these patent applications.

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

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 16, 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. On March 16, 2013, under the America Invents Act, enacted in September 2011, the United States transitioned to a first inventor to file system. A third party that files a patent application in the USPTO on or after March 16, 2013, but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our or our licensor's patents or patent applications.

The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter-partes review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned or in-licensed patent applications and the enforcement or defense of our owned or in-licensed issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, the patent positions of companies in the development and commercialization of biopharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts, the USPTO, and courts or legislative bodies in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

We have limited foreign intellectual property rights and may not be able to protect our intellectual property rights throughout the world.

We have limited intellectual property rights outside the United States. Filing, prosecuting, and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions.

Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of, and may require a compulsory license to, patents, trade secrets and other intellectual property protection, particularly those relating to biopharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products against third parties in violation of our proprietary rights generally. The initiation of proceedings by third parties to challenge the scope or validity of our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions such as patent term adjustments and/or extensions, may be available, but 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, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

At the EU level, the Court of Justice of the EU (CJEU), has recently narrowed the availability of patent term extension for second medical use therefore affecting the scope of patent protection available.

If we do not obtain patent term extension, data exclusivity and orphan exclusivity for any product candidates we may develop, our business may be materially harmed.

Depending upon the timing, duration, and specifics of any FDA or foreign marketing approval of any product candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984 Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for 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 product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing 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 period or the scope of patent protection afforded could be less than we request. In addition, within the EU, regulatory protections afforded to medicinal products such as data exclusivity, marketing protection, market exclusivity for orphan indications and pediatric extensions are currently under review and is likely to be curtailed in future years. On April 26, 2023, the European Commission adopted a proposal for a new Regulation set to replace Regulation (EC) No 726/2004 and a new Directive replacing Directive 2001/83 on the Community Code relating to medicinal products for human use. If made into law, this proposal will revise and replace the existing general pharmaceutical legislation and will affect the existing period of regulatory protection afforded to medicinal products in the European Union. If we are unable to obtain patent term extension or the term of any such extension is less than we request, or if data exclusivity or other regulatory protections are reduced, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations, and prospects could be materially harmed. It should be noted that the European Commission's new proposed legislation, if implemented, will also affect the current EU legal framework of pediatric medicines as well as the framework applicable to patent term extension, also called Supplementary Protection Certificates (SPCs).

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

Our trademarks or trade names may be challenged, infringed, circumvented, or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively, and our business may be adversely affected.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

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:

- others may be able to make drug candidates that are similar to ours but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- we cannot predict the scope of protection of any patent issuing based on our patent applications, including whether the patent applications that we own or in-license will result in issued patents with claims that cover our drug candidates, drug products or uses thereof in the United States or in other foreign countries;
- the claims of any patent issuing based on our patent applications may not provide protection against competitors or any competitive advantages, or may be challenged by third parties;
- if enforced, a court may not hold that our patents are valid, enforceable and/or infringed;
- we may need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose;
- we may choose not to file a patent application in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent application covering such intellectual property;
- we may fail to adequately protect and police our trademarks and trade secrets;
- other parties may independently develop the technology covered by our trade secrets; and
- the patents of others may have an adverse effect on our business, including if others obtain patents claiming subject matter similar to or improving that covered by our patents and patent applications.

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

Risks Related to Our Reliance on Third Parties

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

We depend upon third parties to conduct certain aspects of our preclinical studies and clinical trials, under agreements with universities, medical institutions, CROs, strategic collaborators and others. We expect to have to negotiate budgets and contracts with such third parties, which may result in delays to our development timelines and increased costs.

We will rely especially heavily on third parties over the course of our clinical trials, and, as a result, will have limited control over the clinical investigators and limited visibility into their day-to-day activities, including with respect to their compliance with the approved clinical protocol. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to suspend or terminate these trials or perform additional preclinical studies or clinical trials before approving our marketing applications. We cannot be certain that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP requirements.

Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting aspects of our preclinical studies or clinical trials will not be our employees and, except for remedies that may be available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our preclinical studies and clinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the preclinical or clinical data they obtain is compromised due to the failure to adhere to our protocols or regulatory requirements or for other reasons or if due to federal or state orders or absenteeism due to global conditions, including health epidemics and pandemics, they are unable to meet their contractual and regulatory obligations, our development timelines, including clinical development timelines, may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

If any of our relationships with these third-party CROs or others terminate, we may not be able to enter into arrangements with alternative CROs or other third parties or to do so on commercially reasonable terms.

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

We rely on third parties for tissue samples and other materials required for our research and development activities, and if we are unable to reach agreements with these third parties our research and development activities would be delayed.

We rely on third parties, primarily hospitals, health clinics and academic institutions, for the provision of tissue samples and other materials required in our research and development activities. Obtaining these materials requires various approvals as well as reaching a commercial agreement on acceptable terms with the hospital or other provider of the materials. While we currently have agreements in place with the institutions from which we receive our tissue samples, we do not have any exclusive arrangements with such sources and there is no guarantee that we will be able to maintain or renew such agreements on commercially reasonable terms, if at all. If we were unable to maintain or renew such agreements, we would be forced to seek new arrangements with new hospitals, clinics or health institutions. If so, we may not be able to reach agreements with alternative partners or do so on terms acceptable to us. If we are unable to enter into such agreements, our research and development activities will be delayed and possibly impaired.

Because we rely on third-party manufacturing and supply vendors, including single-source vendors and vendors in foreign jurisdictions, including China, our supply of research and development, preclinical and clinical development materials may become limited or interrupted or may not be of satisfactory quantity or quality.

We rely on third-party contract manufacturers to manufacture our product candidates for preclinical studies and clinical trials. We do not own manufacturing facilities for producing any clinical trial product supplies. There can be no assurance that our preclinical and clinical development product supplies will not be limited, interrupted, or of satisfactory quality or continue to be available at acceptable prices, including due to severe weather events, natural disasters, trade policies or challenging macroeconomic conditions, including the effects of health epidemics and pandemics, such as COVID-19. In addition, we rely

on vendors in foreign jurisdictions, including China for our clinical drug supply. The tensions between the United States and China have led to a series of tariffs and sanctions being imposed by the United States on imports from China mainland, as well as other business restrictions. Geopolitical developments may lead to further developments with respect to the imposition or threat of imposition of trade policies, tariffs, export controls, capital controls, taxes and other limitations on cross-border operations. If our supply chain is interrupted for business or geopolitical reasons, the development of our product candidates could be materially delayed. In particular, any replacement of our manufacturers could require significant time, effort and expertise because there may be a limited number of qualified replacements and the process to transfer technology and initiate manufacturing is complex and time consuming.

The manufacturing process for a product candidate is subject to FDA and foreign regulatory authority review. Suppliers and manufacturers must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as cGMPs. In the event that any of our manufacturers fails to comply with such requirements or to perform its obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to manufacture the materials ourselves, for which we currently do not have the capabilities or resources, or enter into an agreement with another third-party, which we may not be able to do on reasonable terms, if at all. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such skills or technology to another third-party and a feasible alternative may not exist. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to have another third-party manufacture our product candidates. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget.

We expect to continue to rely on third-party manufacturers if we receive regulatory approval for any product candidate. To the extent that we have existing, or enter into future, manufacturing arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. If we are unable to obtain or maintain third-party manufacturing for product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully. Our or a third party's failure to execute on our manufacturing requirements and comply with cGMP could adversely affect our business in a number of ways, including:

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

We rely on sole suppliers for the manufacture of our product candidates. If these sole suppliers are unable to supply to us in the quantities we require, or at all, or otherwise defaults on its supply obligations to us, we may not be able to obtain alternative supplies from other suppliers on acceptable terms, in a timely manner, or at all. We also do not have long-term supply agreements with any of our suppliers. Our current contracts with certain suppliers may be canceled or not extended by such suppliers and, therefore, do not afford us with protection against a reduction or interruption in supplies. Moreover, in the event any of these suppliers breach their contracts with us, our legal remedies associated with such a breach may be insufficient to compensate us for any damages we may suffer.

In addition, we contract with fill and finishing providers with the appropriate expertise, facilities and scale to meet our needs. Failure to maintain cGMP can result in a contractor receiving FDA sanctions, which can impact our ability to operate or lead to delays in any clinical development programs. We believe that our current fill and finish contractor is operating in accordance with cGMP, but we can give no assurance that FDA or other regulatory agencies will not conclude that a lack of compliance exists. In addition, any delay in contracting for fill and finish services, or failure of the contract manufacturer to perform the services as needed, may delay any clinical trials, registration and launches, which could negatively affect our business. In the future, if we advance a biological product candidate into IND-enabling studies, we will need to identify and contract with suppliers who are able to produce biological product candidates and adhere to additional cGMP compliance obligations required for biologicals.

If we are unable to enter into new collaborations, or if these collaborations are not successful, our business could be adversely affected.

A part of our strategy is to selectively evaluate partnerships in indications and geographies where we believe partners can add significant commercial and/or development capabilities. Further, we have limited capabilities for product development and do not yet have any capability for commercialization. Accordingly, we have in the past and may in the future enter into collaborations with other companies to provide us with important technologies and funding for our programs and technology.

Any future collaborations we enter into may pose a number of risks, including the following:

- collaborators may have significant discretion in determining the efforts and resources that they will apply;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs or license arrangements based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as a strategic transaction that may divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products and product candidates if the collaborators believe that the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- collaborators may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a product candidate or product;
- collaborators with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;
- collaborators may not provide us with timely and accurate information regarding development progress and activity under any future license agreement, which could adversely impact our ability to report progress to our investors and otherwise plan development of our product candidates;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or terminations of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- if a collaborator of ours is involved in a business combination, the collaborator might deemphasize or terminate the development or commercialization of any product candidate licensed to it by us; and
- collaborations may be terminated by the collaborator, and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

If collaborations we enter into do not result in the successful discovery, development and commercialization of product candidates or if a future collaborator terminates its agreement with us, we may not receive any research funding or milestone or royalty payments under such collaboration. All of the risks relating to product development, regulatory approval and commercialization described in this Report also apply to the activities of our therapeutic collaborators.

We face significant competition in seeking appropriate collaborators for our product candidates, and the negotiation process is time consuming and complex. In order for us to successfully establish a collaboration for one or more of our product candidates, potential collaborators must view these product candidates as economically valuable in markets they determine to be attractive in light of the terms that we are seeking and other available products for licensing by other companies. Collaborations are complex and time consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large biopharmaceutical companies that have resulted in a reduced number of potential future collaborators. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms, or at all. If we fail to enter into future collaborations or do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates, bring them to market and generate revenue from sales of drugs or continue to develop our technology, and our business may be materially and adversely affected. Even if we are successful in our efforts to establish new strategic collaborations, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such strategic collaborations if, for example, development or approval of a product candidate is delayed or sales of an approved product are disappointing. Any delay in entering into new strategic collaboration agreements related to our product candidates could delay the development and commercialization of our product candidates and reduce their competitiveness even if they reach the market.

Our suppliers and any future collaborators may need assurances that our financial resources and stability on a stand-alone basis are sufficient to satisfy their requirements for doing or continuing to do business with us.

Our suppliers and any future collaborators may need assurances that our financial resources and stability on a stand-alone basis are sufficient to satisfy their requirements for doing or continuing to do business with us. If these parties are not satisfied with our financial resources and stability, it could have a material adverse effect on our ability to develop our drug candidates, enter into licenses or other agreements and on our business, financial condition or results of operations.

Risks Related to Managing Our Business and Operations

We may encounter difficulties in managing our growth, which could adversely affect our operations.

As our clinical development and commercialization plans and strategies develop, we will need to expand our managerial, clinical, regulatory, sales, marketing, financial, development, manufacturing and legal capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic collaborators, suppliers and other third parties. Our future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, retaining and motivating additional employees;
- managing our development and commercialization efforts effectively, including the clinical and FDA review process for any product candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

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

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

We may acquire additional technology and complementary businesses in the future. Acquisitions involve many risks, any of which could materially harm our business, including the diversion of management's attention from core business concerns, failure to effectively exploit acquired technologies, failure to successfully integrate the acquired business or realize expected synergies or the loss of key employees from either our business or the acquired businesses.

If we lose key management personnel, or if we fail to recruit additional highly skilled personnel, our ability to develop current product candidates or identify and develop new product candidates will be impaired, could result in loss of markets or market share and could make us less competitive.

Our ability to compete in the highly competitive biotechnology and biopharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific, and medical personnel. We are highly dependent on our management, scientific and medical personnel, including key members of our senior management and executive team. The loss of the services of any of our executive officers, other key employees and other scientific and medical advisors, and our inability to find suitable replacements could result in delays in product development and harm our business. In addition, on May 1, 2025, we announced a strategic restructuring that reduced our then-current workforce by approximately 45%. The current restructuring plan, which was largely completed by the end of the second quarter of 2025, is intended to reduce our costs and preserve cash reserves following the discontinuation of BEACON-IPF. However, this restructuring may increase our dependence on the remaining key members of our senior management and executive team and could result in other unintended consequences and costs, such as the loss of institutional knowledge and expertise, decreased morale or attrition among our remaining employees, and the risk that we may not achieve the anticipated benefits of the reduction in force.

We conduct our operations at our facility in South San Francisco, California. This region is headquarters to many other biopharmaceutical companies, biotechnology companies and research institutions. Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. These challenges may be intensified following our discontinuations of BEACON-IPF and our development of bexotegrast for IPF and workforce reduction, any of which could harm our ability to attract and retain qualified management, scientific and medical personnel who are critical to our business.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided equity awards that vest over time. The value to employees of equity awards that vest over time may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Our key employees are at-will employees, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain "key person" insurance policies on the lives of these individuals or the lives of any of our other employees. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior scientific and medical personnel.

Our current operations are concentrated in one location, and we or the third parties upon whom we depend may be adversely affected by earthquakes or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster, including earthquakes, outbreak of disease or other natural disasters.

Our operations are located in our facilities in South San Francisco, California. Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemics, power shortage, telecommunication failure or other natural or man-made accidents or incidents that result in us being unable to fully utilize our facilities, or the manufacturing facilities of our third-party contract manufacturers, may have a material and adverse effect on our ability to operate our business and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our product candidates or interruption of our business operations. Earthquakes or other natural disasters could further disrupt our operations and have a material and adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our research facilities or the manufacturing facilities of our third-party contract manufacturers, 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.

As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our third-party contract manufacturers, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed.

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

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners, collaborators, and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to comply with the laws of the FDA and other similar foreign regulatory bodies, provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent

misconduct laws, or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws will also increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing, and education programs. We adopted a code of business conduct and ethics, but it is not always possible to identify and deter misconduct by our employees, independent contractors, consultants, commercial partners and vendors, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of civil, criminal and administrative penalties, damages, monetary fines, imprisonment, disgorgement, possible exclusion from participation in government healthcare programs, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm, diminished profits and future earnings and the curtailment of our operations.

We use and generate materials that may expose us to material liability.

Our research programs involve the use of hazardous materials and chemicals, which are generally handled by third parties. We are subject to foreign, federal, state, and local environmental and health and safety laws and regulations governing, among other matters, the use, manufacture, handling, storage and disposal of hazardous materials and waste products such as human tissue samples that may have the potential to transmit diseases. We may incur significant costs to comply with these current or future environmental and health and safety laws and regulations. In addition, we cannot completely eliminate the risk of contamination or injury from hazardous materials and may incur material liability as a result of such contamination or injury. In the event of an accident, an injured party may seek to hold us liable for any damages that result. Any liability could exceed the limits or fall outside the coverage of our workers' compensation, property and business interruption insurance and we may not be able to maintain insurance on acceptable terms, if at all. We currently carry no insurance specifically covering environmental claims.

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 have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our research and development activities involve the use of biological and hazardous materials and produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. 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. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological waste or hazardous waste insurance coverage, workers' compensation or property and casualty and general liability insurance policies that include coverage for damages and fines arising from biological or hazardous waste exposure or contamination.

Compliance with governmental regulations regarding the treatment of animals used in research could increase our operating costs, which would adversely affect the commercialization of our products.

The Animal Welfare Act, or AWA, is the federal law that covers the treatment of certain animals used in research. Currently, the AWA imposes a wide variety of specific regulations that govern the humane handling, care, treatment, and transportation of certain animals by producers and users of research animals, most notably relating to personnel, facilities, sanitation, cage size, and feeding, watering, and shipping conditions. Third parties with whom we contract are subject to

registration, inspections, and reporting requirements under the AWA. Furthermore, some states have their own regulations, including general anti-cruelty legislation, which establish certain standards in handling animals. Comparable rules, regulations, and or obligations exist in many foreign jurisdictions. If we or our contractors fail to comply with regulations concerning the treatment of animals used in research, we may be subject to fines and penalties and adverse publicity, and our operations could be adversely affected.

Our ability to use our net operating loss carryforwards and certain tax credit carryforwards may be subject to limitation.

As of December 31, 2024, we had net operating loss carryforwards for U.S. federal and state income tax purposes of $318.7 million and $397.9 million, respectively, some of which will begin to expire in 2035. As of December 31, 2024, we also had available tax credit carryforwards for U.S. federal income tax purposes of $40.5 million, which begin to expire in 2036, and state income tax purposes of $9.1 million, which can be carried forward indefinitely. Under Section 382 of the Internal Revenue Code, as amended, or the Code, changes in our ownership may limit the amount of our net operating loss carryforwards and tax credit carryforwards that could be utilized annually to offset our future taxable income, if any. This limitation would generally apply in the event of a cumulative change in ownership of our company of more than 50 percentage points within a three-year period. Any such limitation may significantly reduce our ability to utilize our net operating loss carryforwards and tax credit carryforwards before they expire. We have performed an analysis under Internal Revenue Code Sections 382 and 383 to determine the amount of our net operating loss carryforwards and research and development credit carryforwards that will be subject to annual limitation. This analysis concluded that we have experienced one or more such ownership changes prior to December 31, 2024, and the Company's net operating losses and tax credit carryforwards generated prior to the identified ownership changes are subject to no permanent limitation under Sections 382 or 383. In addition, we may experience subsequent ownership changes as a result of future equity offerings or other changes in our stock ownership. Any such limitation could have a material adverse effect on our results of operations in future years. Our ability to utilize those net operating loss carryforwards could be limited by an "ownership change" as described above, which could result in increased tax liability to us. Net operating losses generated after December 31, 2017 are not subject to expiration, but may not be carried back to prior taxable years, except that net operating losses generated in 2018, 2019 and 2020 may be carried back five taxable years. Additionally, the deductibility of such U.S. federal net operating losses is limited to 80% of our taxable income in any taxable year beginning after December 31, 2020.

Risks Related to Our Common Stock

The price of our stock may be volatile, and you could lose all or part of your investment.

The trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Report, these factors include:

- the commencement, enrollment or results of preclinical and clinical trials for our product candidates conducted by us or our collaborators;
- any delay in identifying and advancing a clinical candidate for our other development programs;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- adverse results or delays in future clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- adverse regulatory decisions, including failure to receive regulatory approval of any product candidate;
- changes in laws or regulations applicable to any product candidate, including but not limited to clinical trial requirements for approvals;
- adverse developments concerning our manufacturers;
- our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices;
- failure to secure a positive health technology assessment recommendation;
- our inability to establish collaborations, if needed;
- our failure to commercialize our product candidates, if approved;
- additions or departures of key scientific or management personnel;

- unanticipated serious safety concerns related to the use of any product candidate;
- introduction of new products or services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- actual or anticipated variations in quarterly operating results;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or product candidates in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- changes in the structure of the healthcare payment systems;
- overall performance of the equity markets;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and the market for biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies, including as a result of effects of health epidemics and pandemics, such as COVID-19, geopolitical events, such as the Russian invasion of Ukraine, conflict in the Middle East and related global escalation of geopolitical tensions, domestic or international trade policies and rising inflationary pressures. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to fund the development, operation and growth of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Furthermore, the Amended Loan Agreement contains, and future debt or other financing arrangements may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Any return to stockholders will therefore be limited to the appreciation of their stock.

Our executive officers, directors and their affiliates and our principal stockholders 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 and our principal stockholders beneficially hold a significant portion of our voting stock. These stockholders, acting together, may be able to significantly influence matters requiring stockholder approval. For example, these stockholders would be able to significantly influence 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 feel are in your best interest as one of our stockholders.

If there are substantial sales of shares of our common stock, the price of our common stock could decline.

Shares of common stock that are either subject to outstanding options or reserved for future issuance under our existing equity compensation plans will become eligible for sale in the public market as they become vested. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline. Additionally, the number of shares of our common stock reserved for issuance under our 2020 Stock Option and Incentive Plan will automatically increase on January 1 of each year by 5% of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors or compensation committee. Moreover, the number of shares of our common stock reserved for issuance under our 2020 Employee Stock Purchase Plan, or ESPP, will automatically increase on January 1 of each year by the lesser of 700,000 shares of common stock, 1% of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors or compensation committee. Unless our board of directors elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution.

Anti-takeover provisions under our charter documents, our stockholder rights plan, and Delaware law could delay or prevent a change of control which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.

Our certificate of incorporation and bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the board of directors acting pursuant to a resolution approved by the affirmative vote of a majority of the directors then in office;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than two-thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

Our stockholder rights plan also may have certain anti-takeover effects. Specifically, the rights issued pursuant to the plan will cause substantial dilution to a person or group that acquires beneficial ownership of more than a specified percentage of our outstanding common stock without the prior approval of our Board of Directors. The rights plan is not intended to interfere with any merger or other business combination approved by the Board, but the rights plan may deter certain parties from pursuing strategic transactions involving us, including potential acquisitions.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, or the DGCL, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our certificate of incorporation and bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for stockholders to elect directors of their choosing or cause us to take other corporate actions our stockholders desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

Our bylaws designate certain courts as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to litigate disputes with us in a different judicial forum.

Pursuant to our bylaws, unless we consent in writing to the selection of 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 a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders; (iii) any action asserting a claim against us arising pursuant to

any provision of the DGCL, our certificate of incorporation or our bylaws; (iv) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or bylaws; or (v) any action asserting a claim governed by the internal affairs doctrine; or (vi) any other action asserting an "internal corporate claim" as defined in Section 115 of the DGCL, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein, or the Delaware forum provision. This exclusive forum provision will not apply to any causes of action arising under the Securities Act or the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Unless we consent in writing to the selection of an alternate forum, the federal district courts shall be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, or the federal forum provision. In addition, our 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 Delaware forum provision and the federal forum provision; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

The Delaware forum provision and the federal forum provision may impose additional litigation costs on stockholders who assert the provision is not enforceable and may impose more general additional litigation costs in pursuing any such claims, particularly if the stockholders do not reside in or near the State of Delaware or the State of California. In addition, these forum selection clauses in our bylaws may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage 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 the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the federal district courts 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

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

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

We are required to disclose changes made in our internal controls and procedures on a quarterly basis. If we are unable to assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion on the effectiveness of our internal control, including as a result of any identified material weakness, we could lose investor confidence in the accuracy and completeness of our financial reports, which would cause the price of our common stock to decline, and we may be subject to investigation or sanctions by the SEC. In addition, if we are unable to continue to meet these requirements, we may not be able to remain listed on Nasdaq.

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

As a public reporting company, we are subject to certain reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. 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 or insufficient disclosures due to error or fraud may occur and not be detected.

Our issuance of additional capital stock in connection with financings, acquisitions, investments, our stock incentive plans or otherwise will dilute all other stockholders.

We expect to issue additional capital stock in the future that will result in dilution to all other stockholders. We expect to continue to grant equity awards to employees, directors, and consultants under our stock incentive plans. In July 2022 and January 2023, we completed underwritten public offerings of our common stock. In July 2021, we entered into the Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co., as sales agent, pursuant to which we may issue and sell shares of common stock from time to time. On March 27, 2023, we filed a registration statement on Form S-3 (File No. 333-270862) which included a sales agreement prospectus registering the offer and sale of up to $150.0 million of shares under the Sales Agreement (the Sales Agreement Prospectus). As part of our business strategy, we may acquire or make investments in complementary companies, products or technologies and issue equity securities to pay for any such acquisition or investment. Any such issuances of additional capital stock may cause stockholders to experience significant dilution of their ownership interests and the per share value of our common stock to decline.

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

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

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

As a public company, we incur significant legal, accounting and other expenses. We are subject to the reporting requirements of the Exchange Act, which requires, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and the Nasdaq Stock Market, or Nasdaq, to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial reporting controls and changes in corporate governance practices. Further, there are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

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

We may incur substantial costs in our efforts to comply with evolving global data protection laws and regulations, and any failure or perceived failure by us to comply with such laws and regulations may harm our business and operations.

The global data protection landscape is rapidly evolving, and we may be or become subject to or affected by numerous federal, state and foreign laws and regulations, as well as regulatory guidance, governing the collection, use, disclosure, transfer, security and processing of personal data, such as information that we collect about participants and healthcare providers in connection with clinical trials. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, which may create uncertainty in our business, affect our or our service providers' ability to operate in certain jurisdictions or to collect, store, transfer use and share personal data, result in liability or impose additional compliance or other costs on us. Any failure or perceived failure by us to comply with federal, state, or foreign laws or self-regulatory standards could result in negative publicity, diversion of management time and effort and proceedings against us by governmental entities or others.

Numerous federal and state laws and regulations, including the Health Insurance Portability and Accountability Act (HIPAA) and the Health Information Technology for Economic and Clinical Health Act (HITECH), govern the collection,

dissemination, security, use and confidentiality of patient-identifiable health information or personal information. In the course of performing our business we obtain personally identifiable information (PII), including health-related information. Such laws and regulations relating to privacy, data protection, and consumer protection are evolving and subject to potentially differing interpretations. These requirements may be interpreted and applied in a manner that varies from one jurisdiction to another and/or may conflict with other laws or regulations. HIPAA establishes national privacy and security standards for the protection of individually identifiable health information, including protected health information (PHI) for certain covered entities, including healthcare providers that submit certain covered transactions electronically, as well as their "business associates." Penalties for failure to comply with a requirement of HIPAA and HITECH vary significantly depending on the failure and could include civil monetary or criminal penalties. HIPAA also authorizes state attorneys general to file suit under HIPAA on behalf of state residents. Courts can award damages, costs and attorneys' fees related to violations of HIPAA in such cases. While HIPAA does not create a private right of action allowing individuals to sue us in civil court for HIPAA violations, its standards have been used as the basis for a duty of care claim in state civil suits such as those for negligence or recklessness in the misuse or breach of PHI. HHS has recently increased its enforcement efforts on compliance with HIPAA, including the security regulations (Security Rule), bringing actions against entities which have failed to implement security measures sufficient to reduce risks to electronic protected health information or to conduct an accurate and thorough risk analysis, among other violations. HIPAA enforcement actions may lead to monetary penalties and costly and burdensome corrective action plans. Moreover, compliance with state laws related to health privacy may cause additional compliance costs. For instance, Washington State recently passed the "My Health My Data Act" which regulates "consumer health data" which is defined as "personal information that is linked or reasonably linkable to a consumer and that identifies a consumer's past, present, or future physical or mental health." The "My Health My Data Act" provides exemptions for PHI as well as personal data used or shared in research, including data subject to 45 C.F.R. Parts 46, 50, and 56. Nevada has also enacted a consumer health data privacy bill, and additional states may adopt health-specific privacy laws that could impact our business activities depending on how they are interpreted.

We may encounter vendors that engage in information blocking practices that may inhibit our ability to access the relevant data on behalf of clients or impose new or additional costs. In 2020, the U.S. Department of Health and Human Services' Office of the National Coordinator for Health Information Technology (ONC) and the CMS promulgated final rules to support access, exchange, and use of electronic health information (EHI). Specifically, the information blocking rules were implemented as part of the 21st Century Cures Act, and are primarily designed to facilitate technology interoperability and enable the free flow of healthcare information for healthcare treatment, payment or operation purposes. On June 27, 2023, the Department of Health and Human Services Office of the Inspector General (HHS-OIG) published its final rule implementing information blocking penalties for "actors," which is supplemented by ONC's January 9, 2024 final rule enhancing certain blocking requirements. HHS-OIG may impose penalties for information blocking that has occurred after September 1, 2023, and ONC and HHS proposed a rule on November 1, 2023 listing certain disincentives for actors that conduct information blocking. The impact on the information blocking rules to our business is currently unclear.

California passed the California Consumer Protection Act of 2018, or the CCPA, which went into effect in January 2020 and provides data privacy rights for consumers and operational requirements for companies. In addition, the CCPA was expanded on January 1, 2023, when the California Privacy Rights Act of 2020, or the CPRA, became operative. The CCPA, and its later amendments through the CPRA, gives California residents expanded data privacy rights, such as rights to access and delete their personal information, opt out of certain personal information sharing, and the ability to limit use of certain sensitive personal information in certain contexts, among other privacy right. Failure to comply with the CCPA risks regulatory fines, and the CCPA grants a private right of action and statutory damages for an unauthorized access and exfiltration, theft, or disclosure of certain types of personal information resulting from the company's violation of a duty to maintain reasonable security procedures and practices. The CCPA also provides authority to the California Attorney General to seek civil penalties for intentional violations of the CCPA, and the CPRA established a new California Privacy Protection Agency to implement the law through additional regulations and enforcement. While there is currently an exception for protected health information that is subject to HIPAA and other personal information subject to clinical trial regulations, as currently written, the CCPA may impact certain of our business activities. Additionally, this exception does not apply to the private cause of action afforded to individuals for information security incidents. Compliance with the CCPA may increase our compliance costs and potential liability, and impact our business activities depending on how it is interpreted. In the interim, implementing the evolving CPRA regulations will require additional investment in compliance programs and potential modifications to business processes.

Multiple other states have followed California and enacted comprehensive privacy laws. Additionally, multiple states have enacted or are considering similar legislation which will go into effect in the coming years, and Congress continues to consider federal privacy legislation. While these proposals and new laws generally include exemptions for HIPAA-covered and clinical trial data, they add layers of complexity to compliance in the U.S. market, and could increase our compliance costs and adversely affect our business.

Additionally, the Federal Trade Commission (FTC) and many state attorneys general are interpreting existing federal and state consumer protection laws to impose evolving standards for the collection, use, dissemination and security of health-related

and other personal information and in particular health information. Courts may also adopt the standards for fair information practices promulgated by the FTC, which concern consumer notice, choice, security and access. Consumer protection laws require us to publish statements that describe how we handle personal information and choices individuals may have about the way we handle their personal information. If such information that we publish is considered untrue, we may be subject to government claims of unfair or deceptive trade practices, which could lead to significant liabilities and consequences. Furthermore, according to the FTC, violating consumers' privacy rights or failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5 of the FTC Act. The FTC has also been active with respect to enforcement of its Health Breach Notification Rule and in scrutinizing the use and disclosure of sensitive personal information. The FTC finalized changes to the Health Breach Notification Rule in April 2024.

Our business relies on secure and continuous processing of information and the availability of our Information Technology (IT) networks and IT resources, as well as critical IT vendors that support our technology and data processing operations. Security breaches, computer malware and computer hacking attacks have become more prevalent across industries and may occur on our systems or those of our third-party service providers. Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. HHS, pursuant to legislation passed in 2021, issued guidance on recognized security practices for covered entities and business associates. HHS indicated that recognized security practices will not be an aggravating factor in HHS investigations, but that implementation of recognized security practices strengthen an organization's cybersecurity and regulatory posture, as well as possibly lessening enforcement penalties in a potential regulatory enforcement.

We regularly monitor, defend against and respond to attacks to our networks and other information security incidents. Despite our information security efforts, our facilities, systems, and data, as well as those of our third party service providers, may be vulnerable to privacy and information security incidents such as data breaches, viruses or other malicious code, coordinated attacks, data loss, phishing attacks, ransomware, denial of service attacks, or other security or IT incidents caused by threat actors, technological vulnerabilities or human error. If we, or any of our IT support vendors, fail to comply with laws requiring the protection of sensitive personal information, or fail to safeguard and defend personal information or other critical data assets or IT systems, we may be subject to regulatory enforcement and fines as well as private civil actions. We may be required to expend significant resources in the response, containment, mitigation of cybersecurity incidents as well as in defense against claims that our information security was unreasonable or otherwise violated applicable laws or contractual obligations.

In addition to our operations in the United States, which may be subject to healthcare and other laws relating to the privacy and security of health information and other personal data, we may seek to conduct clinical trials in the EEA/UK and may become subject to additional EEA/UK data privacy laws, regulations and guidelines.

In the EU, the processing of personal data (i.e., data which identifies an individual or from which an individual is identifiable) is governed by the EU General Data Protection Regulation 2016/679 (EU GDPR). The U.K. has implemented the EU GDPR as the U.K. GDPR (together with the EU GDPR, the GDPR) which sits alongside the U.K. Data Protection Act 2018 (as amended). The GDPR has direct effect where an entity is established in the EEA or the U.K. (as applicable) and has extra-territorial effect where an entity established outside of the EEA or the UK processes personal data in relation to the offering of goods or services to individuals in the EEA and/or the UK or the monitoring of their behavior.

The GDPR imposes obligations on controllers, including, among others: (i) accountability and transparency requirements, requiring controllers to demonstrate and record compliance with the GDPR and to provide detailed information to individuals regarding the processing of their personal data (e.g., via informed consent forms); (ii) requirements to process personal data lawfully including specific requirements for obtaining valid consent where consent is the lawful basis for processing; (iii) obligations to consider data protection when any new products or services are developed and designed (including e.g., to limit the amount of personal data processed); (iv) obligations to comply with individuals' data protection rights; and (v) an obligation to report certain personal data breaches to the competent data protection authority and affected individuals.

In addition, the EU GDPR prohibits the international transfer of personal data from the EEA to jurisdictions that the European Commission does not recognize as having an 'adequate' level of data protection unless a data transfer mechanism has been put in place or a derogation under the EU GDPR can be relied on. In July 2020, the CJEU in its Schrems II judgement limited how organizations could lawfully transfer personal data from the EEA to the U.S. by invalidating the EU-U.S. Privacy Shield for purposes of international transfers and imposing further restrictions on the use of standard contractual clauses (EU SCCs), including a requirement for companies to carry out a transfer privacy impact assessment (TIA). A TIA, among other things, assesses laws governing access to personal data in the recipient country. On 10 July 2023, the European Commission adopted its Final Implementing Decision granting the U.S. adequacy (Adequacy Decision) for EU-U.S. transfers of personal data for entities self-certified to the new Trans-Atlantic Data Privacy Framework (DPF). Entities relying on EU SCCs for transfers to the U.S. are also able to rely on the analysis in the Adequacy Decision as support for their TIA regarding the equivalence of U.S. national security safeguards and redress.

The U.K. GDPR also imposes similar restrictions on transfers of personal data from the U.K. to jurisdictions that the U.K. Government does not consider adequate, including the US. The U.K. Government has published its own form of the EU SCCs, known as the International Data Transfer Agreement and an International Data Transfer Addendum to the new EU SCCs. The U.K. Information Commissioner's Office (ICO) has also published its own version of the TIA. Further, on September 21, 2023, the U.K., Secretary of State for Science, Innovation and Technology established a UK-U.S. data bridge (i.e., a U.K. equivalent of the Adequacy Decision) and adopted UK regulations to implement the U.K.-U.S. data bridge (U.K. Adequacy Regulations). Personal data may now be transferred from the UK under the UK-U.S. data bridge through the UK extension to the DPF to organizations self-certified under the UK extension to DPF.

Data protection supervisory authorities have the power under the GDPR to (amongst other things) impose fines for serious breaches of up to the higher of 4% of the organization's annual worldwide turnover or €20m (under the EU GDPR) or £17.5m (under the U.K. GDPR). Individuals also have a right to compensation, as a result of an organization's breach of the GDPR which has affected them, for financial or non-financial losses (e.g., distress).

In the event we commence clinical trials in the EEA, the U.K. or Switzerland, applicable data protection laws may increase our responsibility and liability in relation to personal data that we process, and we may be required to put in place additional mechanisms and safeguards to ensure compliance, including as implemented by member states in the European Union. Compliance with data protection laws in the EEA, the U.K. and Switzerland is a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation and reputational harm in connection with our European activities. We expect that we will continue to face uncertainty as to whether our efforts to comply with any obligations under European or Swiss privacy laws will be sufficient. Further, as the EU GDPR may be implemented differently in national laws of member states of the European Union, we may face additional costs associated with complying with potentially varying data protection requirements in these member states.

If we are investigated by a European or Swiss data protection authority, we may face fines and other penalties. Any such investigation or charges by European or Swiss data protection authorities could have a negative effect on our existing business and on our ability to attract and retain new clients or biopharmaceutical partners. We may also experience hesitancy, reluctance, or refusal by European or multi-national clients or biopharmaceutical partners to continue to use our products and solutions due to the potential risk exposure as a result of the current (and, in particular, future) data protection obligations imposed on them by certain data protection authorities in interpretation of current law. Such clients or biopharmaceutical partners may also view any alternative approaches to compliance as being too costly, too burdensome, too legally uncertain, or otherwise objectionable and therefore decide not to do business with us. Any of the forgoing could materially harm our business, prospects, financial condition and results of operations.

The European Health Data Space Regulations (the "EHDS Regulations") came into force on March 26, 2025. The aims of the EHDS Regulations are to provide individuals with more control over their electronic health data, enable cross-border sharing of European Health Data ("EHD") between national EU healthcare systems and facilitate the sharing of EHD for secondary research purposes. The EHDS Regulations impose new obligations, but also create opportunities for companies engaged in health-related research to share and access health data on a large scale. Although the EHDS Regulations have come into force, key obligations will not apply until March 2029.

Following Brexit, legal, political and economic uncertainty surrounding the exit of the U.K. from the EU may be a source of instability in international markets, create significant currency fluctuations, adversely affect our operations in the U.K. and pose additional risks to our business, revenue, financial condition and results of operations.

On January 31, 2020, the U.K. ceased being a Member State of the EU. The U.K. and the EU signed a EU-U.K. Trade and Cooperation Agreement, or TCA, which became effective on May 1, 2021. Such a withdrawal from the EU is unprecedented, and it is unclear how the restrictions on the U.K.'s access to the European single market for goods, capital, services and labor within the EU, or single market, and the wider commercial, legal and regulatory environment, will impact our current and future operations (including business activities conducted by third parties and contract manufacturers on our behalf) and clinical activities in the U.K.

We may also face new regulatory costs and challenges that could have an adverse effect on our operations. Since the regulatory framework in the U.K. covering quality, safety and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from EU Directives and Regulations, Brexit could materially impact the future regulatory regime with respect to the approval of our product candidates in the U.K., now that U.K. legislation may depart from EU legislation. For instance, now the transition period has expired, Great Britain will no longer be covered by the centralized procedure for obtaining an EEA-wide marketing authorization from the EMA and a separate process will be required for authorization of drug products covering the U.K. or Great Britain only. In addition, the MHRA has launched new procedures designed to accelerate the marketing authorization application process including the Innovative Licensing and Access Pathway (ILAP) and the International Recognition Procedure. The ILAP is an accelerated

assessment procedure for marketing authorization applications facilitating the early interaction with pricing authorities and HTA bodies which aims to enable companies to enter the U.K. market faster. In January 2024, the MHRA also launched a new International Recognition Procedure for Great Britain (England, Scotland and Wales) marketing authorization applications whereby the MHRA will, when considering such applications, recognize the approval of medicines by trusted reference regulators in Australia, Canada, Switzerland, Singapore, Japan, United States and EU following its own abbreviated assessment. Any delay in obtaining, or an inability to obtain, any regulatory approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the U.K. and/or the EU and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the U.K. and/or EU for our product candidates, which could significantly and materially harm our business.

The TCA allows for future deviation from the current regulatory framework and it is not known if and/or when any deviations may occur, which may have an impact on development, manufacture, marketing authorization, commercial sales and distribution of pharmaceutical products. The U.K. Government and the EU recently adopted a new agreement, the "Windsor Framework," which amended the Northern Ireland Protocol. According to the Windsor Framework, medicinal products intended for the U.K. market, including Northern Ireland, will be authorized by the MHRA and will bear a "U.K. only" label. This means that medicinal products placed on the market in Northern Ireland will no longer need to be compliant with EU law. These new measures were implemented on January 1, 2025.

Changes in U.S. tax law could adversely affect our financial condition and results of operations.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the U.S. Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in U.S. tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. We urge investors to consult with their legal and tax advisors regarding the implications of potential changes in U.S. tax laws on an investment in our common stock.

Our information systems, or those of our collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.

Our information systems and those of our current and any future collaborators, other contractors or consultants, and third-party suppliers (i.e. our supply chain) are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. We exercise little or no direct control over how these third parties operate their networks, which increases our vulnerability to problems with their systems. While we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our information systems or those of our collaborators, vendors, contractors or consultants, it could result in a disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions, as well as reputational harm and adverse legal and regulatory consequences. For example, the loss of clinical trial data from future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed.

We are also subject to cybersecurity risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release, exposure or loss of information maintained in the information systems and networks of our company and our vendors, including personal information of our employees and study subjects, and company and vendor confidential data. In addition, outside parties may attempt to penetrate our systems or those of our vendors or fraudulently induce our personnel or the personnel of our vendors to disclose sensitive information in order to gain access to our data and/or systems. We may experience threats to our data and systems, including malicious code and viruses, supply chain attacks, phishing and other cyberattacks. The number and complexity of these threats continue to increase over time. While we have not experienced, to date, a cybersecurity threat, including as a result of any previous cybersecurity incidents, that has materially affected or is reasonably likely to materially affect us, including our business strategy, results of operations, or financial condition, we cannot guarantee that we will not experience such a threat or incident in the future. If a material breach of, or accidental or intentional loss of data from, our information technology systems or those of our vendors occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged and we could be subject to adverse legal and regulatory consequences. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks.

In addition, we could be subject to regulatory actions and/or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices. Although we develop and maintain systems and controls designed to prevent these events from occurring, and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely. As we outsource more of our information systems to vendors, engage in more electronic transactions with payors and patients, and rely more on cloud- based information systems, the related security risks will increase and we will need to expend additional resources to protect our technology and information systems.

In addition, there can be no assurance that our internal information technology systems or those of our third- party contractors, or our consultants' efforts to implement adequate security and control measures, will be sufficient to protect us against breakdowns, service disruption, data deterioration or loss in the event of a system malfunction, or prevent data from being stolen or corrupted in the event of a cyberattack, security breach, industrial espionage attacks or insider threat attacks which could result in financial, legal, business or reputational harm.

In addition, while we maintain insurance policies that may cover certain liabilities in connection with a cybersecurity incident, we cannot be certain that the insurance coverage will be adequate for liabilities actually incurred, that insurance will continue to be available to us on commercially reasonable terms, or at all, or that any insurer will not deny coverage as to any future claim. The successful assertion of one or more large claims that exceed available insurance coverage, or the occurrence of changes in insurance policies, including premium increases or the imposition of large deductible or co-insurance requirements, could have a material adverse effect on our business, including its financial condition, results of operations and reputation.

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

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. Portions of our future clinical trials may be conducted outside of the United States and unfavorable economic conditions resulting in the weakening of the U.S. dollar would make those clinical trials costlier to operate. Furthermore, the most recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, due to factors including the effects of health epidemics and pandemics, such as COVID-19, geopolitical events, such as the Russian invasion of Ukraine, conflict in the Middle East and related global escalation of geopolitical tensions, inflationary pressures, interest rates volatility and domestic or international trade policy could result in a variety of risks to our business, including a reduced ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or international trade disputes could also strain our suppliers, some of which are located outside of the United States, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Use of social media platforms presents risks and challenges.

Social media is a medium through which we communicate about our clinical development programs and the diseases our therapeutics are being developed to treat, and we intend to utilize appropriate social media in connection with our commercialization efforts following approval of our product candidates, if any. Social media practices in the biopharmaceutical industry continue to evolve and regulations and regulatory guidance relating to such use are evolving and not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business, resulting in potential regulatory actions against us, along with the potential for litigation related to off-label marketing or other prohibited activities. For example, patients may use social media channels to comment on their experience in an ongoing blinded clinical trial or to report an alleged adverse event. When such disclosures occur, there is a risk that trial enrollment may be adversely impacted, that we may fail to monitor and comply with applicable adverse event reporting obligations or that we may not be able to defend our business or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our product candidates. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions or incur other harm to our business.

Our estimates of market opportunity and forecasts of market growth may prove to be inaccurate, and even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, or at all.

Our market opportunity estimates and growth forecasts are subject to significant uncertainty and are based on assumptions and estimates which may not prove to be accurate. Our estimates and forecasts relating to size and expected growth of our

target market may prove to be inaccurate. Even if the markets in which we compete meet our size estimates and growth forecasts, our business may not grow at similar rates, or at all. Our growth is subject to many factors, including our success in implementing our business strategy, which is subject to many risks and uncertainties.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None of the Company's directors or officers adopted, modified or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement during the three months ended June 30, 2025, as such terms are defined under Item 408(a) of Regulation S-K.

Item 6. Exhibits.

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant, as currently in effect (incorporated by reference to Exhibit 3 Registrant's quarterly report on Form 10-Q (File No. 001-39303) filed on August 11, 2020).
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Registrant, as currently in effect (incor by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K (File No. 001-39303) filed on June 9, 2025
3.3	Third Amended and Restated Bylaws of the Registrant, as currently in effect (incorporated by reference to Exhibit 3.1 of the Regi Current Report on Form 8-K (File No. 001-39303) filed on September 27, 2024).
3.4	Certificate of Designation of Series A Junior Participating Preferred Stock (incorporated by reference to Exhibit 3.1 of the Registr Current Form on 8-K (File No. 001-39303) filed March 13, 2025).
4.1	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 of the Registrant's Registration Statement on Form amended (File No. 333-238146) filed on May 26, 2020).
4.2	Stockholder Rights Agreement, dated as of March 12, 2025, by and between the Company and Computershare Trust Company, N rights agent (which includes the Form of Rights Certificate as Exhibit B thereto) (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form 8-A, filed with the Securities and Exchange Commission on March 13, 2025, File No 39303).
10.1*	Form of Retention Agreement
31.1*	Certification of Chief Executive Officer required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*(1)	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to S 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	XBRL Instance Document - the Instance Document does not appear in the Interactive Data File because its XBRL tags are embed within the Inline XBRL document.
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Document
101.LAB*	Inline XBRL Taxonomy Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Presentation Linkbase Document
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* Filed herewith

(1) The certifications furnished in Exhibit 32.1 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 Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates them by reference.

Signatures

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

Date: August 7, 2025

PLIANT THERAPEUTICS, INC.

By: /s/ Bernard Coulie
Bernard Coulie, M.D., Ph.D.
President and Chief Executive Officer

By: /s/ Keith Cummings
Keith Cummings, M.D., M.B.A.
Chief Financial Officer (Principal Financial Officer)

Pliant Therapeutics, Inc. Retention Agreement

[Date]
[Name]

Dear [Name],

In consideration of the activities necessary for Pliant Therapeutics, Inc. ("Company") to support critical programs, the Company is offering you a cash retention award in an amount equal to **[●]** (the "Retention Award"). The Retention Award is subject to the terms and conditions provided below.

The Retention Award will vest on **[●]** (the "Retention Date"), subject to your continued employment in good standing through such date(s). Good standing shall be determined by the executive leader overseeing your area of responsibility. For the avoidance of doubt, you shall not be considered in good standing if you have provided notice of your resignation, have received a notice of termination due to performance considerations, or are under any disciplinary actions or notices.

The Retention Award will be paid within sixty (60) days following the Retention Date, subject to your continued employment in good standing with the Company through the Retention Date (other than as provided below).

If, prior to the Retention Date, your employment is terminated (i) by the Company due to a reduction in force or (ii) by the Company without Cause or due to your resignation for Good Reason on or following the date on which a Change in Control occurs (each, a "Qualifying Termination"), you shall be paid the Retention Award. If the Retention Award becomes payable under this paragraph, it shall be payable on the first regularly scheduled payroll date following such Qualifying Termination (but in any event no later than March 15, 202**[●]**) and shall be subject to your execution and non-revocation of a release of claims in favor of the Company and its affiliates in the time period set forth in the release (but in any event no later than sixty (60) days following your Qualifying Termination). For purposes of this Retention Agreement, "Change in Control," "Cause" and "Good Reason" shall have the same meanings as set forth in the Company's Executive Severance Plan in effect as of the date of this Retention Agreement.

This Retention Agreement and the payment hereunder are intended to be exempt from Section 409A of the U.S. Internal Revenue Code of 1986, as amended from time to time, and any regulations promulgated thereunder and this Retention Agreement shall be limited, construed and interpreted in accordance with such intent.

Please note that this Retention Agreement is not intended to guarantee employment for any specific duration and your employment with the Company remains "at will." The Retention Award shall be subject to taxes and other required deductions.

Please acknowledge your agreement to the terms contained herein by signing in the space below.

Thank you for all your hard work and commitment to the Company.

Sincerely,

_____

Acknowledged and Agreed to:

____

Date: ______________________________

Exhibit 31.1

CERTIFICATION

I, Bernard Coulie, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Pliant Therapeutics, 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    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: August 7, 2025

/s/ Bernard Coulie

Bernard Coulie, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Keith Cummings, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Pliant Therapeutics, 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    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: August 7, 2025

/s/ Keith Cummings

Keith Cummings, M.D., MBA
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Bernard Coulie, Chief Executive Officer of Pliant Therapeutics, Inc. (the "Company"), and Keith Cummings, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended June 30, 2025, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

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

Dated: August 7, 2025

/s/ Bernard Coulie
Bernard Coulie, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

/s/ Keith Cummings
Keith Cummings, M.D., MBA
Chief Financial Officer
(Principal Financial Officer)

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