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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2025

or

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

For the transition period from_____to

Commission File Number: 001-40925

Xilio Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**85-1623397**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
828 Winter Street, Suite 300 Waltham, Massachusetts	**02451**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (857) 524-2466

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

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common stock, par value $0.0001 per share	XLO	Nasdaq Capital Market

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a 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 ☒

Number of shares of the registrant's common stock, $0.0001 par value per share, outstanding on November 11, 2025: 52,500,328

References to Xilio

Unless otherwise stated, all references to "us," "our," "we," "Xilio," "Xilio Therapeutics," "the Company" and similar references in this Quarterly Report on Form 10-Q refer to Xilio Therapeutics, Inc. and its consolidated subsidiaries. Xilio Therapeutics and its associated logos are registered trademarks of Xilio Therapeutics, Inc. Other brands, names and trademarks contained in this Quarterly Report on Form 10-Q are the property of their respective owners.

Cautionary Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995 that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Quarterly Report on Form 10-Q are forward-looking statements. In some cases, you can identify forward-looking statements by words such as "aim," "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "potential," "predict," "project," "should," "target," "would," or the negative of these words or other comparable terminology, although not all forward-looking statements contain these identifying words.

The forward-looking statements in this Quarterly Report on Form 10-Q include, but are not limited to, statements about:

- the initiation, timing, progress and results of our research and development programs, including preclinical studies and clinical trials;
- our estimates regarding expenses, future revenue and capital requirements and our expectations regarding our ability to fund our operating expenses and capital expenditure requirements with our cash and cash equivalents;
- our ability to establish and maintain collaborations and strategic partnerships and realize the expected benefits of such arrangements, including our collaboration agreement with AbbVie Group Holdings Limited, or AbbVie, our license agreement with Gilead Sciences, Inc., or Gilead, and our clinical collaboration with F. Hoffmann-La Roche Ltd;
- our expectations regarding milestones, option-related fees and other contingent payments under our collaboration agreement with AbbVie and our license agreement with Gilead;
- the potential receipt of up to $100.0 million in additional gross proceeds if all of the Series B and Series C common stock warrants issued in connection with our June 2025 follow-on public offering are exercised;
- our ability to secure sufficient additional capital or implement other strategies needed to alleviate the substantial doubt about our ability to continue as a going concern;
- the potential advantages and benefits of our current and future product candidates, including our beliefs regarding the potential benefits of our current and future product candidates in combination with other agents;
- our strategic plans to research, develop and, if approved, subsequently commercialize any product candidates we may develop;
- our ability to identify additional products, product candidates or technologies with significant potential that are consistent with our research, development and commercial objectives;
- our manufacturing capabilities and strategy, including our reliance on third parties to manufacture our current or future product candidates;
- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates;
- the timing of and our ability to submit investigational new drug applications or biologic license applications for, and, if cleared or approved, maintain such regulatory applications or approvals for our product candidates;
- our commercialization and marketing capabilities and strategy related to our product candidates, if approved;
- the rate and degree of market acceptance of our product candidates, if approved;
- our estimates regarding the addressable patient population and potential market opportunity for our current and future product candidates;

- developments relating to or impacting our competitors and our industry, including the impact of current or future government laws and regulations on us, third parties with whom we do business and our industry;
- the impact of current or future government laws and regulations on us or third parties with whom we do business and our industry;
- our competitive position and expectations regarding developments and projections relating to our current or future competitors and any competing therapies that are or become available;
- our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act, or JOBS Act; and
- the impact of general economic conditions, including inflation and the imposition of new or revised global trade tariffs.

Any forward-looking statements in this Quarterly Report on Form 10-Q reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Quarterly Report on Form 10-Q, particularly those described in the "Risk Factor Summary" and "Risk Factors" section in Part II, Item 1A of this Quarterly Report on Form 10-Q, that could cause actual results or events to differ materially from the forward-looking statements that we make. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make or enter into.

You should read this Quarterly Report on Form 10-Q and the documents that we have filed as exhibits to this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results, performance or achievements may be materially different from what we expect. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

Risk Factor Summary

Our business is subject to numerous risks that, if realized, could materially and adversely affect our business, financial condition, results of operations and future growth prospects. These risks are discussed more fully in Part II, Item 1A. "Risk Factors" in this Quarterly Report on Form 10-Q. These risks include, but are not limited to, the following:

- Our recurring losses from operations raise substantial doubt regarding our ability to continue as a going concern. If we are unable to raise sufficient additional capital, we will need to implement additional cost reduction strategies, which could include delaying, limiting, reducing or eliminating both internal and external costs related to our operations and research and development programs.
- If we fail to regain compliance with the continued listing requirements of The Nasdaq Capital Market, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.
- Our business is highly dependent on the success of our current product candidates, which are in the early stages of development and will require significant additional preclinical and clinical development before we can seek regulatory approval for and commercially launch a product.
- Our approach to the discovery and development of product candidates based on our technological approaches is unproven, and we do not know whether we will be able to develop any products of commercial value.
- Preclinical development is uncertain. Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all, which would have an adverse effect on our business.
- We may encounter substantial delays in the commencement or completion, or termination or suspension, of our clinical trials, which could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.
- Our product candidates may cause undesirable or unexpectedly severe side effects that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.
- Interim top-line and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.
- We expect to develop certain of our product candidates in combination with third-party drugs and we will have limited or no control over the safety, supply, regulatory status or regulatory approval of such drugs.
- Manufacturing biologics is complex, and we may experience manufacturing problems that result in delays in our development or commercialization programs.
- We face risk related to our reliance on our current and any future third-party contract development and manufacturing organizations, or CDMOs. For example, the CDMO on which we rely may not continue to meet regulatory requirements, may have limited capacity and may experience interruptions in supply, any of which could adversely affect our development and commercialization plans for our product candidates.
- We expect to rely on third parties to conduct, supervise and monitor IND-enabling studies and clinical trials, and if these third parties perform in an unsatisfactory manner, it may harm our business, reputation and results of operations.
- We have entered into, and may in the future seek to enter into, collaborations, licenses, or similar arrangements with third parties for the research, development and commercialization of certain of our current or future product candidates. If any such arrangements are not successful, we may not be able to capitalize on the market potential of those product candidates.
- Certain of our research and development and manufacturing activities take place in China through WuXi Biologics (Hong Kong) Limited, or WuXi Biologics. A significant disruption in our ability to rely on WuXi Biologics could materially adversely affect our business, financial condition and results of operations.

- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.
- If we are unable to obtain and maintain patent protection for any product candidates we develop or for other proprietary technologies we may develop, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize product candidates and technology similar or identical to our product candidates and technology, and our ability to successfully commercialize any product candidates we may develop, and our technology may be adversely affected.
- We rely on in-license agreements for patent rights with respect to our product candidates and may in the future acquire or in-license additional third-party intellectual property rights on which we may similarly rely. We face risks with respect to such reliance, including the risk that we could lose these rights that are important to our business if we fail to comply with our obligations under these licenses or that we may be unable to acquire or in-license third-party intellectual property that may be necessary or important to our business operations.
- Even if we complete the necessary preclinical studies and clinical trials, the regulatory approval process is expensive, time consuming and uncertain and may prevent us from obtaining approvals for the commercialization of some or all of our product candidates. As a result, we cannot predict when or if, and in which territories, we will obtain marketing approval to commercialize a product candidate.
- The price of our common stock has been and, in the future, could be subject to volatility related or unrelated to our operations, and purchasers of our common stock could suffer a decline in value.

Availability of Other Information About Xilio Therapeutics, Inc.

Investors and others should note that we communicate with our investors and the public using our company website (www.xiliotx.com), including but not limited to investor presentations and scientific presentations, filings with the U.S. Securities and Exchange Commission, press releases, public conference calls and webcasts. You can also connect with us on LinkedIn. The information that we post on these channels and websites could be deemed to be material information. As a result, we encourage investors, the media and others interested in our company to review the information that we post on these channels, including our investor relations website, on a regular basis. This list of channels may be updated from time to time on our investor relations website (ir.xiliotx.com) and may include other social media channels than the ones described above. The contents of our website or these channels, or any other website that may be accessed from our website or these channels, shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements

XILIO THERAPEUTICS, INC.
Condensed Consolidated Balance Sheets
(In thousands, except share and per share data)
(Unaudited)

	September 30, 2025	December 31, 2024
ASSETS		
Current assets		
Cash and cash equivalents	$ 103,764	$ 55,291
License agreement receivable	17,500	—
Prepaid expenses and other current assets	2,825	4,943
Total current assets	124,089	60,234
Restricted cash	1,801	1,782
Property and equipment, net	3,679	4,472
Operating lease right-of-use asset	4,125	4,587
Total assets	$ 133,694	$ 71,075
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current liabilities		
Accounts payable	$ 2,300	$ 2,574
Accrued expenses	8,952	9,981
Deferred revenue, current portion	43,846	13,518
Operating lease liability, current portion	1,303	1,188
Total current liabilities	56,401	27,261
Deferred revenue, net of current portion	25,498	19,262
Operating lease liability, net of current portion	5,960	6,954
Common stock warrant liabilities	53,930	—
Total liabilities	141,789	53,477
Commitments and contingencies (Note 7)		
Stockholders' (deficit) equity		
Preferred stock, $0.0001 par value; 5,000,000 shares authorized, no shares issued or outstanding	—	—
Common stock, $0.0001 par value; 600,000,000 shares authorized at September 30, 2025 and 200,000,000 shares authorized at December 31, 2024; 51,829,013 shares issued and outstanding at September 30, 2025; 45,756,773 shares issued and outstanding at December 31, 2024	5	5
Additional paid-in capital	421,049	401,346
Accumulated deficit	(429,149)	(383,753)
Total stockholders' (deficit) equity	(8,095)	17,598
Total liabilities and stockholders' (deficit) equity	$ 133,694	$ 71,075

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

XILIO THERAPEUTICS, INC.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Revenue				
Collaboration and license revenue	$ 19,066	$ 2,263	$ 30,080	$ 4,620
Total revenue	19,066	2,263	30,080	4,620
Operating expenses				
Research and development	$ 14,321	$ 10,759	$ 37,917	$ 32,375
General and administrative	6,674	6,307	22,309	18,261
Restructuring	—	(41)	—	937
Total operating expenses	20,995	17,025	60,226	51,573
Loss from operations	(1,929)	(14,762)	(30,146)	(46,953)
Other income (expense), net				
Change in fair value of common stock warrant liabilities	(15,380)	—	(15,430)	—
Other income (expense), net	1,022	742	180	1,805
Total other income (expense), net	(14,358)	742	(15,250)	1,805
Net loss and comprehensive loss	$ (16,287)	$ (14,020)	$ (45,396)	$ (45,148)
Net loss per share, basic and diluted	$ (0.11)	(0.22)	$ (0.43)	$ (0.91)
Weighted average common shares outstanding, basic and diluted	144,106,869	63,465,063	105,339,205	49,762,800

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

XILIO THERAPEUTICS, INC.
Condensed Consolidated Statements of Stockholders' (Deficit) Equity
For the three months ended September 30, 2025 and 2024
(In thousands, except share data)
(Unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' (Deficit) Equity
	Shares	Amount			
Balance at June 30, 2025	51,827,910	$ 5	$ 419,926	$ (412,862)	$ 7,069
Exercise of stock options	1,103	—	—	—	—
Stock-based compensation expense	—	—	1,123	—	1,123
Net loss	—	—	—	(16,287)	(16,287)
Balance at September 30, 2025	51,829,013	$ 5	$ 421,049	$ (429,149)	$ (8,095)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at June 30, 2024	43,951,922	$ 4	$ 390,052	$ (356,640)	$ 33,416
Exercise of stock options	6,152	—	4	—	4
Stock-based compensation expense	—	—	1,574	—	1,574
Net loss	—	—	—	(14,020)	(14,020)
Balance at September 30, 2024	43,958,074	$ 4	$ 391,630	$ (370,660)	$ 20,974

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

XILIO THERAPEUTICS, INC.
Condensed Consolidated Statements of Stockholders' (Deficit) Equity
For the nine months ended September 30, 2025 and 2024
(In thousands, except share data)
(Unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' (Deficit) Equity
	Shares	Amount			
Balance at December 31, 2024	45,756,773	$ 5	$ 401,346	$ (383,753)	$ 17,598
Issuance of prefunded warrants in connection with a follow-on public offering, net of issuance costs	—	—	10,818	—	10,818
Issuance of common stock in connection with the AbbVie stock purchase agreement, net of issuance costs	4,347,826	—	2,810	—	2,810
Issuance of common stock in connection with at-the-market offerings, net of issuance costs	1,550,000	—	2,017	—	2,017
Issuance of common stock under employee stock purchase plan	45,505	—	40	—	40
Vesting of restricted stock units	111,375	—	—	—	—
Exercise of stock options	17,534	—	9	—	9
Stock-based compensation expense	—	—	4,009	—	4,009
Net loss	—	—	—	(45,396)	(45,396)
Balance at September 30, 2025	51,829,013	$ 5	$ 421,049	$ (429,149)	$ (8,095)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2023	27,607,646	$ 3	$ 362,336	$ (325,512)	$ 36,827
Issuance of common stock and prefunded warrants to Gilead and certain accredited investors in private placements, net of issuance costs	9,298,598	—	17,513	—	17,513
Issuance of common stock in connection with at-the-market offerings, net of issuance costs	7,000,000	1	6,824	—	6,825
Issuance of common stock under employee stock purchase plan	38,998	—	34	—	34
Vesting of restricted common stock	5,617	—	—	—	—
Exercise of stock options	7,215	—	5	—	5
Stock-based compensation expense	—	—	4,918	—	4,918
Net loss	—	—	—	(45,148)	(45,148)
Balance at September 30, 2024	43,958,074	$ 4	$ 391,630	$ (370,660)	$ 20,974

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

XILIO THERAPEUTICS, INC.
Condensed Consolidated Statements of Cash Flows
(In thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2025	2024
Cash flows from operating activities:		
Net loss	$ (45,396)	$ (45,148)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization	1,218	1,268
Stock-based compensation expense	4,009	4,918
Change in fair value of common stock warrant liabilities	15,430	—
Issuance costs allocated to common stock warrant liabilities	2,284	—
Loss on disposal of property and equipment	—	2
Changes in operating assets and liabilities:		
License agreement receivable	(17,500)	—
Prepaid and other assets	2,580	1,769
Accounts payable	(276)	(76)
Accrued expenses and other liabilities	(1,907)	(1,458)
Deferred revenue	36,564	34,504
Net cash used in operating activities	(2,994)	(4,221)
Cash flows from investing activities:		
Purchases of property and equipment	(423)	(30)
Net cash used in investing activities	(423)	(30)
Cash flows from financing activities:		
Repayments of debt principal	—	(3,333)
Payments of finance lease	—	(49)
Proceeds from issuance of common stock under employee stock purchase plan	40	34
Proceeds from exercise of stock options	9	5
Proceeds from issuance of prefunded warrants and common stock warrants in connection with a follow-on public offering, net of issuance costs	47,033	—
Proceeds from issuance of common stock in connection with the AbbVie stock purchase agreement, net of issuance costs	2,810	—
Proceeds from issuance of common stock in connection with at-the-market offerings, net of issuance costs	2,017	6,824
Proceeds from issuance of common stock and prefunded warrants to Gilead and certain accredited investors in private placements, net of issuance costs	—	17,513
Net cash provided by financing activities	51,909	20,994
Increase in cash, cash equivalents and restricted cash	48,492	16,743
Cash, cash equivalents and restricted cash, beginning of period	57,073	46,291
Cash, cash equivalents and restricted cash, end of period	$ 105,565	$ 63,034
Supplemental cash flow disclosure:		
Cash paid for interest	$ —	$ 62
Supplemental disclosure of non-cash activities:		
Transfer of finance lease asset to property and equipment	$ —	$ 85
Reconciliation to amounts within the consolidated balance sheets:		
Cash and cash equivalents	$ 103,764	$ 61,259
Restricted cash	1,801	1,775
Cash, cash equivalents and restricted cash, end of period	$ 105,565	$ 63,034

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

XILIO THERAPEUTICS, INC.
Notes to Condensed Consolidated Financial Statements
(Dollars in thousands, unless otherwise stated)
(Unaudited)

1. Description of Business, Liquidity and Going Concern

Xilio Therapeutics, Inc. ("Xilio" or the "Company") is a clinical-stage biotechnology company dedicated to discovering and developing tumor-activated immuno-oncology ("I-O") therapies with the goal of significantly improving outcomes for people living with cancer without the systemic side effects of current I-O treatments. The Company was incorporated in Delaware in June 2020, and its headquarters are located in Waltham, Massachusetts.

In June 2025, the Company received initial gross proceeds of $50.0 million upon the closing of a follow-on public offering of prefunded warrants and accompanying common stock warrants. If certain of the common stock warrants are exercised in cash at their initial exercise price of $0.75 per warrant, the Company will receive up to $100.0 million of additional gross proceeds by the second half of 2026. See Note 8 for additional information.

Since its inception, the Company has devoted substantially all of its financial resources and efforts to research and development activities. As of September 30, 2025, the Company had an accumulated deficit of $429.1 million and has incurred significant operating losses, including net losses of $45.4 million and $45.1 million for the nine months ended September 30, 2025 and 2024, respectively. The Company expects its operating losses and negative operating cash flows to continue for the foreseeable future as it continues to advance its pipeline of novel, tumor-activated I-O molecules through preclinical and clinical development, maintains the infrastructure necessary to support these activities and continues to incur costs associated with operating as a public company. These conditions raise substantial doubt about the Company's ability to continue as a going concern within twelve months from the date of the issuance of these condensed consolidated financial statements.

In order to fund its operations, the Company will need to raise additional capital, which could be obtained through the cash exercise of common stock warrants issued in connection with the June 2025 follow-on public offering, the receipt of milestone payments, option-related fees or other contingent payments under the Company's existing agreements with Gilead Sciences, Inc. ("Gilead") and AbbVie Group Holdings Limited ("AbbVie"), additional public or private equity offerings, debt financings, additional collaborations, partnerships or licensing arrangements or other sources. In the fourth quarter of 2025, the Company received a $17.5 million development milestone payment from Gilead. However, there can be no assurance that the Company will receive additional proceeds from the exercise of the common stock warrants or from contingent payments under its existing agreements with Gilead or AbbVie or that the Company will be able to complete any additional transactions on acceptable terms or otherwise. If the Company is not able to secure sufficient additional capital when needed, the Company may need to implement additional cost reduction strategies, which could include delaying, limiting, further reducing or eliminating both internal and external costs related to its operations and research and development programs. In addition, the Company has based its estimates on assumptions that may prove to be wrong, and the Company could exhaust its available capital resources sooner than it anticipates.

The accompanying condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

2. Summary of Significant Accounting Policies

Basis of Presentation

The Company's unaudited interim condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States ("U.S. GAAP"), and pursuant to the rules and regulations of the U.S. Securities and Exchange Commission (the "SEC"). Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASUs") of the Financial Accounting Standards Board ("FASB"). Certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted from this report, as is permitted by such rules and regulations. Accordingly, these unaudited interim condensed consolidated financial statements should be read in conjunction with the audited

financial statements as of and for the year ended December 31, 2024 and notes thereto, included in the Company's Annual Report on Form 10-K filed with the SEC on March 11, 2025. The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited financial statements. In the opinion of the Company's management, the unaudited interim condensed consolidated financial statements contain all adjustments which are necessary to present fairly the Company's financial position as of September 30, 2025 and the results of its operations for the three and nine months ended September 30, 2025 and 2024 and cash flows for the nine months ended September 30, 2025 and 2024. Such adjustments are of a normal and recurring nature. The results for the three and nine months ended September 30, 2025 are not necessarily indicative of the results for the year ending December 31, 2025 or for any future period.

Principles of Consolidation

The accompanying condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries: Xilio Development, Inc. ("Xilio Development"), a Delaware corporation, and Xilio Securities Corporation, a Massachusetts security corporation. All intercompany accounts and transactions have been eliminated in consolidation.

Significant Accounting Policies

The significant accounting policies used in preparation of the unaudited condensed consolidated financial statements are described in Note 2, "*Summary of Significant Accounting Policies*" of the audited consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2024. Except as described below, there have been no material changes to the significant accounting policies previously disclosed in the Company's Annual Report on Form 10-K for the year ended December 31, 2024.

Common Stock Warrants

The Company accounts for warrants to purchase shares of its common stock in accordance with the guidance in ASC 480, *Distinguishing Liabilities from Equity* ("ASC 480") and ASC 815, *Derivatives and Hedging* ("ASC 815"). The Company classifies warrants issued for the purchase of shares of its common stock as either equity or liability instruments based on an assessment of the specific terms and conditions of each respective contract. Such assessment includes determining whether the warrants are freestanding financial instruments or embedded in a host instrument, whether the warrants are liabilities within the scope of ASC 480, whether the warrants meet the definition of a derivative in ASC 815 and whether the warrants meet the requirements for equity classification pursuant to the indexation and equity classification criteria in ASC 815.

The Company determines the classification for its warrants at the time of issuance and updates its assessment as necessary. Warrants that meet all of the criteria for equity classification are recorded as a component of additional paid-in capital and are not subsequently remeasured. Warrants that are classified as liabilities are recorded at fair value on the issuance date and remeasured to fair value at each reporting period, with the change in fair value recorded as a component of other income (expense), net, on the condensed consolidated statements of operations and comprehensive loss.

Use of Estimates

The preparation of financial statements in accordance with GAAP requires management to make estimates and judgments that may affect the reported amounts of assets and liabilities and related disclosures of contingent assets and liabilities at the date of the financial statements and the related reporting of revenue and expenses during the reporting period. Management considers many factors in selecting appropriate financial accounting policies and controls and in developing the estimates and assumptions that are used in the preparation of these condensed consolidated financial statements. Factors that may affect estimates include expected business and operational changes, sensitivity and volatility associated with the assumptions used in developing estimates, and whether historical trends are expected to be representative of future trends. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes and management must select an amount that falls within that range of reasonable estimates. Significant estimates of accounting reflected in these condensed consolidated financial statements include, but are not limited to, estimates related to revenue recognition, accrued expenses, the valuation of the common stock warrant liabilities, the valuation of

stock-based compensation, including stock options and restricted stock units, useful life of long-lived assets and income taxes. Actual results could differ from those estimates.

Concentrations of Credit Risk

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents. The Company holds all cash and cash equivalents at accredited financial institutions. Bank accounts in the United States are generally insured by the Federal Deposit Insurance Corporation ("FDIC") up to $250,000. Substantially all of the Company's cash and cash equivalents are FDIC insured, including funds held through an insured cash sweep program. The Company has not experienced any losses in its cash and cash equivalents and does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

Segments

The Company has one operating and reportable segment, the consolidated Company operations, reflecting the integrated nature of its business focused on discovering and developing tumor-activated I-O therapies. The Company's chief operating decision maker ("CODM") is its chief executive officer. The CODM allocates resources and assesses performance on a consolidated basis, focused on the Company's cash resources and an assessment of the probability of success of its ongoing research and development activities. Resource allocation decisions are informed by forecasted cash expenditures and actual expenses incurred to date. The CODM is not regularly provided with disaggregated actual expense information, other than the actual expense information included in the consolidated statements of operations and comprehensive loss, as the Company's integrated operating model emphasizes shared resources and centralized decision-making.

All of the Company's collaboration and license revenue is generated in the United States and all of the Company's long-lived assets are held in the United States.

Recent Accounting Pronouncements Not Yet Adopted

In December 2023, the FASB issued ASU No. 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures ("ASU 2023-09"), which modifies the rules on income tax disclosures to require entities to disclose (1) specific categories in the rate reconciliation, (2) the income or loss from continuing operations before income tax expense or benefit (separated between domestic and foreign) and (3) income tax expense or benefit from continuing operations (separated by federal, state and foreign). ASU 2023-09 also requires entities to disclose their income tax payments to international, federal, state and local jurisdictions, among other changes. The guidance is effective for annual periods beginning after December 15, 2024. Early adoption is permitted for annual financial statements that have not yet been issued or made available for issuance. ASU 2023-09 should be applied on a prospective basis, but retrospective application is permitted. The Company anticipates that the adoption of ASU 2023-09 will expand its income tax footnote disclosures, including a more detailed effective tax rate reconciliation.

In November 2024, the FASB issued ASU No. 2024-03, Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses ("ASU 2024-03"), and in January 2025, the FASB issued ASU No. 2025-01, Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Clarifying the Effective Date ("ASU 2025-01"). ASU 2024-03 requires additional disclosure of the nature of expenses included in the income statement as well as disclosures about specific types of expenses included in the expense captions presented in the income statement. ASU 2024-03, as clarified by ASU 2025-01, is effective for public companies for annual periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. Early adoption is permitted. The Company is currently evaluating the potential impact of adopting this new guidance on its condensed consolidated financial statements and related disclosures.

3. Fair Value Measurements

The Company measures the following liabilities at fair value on a recurring basis:

	Quoted Prices in Active Markets for Identical Assets Level 1	Significant Other Observable Inputs Level 2	Significant Unobservable Inputs Level 3	Total
Financial liabilities:				
Series A warrant to purchase common stock	$ —	$ —	$ 35,150	$ 35,150
Series B warrant to purchase common stock	—	—	11,070	11,070
Series C warrant to purchase common stock	—	—	7,710	7,710
Total financial liabilities	$ —	$ —	$ 53,930	$ 53,930

The fair value of the common stock warrant liabilities, which are described in more detail in Note 8, are calculated utilizing a Black-Scholes option pricing model for the Series A warrants and a Monte Carlo simulation model for the Series B warrants and the Series C warrants. The Black-Scholes option pricing model and the Monte Carlo simulation model both require the use of assumptions, certain of which are not observable in the market, which represent Level 3 measurements within the fair value hierarchy. The Black-Scholes pricing model and the Monte Carlo simulation model assumptions include the warrant exercise price, the expected life of the warrant, the current price of the Company's common stock, expected volatility, the risk-free interest rate for the expected life of the warrant and expected dividend yield. The Monte Carlo simulation assumptions also include the potential impacts of the warrant strike price reset features.

The inputs used in the fair market value of the Company's common stock warrants liabilities as of the issuance date and September 30, 2025 were the following:

	June 5, 2025 (issuance date)	September 30, 2025
Closing price of common stock	$ 0.68	$ 0.84
Warrant exercise price	$ 0.75	$ 0.75
Expected volatility	70 %	70 %
Risk free interest rate	3.91 %	3.67 %
Expected dividend yield	—	—
Expected term (in years)	0.57 - 5.00	0.17 - 4.68

The following table summarizes the changes in the fair market value of the Company's common stock warrant liabilities, which are classified within the Level 3 fair value hierarchy:

	Series A	Series B	Series C	Total level 3 financial liabilities
Balance at December 31, 2024	$ —	$ —	$ —	$ —
Initial fair value of common stock warrant liabilities	26,840	6,600	5,060	38,500
Change in fair value of common stock warrant liabilities	8,310	4,470	2,650	15,430
Balance at September 30, 2025	$ 35,150	$ 11,070	$ 7,710	$ 53,930

4. Property and Equipment, Net

Property and equipment, net consists of the following as of September 30, 2025 and December 31, 2024:

	September 30, 2025	December 31, 2024
Laboratory equipment	$ 6,334	$ 5,911
Computers and software	—	183
Furniture and fixtures	681	681
Leasehold improvements	5,124	5,124
Total property and equipment	12,139	11,899
Less: accumulated depreciation	(8,460)	(7,427)
Property and equipment, net	$ 3,679	$ 4,472

The Company recognized depreciation and amortization expense related to property and equipment of $0.3 million and $0.4 million for the three months ended September 30, 2025 and 2024, respectively. The Company recognized depreciation and amortization expense related to property and equipment of $1.2 million for each of the nine months ended September 30, 2025 and 2024.

5. Accrued Expenses

Accrued expenses consist of the following as of September 30, 2025 and December 31, 2024:

	September 30, 2025	December 31, 2024
External research and development	$ 3,488	$ 4,899
Personnel-related	4,194	4,208
Professional and consulting fees	1,182	743
Other	88	131
Total accrued expenses	$ 8,952	$ 9,981

6. Collaboration and License Agreements

Collaboration, License and Option Agreement with AbbVie

In February 2025, Xilio Development entered into a collaboration, license and option agreement (the "Collaboration Agreement") with AbbVie for up to four programs leveraging the Company's proprietary tumor-activation technology and platform, consisting of (i) an exclusive license for a program to develop and commercialize a masked antibody-based immunotherapy (the "Collaboration Program") and (ii) an exclusive option for (a) an initial program to discover, develop and commercialize masked T cell engager molecules for an agreed upon initial target and backup target ("Initial Option Program"), and (b) subject to the terms of the Collaboration Agreement, up to two additional programs (each, an "Additional Option Program" and together with the Initial Option Program, the "Option Programs").

In connection with the Collaboration Program, Xilio Development is responsible for conducting all preclinical development through lead generation ("Collaboration Program Services"). For the Initial Option Program, AbbVie's option right is exercisable beginning on the effective date of the Collaboration Agreement, and for each Additional Option Program, AbbVie's option right is exercisable following delivery of written notice of nomination of such Additional Option Program. During the **three-year** period following the effective date of the Collaboration Agreement, AbbVie has the right to initiate up to two Additional Option Programs by (a) selecting an initial target and backup target for each such Additional Option Program (excluding the target known as prostate-specific membrane antigen and any other target for which Xilio Development has completed specified activities prior to lead selection) and (b) paying Xilio Development an additional program nomination fee for each Additional Option Program. For each Option Program, prior to option exercise, Xilio Development is responsible for conducting preclinical discovery and development up to the completion of investigational new drug application ("IND") enabling studies, subject to AbbVie paying Xilio Development option extension fees upon completion of specified stages of preclinical discovery and development ("Option Program Services"). Unless AbbVie elects to extend preclinical development through the next stage and pays the applicable option extension fee, AbbVie's option right terminates within a specified

time period following completion of each stage of preclinical development. Upon exercising its option for an Option Program, AbbVie will be responsible for any remaining preclinical development, if applicable, and all clinical development, regulatory and commercialization activities with respect to licensed products under the applicable Option Program.

In addition, on an Option Program-by-Option Program basis, prior to the initiation of specified activities related to lead optimization and selection for the initial target for such Option Program, AbbVie has a one-time right to substitute the initial target with the backup target agreed upon by the parties at the time of Option Program initiation, subject to the payment by AbbVie of a one-time substitution fee with respect to such substituted target and the other terms of the Collaboration Agreement.

In connection with the execution of the Collaboration Agreement, in February 2025, the Company also entered into a stock purchase agreement with AbbVie Inc. pursuant to which the Company issued and sold 4,347,826 shares of its common stock to AbbVie Inc. in a private placement at a purchase price of $2.30 per share for an aggregate purchase price of $10.0 million.

As of September 30, 2025, the Company has received $52.0 million in payments under the AbbVie agreements, consisting of a $42.0 million upfront cash payment under the Collaboration Agreement and $10.0 million in gross proceeds from the private placement under the stock purchase agreement. In addition, as of September 30, 2025, the Company is eligible to receive up to approximately $2.1 billion in additional contingent payments under the Collaboration Agreement, consisting of (i) up to $305.0 million in aggregate program nomination fees, preclinical development option extension fees and option fees for the Option Programs and (ii) up to $1.8 billion in aggregate development, regulatory and sales-based milestones for all Option Programs and the Collaboration Program. In addition, the Company is eligible to receive tiered royalties ranging in the high single digits on annual global net product sales for the Option Program and is eligible to receive tiered royalties ranging in the mid-single digits on annual global net product sales for the Collaboration Program.

The Company considered the criteria of ASC 606, *Revenue from Contracts with Customers* (“ASC 606”) for combining contracts and determined the Collaboration Agreement and the stock purchase agreement should be combined into a single contract because they were negotiated and entered into in contemplation of one another. The Company accounted for the common stock issued to AbbVie Inc. based on the fair market value of the common stock on the date of issuance. The fair market value of the common stock issued to AbbVie Inc. was $2.9 million, based on the closing price of the Company’s common stock on the date of issuance, resulting in a $7.1 million premium. The Company determined that the premium paid by AbbVie Inc. for the common stock purchased should be attributed to the transaction price of the Collaboration Agreement.

The Company determined that the Collaboration Agreement represents a contract with a customer within the scope of ASC 606 and identified the following promises under the Collaboration Agreement: (i) the exclusive license granted to AbbVie related to the Collaboration Program, (ii) the Collaboration Program Services and (iii) the Option Program Services for the Initial Option Program. In addition, the Company identified several customer options that were evaluated to determine if such options represented material rights, each of which would be considered a performance obligation at contract inception only if the option provides a material right to AbbVie that it would not receive without entering into that contract.

The Company determined that the exclusive license and development services related to the Collaboration Program Services were not capable of being distinct on the basis that the services to be provided by Xilio Development are specialized in nature, specifically with respect to its specialized expertise in developing masked antibody-based immunotherapies and the Company’s proprietary platform for tumor-activated biologics. Accordingly, the Company concluded that these promises should be a combined performance obligation consisting of the exclusive license and the development services for the Collaboration Program Services. As such, the Company identified the following performance obligations at contract inception: (i) the performance obligation consisting of the exclusive license and the Collaboration Program Services (the “Collaboration Program Performance Obligation”); (ii) the Option Program Services for the Initial Option Program (the “Initial Option Program Performance Obligation”); (iii) a material right to receive an exclusive license to the Initial Option Program; (iv) a material right to receive additional services related to the Initial Option Program; and (v) a material right related to AbbVie’s one-time right to substitute the initial target with the backup target for the Initial Option Program.

For purposes of ASC 606, the transaction price at the outset of the arrangement was determined to be $49.1 million, which consisted of the upfront cash payment of $42.0 million under the Collaboration Agreement and the $7.1 million premium on the sale of common stock to AbbVie Inc. The Company used the most likely amount method to estimate variable consideration. All contingent payments are fully constrained as of September 30, 2025, as the achievement of the milestones underlying such contingent payments is based on either the Company or AbbVie’s ability to execute under the development plan which is not certain at contact inception. Accordingly,

all such contingent payments are excluded from the transaction price. The Company reevaluates the transaction price at the end of each reporting period and as uncertain events are resolved or other changes in circumstances occur and may adjust the transaction price as necessary. Sales-based royalties, including milestone payments based on the level of sales, were also excluded from the transaction price, as the license is deemed to be the predominant item to which the royalties relate. The Company plans to recognize such revenue at the later of (i) when the related sales occur or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

The Company allocated the transaction price to the performance obligations on a relative selling price basis as follows: (i) $32.4 million related to the Collaboration Program Performance Obligation; (ii) $6.9 million related to the Initial Option Program Performance Obligation; (iii) $8.2 million related to the material right to receive an exclusive license to the Initial Option Program; (iv) $1.1 million related to the material right to receive additional services related to the Initial Option Program; and (v) $0.5 million related to the material right for AbbVie's one-time right to substitute the initial target with the backup target for the Initial Option Program. The Company determined the estimated standalone selling price for the licenses using an adjusted market assessment approach, whereby the Company adjusted a comparable transaction previously entered into by the Company and comparable third-party transactions to reflect the stage of development of the Company's assets under the Collaboration Agreement. The Company determined the estimated standalone selling price for services based on estimated costs to be incurred plus a reasonable margin. The Company determined the estimated standalone selling price for material rights by estimating the standalone selling price of the underlying performance obligations included in the material right and estimating the probability that AbbVie will exercise such material right.

Revenue associated with the Collaboration Program Performance Obligation and the Initial Option Program Performance Obligation is recognized as the underlying services are provided as control is transferred over time. The Company measures progress based on the amount of costs incurred relative to the total costs expected to fulfill the combined performance obligation. In management's judgment, this input method is the best measure of progress towards satisfying the combined performance obligation and reflects a faithful depiction of the transfer of goods and services. Revenue associated with the material rights will be recognized upon expiry if the option is not exercised. If the material right is exercised, the Company will evaluate the performance obligations underlying the option exercised and recognize the amount allocated to the material right and any additional consideration over the appropriate recognition period associated with the underlying performance obligations.

During the three and nine months ended September 30, 2025, the Company recognized collaboration and license revenue of $8.3 million and $13.9 million, respectively, under the Collaboration Agreement and the stock purchase agreement. As of September 30, 2025, the Company recorded deferred revenue of $35.3 million, of which $24.3 million was recorded as a current liability on the Company's condensed consolidated balance sheet. The deferred revenue is expected to be recognized as collaboration and license revenue through at least 2026 depending on (i) the timing of services being provided for the Collaboration Program and the Initial Option Program and (ii) the timing of AbbVie's exercise or expiration of the material rights.

License Agreement with Gilead Sciences, Inc.

In March 2024, Xilio Development entered into a license agreement with Gilead, pursuant to which it granted Gilead an exclusive global license to develop and commercialize efarindodekin alfa (XTX301), the Company's tumor-activated IL-12 product candidate, and specified other molecules directed to IL-12. Xilio Development is responsible for conducting clinical development for efarindodekin alfa through an initial Phase 2 clinical trial. Following the delivery by Xilio Development of a specified clinical data package for efarindodekin alfa related to the Phase 1 clinical trial and the initial Phase 2 clinical trial, Gilead can elect to transition responsibilities for the development and commercialization of efarindodekin alfa to Gilead, subject to the terms of the license agreement and payment by Gilead of a $75.0 million transition fee.

In connection with the execution of the license agreement, in March 2024, the Company also entered into a stock purchase agreement with Gilead. Under the stock purchase agreement, Gilead purchased $25.0 million of the Company's common stock and prefunded warrants in three private placements, consisting of an aggregate of 9,105,451 shares of common stock and prefunded warrants to purchase up to an aggregate of 9,975,266 shares of its common stock. The prefunded warrants are exercisable any time at an exercise price of $0.0001 per share, subject to Gilead not being deemed a beneficial owner of greater than 19.9% of the Company's common stock upon the exercise of the prefunded warrants.

As of September 30, 2025, the Company has received $55.0 million in payments under the Gilead agreements, consisting of the $30.0 million upfront cash payment under the license agreement and $25.0 million in gross proceeds from private placements under the stock purchase agreement. As of September 30, 2025, the Company is eligible to receive up to $592.5 million in additional contingent payments, which consist of a $17.5 million development milestone prior to opt-in, a $75.0 million transition fee if Gilead exercises its option for the IL-12 program and up to $500.0 million in specified development, regulatory and sales-based milestones after opt-in. The Company achieved the $17.5 million development milestone in the third quarter of 2025 in connection with the initiation of the Phase 2 trial and recorded the milestone as a receivable on the condensed consolidated balance sheet as of September 30, 2025. The Company received payment of the milestone from Gilead during the fourth quarter of 2025. In addition, the Company is eligible to receive tiered royalties ranging from high single digits to mid-teens on annual global net product sales.

The Company considered the ASC 606 criteria for combining contracts and determined the license agreement and the stock purchase agreement should be combined into a single contract because they were negotiated and entered into in contemplation of one another. The Company concluded the initial private placement and the additional private placements do not represent freestanding financial instruments as such instruments are not legally detachable due to contractual transfer restrictions. The Company accounted for the common stock issued to Gilead in the initial private placement based on the fair market value of the common stock on the date of issuance. The fair market value of the common stock issued to Gilead in the initial private placement was $4.4 million, based on the closing price of the Company's common stock on the date of issuance, resulting in a $9.1 million premium. The Company determined that the premium paid by Gilead for the common stock purchased in the initial private placement should be attributed to the transaction price of the license agreement.

The Company determined that the license agreement represents a contract with a customer within the scope of ASC 606 and identified two promises under the license agreement: (i) the exclusive licenses granted to Gilead related to the Company's IL-12 program and (ii) the provision by Xilio Development and its affiliates of development services related to ongoing and planned clinical trials for efarindodekin alfa through an initial Phase 2 clinical trial. The Company determined that the exclusive license and development services were not capable of being distinct on the basis that the development services to be provided by Xilio Development are specialized in nature, specifically with respect to its specialized expertise related to efarindodekin alfa, the IL-12 program and the Company's proprietary platform for tumor-activated biologics. Accordingly, the Company concluded that there is a single identified combined performance obligation consisting of the exclusive license and the development services.

For purposes of ASC 606, the transaction price of the license agreement at the outset of the arrangement was determined to be $39.1 million, which consisted of the upfront cash payment of $30.0 million under the license agreement and the $9.1 million premium on the sale of common stock to Gilead in the initial private placement, which was allocated to the single combined performance obligation. The Company used the most likely amount method to estimate variable consideration. During the three and nine months ended September 30, 2025, the overall transaction price was adjusted to include the achievement of the $17.5 million development milestone in the third quarter of 2025. All additional contingent payments are fully constrained as of September 30, 2025, as the achievement of the milestones underlying such contingent payments are uncertain and highly susceptible to factors outside of the Company's control. Accordingly, all such additional contingent payments are excluded from the transaction price. The Company reevaluates the transaction price at the end of each reporting period and as uncertain events are resolved or other changes in circumstances occur and may adjust the transaction price as necessary. Sales-based royalties, including milestone payments based on the level of sales, were also excluded from the transaction price, as the license is deemed to be the predominant item to which the royalties relate. The Company plans to recognize such revenue at the later of (i) when the related sales occur or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Revenue associated with the combined performance obligation is recognized as services are provided as control is transferred over time. The Company measures progress based on the amount of costs incurred relative to the total costs expected to fulfill the combined performance obligation. In management's judgment, this input method is the best measure of progress towards satisfying the combined performance obligation and reflects a faithful depiction of the transfer of goods and services.

During the three and nine months ended September 30, 2025, the Company recognized collaboration and license revenue of $10.7 million and $16.2 million, respectively, under the license agreement and the stock purchase agreement with Gilead. Each of the three and nine months ended September 30, 2025 included a cumulative catch-up of revenue of $7.0 million related to the adjustment of the overall transaction price due to the achievement of the $17.5 million development milestone during the third quarter of 2025. During the three and nine months ended September 30, 2024, the Company recognized collaboration and license revenue of $2.3 million and $4.6 million, respectively, under the license agreement and the stock purchase agreement with Gilead. As of September 30, 2025, the

Company recorded deferred revenue under the license agreement and the stock purchase agreement of $34.1 million, of which $19.6 million was recorded as a current liability on the Company's condensed consolidated balance sheet. The deferred revenue is expected to be recognized as collaboration and license revenue through at least 2027 depending on the timing of certain clinical development activities.

Summary of Contract Assets and Liabilities

The following table presents changes in the balances of the Company's contract liabilities:

	Gilead	AbbVie	Total
Deferred revenue as of December 31, 2024	$ 32,780	$ —	$ 32,780
Additions	17,500	49,144	66,644
Collaboration and license revenue recognized	(16,188)	(13,892)	(30,080)
Deferred revenue as of September 30, 2025	$ 34,092	$ 35,252	$ 69,344

Clinical Trial Collaboration with F. Hoffmann-La Roche Ltd

In July 2023, the Company and F. Hoffmann-La Roche Ltd ("Roche") entered into a clinical trial collaboration pursuant to a clinical supply agreement to evaluate vilastobart in combination with atezolizumab (Tecentriq®) in a Phase 1/2 clinical trial consisting of Phase 1 dose escalation assessing the combination in patients with advanced solid tumors and Phase 2 assessing the combination in patients with microsatellite stable metastatic colorectal cancer.

Under the clinical supply agreement, the Company is eligible to receive specified cost-sharing payments from Roche, and each company will supply its respective anti-cancer agent to support the Phase 1/2 clinical trial. As of September 30, 2025, the Company has received $8.0 million in total cost-sharing payments from Roche. The Company is responsible for conducting the Phase 1/2 clinical trial and retains global development and commercialization rights to vilastobart.

The Company concluded that the cost-sharing payments under the clinical supply agreement are not in the scope of ASC 606 because the Company does not consider performing research and development services for reimbursement to be part of its ongoing major or central operations. Therefore, the Company applied a reasonable, rational, and consistently applied accounting policy election to record the cost-sharing payments under the clinical supply agreement as a reduction of research and development expenses in the condensed consolidated statements of operations and comprehensive loss for the period in which a study development event is achieved. The Company did not recognize a reduction of research and development expense during each of the three months ended September 30, 2025 and 2024. The Company recognized a reduction of research and development expense of $2.0 million during each of the nine months ended September 30, 2025 and 2024.

7. Commitments and Contingencies

The Company has an operating lease for its headquarters and a finance lease for certain lab equipment. In August 2019, the Company entered into a facility lease agreement with a landlord providing funding for tenant improvements and occupancy of approximately 27,830 square feet of office and laboratory space (the "premises") at 828 Winter Street, Waltham, Massachusetts. The initial term of the lease expires in March 2030, unless terminated earlier in accordance with the terms of the lease. The Company has an option **to extend** the lease for an additional term of **five years** at then-market rates. The Company is obligated to pay its portion of real estate taxes and costs related to the premises, including costs of operations, maintenance, repair, replacement, and management of the leased premises, which it began paying simultaneous with the rent commencement date in March 2020. As of September 30, 2025 and December 31, 2024, the Company had a letter of credit for the benefit of its landlord in the amount of $1.8 million, collateralized by a money market account, which is recorded as restricted cash on the condensed consolidated balance sheets.

8. Preferred Stock and Common Stock

Undesignated Preferred Stock

As of September 30, 2025 and December 31, 2024, the Company's restated certificate of incorporation, as amended, authorizes the Company to issue up to 5,000,000 shares of undesignated preferred stock at $0.0001 par value per share. As of September 30, 2025 and December 31, 2024, there were no shares of preferred stock issued or outstanding.

Common Stock

As of September 30, 2025, the Company's restated certificate of incorporation, as amended, authorized the Company to issue up to 600,000,000 shares of common stock, $0.0001 par value per share. As of December 31, 2024, the Company's restated certificate of incorporation, as amended, authorized the Company to issue up to 200,000,000 shares of common stock, $0.0001 par value per share.

Follow-On Public Offering

In June 2025, the Company closed a follow-on public offering of prefunded warrants and accompanying common stock warrants and received initial gross proceeds of $50.0 million before deducting underwriting discounts and commissions and offering expenses payable by the Company. In connection with the offering, the Company issued prefunded warrants to purchase 66,676,000 shares of common stock, accompanied by Series A warrants to purchase 66,676,000 shares of common stock (or, in certain circumstances, prefunded warrants) (the "Series A warrants"), Series B warrants to purchase 66,676,000 shares of common stock (or, in certain circumstances, prefunded warrants) (the "Series B warrants"), and Series C warrants to purchase 66,676,000 shares of common stock (or, in certain circumstances, prefunded warrants) (the "Series C warrants"). The combined public offering price of one prefunded warrant, one Series A warrant, one Series B warrant and one Series C warrant, which were sold together but are immediately separable, was $0.7499, which was equal to the combined offering price of the prefunded warrants, Series A warrants, Series B warrants and Series C warrants, less the $0.0001 per share exercise price of the prefunded warrants.

The exercisability of the prefunded warrants and common stock warrants is subject to limitations on exercise. Specifically, a holder will be prohibited from exercising any portion of any warrant if immediately prior to or following such exercise such holder (together with its affiliates) would beneficially own more than 4.99% (or up to 19.99% at the election of the holder) of the Company's issued and outstanding common stock immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the warrant. However, any holder of any warrant may increase or decrease such percentage to any other percentage not in excess of 19.99%, provided that any such increase will not be effective until the 61st day after notice from the holder is delivered to the Company.

Each Series A warrant will be exercisable on the earlier of (i) December 1, 2025 and (ii) the trading day immediately following a period of five consecutive trading days on which the closing sale price of the Company's common stock is a minimum of $1.50 per share for one share of common stock and will have an exercise price of $0.75 per share of common stock. In addition, each Series A warrant will expire upon the earlier of (i) June 5, 2030 or (ii) immediately upon the exercise of the corresponding prefunded warrant held by a holder in proportion to the extent that such corresponding prefunded warrant is exercised prior to December 1, 2025; provided that this term (ii) will no longer apply to the Series A warrants beginning on the first trading day immediately following a period of five consecutive trading days on which the closing sale price of the Company's common stock is a minimum of $1.50 per share for one share of common stock.

Each Series B warrant is exercisable beginning on November 1, 2025, with an exercise price of $0.75 per share of common stock, and will expire on December 2, 2025, provided that if the closing sale price of the Company's common stock is below the exercise price on such date, the exercise price will reset to the closing sale price on December 1, 2025 and the expiration time will be extended to December 31, 2025.

Each Series C warrant will be exercisable on or after June 1, 2026, with an exercise price of $0.75 per share of common stock, and will expire on the earlier of (i) December 2, 2026 and (ii) the expiration time of the Series B warrant held by a holder in proportion to the extent that the corresponding Series B warrant expires without being exercised. In addition, if the closing sale price of the Company's common stock is below the exercise price on December 2, 2026, the exercise price will reset to the closing sale price on December 1, 2026 and the expiration time will be extended to December 31, 2026.

The prefunded warrants and Series A warrants may be exercised for cash or on a net exercise or "cashless" basis, and the Series B warrants and Series C warrants may be exercised for cash or on a net exercise or "cashless" basis in the event there is no effective registration statement or prospectus available which covers the Series B warrants and Series C warrants and shares of common stock issuable upon exercise of the Series B warrants and Series C warrants. There can be no assurance that any of the warrants will be exercised for cash or at all, and it is possible that the common stock warrants may expire without being exercised. If all of the Series B warrants and the Series C warrants sold in the offering are exercised in cash at their initial exercise price, the Company will receive additional gross proceeds of approximately $100.0 million by the end of 2026.

In the event of certain fundamental transactions, each holder of the prefunded warrants and the common stock warrants has the right to receive, upon exercise of such warrant, the same amount and kind of securities, cash or property as such holder would have been entitled to receive upon the occurrence of such fundamental transaction if it had been, immediately prior to such fundamental transaction, the holder of the number of shares of common stock underlying such holder's warrant without regard to any limitations on exercise contained in such holder's warrant. The holders of Series A warrants are alternatively entitled to elect to receive consideration in an amount equal to the Black Scholes value of the unexercised portion of such holder's Series A warrants and if the fundamental transaction is within the Company's control, the Series A warrant holders can require the Black Scholes value to be paid in cash.

In addition, for each dollar of non-dilutive capital received by the Company prior to the exercise or expiration of the Series B warrants and Series C warrants, the Company may elect to cancel a number of warrant shares equal to $1.00 divided by the $0.75 warrant exercise price (or one and one-third warrants) without any compensation paid by the Company to the warrant holders. For example, if the Company received $30.0 million in non-dilutive capital, it could elect to cancel 40.0 million of warrant shares. Subject to certain specified exceptions, non-dilutive capital includes: upfront payments under any future collaboration, license or similar agreement; milestone payments and option fees under any current or future collaboration, license or similar agreement; and net proceeds pursuant to any equity issuance where the purchase price per share is above $1.50.

The Company concluded that the prefunded warrants, the Series A warrants, the Series B warrants and the Series C warrants are freestanding financial instruments because each of these instruments can be transferred or assigned by the holder subject to compliance with the applicable securities laws and are legally detachable and separately exercisable. The Company determined the classification of each warrant based on the guidance in ASC 480 and ASC 815. As part of this assessment under ASC 815, the Company was required to allocate its available authorized shares of common stock to its outstanding contracts and commitments. The Company applied an accounting policy to first allocate available authorized shares of common stock based on the earliest issuance date of the contract. To the extent more than one contract or commitment made was issued on the same date, the available shares of common stock were allocated first to the contract with the earliest potential exercise date. The Company concluded that the prefunded warrants are classified as equity. The Company concluded the Series A warrants, the Series B warrants and the Series C warrants are required to be initially classified as liabilities as a result of their settlement provisions. The Series A warrants, the Series B warrants and the Series C warrants will continue to be classified as liabilities until such time as the applicable warrant is exercised, expires, or qualifies for equity classification.

The Company received initial gross proceeds from the offering of $50.0 million, before deducting approximately $3.0 million in aggregate issuance costs related to the offering, which consisted of underwriting discounts and commissions and offering expenses payable by the Company. The Company allocated the initial gross proceeds as follows: $26.8 million to the Series A warrants, $6.6 million to the Series B warrants and $5.1 million to the Series C warrants, in each case, based on the fair value of each instrument on the date of issuance with the remaining $11.5 million allocated to the prefunded warrants. The Company allocated the issuance costs to the financial instruments in a manner consistent with the allocation of the proceeds. The Company allocated approximately $2.3 million in issuance costs to the common stock warrants that are classified as liabilities, which was recorded as a component of other income (expense), net, on the condensed consolidated statements of operations and comprehensive loss during the nine months ended September 30, 2025. The Company allocated approximately $0.7 million in issuance costs to the prefunded warrants that are classified in equity, which was recorded as a reduction to additional paid in capital on the condensed consolidated balance sheets as of September 30, 2025.

During each of the three and nine months ended September 30, 2025, the Company recognized a loss of $15.4 million, related to the change in fair value of the common stock warrants, which is recorded as a component of the change in fair value of common stock warrant liabilities on the condensed consolidated statements of operations and comprehensive loss.

Private Placement

In March 2024, the Company entered into a securities purchase agreement with certain existing accredited investors pursuant to which the Company issued and sold an aggregate of 1,953,125 shares of its common stock at a purchase price of $0.64 per share and, in lieu

of shares of the Company's common stock, prefunded warrants to purchase up to an aggregate of 15,627,441 shares of its common stock at a purchase price of $0.6399 per prefunded warrant, through a private placement. The prefunded warrants are exercisable any time at an exercise price of $0.0001 per share. The private placement closed in April 2024. The Company received aggregate gross proceeds of $11.3 million from the private placement, before deducting placement agent fees and expenses payable by the Company. The shares of common stock issued and sold in the private placement were registered for resale pursuant to the Company's registration statement on Form S-3 filed with the SEC on April 30, 2024, which became effective on May 6, 2024.

"At-The-Market" Offering Program

In November 2022, the Company filed a universal shelf registration statement on Form S-3 with the SEC to register for sale up to $250.0 million of its common stock, preferred stock, debt securities, units and warrants, which the Company could issue and sell from time to time in one or more offerings, which became effective on November 18, 2022 (333-268264) (the "Prior S-3 Shelf"). In November 2022, the Company entered into a sales agreement (the "Cowen Sales Agreement") with Cowen and Company LLC under which the Company could issue and sell shares of its common stock, from time to time, having an aggregate offering price of up to $75.0 million under a sales agreement prospectus filed as part of the Prior S-3 Shelf. During the year ended December 31, 2024, the Company issued and sold 7,000,000 shares of its common stock pursuant to the Cowen Sales Agreement at a price of $1.00 per share for aggregate gross proceeds of $7.0 million. During the nine months ended September 30, 2025, the Company issued and sold an additional 1,550,000 shares of its common stock pursuant to the Cowen Sales Agreement at a weighted average price of $1.3348 per share for aggregate gross proceeds of approximately $2.1 million. In March 2025, the Company filed a universal shelf registration statement on Form S-3 with the SEC to register for sale up to $250.0 million of its common stock, preferred stock, debt securities, units and warrants, which the Company may issue and sell from time to time in one or more offerings, which became effective on May 8, 2025 (333-285703) (the "New S-3 Shelf"). In March 2025, the Company terminated the Cowen Sales Agreement, and the Company entered into a new sales agreement with Leerink Partners, LLC (the "Leerink Sales Agreement"), under which the Company may issue and sell shares of its common stock from time to time at an aggregate offering price of up to $50.0 million. Prior to the effectiveness of the New S-3 Shelf, the offering of shares under the Leerink Sales Agreement was registered under the Prior S-3 Shelf. In connection with the effectiveness of the New S-3 Shelf, the registration of such offering under the Prior S-3 Shelf was terminated and such offering was registered under the New S-3 Shelf.

Shares Reserved for Future Issuance

The Company has reserved for future issuances the following shares of common stock underlying the securities issued below as of September 30, 2025 and December 31, 2024:

	September 30, 2025	December 31, 2024
Stock options and unvested restricted stock units	13,992,630	11,328,134
Employee stock purchase plan	1,314,384	901,208
Prefunded warrants	92,278,707	25,602,707
Common stock warrants	200,030,631	2,631
Total shares reserved for future issuance	307,616,352	37,834,680

9. Stock-Based Compensation

Equity Incentive Plans

2020 Stock Incentive Plan

Under the 2020 Stock Incentive Plan (as amended, the "2020 Plan"), the Company was authorized to issue shares of common stock to the Company's employees, officers, directors, consultants and advisors in the form of options, restricted stock awards or other stock-based awards.

2021 Stock Incentive Plan

In September 2021, the Company's board of directors and stockholders adopted the 2021 Stock Incentive Plan (the "2021 Plan"), which became effective immediately prior to the Company's initial public offering of common stock ("IPO") in October 2021. Upon effectiveness of the 2021 Plan, the Company ceased granting awards under the 2020 Plan. The 2021 Plan provides for the grant of

incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock units and other stock-based awards. The Company initially reserved 6,579,016 shares of common stock under the 2021 Plan. The 2021 Plan provides that the number of shares reserved and available for issuance under the 2021 Plan will be cumulatively increased on January 1 of each calendar year by 5% of the number of shares of common stock outstanding on such date or such lesser amount determined by the Company's board of directors. On January 1, 2025, the number of shares reserved for issuance under the 2021 Plan automatically increased by 2,293,405 shares. As of September 30, 2025, there were 1,907,013 shares of common stock available for future issuance under the 2021 Plan.

2022 Inducement Plan

In 2022, the Company's board of directors adopted the 2022 Inducement Stock Incentive Plan pursuant to Nasdaq Rule 5635(c)(4) (the "2022 Inducement Plan"). In accordance with Rule 5635(c)(4), stock-based incentive awards under the 2022 Inducement Plan may only be made to a newly hired employee who has not previously been a member of the Company's board of directors, or an employee who is being rehired following a bona fide period of non-employment by the Company as a material inducement to the employee's entering into employment with the Company. The Company initially reserved 275,000 shares of the Company's common stock for issuance under the 2022 Inducement Plan. In November 2024, the number of shares reserved for issuance under the 2022 Inducement Plan increased by 500,000 shares. In March 2025, the number of shares reserved for issuance under the 2022 Inducement Plan increased by an additional 500,000 shares. As of September 30, 2025, there were 238,300 shares of common stock available for future issuance under the 2022 Inducement Plan.

2021 Employee Stock Purchase Plan

In 2021, the Company's board of directors and stockholders adopted the 2021 Employee Stock Purchase Plan (the "2021 ESPP"), which became effective immediately prior to the IPO in October 2021. The Company initially reserved 292,031 shares of common stock for issuance under the 2021 ESPP. The 2021 ESPP provides that the number of shares of common stock reserved for issuance under the 2021 ESPP will be cumulatively increased on January 1 of each calendar year by 1% of the number of shares of the Company's common stock outstanding on such date or such lesser amount determined by the Company's board of directors (up to a maximum increase of 584,062 shares of common stock per year). On January 1, 2025, the number of shares reserved for issuance under the 2021 ESPP was increased by 458,681 shares. During the nine months ended September 30, 2025 and 2024, the Company issued 45,505 shares of common stock and 38,998 shares of common stock under the 2021 ESPP, respectively. As of September 30, 2025, there were 1,314,384 shares available for future issuance under the 2021 ESPP.

Stock-Based Compensation Expense

During the three and nine months ended September 30, 2025 and 2024, the Company recorded compensation expense related to stock options, restricted stock units and restricted common stock for employees and non-employees and share purchases under the 2021 ESPP for employees, which was allocated as follows in the condensed consolidated statements of operations and comprehensive loss:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Research and development expense	$ 319	$ 384	$ 1,054	$ 1,275
General and administrative expense	804	1,190	2,955	3,643
Total stock-based compensation expense	$ 1,123	$ 1,574	$ 4,009	$ 4,918

Stock Options

A summary of stock option activity under the Company's 2020 Plan, 2021 Plan and 2022 Inducement Plan is as follows:

	Number of Stock Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (In years)	Aggregate Intrinsic Value [1] (In thousands)
Outstanding as of December 31, 2024	8,333,932	$ 4.15	8.0	$ 282
Granted	3,882,830	$ 0.90		
Exercised	(17,534)	$ 0.58		
Forfeited	(686,036)	$ 3.70		
Outstanding as of September 30, 2025	11,513,192	$ 3.09	7.9	$ 263
Exercisable as of September 30, 2025	6,453,329	$ 4.55	7.0	$ 68

(1) The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock as of the end of the period.

Using the Black-Scholes option pricing model, the weighted average fair value of options granted to employees and directors during the nine months ended September 30, 2025 and 2024 was $0.71 per share and $0.68 per share, respectively. The following assumptions were used in determining the fair value of options granted during the nine months ended September 30, 2025 and 2024:

	Nine Months Ended September 30,	
	2025	2024
Risk-free interest rate	3.9 - 4.4 %	3.7 - 4.6 %
Expected dividend yield	0 %	0 %
Expected term (in years)	5.5 - 6.1	5.5 - 6.1
Expected volatility	94.5 - 100.8 %	87.7 - 91.4 %

As of September 30, 2025, the Company had unrecognized stock-based compensation expense of $4.1 million related to stock options issued to employees and directors, which is expected to be recognized over a weighted-average period of 2.8 years.

Restricted Stock Units

In January 2024, the Company awarded 481,500 restricted stock units to certain employees of the Company. The restricted stock units vest in four equal annual installments beginning on the first anniversary of the grant date. The restricted stock units are generally forfeited if the individual's service relationship with the Company or any subsidiary terminates prior to vesting.

A summary of the Company's restricted stock unit activity and related information is as follows:

	Number of Shares of Restricted Stock Units	Weighted Average Grant Date Fair Value
Unvested as of December 31, 2024	445,500	$ 0.55
Granted	—	$ —
Vested	(111,375)	$ 0.55
Forfeited	—	$ —
Unvested as of September 30, 2025	334,125	$ 0.55

For each of the nine months ended September 30, 2025 and 2024, the Company recognized less than $0.1 million of stock-based compensation expense related to these awards. As of September 30, 2025, the Company had unrecognized stock-based compensation expense of $0.2 million related to these restricted stock units, which is expected to be recognized over 2.3 years.

10. Net Loss Per Share

The Company calculates basic net loss per share by dividing net loss by the weighted average number of shares of common stock outstanding. The weighted average number of shares of common stock used in the basic and diluted net loss per share calculation includes the prefunded warrants to purchase common stock issued in connection with the Company's private placements with certain existing investors and Gilead and the Company's follow-on public offering, as the prefunded warrants are exercisable at any time for nominal cash consideration. As of September 30, 2025, no prefunded warrants have been exercised and 92,278,707 prefunded warrants are outstanding.

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

	Nine Months Ended September 30,	
	2025	2024
Unvested restricted stock units	334,125	445,500
Outstanding stock options	11,513,192	8,006,371
Common stock warrants	200,030,631	2,631
Unvested employee stock purchase plan shares	62,339	37,097
Total common stock equivalents	211,940,287	8,491,599

11. Subsequent Events

On October 20, 2025, the Company filed a proxy statement seeking stockholder approval of the following: (i) a one-time repricing of certain outstanding employee stock options and (ii) the Xilio Therapeutics, Inc. 2025 Stock Incentive Plan, with an aggregate of 32.0 million shares of common stock reserved for issuing stock options to employees. The stockholder meeting to vote on the proposals stated within the proxy statement is scheduled to be held on November 21, 2025.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K for the year ended December 31, 2024.

Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the section entitled "Risk Factors" in Part II, Item 1A of this Quarterly Report on Form 10-Q, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical-stage biotechnology company discovering and developing tumor-activated, or masked, immuno-oncology, or I-O, therapies with the goal of significantly improving outcomes for people living with cancer without the systemic side effects of current I-O treatments. We are leveraging our proprietary platform to advance a pipeline of novel, tumor-activated I-O molecules that are designed to optimize the therapeutic index by localizing anti-tumor activity within the tumor microenvironment, including masked antibodies, bispecifics, cytokines and immune cell engagers. Current I-O therapies have curative potential for patients with cancer. However, their potential is significantly curtailed by systemic toxicity that results from activity of the therapeutic molecule outside the tumor microenvironment. Our molecules are engineered to localize activity within the tumor microenvironment with minimal systemic effects, resulting in the potential to achieve enhanced anti-tumor activity and increasing the population of patients who may be eligible to receive our medicines. To date, we have presented data across our clinical-stage programs showing clinical validation for our tumor-activation platform. Our most advanced clinical-stage product candidates are vilastobart, a tumor-activated, Fc-enhanced anti-CTLA-4 monoclonal antibody, or mAb, and efarindodekin alfa (XTX301), a tumor-activated, engineered interleukin 12, or IL-12, therapy. We are currently advancing clinical development for vilastobart in combination with atezolizumab (Tecentriq®) in a Phase 2 clinical trial in patients with microsatellite stable metastatic colorectal cancer, or MSS mCRC, under a co-funded clinical trial collaboration with F. Hoffmann-La Roche Ltd, or Roche. In November 2025, we announced new data from the ongoing Phase 2 clinical trial at the Society for Immunotherapy of Cancer (SITC) 40th Annual Meeting in patients with MSS mCRC without liver metastases and high plasma tumor mutational burden, or TMB, and we anticipate reporting additional data from the Phase 2 trial in the first half of 2026. Based on the promising clinical activity and safety profile demonstrated by vilastobart to date as a combination therapy, including in patients who had high plasma TMB, we are actively seeking a partner to develop vilastobart in combination with PD-(L)1 or PD1-VEGF in MSS mCRC and other tumor types. For efarindodekin alfa, in the third quarter of 2025, we initiated a Phase 2 trial in patients with advanced solid tumors and achieved a $17.5 million development milestone under our exclusive license agreement with Gilead Sciences, Inc., or Gilead. We have completed enrollment in the Phase 1A monotherapy dose escalation and Phase 1B monotherapy dose expansion portions of our ongoing Phase 1/2 clinical trial, and evaluation of patients is ongoing. In addition to our clinical-stage product candidates, we are leveraging our proprietary tumor-activation platform to advance multiple preclinical programs for XTX501, a bispecific PD-1/masked IL-2 and our masked T cell engager molecules, including wholly owned programs targeting the tumor-associated antigens for PSMA, CLDN18.2 and STEAP1 and an additional program under our collaboration, license and option agreement with AbbVie Group Holdings Limited, or AbbVie.

Liquidity and Going Concern Overview

To date, we have financed our operations primarily from proceeds raised through private placements of preferred units, convertible preferred stock, common stock and prefunded warrants; sales of common stock in our initial public offering, or IPO, and through "at-the-market" offerings; the sale of prefunded warrants and common stock warrants in a follow-on public offering; and upfront payments under our collaboration and license agreements with AbbVie and Gilead. We have not generated any revenue from product sales and do not expect to generate any revenue from product sales for at least the next several years, if at all. All of our programs are in early clinical or preclinical development. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our product candidates, if approved. Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve profitability. Even if we are able to generate revenue from product sales, we may not become profitable.

In June 2025, we closed a follow-on public offering of prefunded warrants and accompanying common stock warrants and received net proceeds of $47.0 million after deducting underwriting discounts and commissions and offering expenses payable by us. In connection

with the offering, we issued prefunded warrants to purchase 66,676,000 shares of common stock, accompanied by Series A warrants to purchase 66,676,000 shares of common stock (or, in certain circumstances, prefunded warrants), Series B warrants to purchase 66,676,000 shares of common stock (or, in certain circumstances, prefunded warrants) and Series C warrants to purchase 66,676,000 shares of common stock (or, in certain circumstances, prefunded warrants). If all of the Series B warrants and Series C warrants are exercised in cash at their initial exercise price of $0.75 per warrant, we will receive up to $100.0 million of additional gross proceeds by the second half of 2026. For more information, refer to Note 8 to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Since inception, we have incurred significant operating losses, including net losses of $45.4 million and $45.1 million for the nine months ended September 30, 2025 and 2024, respectively, and a net loss of $58.2 million for the year ended December 31, 2024. As of September 30, 2025, we had an accumulated deficit of $429.1 million. We expect to continue to incur significant expenses and operating losses for the foreseeable future, particularly to the extent we:

- continue to advance our current research programs and conduct additional research programs;
- advance our current product candidates and any future product candidates we may develop into preclinical and clinical development;
- seek marketing approvals for product candidates that successfully complete clinical trials, if any;
- obtain, expand, maintain, defend and enforce our intellectual property;
- continue to discover, validate and develop additional product candidates;
- continue to manufacture increasing quantities of our current or future product candidates for use in preclinical studies, clinical trials and for any potential commercialization;
- acquire or in-license other product candidates, technologies or intellectual property;
- hire additional personnel to support current or future programs;
- establish a commercial and distribution infrastructure to commercialize products for which we may obtain marketing approval, if any; and
- incur additional costs associated with current and future research, development and commercialization efforts and operations as a public company.

As a result, we will need substantial additional capital to support our continuing operations and pursue our strategy. As of September 30, 2025, we had cash and cash equivalents of $103.8 million. In the fourth quarter of 2025, we received a $17.5 million development milestone under our license agreement with Gilead. Based on our current operating plans, we anticipate that our existing cash and cash equivalents as of September 30, 2025, together with the $17.5 million development milestone received under our license agreement with Gilead, will be sufficient to enable us to fund our operating expenses and capital expenditure requirements into the first quarter of 2027. However, we have based our estimates on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we anticipate. In addition, we expect our operating losses and negative operating cash flows to continue for the foreseeable future as we continue to advance our pipeline of novel, tumor-activated I-O molecules through preclinical and clinical development, maintain the infrastructure necessary to support these activities and continue to incur costs associated with operating as a public company. These conditions raise substantial doubt about our ability to continue as a going concern. In order to fund our operations, we will need to raise additional capital, which could be obtained through the cash exercise of the Series B warrants and Series C warrants issued in connection with our June 2025 follow-on public offering, the receipt of milestone payments, option-related fees or other contingent payments under our existing agreements with Gilead and AbbVie, additional public or private equity offerings, debt financings, additional collaborations, partnerships or licensing arrangements or other sources. However, there can be no assurance that we will receive additional proceeds from the exercise of the common stock warrants or from contingent payments under our existing agreements with Gilead or AbbVie or that we will be able to complete any such transaction on acceptable terms or otherwise. If we are not able to secure sufficient additional capital when needed, we may need to implement additional cost reduction strategies, which could include delaying, limiting, further reducing or eliminating both internal and external costs related to our operations and research and development programs.

For more information regarding our liquidity and going concern, refer to "—Liquidity and Capital Resources—Capital Requirements and Going Concern" below and Note 1 to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q. For more information regarding the terms of the warrants we issued in our June 2025 follow-on public offering, refer to Note 8 to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Financial Operations Overview

Revenue

We have not generated any revenue from the sale of products since inception and do not expect to generate any revenue from the sale of products for at least the next several years, if at all. If our development efforts for our current or future product candidates are successful and result in regulatory approval, we may generate revenue in the future from product sales. For the foreseeable future, we expect substantially all of our revenue, if any, would be generated from our collaboration and license agreements with AbbVie and Gilead. For more information on our collaboration, license and option agreement with AbbVie and our license agreement with Gilead, please see Note 6 to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our discovery efforts, research activities and development and testing of our programs and product candidates. These expenses include:

- personnel-related expenses, including salaries, bonuses, benefits and stock-based compensation expense for employees engaged in research and development functions;
- costs incurred with third-party contract development and manufacturing organizations, or CDMOs, to acquire, develop and manufacture materials for both preclinical studies and current or future clinical trials;
- costs of funding research performed by third parties that conduct research and development and preclinical activities on our behalf;
- costs incurred with third-party contract research organizations, or CROs, and other third parties in connection with the conduct of our current or future clinical trials;
- costs of sponsored research agreements and outside consultants, including their fees and related expenses;
- costs incurred to maintain compliance with regulatory requirements;
- fees for maintaining licenses and other amounts due under our third-party licensing agreements;
- expenses incurred for the procurement of materials, laboratory supplies and non-capital equipment used in the research and development process; and
- depreciation, amortization and other direct and allocated expenses, including rent, maintenance of facilities and other operating costs, incurred as a result of our research and development activities.

We expense research and development costs as incurred. We recognize external development costs based on an evaluation of the progress to completion of specific deliverables using information provided to us by our vendors. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in our condensed consolidated balance sheets as prepaid expenses or accrued research and development expenses. We record cost-sharing payments under our clinical trial collaboration with Roche as a reduction of research and development costs upon the achievement of each study development event specified in the clinical supply agreement. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are capitalized as assets, even when there is no alternative future use for the research and development. The capitalized amounts are expensed as the related goods are delivered or the services are performed.

We use our personnel and infrastructure resources for our discovery efforts, including the advancement of our platform technology, developing programs and product candidates and managing external research efforts. A significant portion of our research and development costs have been, and will continue to be, external costs. We track these external costs, such as fees paid to CDMOs, CROs,

preclinical study vendors and other third parties in connection with our manufacturing and manufacturing process development, clinical trials, preclinical studies and other research activities by program. Due to the number of ongoing programs and our ability to use resources across several projects, personnel-related expenses and indirect or shared operating costs incurred for our research and development programs are not recorded or maintained on a program-by-program basis.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect that our research and development expenses will remain approximately the same or will continue to increase for the foreseeable future as we advance our programs and our current or future product candidates into and through the development phase. We expect our discovery research efforts and our related personnel costs to remain consistent with historical levels. In addition, as we progress our most advanced product candidates in clinical development, we may incur additional expenses related to milestone and royalty payments payable to third parties with whom we have entered into, or may enter into license, acquisition, option or other agreements to acquire the rights to future products and product candidates. In the event we are unable to raise sufficient additional capital to fund our operations, we may need to implement cost reduction strategies that seek to maintain our ability to continue the development of our most advanced product candidates in clinical development while otherwise reducing our overall research and development expenses.

At this time, we cannot reasonably estimate or know the nature, timing and projected costs of the efforts that will be necessary to complete the development of, and obtain regulatory approval for, any of our product candidates or programs. This is due to the numerous risks and uncertainties associated with drug development, including the uncertainty of:

- the scope, timing, costs and progress of preclinical and clinical development activities;
- the number and scope of preclinical and clinical programs we decide to pursue;
- our ability to implement and maintain cost reduction strategies, as well as the timing of such cost reductions;
- our ability to maintain our current research and development programs;
- our ability to establish an appropriate safety profile for our product candidates with IND-enabling studies;
- our ability to hire and retain key research and development personnel;
- the costs associated with the development of any additional product candidates we acquire or develop through collaborations, partnerships, licenses or similar transactions;
- our successful enrollment in and completion of clinical trials;
- our ability to successfully complete clinical trials with safety, potency and purity profiles that are satisfactory to the U.S. Food and Drug Administration, or the FDA, or any comparable foreign regulatory authority;
- our receipt of regulatory approvals from applicable regulatory authorities;
- our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize, our product candidates;
- our ability to commercialize products, if and when approved, whether alone or in collaboration with others;
- the continued acceptable safety profiles of the product candidates following approval, if any;
- our ability to establish and maintain agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing, if any of our product candidates are approved;
- the terms and timing of any collaboration, license or other arrangement, including the terms and timing of any milestone payments thereunder, if any;
- our ability to obtain and maintain patent, trade secret and other intellectual property protection and regulatory exclusivity for our product candidates if and when approved; and
- general economic conditions, including inflation and the imposition of new or revised global trade tariffs.

A change in any of these variables with respect to the development of any of our product candidates would significantly change the costs, timing and viability associated with the development of that product candidate. We may never succeed in obtaining regulatory approval for any product candidate we may develop.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel-related costs, including salaries, bonuses, benefits, recruiting and stock-based compensation, for personnel in our executive, finance, legal, business development, human resources and other administrative functions. General and administrative expenses also include legal fees relating to corporate matters; professional and consulting fees for accounting, auditing, tax, human resources and administrative consulting services; board of directors' fees; insurance costs; and facility-related expenses, which include depreciation costs and other allocated expenses for rent, maintenance of facilities and other general administrative costs. These costs relate to the operation of the business and are in support of but separate from the research and development function and our individual development programs. Costs to secure and defend our intellectual property are expensed as incurred and are classified as general and administrative expenses.

We anticipate that our general and administrative expenses will remain consistent with historical levels as we maintain our infrastructure to support our research and development activities. We also expect to continue to incur significant expenses associated with operating as a public company, including increased costs for accounting, audit, legal, regulatory and tax-related services attributable to maintaining compliance with exchange listing standards and U.S. Securities and Exchange Commission, or SEC, requirements, directors' and officers' liability insurance costs and investor and public relations costs. We also expect to continue to incur additional expenses related to intellectual property as we file patent applications to protect intellectual property arising from our research and development activities. In the event we are unable to obtain sufficient additional capital, we may need to implement cost reduction strategies that seek to reduce our general and administrative expenses while maintaining sufficient infrastructure to support our planned research and development activities and operations as a public company.

Restructuring

In connection with the March 2024 strategic portfolio reprioritization and restructuring, we undertook efforts to reduce our expenses and streamline our operations, including a reduction in headcount of 15 employees, representing approximately 21% of our workforce immediately prior to the workforce reduction. Restructuring expense consists of costs directly incurred as a result of restructuring initiatives, and includes employee severance payments, benefits continuation, outplacement services and related expenses.

Other Income (Expense), Net

Change in Fair Value of Common Stock Warrant Liabilities

The change in fair value of common stock warrant liabilities consists of the change in the fair value of the common stock warrant liabilities from the issuance date of June 5, 2025 to September 30, 2025.

Other Income (Expense), Net

Other income (expense), net consists primarily of the portion of the issuance costs we incurred in connection with the issuance of the prefunded warrants and common stock warrants in June 2025 in connection with a follow-on public offering which were allocated to the common stock warrant liabilities, interest income earned from our cash and cash equivalents, interest expense principally on the note payable under our former debt arrangement with Pacific Western Bank, or PacWest, and amortization of the debt discount related to debt issuance costs.

Results of Operations

Comparison of the three months ended September 30, 2025 and 2024

The following table summarizes our results of operations for the three months ended September 30, 2025 and 2024 (in thousands):

	Three Months Ended September 30,		
	2025	2024	Change
Revenue			
Collaboration and license revenue	$ 19,066	$ 2,263	$ 16,803
Total revenue	19,066	2,263	16,803
Operating expenses			
Research and development	$ 14,321	$ 10,759	$ 3,562
General and administrative	6,674	6,307	367
Restructuring	—	(41)	41
Total operating expenses	20,995	17,025	3,970
Loss from operations	(1,929)	(14,762)	12,833
Other income (expense), net			
Change in fair value of common stock warrant liabilities	(15,380)	—	(15,380)
Other income (expense), net	1,022	742	280
Total other income (expense), net	(14,358)	742	(15,100)
Net loss	$ (16,287)	$ (14,020)	$ (2,267)

Collaboration and License Revenue

Collaboration and license revenue increased by $16.8 million from $2.3 million for the three months ended September 30, 2024 to $19.1 million for the three months ended September 30, 2025. The increase was due to collaboration and license revenue recognized under the collaboration, license and option agreement and stock purchase agreement that we entered into in February 2025 with AbbVie and an increase in collaboration and license revenue recognized under the license agreement and stock purchase agreement with Gilead, which included a cumulative catch-up of collaboration and license revenue of $7.0 million related to the adjustment of the overall transaction price due to the achievement of the $17.5 million development milestone during the third quarter of 2025.

Research and Development Expenses

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

	Three Months Ended September 30,		
	2025	2024	Change
vilastobart	$ 1,677	$ 5,368	$ (3,691)
efarindodekin alfa (XTX301)	2,065	1,112	953
XTX501	2,189	—	2,189
XTX202	93	(1,237)	1,330
Other early programs and indirect research and development	3,381	1,997	1,384
Personnel-related	4,916	3,519	1,397
Total research and development expenses	$ 14,321	$ 10,759	$ 3,562

Research and development expenses increased by $3.6 million from $10.8 million for the three months ended September 30, 2024 to $14.3 million for the three months ended September 30, 2025. The changes in research and development expenses were primarily due to the following:

- vilastobart costs decreased by $3.7 million, primarily driven by $3.5 million in aggregate development milestones that we incurred during the three months ended September 30, 2024 under our CTLA-4 monoclonal antibody license agreement with WuXi Biologics (Hong Kong) Limited, or WuXi Biologics, and our amended and restated exclusive license agreement with City of Hope, for which there was no comparable cost during the three months ended September 30, 2025;
- efarindodekin alfa costs increased by $1.0 million, primarily driven by a $0.8 million increase in clinical development activities related to initiation of our Phase 2 clinical trial evaluating efarindodekin alfa as a monotherapy in patients with certain advanced solid tumors and a $0.2 million increase in manufacturing activities;
- XTX501 costs for the three months ended September 30, 2025 consisted of manufacturing activities related to IND-enabling studies and pre-clinical development activities; for the three months ended September 30, 2024, XTX501 costs were not separately tracked as we had not begun performing IND-enabling studies;
- XTX202 costs for the three months ended September 30, 2025 consisted of investigator costs invoiced during the final winddown process of the discontinued XTX202 study; and XTX202 costs for the three months ended September 30, 2024 include the effect of invoiced investigator costs being lower than previously estimated amounts;
- other early programs and indirect research and development costs increased by $1.4 million, primarily driven by an increase in external expenses related to preclinical research and development activities; and
- personnel-related costs increased by $1.4 million, primarily driven by an increase in salaries, bonuses and benefits due to higher research and development headcount.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the three months ended September 30, 2025 and 2024 (in thousands):

	Three Months Ended September 30,		
	2025	2024	Change
Personnel-related	$ 3,414	$ 3,688	$ (274)
Professional and consulting fees	2,374	1,658	716
Facility-related and other general and administrative expenses	886	961	(75)
Total general and administrative expenses	$ 6,674	$ 6,307	$ 367

General and administrative expenses increased by $0.4 million from $6.3 million for the three months ended September 30, 2024 to $6.7 million for the three months ended September 30, 2025. The changes in general and administrative expenses were primarily due to the following:

- personnel-related costs decreased by $0.3 million, primarily driven by a $0.4 million decrease in stock-based compensation and a $0.2 million decrease in recruiting and other personnel-related costs, partially offset by a $0.3 million increase in salaries, bonuses and benefits due to higher general and administrative headcount;
- professional and consulting fees increased by $0.7 million, primarily driven by an increase in legal fees and other professional costs; and
- facility-related and other general and administrative expenses decreased by $0.1 million, primarily driven by a decrease in costs related to directors' and officers' liability insurance.

Restructuring

We did not recognize any restructuring expenses for the three months ended September 30, 2025. We recognized a credit of $41,000 in restructuring expenses for the three months ended September 30, 2024 related to a change in estimate for costs of continuation of certain employee benefits related to the workforce reduction announced in March 2024.

Change in Fair Value of Common Stock Warrant Liabilities

The change in fair value of common stock warrant liabilities for the three months ended September 30, 2025 was due to a loss of $15.4 million due to the increase in the fair value of the common stock warrant liabilities between June 30, 2025 and September 30, 2025, which was primarily driven by an increase in the price per share of our common stock.

Other Income (Expense), Net

Other income (expense), net, increased by $0.3 million from $0.7 million for the three months ended September 30, 2024 to $1.0 million for the three months ended September 30, 2025. The increase in other income (expense), net was primarily due to an increase in interest income due to a higher average cash balance.

Comparison of the nine months ended September 30, 2025 and 2024

The following table summarizes our results of operations for the nine months ended September 30, 2025 and 2024 (in thousands):

	Nine Months Ended September 30,		
	2025	2024	Change
Revenue			
Collaboration and license revenue	$ 30,080	$ 4,620	$ 25,460
Total revenue	30,080	4,620	25,460
Operating expenses			
Research and development	$ 37,917	$ 32,375	$ 5,542
General and administrative	22,309	18,261	4,048
Restructuring	—	937	(937)
Total operating expenses	60,226	51,573	8,653
Loss from operations	(30,146)	(46,953)	16,807
Other income (expense), net			
Change in fair value of common stock warrant liabilities	(15,430)	—	(15,430)
Other income (expense), net	180	1,805	(1,625)
Total other income (expense), net	(15,250)	1,805	(17,055)
Net loss	$ (45,396)	$ (45,148)	$ (248)

Collaboration and License Revenue

Collaboration and license revenue increased by $25.5 million from $4.6 million for the nine months ended September 30, 2024 to $30.1 million for the nine months ended September 30, 2025. The increase was due to collaboration and license revenue recognized under the collaboration, license and option agreement and stock purchase agreement that we entered into in February 2025 with AbbVie and an increase in collaboration and license revenue recognized under the license agreement and stock purchase agreement with Gilead, which included a cumulative catch-up of collaboration and license revenue of $7.0 million related to the adjustment of the overall transaction price due to the achievement of the $17.5 million development milestone during the third quarter of 2025.

Research and Development Expenses

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

	Nine Months Ended September 30,		
	2025	2024	Change
vilastobart	$ 5,587	$ 7,160	$ (1,573)
efarindodekin alfa (XTX301)	4,869	4,176	693
XTX501	4,253	—	4,253
XTX202	70	3,364	(3,294)
Other early programs and indirect research and development	8,835	5,695	3,140
Personnel-related	14,303	11,980	2,323
Total research and development expenses	$ 37,917	$ 32,375	$ 5,542

Research and development expenses increased by $5.5 million from $32.4 million for the nine months ended September 30, 2024 to $37.9 million for the nine months ended September 30, 2025. The changes in research and development expenses were primarily due to the following:

- vilastobart costs decreased by $1.6 million, primarily driven by $4.5 million in aggregate development milestones that we incurred during the nine months ended September 30, 2024 under our CTLA-4 monoclonal antibody license agreement with WuXi Biologics and our amended and restated exclusive license agreement with City of Hope, for which there was no comparable costs during the nine months ended September 30, 2025, partially offset by a $2.8 million increase in clinical development activities related to our ongoing Phase 1/2 clinical trial evaluating vilastobart in combination with atezolizumab;
- efarindodekin alfa costs increased by $0.7 million, primarily driven by an increase in clinical development activities related to our ongoing Phase 1/2 clinical trial evaluating efarindodekin alfa as a monotherapy in patients with certain advanced solid tumors;
- XTX501 costs for the nine months ended September 30, 2025 consisted of manufacturing activities related to IND-enabling studies and pre-clinical development activities; for the nine months ended September 30, 2024, XTX501 costs were not separately tracked as we had not begun performing IND-enabling studies;
- XTX202 costs decreased by $3.3 million, primarily driven by a decrease in clinical development activities as a result of discontinuing further investment in XTX202;
- other early programs and indirect research and development costs increased by $3.1 million, primarily driven by an increase in external expenses related to preclinical research and development activities; and
- personnel-related costs increased by $2.3 million, primarily driven by a $2.4 million increase in salaries, bonuses and benefits due to higher research and development headcount and a $0.1 million increase in recruiting and other personnel-related costs, partially offset by a $0.2 million decrease in stock-based compensation.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the nine months ended September 30, 2025 and 2024 (in thousands):

	Nine Months Ended September 30,		
	2025	2024	Change
Personnel-related	$ 11,985	$ 10,894	$ 1,091
Professional and consulting fees	7,799	4,522	3,277
Facility-related and other general and administrative expenses	2,525	2,845	(320)
Total general and administrative expenses	$ 22,309	$ 18,261	$ 4,048

General and administrative expenses increased by $4.0 million from $18.3 million for the nine months ended September 30, 2024 to $22.3 million for the nine months ended September 30, 2025. The changes in general and administrative expenses were primarily due to the following:

- personnel-related costs increased by $1.1 million, primarily driven by a $1.4 million increase in salaries, bonuses and benefits due to higher general and administrative headcount and a $0.4 million increase in recruiting and other personnel-related costs, partially offset by a $0.7 million decrease in stock-based compensation;
- professional and consulting fees increased by $3.3 million, primarily driven by an increase in legal fees and other professional costs; and
- facility-related and other general and administrative expenses decreased by $0.3 million, primarily driven by a decrease in costs related to directors' and officers' liability insurance.

Restructuring

We did not recognize any restructuring expenses for the nine months ended September 30, 2025. We recognized $0.9 million in restructuring expenses for the nine months ended September 30, 2024. The restructuring expenses were associated with the workforce reduction announced in March 2024 and consisted of employee severance, benefits continuation and outplacement service costs.

Change in Fair Value of Common Stock Warrant Liabilities

The change in fair value of common stock warrant liabilities for the nine months ended September 30, 2025 was due to a loss of $15.4 million due to an increase in the fair value of the common stock warrant liabilities between the issuance date of June 5, 2025 and September 30, 2025, which was primarily driven by an increase in the price per share of our common stock.

Other Income (Expense), Net

Other income (expense), net of $0.2 million for the nine months ended September 30, 2025 included $2.3 million of the issuance costs we incurred in connection with the sale and issuance of the prefunded warrants and common stock warrants in June 2025 in connection with our follow-on public offering, which were allocated to the common stock warrant liabilities and were partially offset by $2.5 million of interest income. Other income (expense), net of $1.8 million for the nine months ended September 30, 2024 consisted of interest income.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have incurred significant operating losses and negative cash flows from operations. We have not yet commercialized any of our product candidates, which are in preclinical or early clinical development, and we do not expect to generate revenue from sales of any products for several years, if at all. To date, we have financed our operations primarily from proceeds raised through private placements of preferred units, convertible preferred stock, common stock and prefunded warrants; sales of common stock in our IPO and through at-the-market offerings; the sale of prefunded warrants and common stock warrants in a follow-on public

offering; and upfront payments under our collaboration and license agreements with AbbVie and Gilead. Through September 30, 2025, we have received an aggregate of $531.8 million in gross proceeds from such transactions, including $224.5 million in gross proceeds from the sale and issuance of preferred units and convertible preferred stock, $129.9 million in gross proceeds from our IPO, $72.0 million in upfront cash payments under our collaboration and license agreements with AbbVie and Gilead, $46.3 million in gross proceeds from the sale and issuance of common stock and prefunded warrants in private placements with certain existing accredited investors, Gilead and AbbVie, $9.1 million in gross proceeds from the sale and issuance of common stock through at-the-market offerings and $50.0 million in gross proceeds from the sale of prefunded warrants and common stock warrants through a follow-on public offering. As of September 30, 2025, we had cash and cash equivalents of $103.8 million. In the fourth quarter of 2025, we received a $17.5 million development milestone under our license agreement with Gilead. Based on our current operating plans, we anticipate that our existing cash and cash equivalents as of September 30, 2025, together with the $17.5 million development milestone received under our license agreement with Gilead, will be sufficient to enable us to fund our operating expenses and capital expenditure requirements into the first quarter of 2027.

In March 2025, we filed a universal shelf registration statement on Form S-3 with the SEC to register for sale up to $250.0 million of our common stock, preferred stock, debt securities, units and warrants, which we may issue and sell from time to time in one or more offerings, which became effective on May 8, 2025 (333-285703), or the S-3 Shelf. In March 2025, we entered into a sales agreement with Leerink Partners, LLC, under which we may issue and sell shares of our common stock from time to time at an aggregate offering price of up to $50.0 million. Please see Note 8 to our condensed consolidated financial statements appearing elsewhere in our Quarterly Report on Form 10-Q for additional information about our at-the-market offering program.

Cash Flows

The following table provides information regarding our cash flows for each period presented (in thousands):

	Nine Months Ended September 30,	
	2025	2024
Net cash provided by (used in):		
Operating activities	$ (2,994)	$ (4,221)
Investing activities	(423)	(30)
Financing activities	51,909	20,994
Net increase in cash, cash equivalents and restricted cash	$ 48,492	$ 16,743

Operating Activities

Our cash flows from operating activities are greatly influenced by our use of cash for operating expenses and working capital requirements to support our business. We have historically experienced negative cash flows from operating activities as we invested in research and development of our product candidates, including preclinical studies, clinical trials, manufacturing and manufacturing process development. The cash used in operating activities resulted primarily from our net losses adjusted for non-cash charges, which are generally due to stock-based compensation, depreciation and amortization, as well as changes in components of operating assets and liabilities, which are generally due to increased expenses and timing of vendor payments.

During the nine months ended September 30, 2025, net cash used in operating activities of $3.0 million was primarily driven by net changes in operating assets and liabilities of $19.5 million, which includes the $49.1 million received from AbbVie under the collaboration, license and option agreement and stock purchase agreement that was recorded as deferred revenue at the outset of the arrangement, and net non-cash expenses of $22.9 million, which includes the $15.4 million loss recorded on the change in fair value of our common stock warrant liabilities, partially offset by our net loss of $45.4 million.

During the nine months ended September 30, 2024, net cash used in operating activities of $4.2 million was primarily driven by our net loss of $45.1 million, partially offset by changes in operating assets and liabilities of $34.8 million, which includes the $39.1 million received from Gilead under the license agreement and stock purchase agreement that was recorded as deferred revenue at the outset of the arrangement, and net non-cash expenses of $6.2 million.

Investing Activities

During the nine months ended September 30, 2025 and 2024, net cash used in investing activities consisted of purchases of property and equipment.

Financing Activities

During the nine months ended September 30, 2025, net cash provided by financing activities of $51.9 million consisted of proceeds from the sale of prefunded warrants and common stock warrants through a follow-on public offering, proceeds from the sale and issuance of common stock to AbbVie in a private placement and proceeds from the sale and issuance of common stock through ATM offerings.

During the nine months ended September 30, 2024, net cash provided by financing activities of $21.0 million consisted of proceeds from the sale and issuance of common stock and prefunded warrants in private placements with certain existing accredited investors and Gilead and proceeds from the sale and issuance of common stock under our at-the-market offering program, partially offset by repayments of debt principal under our loan agreement with PacWest and payments on our finance lease for certain lab equipment.

Capital Requirements and Going Concern

We expect our future capital requirements to increase substantially over time in connection with our ongoing research and development activities, particularly as we advance our current and planned clinical development of our product candidates and maintain the research efforts and preclinical activities associated with our other existing programs and discovery platform. In addition, we expect to continue to incur additional costs associated with operating as a public company. As a result, we expect to incur substantial operating losses and negative operating cash flows for the foreseeable future.

Inflation generally affects us by increasing our cost of labor and certain services. We do not believe that inflation had a material effect on our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q. However, the United States has recently experienced historically high levels of inflation. If the inflation rate continues to increase it may affect our expenses, such as employee compensation and research and development charges due to, for example, increases in the costs of labor and supplies. Additionally, the biotechnology industry is subject to a competitive wage environment that may also increase our operating costs in the future.

As of September 30, 2025, we had cash and cash equivalents of $103.8 million. Based on our current operating plans, we anticipate that our existing cash and cash equivalents as of September 30, 2025, together with the $17.5 million development milestone received under our license agreement with Gilead, will be sufficient to enable us to fund our operating expenses and capital expenditure requirements into the first quarter of 2027. However, we have based our estimates on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we anticipate. In addition, we expect our operating losses and negative operating cash flows to continue for the foreseeable future as we continue to advance our pipeline of novel, tumor-activated I-O molecules through preclinical and clinical development, maintain the infrastructure necessary to support these activities and continue to incur costs associated with operating as a public company. These conditions raise substantial doubt about our ability to continue as a going concern. In order to fund our operations, we will need to raise additional capital, which could be obtained through the cash exercise of the Series B warrants and Series C warrants issued in connection with our June 2025 follow-on public offering, the receipt of milestone payments, option-related fees or other contingent payments under our existing agreements with Gilead and AbbVie, additional public or private equity offerings, debt financings, additional collaborations, partnerships or licensing arrangements or other sources. However, there can be no assurance that we will receive additional proceeds from the exercise of the common stock warrants or from contingent payments under our existing agreements with Gilead or AbbVie or that we will be able to complete any such transaction on acceptable terms or otherwise. If we are not able to secure sufficient additional capital when needed, we may need to implement additional cost reduction strategies, which could include delaying, limiting, further reducing or eliminating both internal and external costs related to our operations and research and development programs. For more information regarding our liquidity and going concern, refer to Note 1 to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q. For more information regarding the terms of the warrants we issued in our June 2025 follow-on public offering, refer to Note 8 to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

The accompanying condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of

business for the foreseeable future. The condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

Because of the numerous risks and uncertainties associated with product development, and because the extent to which we may enter into additional collaborations with third parties for the development of our product candidates is unknown, we may incorrectly estimate the timing and amounts of increased capital outlays and operating expenses associated with advancing the research and development of our product candidates.

Our future capital requirements, both short-term and long-term, will depend on many factors, including, but not limited to:

- the scope, progress, results and costs of research and development for our current and future product candidates, including our current and planned clinical trials for our clinical-stage product candidates, vilastobart and efarindodekin alfa, and ongoing preclinical development for our current and future product candidates;
- our ability to maintain our collaboration and license agreements with AbbVie and Gilead;
- the timing and amount of milestones, option-related fees and other contingent payments under our collaboration, license and option agreement with AbbVie for tumor-activated immunotherapies and our license agreement with Gilead for efarindodekin alfa, as well as the scope, costs and timing of our development obligations under these agreements;
- our ability to maintain our co-funded clinical trial collaboration with Roche to further develop vilastobart in combination with atezolizumab, including the timing and amount of cost-sharing payments under the collaboration;
- the potential receipt of up to $100.0 million in additional gross proceeds, if all of the Series B and Series C common stock warrants issued in connection with our June 2025 follow-on public offering are exercised;
- our ability to secure sufficient additional capital or implement other strategies needed to alleviate the substantial doubt about our ability to continue as a going concern;
- the scope, prioritization and number of our research and development programs;
- the costs of securing manufacturing materials for use in preclinical studies, clinical trials and, for any product candidates for which we receive regulatory approval, if any, commercial supply;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property and proprietary rights and defending any intellectual property-related claims;
- the extent to which we may acquire or in-license other products, product candidates, technologies or intellectual property, as well as the terms of any such arrangements;
- the scope, costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of future commercialization activities for any of our product candidates for which we receive regulatory approval;
- the amount and timing of revenue, if any, received from commercial sales of any product candidates for which we receive regulatory approval;
- general economic conditions, including inflation and the imposition of new or revised global trade tariffs; and
- the costs of maintaining our operations and continuing to operate as a public company.

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

Our expectation with respect to our ability to fund our currently planned operations is based on estimates that are subject to various risks and uncertainties. Our operating plan may change as a result of many factors currently unknown to management and there can be no assurance that our current operating plan will be achieved in the time frame anticipated by us, and we may exhaust our available capital resources sooner than we expect.

Adequate additional capital may not be available to us on acceptable terms, or at all. Market volatility resulting from adverse changes in domestic and international fiscal, monetary and other policies and political relations, regional or global conflicts, uncertainty around global economic conditions, instability in the financial markets, current or future pandemics or other factors could also adversely impact our ability to access capital as and when needed. To the extent that we raise additional capital through the sale of equity or securities convertible into or exchangeable for equity, the ownership interest of our existing stockholders may be diluted, and the terms of such securities may include liquidation or other preferences that adversely affect the rights of our existing stockholders. Additional debt and preferred equity, if available, may also involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends and may require that we issue additional warrants, which could potentially dilute the ownership interest of our existing stockholders.

Contractual Obligations

During the nine months ended September 30, 2025, there have been no material changes to our contractual obligations as reported in our Annual Report on Form 10-K for the year ended December 31, 2024.

Critical Accounting Policies and Use of Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of these condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities as of the date of the condensed consolidated financial statements, as well as the reported revenue and 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 materially from these estimates under different assumptions or conditions. Except as described in Note 2, *Summary of Significant Accounting Policies,* to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q, there have been no changes to our critical accounting policies appearing in our Annual Report on Form 10-K for the year ended December 31, 2024, other than the estimates required in determining the fair value of the common stock warrant liabilities that are described in Note 3 to the condensed consolidated financial statements appearing elsewhere in our Quarterly Report on Form 10-Q.

Emerging Growth Company and Smaller Reporting Company Status

As an emerging growth company, or EGC, under the Jumpstart Our Business Startups Act of 2012, or JOBS Act, we may delay the adoption of certain accounting standards until such time as those standards apply to private companies. Other exemptions and reduced reporting requirements under the JOBS Act for EGCs include presentation of only two years of audited financial statements in a registration statement for an IPO, an exemption from the requirement to provide an auditor's report on internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002, an exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation, and less extensive disclosure about our executive compensation arrangements.

In addition, the JOBS Act provides that an EGC can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an EGC to delay the adoption of some accounting standards until those standards would otherwise apply to private companies. We have elected not to "opt out" of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we can adopt the new or revised standard at the time private companies adopt the new or revised standard and may do so until such time that we either (1) irrevocably elect to "opt out" of such extended transition period or (2) no longer qualify as an emerging growth company. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

We are also a "smaller reporting company," as defined in the Securities Exchange Act of 1934, as amended, or the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an EGC, in which case we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our chief executive officer (our principal executive officer) and our chief financial and operating officer (our principal financial officer) evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2025. Based upon such evaluation, our principal executive officer and principal financial officer have concluded that, as of September 30, 2025, our disclosure controls and procedures were effective at a reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the period covered by this Quarterly Report on Form 10-Q that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1A. Risk Factors

The following information sets forth risk factors that could cause our actual results to differ materially from those contained in forward-looking statements we have made in this Quarterly Report on Form 10-Q and those we may make from time to time. You should carefully consider the risks described below, in addition to the other information contained in this Quarterly Report on Form 10-Q and our other public filings. Our business, financial condition or results of operations could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. Additional risks not presently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations.

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

Our recurring losses from operations raise substantial doubt regarding our ability to continue as a going concern. If we are unable to raise sufficient additional capital, we will need to implement additional cost reduction strategies, which could include delaying, limiting, reducing or eliminating both internal and external costs related to our operations and research and development programs.

As of September 30, 2025, we had cash and cash equivalents of $103.8 million. In the fourth quarter of 2025, we received a $17.5 million development milestone under our license agreement with Gilead. Based on our current operating plans, we anticipate that our existing cash and cash equivalents as of September 30, 2025, together with the $17.5 million development milestone received under our license agreement with Gilead, will be sufficient to enable us to fund our operating expenses and capital expenditure requirements into the first quarter of 2027. However, we have based our estimates on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we anticipate. In addition, we expect our operating losses and negative operating cash flows to continue for the foreseeable future as we continue to advance our pipeline of novel, tumor-activated immuno-oncology, or I-O, molecules through preclinical and clinical development, maintain the infrastructure necessary to support these activities and continue to incur costs associated with operating as a public company. These conditions raise substantial doubt about our ability to continue as a going concern. In order to fund our operations, we will need to raise additional capital, which could be obtained through the cash exercise of the Series B warrants and Series C warrants issued in connection with our June 2025 follow-on public offering, the receipt of milestone payments, option-related fees or other contingent payments under our existing agreements with AbbVie Group Holdings Limited, or AbbVie, and Gilead Sciences, Inc., or Gilead, additional public or private equity offerings, debt financings, additional collaborations, partnerships or licensing arrangements or other sources. However, there can be no assurance that we will receive additional proceeds from the exercise of the common stock warrants or from contingent payments under our existing agreements with Gilead or AbbVie or that we will be able to complete any such transaction on acceptable terms or otherwise. If we are not able to secure sufficient additional capital when needed, we may need to implement additional cost reduction strategies, which could include delaying, limiting, further reducing or eliminating both internal and external costs related to our operations and research and development programs. Please see Note 1 to our condensed consolidated financial statements appearing elsewhere in our Quarterly Report on Form 10-Q for additional information about our liquidity and going concern. Please see Note 8 to our condensed consolidated financial statements appearing elsewhere in our Quarterly Report on Form 10-Q for additional information about the terms of the warrants we issued in our June 2025 follow-on public offering, including certain potential adjustments to the exercise price of such warrants.

We expect to continue to incur operating losses in connection with our ongoing research and development activities, particularly as we advance our product candidates through clinical trials, maintain the infrastructure necessary to support these activities and incur costs associated with operating as a public company. We do not expect to generate any revenue from the sale of products for a number of years, if at all, and any such revenue will not be realized unless and until we obtain marketing approval for and successfully launch and commercialize a product candidate. If we obtain marketing approval for any current or future product candidates that we develop, we expect to incur significant commercialization expenses related to product sales, marketing, distribution and manufacturing. Some of these expenses may be incurred in advance of marketing approval and could be substantial.

Our future capital requirements, both short-term and long-term, will depend on many factors, including, but not limited to:

- the scope, progress, results and costs of research and development for our current and future product candidates, including our current and planned clinical trials for our clinical-stage product candidates, vilastobart and efarindodekin alfa (XTX301), and ongoing preclinical development for our current and future product candidates;
- our ability to maintain our collaboration and license agreements with AbbVie and Gilead;

- the timing and amount of milestones, option-related fees and other contingent payments under our collaboration, license and option agreement with AbbVie for tumor-activated immunotherapies and our license agreement with Gilead for efarindodekin alfa, as well as the scope, costs and timing of our development obligations under these agreements;
- our ability to maintain our co-funded clinical trial collaboration with F. Hoffmann-La Roche Ltd, or Roche, to further develop vilastobart in combination with atezolizumab, including the timing and amount of cost-sharing payments under the collaboration;
- the potential receipt of up to $100.0 million in additional gross proceeds if all of the Series B and Series C common stock warrants issued in connection with our June 2025 follow-on public offering are exercised;
- our ability to secure sufficient additional capital or implement other strategies needed to alleviate the substantial doubt about our ability to continue as a going concern;
- the scope, prioritization and number of our research and development programs;
- the costs of securing manufacturing materials for use in preclinical studies, clinical trials and, for any product candidates for which we receive regulatory approval, if any, commercial supply;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property and proprietary rights and defending any intellectual property-related claims;
- the extent to which we may acquire or in-license other products, product candidates, technologies or intellectual property, as well as the terms of any such arrangements;
- the scope, costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of future commercialization activities for any of our product candidates for which we receive regulatory approval;
- the amount and timing of revenue, if any, received from commercial sales of any product candidates for which we receive regulatory approval;
- general economic conditions, including inflation and the imposition of new or revised global trade tariffs; and
- the costs of maintaining our operations and continuing to operate as a public company.

As a result, we will need substantial additional capital to support our continuing operations and pursue our strategy. We currently do not have any committed external sources of funds and adequate additional capital may not be available to us on acceptable terms, or at all. In addition, our ability to raise additional capital may be adversely impacted by potential worsening economic conditions, both inside and outside the United States, or U.S., including without limitation heightened inflation, capital market volatility, interest rate and currency rate fluctuations, any potential economic slowdown or recession, future pandemics, geopolitical tensions, including trade wars or civil or political unrest, or wars or other armed conflicts. We can give no assurance that we will be able to secure additional capital to support our operations, or if such funds are available to us, that such additional funding will be sufficient to meet our needs. These factors raise substantial doubt about our ability to continue as a going concern, and our failure to raise sufficient additional capital, on attractive terms or at all, would have a material adverse effect on our business, results of operations and financial condition.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to product candidates or our technology. In addition, the issuance of shares of common stock upon the exercise of our outstanding prefunded warrants or common stock warrants will result in immediate and substantial dilution to our existing stockholders.

Unless and until we can generate a substantial amount of product revenue, we expect to seek additional capital through a combination of public or private equity offerings, debt, collaborations, licensing arrangements or other sources. Our issuance of additional securities, whether equity or debt, or the possibility of such issuance, may cause the market price of our common stock to decline, and our stockholders may not agree with our plans for additional capital or the terms of such capital. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing stockholders. In addition, the issuance of shares of common stock upon the exercise of our outstanding prefunded warrants or common stock warrants will result in immediate and substantial dilution to our existing stockholders. Similarly, if we issue additional shares of our common stock in one or

more public or private offerings in the future, our existing stockholders will suffer further dilution. In addition, as a condition to providing additional funds to us, Gilead and AbbVie received rights superior to those of existing stockholders, and in connection with the issuance of prefunded warrants and common stock warrants in June 2025, we agreed to specified restrictions on our future equity issuances, such as minimum purchase price requirements, unless we obtain the requisite prior approval of the warrant holders. Future investors may similarly receive rights that are superior to those of existing investors or which place restrictions on our future equity issuances. In addition, the incurrence of any indebtedness would result in additional payment obligations and is likely to involve restrictive covenants limiting our flexibility in conducting future business activities, and, in the event of insolvency, would be repaid before holders of our equity securities received any distribution of our corporate assets. Further, in raising funds through our collaborations and licensing arrangements with third parties, we have had to, and may in the future need to, relinquish valuable rights, partially or fully, to our technologies, future revenue streams, research programs or product candidates and grant licenses on terms unfavorable to us. In addition, securing additional capital would require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect our management's ability to oversee the development of our product candidates.

If we fail to regain compliance with the continued listing requirements of Nasdaq, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.

On April 4, 2025, we received a deficiency letter from the Listing Qualifications Department, or the Nasdaq Staff, of the Nasdaq Stock Market LLC, or Nasdaq, notifying us that, for the last 30 consecutive business days, the bid price for our common stock had closed below $1.00 per share, which is the minimum bid price required to maintain continued listing on the Nasdaq Global Select Market, referred to as the minimum bid price requirement. In accordance with Nasdaq Listing Rules, we had an initial period of 180 calendar days, or until October 1, 2025, to regain compliance with the minimum bid price requirement.

On August 22, 2025, we received a second deficiency notice from the Nasdaq Staff notifying us that we were not in compliance with the minimum $10.0 million stockholders' equity requirement for continued listing on the Nasdaq Global Select Market. This second deficiency notice was only a notification of deficiency, not of imminent delisting, and had no immediate effect on the listing or trading of our securities on The Nasdaq Global Select Market.

On October 2, 2025, we received a letter from the Nasdaq Staff approving our application to list our securities on the Nasdaq Capital Market. Our securities were transferred to The Nasdaq Capital Market at the opening of business on October 6, 2025. In connection with the transfer to The Nasdaq Capital Market, Nasdaq granted us an additional 180 calendar day period, or until March 30, 2026, to regain compliance with the minimum bid price requirement. If, at any time before March 30, 2026, the closing bid price for our common stock is at least $1.00 per share for a minimum of 10 consecutive business days, the Nasdaq Staff will provide written notification to us that we are in compliance with the minimum bid price requirement, unless the Nasdaq Staff exercises its discretion to extend this 10-day period pursuant to the Nasdaq Listing Rules.

If we do not regain compliance with the minimum bid price requirement by March 30, 2026, or if we do not meet the other listing standards, the Nasdaq Staff will provide us with notice that our common stock may be delisted. At that time, we may appeal the Nasdaq Staff's delisting determination to a Nasdaq Listing Qualifications Panel. However, there can be no assurance that, even if we appeal the Nasdaq Staff's delisting determination to the panel, such appeal would be successful.

We intend to monitor the closing bid price of our common stock and may, if appropriate, consider available options to regain compliance with the minimum bid price requirement, which could include seeking to effect a reverse stock split. However, there can be no assurance that we will be able to regain compliance with the minimum bid price requirement or maintain compliance with any of the other Nasdaq continued listing requirements.

If we are unable to comply with applicable Nasdaq listing standards, shares of our common stock would be subject to delisting, which could have a material adverse effect on the market for, and liquidity and price of, our common stock and would adversely affect our ability to raise capital on terms acceptable to us, or at all. Delisting from Nasdaq could also have other negative results, including, without limitation, the potential loss of confidence by investors, customers and employees and fewer business development opportunities. Any delisting of our common stock from Nasdaq would also make it more difficult for our stockholders to sell their shares of our common stock in the public market.

We have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future.

Since inception, we have incurred significant operating losses, including net losses of $45.4 million and $45.1 million for the nine months ended September 30, 2025 and 2024, respectively, and a net loss of $58.2 million for the year ended December 31, 2024. As of September 30, 2025, we had an accumulated deficit of $429.1 million. As of September 30, 2025, we had cash and cash equivalents of $103.8 million. To date, we have financed our operations primarily from proceeds raised through private placements of preferred units, convertible preferred stock, common stock and prefunded warrants; sales of common stock in our initial public offering, or IPO, and through "at-the-market" offerings; the sale of prefunded warrants and common stock warrants in a follow-on public offering; and upfront payments under our collaboration and license agreements with AbbVie and Gilead. All of our programs are in clinical or preclinical development. As a result, we have not generated any revenue from product sales and do not expect to generate any revenue from product sales for at least the next several years, if at all. Our operating expenses and net losses may fluctuate significantly from quarter to quarter and year to year, and we expect to continue to incur significant expenses and operating losses for the foreseeable future, particularly to the extent we:

- continue to advance our current research programs and conduct additional research programs;
- advance our current product candidates and any future product candidates we may develop into preclinical and clinical development;
- seek marketing approvals for product candidates that successfully complete clinical trials, if any;
- obtain, expand, maintain, defend and enforce our intellectual property;
- continue to discover, validate and develop additional product candidates;
- continue to manufacture increasing quantities of our current or future product candidates for use in preclinical studies, clinical trials and for any potential commercialization;
- acquire or in-license other product candidates, technologies or intellectual property;
- hire additional personnel to support current or future programs;
- establish a commercial and distribution infrastructure to commercialize products for which we may obtain marketing approval, if any; and
- incur additional costs associated with current and future research development and commercialization efforts and operations as a public company.

Even if we successfully complete clinical trials and obtain regulatory approval for one or more of our product candidates, our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful commercialization of those product candidates. Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve profitability. In addition, even if we are able to generate revenue from product sales, we may not become profitable.

We have no products approved for commercial sale and have not generated any revenue from product sales. We may never generate any revenue from product sales or become profitable and, if we achieve profitability, we may not be able to sustain it.

To date, we have not generated any revenue from product sales. We do not expect to generate any revenue from the sale of products for a number of years, and we may never generate revenue from the sale of products. Our ability to generate revenue from product sales depends on a number of factors, including our ability to:

- successfully complete our ongoing and planned preclinical studies and clinical trials for any current or future product candidates;
- successfully receive U.S. Food and Drug Administration, or FDA, clearance for any investigational new drug application, or IND, for any current or future product candidates;
- successfully initiate and complete clinical trials for our clinical-stage product candidates and any other current or future product candidates, including all safety and efficacy studies necessary to obtain U.S. and foreign regulatory approval for our product candidates;

- establish and maintain clinical and commercial manufacturing capabilities or make arrangements with third-party manufacturers for clinical supply and commercial manufacturing;
- launch commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- obtain and maintain acceptance of the products, if and when approved, by patients, the medical community and third-party payors;
- effectively compete with other therapies;
- obtain and maintain healthcare coverage and adequate reimbursement for our products, if and when approved;
- maintain a continued acceptable safety profile of our products following approval; and
- enforce and defend intellectual property rights and claims.

Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of expenses we may incur in connection with these activities prior to generating revenue from product sales. In addition, we may never succeed in these activities, and, even if we do, we may never generate revenues that are significant enough to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product candidates or even continue our operations. A decline in the value of our company could also cause our stockholders to lose all or part of their investment.

Our limited operating history may make it difficult for an investor to evaluate the success of our business to date and to assess our future viability.

We are a clinical-stage biotechnology company with a limited operating history upon which investors can evaluate our business and prospects. Since inception, we have devoted substantially all of our financial resources and efforts to performing research and development activities. Our approach to the discovery and development of tumor-activated product candidates using our proprietary platform technology is unproven, and we do not know whether we will be able to develop any approved products of commercial value. In addition, each of our product candidates is either in early clinical or preclinical development, and all of our other development programs are still in discovery stages. We have not yet demonstrated an ability to successfully complete any late-stage clinical trials, obtain regulatory approvals, manufacture a commercial-scale product, or arrange for a third party to do so on our behalf, or conduct the sales and marketing activities necessary for successful product commercialization. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing biopharmaceutical products.

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

We have incurred substantial losses during our history. As of December 31, 2024, we had federal and state net operating loss, or NOL, carryforwards of $245.5 million and $217.5 million, respectively. We do not anticipate generating revenue from sales of products for the foreseeable future, if ever, and we do not know whether or when we will generate taxable income necessary to utilize our NOLs.

In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, and corresponding provisions of state law, if a corporation undergoes an “ownership change” (generally defined as a greater than 50 percentage point change (by value) in the ownership of its equity by certain stockholders over a three-year period), the corporation’s ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income is subject to limitations. In the second quarter of 2024, we had an ownership change as defined by Sections 382 and 383 of the Code. As a result, if we earn net taxable income, our ability to use our pre-change NOL carryforwards and other pre-change tax attributes to offset such taxable income may be subject to limitations, which could result in increased future tax liability to us and could have an adverse effect on our future results of operations.

There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, our existing NOLs could expire or otherwise become unavailable to offset future income tax liabilities. As described below in "Risks Related to Ownership of Our Common Stock—Changes in tax laws or in their implementation or interpretation may adversely affect our business and financial condition," the Tax Cuts and Jobs Act of 2017, or the Tax Act, as amended by the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, includes changes to U.S. federal tax rates and the rules governing NOL carryforwards that may significantly impact our ability to utilize our NOLs to offset taxable income in the future. In addition, state NOLs generated in one state cannot be used to offset income generated in another state. For these reasons, even if we attain profitability, we may be unable to use a material portion of our NOLs and other tax attributes.

Risks Related to the Discovery and Development of Our Product Candidates

Our business is highly dependent on the success of our current product candidates, which are in the early stages of development and will require significant additional preclinical and clinical development before we can seek regulatory approval for and commercially launch a product.

Our business and future success is highly dependent on our ability to obtain regulatory approval for, and if approved, successfully launch and commercialize, our current product candidates, including our clinical-stage, tumor-activated product candidates: vilastobart and efarindodekin alfa. We are currently evaluating vilastobart in combination with atezolizumab (Tecentriq®) in Phase 1C combination dose escalation in patients with advanced solid tumors and in a Phase 2 clinical trial evaluating the combination in patients with microsatellite stable metastatic colorectal cancer, or MSS mCRC. We are evaluating efarindodekin alfa as a monotherapy in patients with certain advanced solid tumors in an ongoing Phase 1/2 clinical trial under our exclusive license agreement with Gilead. We also have a portfolio of programs that are in earlier stages of development and may never advance to clinical-stage development, including XTX501, our bispecific PD-1/masked IL-2, which is designed to selectively stimulate PD-1 positive antigen-experienced T cells and enhance their function and is currently advancing in initial IND-enabling activities, and our wholly owned preclinical programs for masked T cell engagers targeting prostate-specific membrane antigen, or PSMA, claudin 18.2, or CLDN18.2, and six-transmembrane epithelial antigen of prostate 1, or STEAP1, as well as an additional masked T cell engager program in collaboration with AbbVie.

Commencing clinical trials in the U.S. is subject to acceptance by the FDA of an IND and finalizing the trial design based on discussions with the FDA and other regulatory authorities. In the event that the FDA requires us to complete additional preclinical studies, or we are required to satisfy other FDA requests prior to commencing clinical trials, the start of our clinical trials may be delayed. Even after we receive and incorporate guidance from these regulatory authorities, the FDA or other regulatory authorities could disagree that we have satisfied their requirements to commence any clinical trial or change their position on the acceptability of our trial design or the clinical endpoints selected, which may require us to complete additional preclinical studies or clinical trials or impose stricter approval conditions than we currently expect. There are equivalent processes and risks applicable to clinical trial applications in other countries, including countries in the European Union, or EU.

To date, we have only had limited interactions with the FDA regarding our clinical development plans. We may experience issues surrounding preliminary trial execution, such as delays in FDA acceptance of any future INDs, revisions in trial design and finalization of trial protocols, difficulties with patient recruitment and enrollment, quality and provision of clinical supplies, or early safety signals.

We are not permitted to market any biological product in the U.S. until we receive approval of a Biologics License Application, or BLA, from the FDA. We have not previously submitted a BLA to the FDA, or similar marketing application to comparable foreign regulatory authorities. A BLA must include extensive preclinical and clinical data and supporting information to establish that the product candidate is safe, pure and potent for each desired indication. A BLA must also include significant information regarding the chemistry, manufacturing and controls for the product, and the manufacturing facilities must complete a successful pre-license inspection.

FDA approval of a BLA is not guaranteed, and the review and approval process is expensive, uncertain and may take several years. The FDA also has substantial discretion in the approval process. The number and types of preclinical studies and clinical trials that will be required for BLA approval varies depending on the product candidate, the disease or the condition that the product candidate is designed to treat and the regulations applicable to any particular product candidate. Despite the time and expense associated with preclinical studies and clinical trials, failure can occur at any stage.

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 candidate that we develop based on the completed clinical trials.

Generally, public concern regarding the safety of biopharmaceutical products could delay or limit our ability to obtain regulatory approval, result in the inclusion of unfavorable information in our labeling or require us to undertake other activities that may entail additional costs. We have not obtained FDA approval for any product. This lack of experience may impede our ability to obtain FDA approval in a timely manner, if at all, for any current or future product candidates.

The success of our business, including our ability to finance our company and generate any revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization of our current and any future product candidates, which may never occur. However, given our early stage of development, it will be years before we are able to demonstrate the safety and efficacy of a treatment sufficient to warrant approval for commercialization, and we may never be able to do so. If we are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize our current or any future product candidates, we may not be able to generate sufficient revenue to continue our business.

Preclinical development is uncertain. Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all, which would have an adverse effect on our business.

All our product candidates are still in the early clinical stage or preclinical stage of development, and their risk of failure is high. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support our planned INDs in the U.S., or similar applications in other jurisdictions. We cannot be certain of the timely completion or outcome of our preclinical testing and studies, and we cannot predict if the FDA or other regulatory authorities will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of our programs. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our current or future preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin.

Preclinical studies and clinical trials are expensive, time-consuming and difficult to design and implement, and involve uncertain outcomes. Furthermore, results of earlier preclinical studies and clinical trials may not be predictive of results of future preclinical studies or clinical trials.

The risk of failure for our current and any future product candidates is high. It is impossible to predict when or if any of our product candidates will successfully complete preclinical studies or clinical trials evaluating their safety and effectiveness in humans or will ultimately receive regulatory approval. To obtain the requisite regulatory approvals to market and sell any of our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe and effective in humans for use in each target indication. Preclinical and clinical testing is expensive and can take many years to complete, and the outcome is inherently uncertain. Failure can occur at any time during the preclinical or clinical trial process. The outcome of preclinical testing and early clinical trials may not be predictive of the results of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. In particular, while we have conducted certain preclinical studies for each of our clinical stage product candidates, we do not know whether these product candidates will perform in our clinical trials as they have performed in these prior preclinical studies. Similarly, there can be no assurance that early, interim or preliminary clinical data or results will be predictive of or replicated in future clinical data or results, including without limitation, the Phase 1/2 data for vilastobart in combination with atezolizumab and the Phase 1 data for efarindodekin alfa reported to date. Many companies in the biopharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway, or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events, or AEs. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in clinical trial procedures set forth in protocols, differences in the size and type of the patient populations, adherence to the dosing regimen and other clinical trial protocols, and the rate of dropout among clinical trial participants. If we fail to produce positive results in our planned and ongoing preclinical studies or clinical trials, or if we experience material changes in clinical data or results from those we have previously reported, the development timeline and regulatory approval and commercialization prospects for our product candidates, and, correspondingly, our business, financial condition and results of operations would be materially and adversely affected.

We may encounter substantial delays in the commencement or completion, or termination or suspension, of our clinical trials, which could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidate for its intended indications. We cannot guarantee that any clinical trials, including our Phase 2 clinical trial evaluating vilastobart in combination with atezolizumab or our Phase 1 clinical trial evaluating efarindodekin alfa as a monotherapy, will be conducted as planned or completed on schedule, if at all. We may experience numerous unforeseen events leading up to, during or as a result of clinical trials that could delay or prevent the initiation or completion of a clinical trial or our ability to receive marketing approval or commercialize our product candidates, including:

- we may be unable to generate sufficient preclinical, toxicology, or other *in vivo* or *in vitro* data to obtain regulatory authorizations to commence a clinical trial;
- we may experience issues in reaching a consensus with regulatory authorities on trial design;
- regulators or institutional review boards, or 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;
- 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, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trial sites may deviate from a trial protocol or drop out of a trial or fail to conduct the trial in accordance with regulatory requirements;
- the number of subjects required for clinical trials of our product candidates may be larger than we anticipate, or subjects may fail to enroll or remain in clinical trials at the rate we expect;
- subjects that enroll in our studies may misrepresent their eligibility or may otherwise not comply with the clinical trial protocol, resulting in the need to drop the subject from the trial, increase the needed enrollment size for the clinical trial or extend its duration;
- subjects may choose an alternative treatment for the indication for which we are developing our product candidates, or participate in competing clinical trials;
- subjects may experience severe or unexpected treatment-related adverse effects;
- clinical trials of our product candidates may produce unfavorable, inconclusive, or clinically insignificant results;
- we may decide to, or regulators, or IRBs, or ethics committees may require us to, make changes to a clinical trial protocol or conduct additional preclinical studies or clinical trials, or we may decide to abandon product development programs;
- we may need to add new or additional clinical trial sites;
- our third-party contractors, including those manufacturing our product candidates or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we may experience manufacturing delays, and any changes to manufacturing processes or third-party contractors that may be necessary or desired could result in other delays;

- we or our third-party contractors may experience delays due to complications resulting from the impact of public health crises, including epidemics and pandemics, or geopolitical tensions;
- the cost of preclinical testing and studies and clinical trials of any product candidates may be greater than we anticipate or greater than our available financial resources;
- 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 or we may not be able to obtain sufficient quantities of combination therapies for use in current or future clinical trials;
- reports may arise from preclinical or clinical testing of other cancer therapies that raise safety or efficacy concerns about our product candidates; and
- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond the clinical trials and testing that we contemplate, if we are unable to successfully complete clinical trials or other testing of our product candidates, if the results of these clinical trials or tests are unfavorable or are only modestly favorable or if there are safety concerns associated with any of product candidates, we may:

- incur additional unplanned costs;
- be required to suspend or terminate ongoing clinical trials;
- be delayed in obtaining marketing approval, if at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing or other requirements;
- be required to perform additional clinical trials to support approval;
- have regulatory authorities withdraw, or suspend, their approval of the drug or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy, or REMS;
- be subject to the addition of labeling statements, such as warnings or contraindications;
- have the product removed from the market after obtaining marketing approval;
- be subject to lawsuits; or
- experience damage to our reputation.

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

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

In addition to the factors above, we may make formulation or manufacturing changes to our product candidates, in which case we may need to conduct additional preclinical studies or clinical trials to bridge our modified product candidates to earlier versions, which may be costly, time consuming and may not be successful at all.

Our failure to successfully initiate and complete clinical trials of our product candidates and to demonstrate the efficacy and safety necessary to obtain regulatory approval to market any of our product candidates would significantly harm our business. We cannot guarantee that our clinical trials will begin as planned or be completed on schedule, if at all, or that we will not need to restructure our clinical trials. Significant preclinical study or clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates, which may harm our business and results of operations. In addition, many of the factors that cause, or lead to, delays of clinical trials may ultimately lead to the denial of regulatory approval of our product candidates.

If we experience delays or difficulties in the enrollment of patients in 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 study until its conclusion. The enrollment of patients depends on many factors, including:

- clinicians' and patients' perceptions as to the potential advantages 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;
- the severity of the disease under investigation;
- the patient eligibility and the inclusion and exclusion criteria defined in the protocol;
- AEs in our clinical trials and in third-party clinical trials of agents similar to our product candidates;
- the size and health of the patient population required for analysis of the trial's primary endpoints;
- 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;
- our ability to obtain and maintain patient consents;
- our ability to monitor patients adequately during and after treatment;
- the risk that patients enrolled in clinical trials will drop out of the trials before completion; and
- factors we may not be able to control that may limit the availability of patients, principal investigators or staff or clinical sites, such as public health crises, including epidemics and pandemics.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition 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 at such clinical trial site.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or might require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, slow down or halt our product candidate development and approval process and jeopardize our ability to seek and obtain the marketing approval required to commence product sales and generate revenue, which would cause the value of our company to decline and limit our ability to obtain sufficient additional capital.

Our product candidates may cause undesirable or unexpectedly severe side effects that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Undesirable or unexpectedly severe side effects caused by our product candidates could cause us to interrupt, delay or halt preclinical studies or could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. Traditional cytokine therapies and checkpoint inhibitors have long been associated with severe toxicities, which can be life-threatening or fatal, that have resulted in the need to dose-reduce, dose-interrupt and discontinue many patients from treatment. As has been the case with traditional immuno-oncology, or I-O, treatments for cancer, it is possible that there may be severe side effects associated with the use of our current or future product candidates. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, our clinical trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

In addition, clinical trials rely on a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of our product candidates may only be uncovered when a significantly larger number of patients is exposed to the product candidate. If our product candidates receive marketing approval and we or others identify undesirable side effects caused by such product candidates after such approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- regulatory authorities may require a REMS plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools;
- we may be required to change the way such product candidates are distributed or administered, conduct additional clinical trials or change the labeling of the product candidates;
- we may be subject to regulatory investigations and government enforcement actions;
- regulatory authorities may withdraw or limit their approval of such product candidates;
- we may decide to remove such product candidates from the marketplace;
- we could be sued and held liable for injury caused to individuals exposed to or taking our product candidates; and
- we may suffer reputational harm.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

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

From time to time, we may publish interim top-line or preliminary data from our clinical trials. For example, we most recently reported updated data from our Phase 2 clinical trial for vilastobart in combination with atezolizumab and from our Phase 1 clinical trial for efarindodekin alfa in November 2025 at the Society for Immunotherapy of Cancer (SITC) 40th Annual Meeting. Preliminary and interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or “top-line” data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data previously published. As a

result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

We expect to develop certain of our product candidates in combination with third-party drugs and we will have limited or no control over the safety, supply, regulatory status or regulatory approval of such third-party drugs.

We intend to develop our clinical-stage product candidates, and likely other future product candidates, in combination with third-party cancer drugs, which may be either approved or unapproved. For example, we are currently evaluating vilastobart in combination with atezolizumab (Tecentriq®) in Phase 1 combination dose escalation in patients with advanced solid tumors and in a Phase 2 clinical trial evaluating the combination in patients with metastatic MSS mCRC. Our ability to develop and ultimately commercialize our current product candidates, and any future product candidates, used in combination with third-party drugs will depend on our ability to access such drugs on commercially reasonable terms for clinical trials and their availability for use with our commercialized product, if approved. We cannot be certain that current or potential future commercial relationships will provide us with a steady supply of such drugs on commercially reasonable terms or at all. Any failure to maintain or enter into new successful commercial relationships, or the expense of purchasing such third-party drugs in the market, may delay our development timelines, increase our costs and jeopardize our ability to develop our current product candidates and any future product candidates as commercially viable therapies. If any of these occur, our business, financial condition, operating results or prospects may be materially harmed.

Moreover, the development of product candidates for use in combination with another product or product candidate may present challenges that are not faced for single agent product candidates. For example, our plans to evaluate current or future product candidates in combination with other agents may result in AEs based on the combination therapy that may negatively impact the reported safety profile of the monotherapy in clinical trials. In addition, the FDA or comparable foreign regulatory authorities may require us to use more complex clinical trial designs in order to evaluate the contribution of each product and product candidate to any observed effects. It is possible that the results of such trials could show that any positive previous trial results are attributable to the third-party drug and not our product candidate. Developments related to the third-party drug may also impact our clinical trials for the combination therapy as well as our commercial prospects should we receive regulatory approval. Such developments may include changes to the third-party drug's safety or efficacy profile, changes to the availability of the third-party drug, quality, and manufacturing and supply issues with respect to the third-party drug.

If we are able to obtain marketing approval, the FDA or comparable foreign regulatory authorities may require that products used in conjunction with each other be cross labeled for combined use. To the extent that we do not have rights to the third-party drug, this may require us to work with such third party to satisfy such a requirement. We would also continue to be subject to the risks that the FDA or comparable foreign regulatory authorities could revoke approval of the third-party drug used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with such drug. Similarly, if the third-party drugs we use in combination with our product candidates are replaced as the standard of care for the indications we choose for any of our product candidates, the FDA or comparable foreign regulatory authorities may require us to conduct additional clinical trials. The occurrence of any of these risks could result in our own products, if approved, being removed from the market or being less successful commercially.

We may not be successful in our efforts to use our platform technology to enable the development of a pipeline of tumor-activated product candidates.

A key element of our strategy is to use our novel platform technology to engineer and develop tumor-activated molecules with the potential to trigger anti-tumor immunity with minimal systemic toxicity in order to advance a pipeline of product candidates. We may not be able to continue to identify and develop novel I-O therapies. Even if we are successful in continuing to advance our pipeline, the potential product candidates that we identify may not be suitable for clinical development. For example, potential product candidates may be shown to have harmful side effects or other characteristics that indicate that they are unlikely to or will not be drugs that will receive marketing approval and achieve market acceptance. If we do not successfully develop and commercialize product candidates based upon our platform approach or take longer to do so than anticipated, we will not or may not be able to obtain drug revenues in future periods, which likely would result in significant harm to our financial position and adversely affect our stock price.

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

Although we intend to explore other therapeutic opportunities in addition to the product candidates that we are currently developing, we may fail to identify or discover viable new product candidates for clinical development for a number of reasons. If we fail to identify additional potential product candidates, our business could be materially harmed.

Research programs to pursue the development of our existing and planned product candidates for additional indications and to identify new product candidates and disease targets require substantial technical, financial and human resources whether or not they are ultimately successful. We may in the future rely on third parties for certain research, and we will not have complete control over their performance and ability to successfully develop product candidates. Our research programs may initially show promise in identifying potential indications and/or product candidates, yet fail to yield results for clinical development for a number of reasons, including:

- the research methodology used may not be successful in identifying potential indications and/or product candidates;
- potential product candidates may, after further study, be shown to have harmful adverse effects or other characteristics that indicate they are unlikely to be effective drugs; and
- it may take greater human and financial resources than we will possess to identify and advance additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, thereby limiting our ability to develop, diversify and expand our product portfolio.

Accordingly, there can be no assurance that we will ever be able to identify additional therapeutic opportunities for our current product candidates or to develop suitable additional product candidates through internal research programs, which could materially adversely affect our future growth and prospects.

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

The success of our business depends primarily upon our ability to discover, develop and commercialize products based on our technological approaches. While we have had favorable preclinical and early clinical results related to our clinical-stage product candidates, vilastobart and efarindodekin alfa, we have not yet succeeded and may not succeed in demonstrating efficacy and safety for any product candidates in current or future clinical trials or in obtaining marketing approval thereafter. We rely on matrix metalloproteases, or MMPs, to activate our molecules within the tumor microenvironment. If MMP activity in human tumors is not sufficient to cleave the masking protein domain, the potential efficacy of our product candidates would be limited. We have no assurance that our product candidates will successfully progress through clinical development and ultimately marketing approval. We have invested substantially all of our efforts and financial resources in developing our initial product candidates and our future success is highly dependent on the outcome of our ongoing clinical trials and the successful development of our technology and product candidates.

In addition, the clinical trial requirements of the FDA and other regulatory agencies and the criteria these regulators use to determine the safety and efficacy of a product candidate may vary according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates can be more expensive and take longer than for other, better known or extensively studied pharmaceutical or other product candidates. As a result, we may face a greater regulatory burden to initiate clinical trials or to obtain regulatory approval of our product candidates as compared to product candidates based on more established technology. In addition, any product candidates for which we may be able to obtain marketing approval may be subject to extensive post-approval regulatory requirements, including requirements pertaining to manufacturing, distribution and promotion. We may need to devote significant time and resources to comply with these requirements.

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

We have chosen to initially develop each of our clinical-stage product candidates for the treatment of various solid tumor types. Nevertheless, our development efforts will be limited to a small number of cancer types, and we may forego or delay pursuit of opportunities in other cancer types that may prove to have greater potential. Likewise, we may forego or delay the pursuit of opportunities with other potential product candidates that may prove to have greater commercial potential.

In addition, our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any viable product candidates. Similarly, if we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other similar arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to the product candidate.

We may become exposed to costly and damaging liability claims, either when testing our product candidates in the clinic or following commercial sale, and any product liability insurance we may obtain may not cover all damages from such claims.

We are exposed to potential product liability risks that are inherent in the research, development, manufacturing, marketing and use of biopharmaceutical products. The use of product candidates by us in clinical trials, and any sale of approved products in the future, may expose us to liability claims. 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.

Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If any of our product candidates were to cause adverse side effects during clinical trials or after approval thereof, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or cease the development or commercialization of our product candidates or any products for which we may have received marketing approval. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- delay or termination of clinical trials;
- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media and social media attention;
- withdrawal of clinical trial participants or difficulties in recruiting new trial participants;
- initiation of investigations by regulators;
- costs to defend or settle the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- significant negative financial impact; and
- the inability to commercialize any of our product candidates, if approved.

Although we will seek to procure and maintain sufficient product liability insurance coverage, our current insurance coverage and any insurance coverage we obtain in the future may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage each time we commence a clinical trial and if we successfully commercialize any product candidate. As the expense of insurance coverage is increasing, we may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be materially harmed.

Risks Relating to Manufacturing and Supply

Manufacturing biologics is complex, and we may experience manufacturing problems that result in delays in our development or commercialization programs.

The manufacturing of biologics is complex and difficult and we may experience production issues or interruptions in supply for our product candidates, including variability of raw material, consumable or starting material quality, cell line viability, productivity or stability issues, shortages of any kind, shipping, distribution, storage and supply chain failures, media contamination, equipment malfunctions or failures, operator errors, facility contamination, labor problems, quality system and regulatory inspection failures, adverse impacts from current or future trade sanctions, tariffs or similar actions, natural disasters, disruption in utility services, terrorist activities, or acts of god that are beyond our control or the control of our third-party contract development and manufacturing organizations, or CDMOs.

Given the nature of biologics manufacturing, there is a risk of contamination during manufacturing. Any contamination could materially harm our ability to produce product candidates on schedule and could harm our results of operations and cause reputational damage. In the event that raw materials required in our manufacturing process need to be derived from biologic sources, they may be difficult to procure and may be subject to contamination or recall.

Problems with the manufacturing process, even minor deviations from the normal process, could result in product defects, out-of-specification analytical results or manufacturing failures that result in lot failures, product recalls, product liability claims, insufficient inventory or potentially delay progression of our preclinical or clinical development of any product candidates we may develop. If we successfully develop product candidates, we may encounter problems achieving adequate quantities and quality that meet FDA, European Medicines Agency, or EMA, or other comparable applicable foreign standards or specifications with consistent and acceptable production yields and costs. The ability to scale our manufacturing and maintain the manufacturing process at the same levels of quality and efficiency that we are currently manufacturing is yet to be tested. If we or our third-party CDMO is unable to scale our manufacturing and meet the same levels of quality and efficiency, or provide sufficient manufacturing campaign slots to generate materials, we may not be able to supply the required number of doses for clinical trials or commercial supply. A material shortage, contamination event or manufacturing failure in the manufacture of any product candidate we may develop or other adverse impact or disruption in the commercial manufacturing or the production of clinical material could materially harm our development timelines and our business, financial condition, results of operations and prospects.

We face risks related to our reliance on our current and any future CDMOs. For example, we and our CDMO are subject to significant regulation with respect to manufacturing our products. The manufacturing facilities of the CDMO on which we rely may not continue to meet regulatory requirements, may have limited capacity or may experience interruptions in supply, any of which could adversely affect our development and commercialization plans for our product candidates. All entities involved in the preparation and storage of therapeutics for clinical trials or commercial sale, including any CDMOs of any product candidates we may develop, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in clinical trials must be manufactured in accordance with current Good Manufacturing Practices, or cGMP. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We, in partnership with our CDMO, must supply all necessary documentation in support of an IND for clinical product, and later in support of a BLA for any potential commercial product, on a timely basis and must adhere to the FDA's and EMA's current Good Laboratory Practices and cGMP regulations enforced through the applicable regulatory authority's facilities inspection program. Our facilities and quality systems and the facilities and quality systems of our CDMO must pass a pre-approval inspection, or PAI, to confirm validity of the information presented in the BLA and to confirm the capability of the facility to manufacture our product in compliance with the applicable regulations. The PAI is a condition of regulatory approval of any product candidates we may develop or any of our other potential products. If our or our CDMO's quality systems or facilities involved with the preparation of our product candidates do not pass the PAI, FDA approval of such product candidates will not be granted.

In addition, the regulatory authorities may, at any time, conduct a routine or for-cause inspection of a manufacturing facility involved with the preparation of our product candidates, which inspection is related to other products manufactured at the site or the associated quality systems, for compliance with the regulations applicable to the activities being conducted. The regulatory authorities also may, at any time following approval of a product for sale, inspect our facilities or the manufacturing facilities of our CDMOs. If any such inspection identifies a failure to comply with applicable regulations, or if a violation of our product specifications or applicable

regulations occurs independent of such an inspection, we or the relevant regulatory authority may require remedial measures that may be costly and/or time-consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales, the temporary or permanent closure of a facility, or other remedial measures that may delay or disrupt the manufacture or release of our product candidates or other potential products. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

If we or any CDMO with which we contract for manufacturing and supply fails to maintain regulatory compliance, the FDA can impose regulatory sanctions including, among other things, a clinical hold, refusal to approve a pending application for a new drug product or biologic product, revocation of a pre-existing approval, or an import alert. As a result, our business, financial condition and results of operations may be materially harmed.

Currently, we depend on WuXi Biologics (Hong Kong) Limited, or WuXi Biologics, for developing the manufacturing processes required to supply our product candidates. We cannot ensure that this manufacturer will remain in business or have sufficient capacity or supply to meet our needs. Our use of a single manufacturer exposes us to several risks, including price increases or manufacturing delays beyond our control. WuXi Biologics is based in and has significant operations in China, where our product candidates are manufactured, which subjects us to additional risks including those related to U.S. export control laws, potential sanctions or other trade restrictions imposed by the U.S. government. Moreover, reliance on third-party manufacturers generally entails risks to which we would not be subject if we manufactured the product candidates ourselves, including:

- the inability to negotiate manufacturing agreements with third parties under commercially reasonable terms or at all, particularly if they are affiliated with our competitors;
- reduced control as a result of using third-party manufacturers for all aspects of manufacturing activities, particularly if they are under contract with our competitors;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- disruptions to the operations of our third-party manufacturers or suppliers caused by conditions unrelated to our business or operations, including geopolitical tensions or restrictions, such as export controls or sanctions, or the bankruptcy of the manufacturer or supplier;
- the inability to import or obtain components or materials from alternate sources at acceptable prices or with acceptable quality in a timely manner; and
- substantial delays or difficulties related to the establishment of replacement manufacturers who meet regulatory requirements.

Any of these events could lead to clinical trial delays or failure to obtain regulatory approval or impact our ability to successfully commercialize future products. Some of these events could be the basis for FDA action, including injunction, recall, seizure, import alert, or total or partial suspension of production.

Additionally, if supply from one approved manufacturer is interrupted, such as could be the case with our current CDMO, WuXi Biologics, there could be a significant disruption in supply. While we believe there are alternate manufacturers who can provide the manufacturing processes required to develop and manufacture our product candidates, if we have to switch to a replacement manufacturer, the manufacture and delivery of our product candidates could be interrupted for an extended period, which could adversely affect our business. Furthermore, an alternative manufacturer must be able to demonstrate successful technology transfer of the manufacturing process and associated assays, and, to do so, may need to modify the manufacturing process required to develop our product candidates, and the alternative manufacturer would need to be qualified through additional regulatory filings, all of which could result in further delay and significant costs. The regulatory agencies may also require additional studies or trials if a new manufacturer is relied upon for clinical or commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, cause us to incur higher costs and prevent us from commercializing our products successfully. Furthermore, if our suppliers fail to meet contractual requirements, and we are unable to secure one or more replacement suppliers capable of production at a

substantially equivalent cost, our clinical trials may be delayed, or we could lose potential revenue or market share with respect to any product that has received marketing approval.

Certain of our research and development and manufacturing activities take place in China through WuXi Biologics. A significant disruption in our ability to rely on WuXi Biologics could materially adversely affect our business, financial condition and results of operations.

We have relied on WuXi Biologics in China to manufacture and supply certain raw materials used in our product candidates, and we expect to continue to use WuXi Biologics as our CDMO for such purposes. A natural disaster, epidemic or pandemic, such as the COVID-19 pandemic, trade war, political unrest, economic conditions, changes in legislation, including the passage of the People's Republic of China Biosecurity law, which became effective on April 15, 2021, and subsequent legislation that China or the U.S. may adopt in the future, or other events in China could disrupt our ability to continue to rely upon CROs, CDMOs, collaborators, manufacturers or other third parties with whom we conduct business now or in the future. Any disruption in China or the U.S. that significantly impacts such third parties, including services provided by CROs for our research and development programs, or our manufacturers' ability to produce and export raw or manufactured materials in adequate quantities to meet our needs, could impair our ability to operate our business on a day-to-day basis and impede, delay, limit or prevent the research, development or commercialization of our current and future products or product candidates. In addition, for any activities conducted in China, we are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies of the U.S. or Chinese governments, political unrest or unstable economic or geopolitical conditions, including sanctions in China or against certain Chinese companies; changes in U.S. export laws or the imposition by the U.S. of trade barriers; sanctions; limitations on uses of U.S. government executive agency contract, grant or loan funds; or other restrictions on doing business with certain Chinese companies, including WuXi Biologics, which could have a material adverse effect on our business. Additionally, we may be exposed to fluctuations in the value of the local currency in China for goods and services. Our costs for any of these services or activities could also increase as a result of future appreciation of the local currency in China or increased labor costs if the demand for skilled laborers increases and/or the availability of skilled labor declines in China.

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

We and any CDMOs and suppliers we engage are subject to numerous federal, state and local environmental, health, and safety laws, regulations and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment and disposal of biological or hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air and water; and employee health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste. 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. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. Under certain environmental laws, we could be held responsible for costs relating to any contamination at third-party facilities. We also could incur significant costs associated with civil or criminal fines and penalties.

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

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws, regulations and permitting requirements. These current or future laws, regulations and permitting requirements may impair our research, development or production efforts. Failure to comply with these laws, regulations and permitting requirements also may result in

substantial fines, penalties or other sanctions or business disruption, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Risks Related to our Dependence on Third Parties

We expect to rely on third parties to conduct, supervise and monitor IND-enabling studies and clinical trials, and if these third parties perform in an unsatisfactory manner, it may harm our business, reputation and results of operations.

We expect to rely on CROs and research and clinical trial sites to ensure our IND-enabling studies and clinical trials are conducted properly and on time, and we expect to rely in the future on CROs for additional research programs. While we will have agreements governing their activities, we will have limited influence over their actual performance. We will control only certain aspects of our CROs' activities. Nevertheless, we will be responsible for ensuring that each of these studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities.

We and our CROs will be required to comply with the FDA's Good Clinical Practices, or GCPs, for conducting, recording and reporting the results of IND-enabling studies and clinical trials to assure that the data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. The FDA enforces these GCPs through periodic inspections of study sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with applicable GCPs, the preclinical and clinical data generated in our studies may be deemed unreliable and the FDA may require us to perform additional studies before approving any marketing applications. Upon inspection, the FDA may determine that our studies did not comply with GCPs.

Our CROs are not our employees, and we are therefore unable to directly monitor whether or not they devote sufficient time and resources to our clinical and nonclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols or regulatory requirements, or for any other reasons, our studies may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize any product candidates we may develop. As a result, our financial results and commercial prospects would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

We have entered into, and may in the future seek to enter into, licenses, collaborations or similar arrangements with third parties for the research, development and commercialization of certain of our current or future product candidates. If any such arrangements are not successful, we may not be able to capitalize on the market potential of those product candidates.

In March 2024, our wholly owned subsidiary, Xilio Development, Inc., or Xilio Development, entered into a license agreement with Gilead, pursuant to which Gilead was granted an exclusive global license to develop and commercialize efarindodekin alfa, our tumor activated IL-12, and other specified molecules directed toward IL-12. In February 2025, Xilio Development entered into a collaboration, license and option agreement with AbbVie, pursuant to which AbbVie was granted (i) an exclusive option for (a) an initial program to discover, develop and commercialize masked T cell engager molecules for an agreed upon initial target and backup target and (b) subject to the terms of the agreement, up to two additional programs to discover, develop, and commercialize masked T cell engager molecules for an initial target and backup target determined at the time of program initiation and (ii) an exclusive license to develop and commercialize a masked antibody-based immunotherapy. We may in the future seek third-party collaborators or licensors for the research, development and commercialization of other current or future product candidates. With respect to our agreements with Gilead and AbbVie, and what we expect will be the case with any future collaboration agreements we enter into, we have and would likely have limited control over whether such collaborators pursue the development of our product candidates or the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates that we seek to develop with them. For example, under the license agreement with Gilead, if Gilead exercises its right to transition responsibilities for the development and commercialization of efarindodekin alfa and the rest of our IL-12 program, it will have sole decision-making authority with respect to the continued development and future commercialization of our IL-12 program and may elect to prioritize other assets

that it believes are more competitive, or it may exercise its right to terminate the license and return the licensed IL-12 program assets to us. Similarly, subject to limited exceptions, AbbVie has sole decision-making authority with respect to the development and commercialization of the masked antibody-based immunotherapy program. With respect to any T cell engager program for which AbbVie exercises its option, AbbVie will have sole decision-making authority with respect to the continued development and future commercialization of such option program and may elect to prioritize other assets that it believes are more competitive, or it may exercise its right to terminate the license and return the licensed T cell engager program assets to us. As a result, there can be no assurances that any of the programs covered by our existing or future collaborations or licenses will be developed further or reach commercialization. Further, our ability to generate revenues from these existing and future arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. We cannot predict the success of any collaboration that we enter into.

Collaborations, licenses or similar arrangements involving our research programs or any product candidates currently pose, and will continue to pose, numerous risks to us, including the following:

- collaborators or licensors have significant discretion in determining the efforts and resources that they will apply to these arrangements;
- collaborators or licensors may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in such third party's strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators or licensors may delay programs, preclinical studies or clinical trials, provide insufficient funding for programs, preclinical studies or clinical trials, stop a preclinical study or 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 or licensors could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- collaborators or licenses may be acquired by a third party having competitive products or different priorities;
- collaborators or licensors with marketing and distribution rights to one or more product candidates may not commit sufficient resources to the marketing and distribution of such product candidate(s);
- collaborators or licensors may not properly obtain, maintain, enforce or defend our intellectual property or proprietary rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- disputes may arise between the collaborators or licensors and us that result in the delay or termination of the research, development, or commercialization of our product candidates or any of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources or that jeopardize or invalidate our intellectual property or proprietary information;
- we may lose certain valuable rights under certain circumstances, including if we undergo a change of control;
- collaborations or licenses may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and
- collaborations or license agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If a present or future collaborator or licensor of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated.

If our current or future collaborations, licenses or similar transactions do not result in the successful development and commercialization of product candidates, including if one of our current or future collaborators or licensors terminates its agreement with us, we may not receive any future payments for which we might otherwise be eligible under such agreement or we may incur significant costs in re-establishing the development and manufacturing of such product candidates. If we do not receive the funding we expect under these agreements, our development of product candidates could be delayed, and we may need additional resources to develop such product

candidates. In addition, if one of our collaborators terminates its agreement with us, we may find it more difficult to find a suitable replacement collaborator or licensor or for us to attract new collaborators or licensors, and our development programs may be delayed or the perception of us in the business and financial communities could be adversely affected. All of the risks relating to product development, regulatory approval and commercialization described in this Quarterly Report on Form 10-Q apply to the activities of our collaborators or licensors.

These relationships, or those like them, may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business. In addition, we could face significant competition in seeking appropriate collaborators, and the negotiation process is time-consuming and complex. Our ability to reach a definitive collaboration or license agreement with future partners will depend, among other things, upon our assessment of the resources and expertise of such third-party collaborator or licensor and the terms and conditions of the proposed collaboration or license. Further, if we license rights for use in any product candidates we or our collaborators may develop, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture.

If we are not able to establish collaborations on commercially reasonable terms, we may have to alter our development and commercialization plans.

Our product development and research programs and the potential commercialization of any product candidates we may develop will require substantial additional cash to fund expenses. For some of the product candidates we may develop, we have decided and may in the future decide to collaborate with other pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration, and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA, the EMA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us.

Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate future collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidates for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay their potential commercialization, reduce the scope of any sales or marketing activities, or increase our own expenditures on the development of the applicable product candidate.

Risks Related to Commercialization

We have never commercialized a product candidate and we may lack the necessary expertise, personnel and resources to successfully commercialize any products that receive regulatory approval, either on our own or together with collaborators.

We have never commercialized a product candidate. We currently have no sales force or marketing or distribution capabilities. To achieve commercial success of our product candidates, if any are approved, we will have to develop our own sales, marketing and supply capabilities or outsource these activities to one or more third parties. Factors that may affect our ability to commercialize our product candidates on our own include our ability to recruit and retain adequate numbers of effective sales and marketing personnel and obtain access to or persuade adequate numbers of physicians to prescribe our product candidates, as well as any unforeseen costs we may incur in connection with creating an independent sales and marketing organization. Developing a sales and marketing organization requires significant investment and substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities, which could delay the launch of our product candidates. We may not be able to build an effective sales and marketing organization in the U.S., the EU or other key global markets. To the extent we need to rely upon one or

more third parties, we may have little or no control over the marketing and sales efforts of those third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We will also face competition in any search for third parties to assist us with sales and marketing efforts for our product candidates. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our product candidates, we may have difficulties generating revenue from them.

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

The development and commercialization of new products is highly competitive. We face competition with respect to our current product candidates and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical, specialty pharmaceutical and biotechnology companies among others. We compete in the segments of the pharmaceutical, biotechnology and other related markets that develop immunotherapies for the treatment of cancer. There are other companies working to develop immunotherapies for the treatment of cancer including divisions of pharmaceutical and biotechnology companies of various sizes. Some of these competitive therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. 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.

We are developing our most advanced clinical-stage, tumor-activated product candidates for the treatment of cancer and have not completed clinical development or received marketing approval for either vilastobart or efarindodekin alfa. There are already a variety of available therapies marketed for cancer and some of the currently approved therapies are branded and subject to patent protection, and others are available on a generic basis. Many of these approved therapies are well-established and widely accepted by physicians, patients and third-party payors. Insurers and other third-party payors may also encourage the use of generic products. We expect that if our product candidates are approved, they will be priced at a significant premium over competitive generic products. This may make it difficult for us to achieve our business strategy of using our product candidates in combination with existing therapies or replacing existing therapies with our product candidates. Competition may further increase with advances in the commercial applicability of technologies and greater availability of capital for investment in these industries.

Vilastobart, if approved, may face competition from other anti-CTLA-4 based therapies. For example, Yervoy (ipilimumab), an anti-CTLA-4, is approved to treat melanoma, renal cell carcinoma and certain cancers of the large intestine, and Imjudo (tremelimumab) is approved as a combination therapy to treat unresectable hepatocellular carcinoma. In addition, we are aware that several companies have anti-CTLA-4 programs in development, including but not limited to Adagene, Inc., Agenus Inc., AstraZeneca plc, BioAtla, Inc., Chugai Pharmaceutical Co. Ltd., CytomX Therapeutics, Inc., Harbour BioMed Co Ltd., MacroGenics, Inc. and OncoC4, Inc.

With respect to efarindodekin alfa, currently there are no IL-12 therapies approved for the treatment of cancer. However, we are aware of several other companies that have modified IL-12 delivery programs in development, including but not limited to Cullinan Management Inc., Dragonfly Therapeutics, Inc., ImmunityBio, Inc., Shanghai KangaBio Co., Ltd., Mural Oncology, Inc., PDS Biotechnology Corporation, Philogen S.p.A., Sonnet BioTherapeutics, Werewolf Therapeutics, Inc., Xencor Inc. and Zymeworks Inc.

With respect to our most advanced research-stage product candidate, XTX501, currently, there are no bispecific PD-1 targeted IL-2 therapies approved for the treatment of cancer. However, if we continue to advance development of XTX501, we are aware of several other companies that have modified PD-1 targeted IL-2 bispecific antibodies in development, including but not limited to Anaveon AG, Bright Peak Therapeutics, Inc., Innovent Biologics, Inc., Regeneron Pharmaceuticals, Inc., Roche, and Teva Pharmaceutical Industries, Ltd.

With respect to our masked T cell engager programs, currently there are no T cell engager therapies targeting PSMA, CLDN18.2 or STEAP1 approved for the treatment of cancer. We are aware of several other companies that have masked T cell engager programs in development for PSMA, including but not limited to Janux Therapeutics, Inc. and Vir Biotechnology, Inc. We are aware of at least one other company, Werewolf Therapeutics, Inc., currently developing a masked T cell engager program for STEAP1. To our knowledge, there are no companies currently developing a masked T cell engager program for CLDN18.2. However, we are aware of several companies developing non-masked T cell engager programs for CLDN18.2, including but not limited to Amgen Inc., Astellas Pharma

Inc., AstraZeneca PLC, Innovent Biologics, Inc., Transcenta Holding Ltd. and Zai Lab Limited, and for STEAP1, including Amgen Inc., Nutcracker Therapeutics and Xencor Inc.

Our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. We also compete with these organizations in establishing clinical trial sites and patient registration for clinical trials, as well as in recruiting and retaining qualified scientific and management personnel, which could negatively affect our level of expertise and our ability to execute our business plan.

Many of our competitors, either alone or with their collaborators, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products than we do. Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel product candidates or to in-license novel product candidates that could make our product candidates less competitive or obsolete. Smaller or early-stage companies may also prove to be significant competitors, including through collaborative arrangements with large and established companies. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. The availability of competing products could limit the demand and the price we are able to charge for product candidates we commercialize, if any. The inability to compete with existing or subsequently introduced products would harm our business, financial condition and results of operations.

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

For planning purposes, we sometimes estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development objectives. These milestones may include our expectations regarding the commencement or completion of scientific studies and clinical trials, the submission of regulatory filings or commercialization objectives. From time to time, we may publicly announce the expected timing of some of these milestones, such as the release of clinical trial data, the completion of an ongoing clinical trial, the initiation of other clinical trials, receipt of regulatory approval or the commercial launch of a product. The achievement of many of these milestones may be outside of our control. All of these milestones are based on a variety of assumptions which may cause the timing of achievement of the milestones to vary considerably from our estimates, including:

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

If we fail to achieve announced milestones in the timeframes we expect, the commercialization of any of our product candidates may be delayed, and our business, results of operations, financial condition and prospects may be adversely affected.

If approved, our product candidates that are licensed and regulated as biological products, or biologics, may face competition from biosimilars approved through an abbreviated regulatory pathway.

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, was enacted as part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, to establish an abbreviated pathway for the approval of biosimilar and interchangeable with an FDA-licensed reference biologic product. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an approved biologic.

Under the BPCIA, reference biological product is granted 12 years of non-patent data exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. In addition, the licensure of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still develop and receive licensure of a competing biologic, so long as their BLA does not rely on the reference product or sponsor's data or submit the application as a biosimilar application.

We believe that any of the product candidates we develop that is licensed in the U.S. as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider the subject product candidate to be a reference product for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of the reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. The approval of a biosimilar of our product candidates could have a material adverse impact on our business due to increased competition and pricing pressure.

If competitors are able to obtain regulatory approval for biosimilars referencing our product candidates, our product candidates may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences.

The sizes of the potential markets for our product candidates are difficult to estimate and, if any of our assumptions are inaccurate, the actual markets for our product candidates may be smaller than our estimates.

The potential market opportunities for our product candidates are difficult to estimate and, if our product candidates are approved, will ultimately depend on, among other things, the indications for which our product candidates are approved for sale, any products with which our product candidates are co-administered, the success of competing therapies and therapeutic approaches, acceptance by the medical community, patient access, product pricing, reimbursement and our ability to create meaningful value propositions for patients, prescribers and payors. Our estimates of the potential market opportunities for our product candidates are predicated on many assumptions, which may include industry knowledge and publications, third-party research reports and other surveys. Although we believe that our internal assumptions are reasonable, these assumptions involve the exercise of significant judgment on the part of our management, are inherently uncertain, and their reasonableness has not been assessed by an independent source. If any of the assumptions prove to be inaccurate, the actual markets for our product candidates could be smaller than our estimates of the potential market opportunities.

The successful commercialization of our product candidates will depend in part on the extent to which we obtain and maintain favorable insurance coverage, adequate reimbursement levels and cost-effective pricing policies with third-party payors.

The availability and adequacy of coverage and reimbursement by third-party payors, including governmental healthcare programs such as Medicare and Medicaid, managed care organizations, and private health insurers, are essential for most patients to be able to afford prescription medications such as our product candidates, if approved. Our ability to achieve acceptable levels of coverage and reimbursement for products by third-party payors will have an effect on our ability to successfully commercialize our product candidates. We cannot be sure that coverage and reimbursement in the U.S., the EU or elsewhere will be available for our product candidates, if approved, or any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs or biologics when an equivalent generic drug, biosimilar or a less expensive therapy is available. It is possible that a third-party payor may consider our product candidates as substitutable and only offer to reimburse patients for the less expensive product. Even if we show improved efficacy or improved convenience of administration with our product candidates, pricing of existing third-party therapeutics may limit the amount we will be able to charge for our product candidates. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in our product candidates, if approved. Even if our product candidates are approved and we obtain coverage for our product candidates by a third-party payor, such products may not be considered cost-effective and/or the resulting reimbursement payment rates may be insufficient or may require co-payments that patients find unacceptably high. Interim reimbursement levels for new medicines, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Net prices for medicines may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of medicines from countries where they may be sold at lower prices than in the U.S. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates, if approved, and may not be able to obtain a satisfactory financial return on our product candidates.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. The regulations that govern marketing approvals, pricing and reimbursement for new medicines vary widely from country to country. In the U.S., third-party payors play an important role in determining the extent to which new drugs and biologics will be covered. The Medicare and Medicaid programs increasingly are used as models in the U.S. for how third-party payors develop their coverage and reimbursement policies for drugs and biologics. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. We cannot predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates, if approved.

No uniform policy for coverage and reimbursement for products exists among third-party payors in the U.S. and coverage and reimbursement for products can therefore differ significantly from payor to payor and coverage and reimbursement by one payor does not guarantee coverage and reimbursement by another payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Our ability to demonstrate to these third-party payors that any of our approved product candidates creates a meaningful value proposition for patients, prescribers and payors will be important to gaining market access and reimbursement and there is no guarantee that we will be successful in doing so. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases on short notice, and we believe that changes in these rules and regulations are likely.

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

If any product candidate we develop receives marketing approval, whether as a single agent or in combination with other therapies, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, hospitals, cancer treatment centers, third-party payors, and others in the medical community. For example, cancer treatments like chemotherapy, radiation therapy and certain existing immunotherapies are well established in the medical community, and doctors may continue to rely on these therapies. 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, if approved for commercial sale, will depend on a number of factors, including:

- the product’s efficacy, safety and potential advantages compared to alternative treatments;
- the prevalence and severity of any side effects;
- the product’s convenience and ease of administration compared to alternative treatments;
- the clinical indications for which the product is approved;

- the willingness of the target patient population to try a novel treatment and of physicians to prescribe such treatments;
- the recommendations with respect to the product in guidelines published by scientific organizations;
- the ability to obtain sufficient third-party insurance coverage and adequate reimbursement, including, if applicable, with respect to the use of the product as a combination therapy;
- the strength of marketing, sales and distribution support;
- the effectiveness of our sales and marketing efforts;
- the approval of other new products for the same indications; and
- our ability to offer the product for sale at competitive prices.

If we obtain marketing approval for a product but such product does not achieve an adequate level of market acceptance, we may not generate or derive significant revenue from that product and our business, financial condition and results of operations may be adversely affected.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for any product candidates we develop or for other proprietary technologies we may develop, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize product candidates and technology similar or identical to our product candidates and technology, and our ability to successfully commercialize any product candidates we may develop, and our technology may be adversely affected.

Our success depends in large part on our ability to obtain and maintain patent protection in the U.S. and other countries with respect to our product candidates, their respective components, formulations, combination therapies, methods used to manufacture them and methods of treatment and development that are important to our business. If we do not adequately protect our intellectual property rights, competitors may be able to erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. To protect our proprietary position, we file patent applications in the U.S. and abroad related to our product candidates that are important to our business; we also license and may in the future license or purchase additional patents and patent applications filed by others. If we are unable to secure or maintain patent protection with respect to our product candidates and any proprietary products and technology we develop, our business, financial condition, results of operations and prospects could be materially harmed.

We cannot provide any assurances that any of our patents have, or that any of our pending patent applications that mature into issued patents will include, claims with a scope sufficient to protect our current and future product candidates or otherwise provide any competitive advantage. Specifically, our patents and pending patent applications, if issued, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent our patents by developing similar or alternative technologies or therapeutics in a non-infringing manner. For example, a third party may develop a competitive therapy that provides benefits similar to one or more of our product candidates but that uses a different masking moiety that falls outside the scope of our patent protection. If the patent protection provided by the patents and patent applications we hold or have licensed with respect to our product candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize our product candidates could be negatively affected, which would harm our business.

The degree of patent protection we require to successfully compete in the marketplace may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep any competitive advantage. The U.S. Patent and Trademark Office, or the USPTO, and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. Our or our licensor’s failure to comply with all such provisions during the patent process could result in abandonment or lapse of a patent or patent application that we own or license, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market and compete with us earlier than would otherwise have been the case. Moreover, the laws of foreign countries may not protect our rights to the same extent as the laws of the U.S. In addition, to the extent that we license intellectual property in the future, we cannot guarantee that those licenses will remain in force.

Patent positions of life sciences companies can be uncertain and involve complex factual and legal questions and have in recent years been the subject of much litigation. No consistent policy governing the scope of claims allowable in the field of engineered therapeutic proteins has emerged in the U.S. The scope of patent protection in jurisdictions outside of the U.S. is also uncertain. Changes in either the patent laws or their interpretation in any jurisdiction that we seek patent protection may diminish our ability to protect our inventions, maintain and enforce our intellectual property rights; and, more generally, may affect the value of our intellectual property, including the narrowing of the scope of our patents and any that we may license. Under the Leahy-Smith America Invents Act enacted in 2011, or the AIA, the U.S. moved to a first-to-file system in early 2013 (whereby, assuming the other requirements for patentability are met, the first to file a patent application is entitled to the patent), from the previous system under which the first to make a claimed invention was entitled to the patent. Publications of discoveries in the scientific and academic literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to file for patent protection on the inventions claimed in our patents or pending patent applications. Furthermore, for U.S. 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 USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. We cannot be certain that we are the first to invent the inventions covered by pending patent applications and, if we are not, we may be subject to priority disputes. We may be required to disclaim part or all of the term of certain patents or all of the term of certain patent applications.

The patent prosecution process is complex, expensive, time-consuming and inconsistent across jurisdictions. We may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent rights at a commercially reasonable cost or in a timely manner. In addition, we may not pursue or obtain patent protection in all relevant markets. It is possible that we will fail to identify important patentable aspects of our research and development efforts in time to obtain appropriate or any patent protection. While we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development efforts, including for example, our employees, external academic scientific collaborators, CROs, CDMOs, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose our confidential or proprietary information before a patent application is filed, thereby endangering our ability to seek patent protection.

The issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Pending patent applications cannot be enforced against third parties unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology. There can be no assurance that our patent applications or any patent applications that we may license in the future will result in patents being issued. Further, the scope of the invention claimed in a patent application can be significantly reduced before the patent is issued, and this scope can be reinterpreted after issuance. Even if patent applications we currently own or that we may license in the future issue as patents, they may not issue in a form that will provide us with adequate protection to prevent competitors or other third parties from competing with us, or otherwise provide us with a competitive advantage. Any patents that eventually issue may be challenged, narrowed or invalidated by third parties. Consequently, we do not know whether any of our product candidates will be protectable or remain protected by valid and enforceable patent rights. Our competitors or other third parties may be able to evade our patent rights by developing new products that are similar to our product candidates, biosimilars of our product candidates, or alternative technologies or products in a non-infringing manner.

The issuance or grant of a patent is not irrefutable as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the U.S. and abroad. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent 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. We may in the future, become subject to a third-party pre-issuance submission of prior art, pre- or post-issuance opposition, derivation, revocation, re-examination, post-grant and *inter partes* review, or interference proceeding and other similar proceedings challenging our patent rights or the patent rights of others in the USPTO or other foreign patent office. An unfavorable determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us.

Furthermore, patents have a limited lifespan. In the U.S., the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Moreover, third parties may have certain ownership interest in some of our owned and in-licensed patents and patent applications. If we are unable to obtain an exclusive license to any such

third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we or our licensors may need the cooperation of any such co-owners of our owned and in-licensed patents in order to enforce such patents against third parties, and such cooperation may not be provided to us or our licensors. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

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

Some of our patent applications have been granted or may be granted or allowed in the future. We cannot be certain that an allowed patent application will become an issued patent. There may be events that can cause the allowance of a patent application to be withdrawn. For example, after a patent application has been allowed, but prior to being issued, material that could be relevant to patentability may be identified. In such circumstances, the sponsor may pull the application from allowance in order for the USPTO to review the application in view of the new material. We cannot be certain that the USPTO will re-allow the application in view of the new material. Further, periodic maintenance and annuity 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 similar provisions during the patent application process and following the issuance of a patent. Recently, the USPTO implemented new fee rules including Continuing Application Fee, which would increase our cost for obtaining and maintaining patent protection in the U.S. and potentially limit our ability of seeking additional patents in our existing patent families especially those early filed platform families that have been pending for close to or more than six years. We rely on our outside counsel and other professionals or our licensing partners to pay these fees due to the USPTO and non-U.S. government patent agencies and to help us comply with other procedural, documentary and other similar requirements and we are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

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

Despite the measures we take to obtain and maintain patent and other intellectual property rights with respect to our product candidates, our intellectual property rights could be challenged or invalidated. If we or one of our licensors initiate legal proceedings against a third party to enforce a patent covering one of our product candidates or our technology, the defendant could counterclaim that the patent covering our product candidate or technology, as applicable, is invalid and/or unenforceable. In patent litigation in the U.S., 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 U.S. 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 (such as 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 or technology. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, 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 or technology. 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.

Changes to 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.

As is the case with other biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. In addition, the U.S. continues to adapt to wide-ranging patent reform legislation that became effective starting in 2012. Moreover, 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. In addition to increasing uncertainty regarding our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on new legislation and decisions by the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. For example, the U.S. Supreme Court, in the case *Amgen v. Sanofi*, held that broad functional antibody claims are invalid for lack of enablement. In addition, in *Juno v. Kite*, the Federal Circuit held claims reciting broad antibody genus based on function invalid for lack of written description. Recently, the Federal Circuit issued precedential decisions in *In re Cellect* and *Allergan v. MSN* that could shorten or eliminate an extended patent term awarded under patent term adjustment in certain patent family members if challenged on the basis of obviousness-type double patenting. While we do not believe that any of the patents owned or licensed by us will be found invalid based on these decisions, we cannot predict how future decisions by the courts, Congress or the USPTO may impact the value of our patents. Similarly, changes in the patent laws of other jurisdictions could adversely affect our ability to obtain and effectively enforce our patent rights, which would have a material adverse effect on our business and financial condition.

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

We have obtained allowed patents in the U.S. that we consider to be important for certain of our product candidates, however, we may have less robust intellectual property rights outside the U.S., and, in particular, we may not be able to pursue generic coverage of our product candidates outside of the U.S. 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 U.S. can be less extensive than those in the U.S. 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 U.S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from selling or importing products made using our inventions in and into the U.S. 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 enforcement is not as strong as that in the U.S. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Most of our patent portfolio is at the very early stage. We will need to decide whether and in which jurisdictions to pursue protection for the various inventions in our portfolio prior to applicable deadlines.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property 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 in violation of our proprietary rights generally. 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.

In addition, many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. Many countries also limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business and financial condition may be adversely affected.

We rely on in-license agreements for patent rights with respect to our product candidates and may in the future acquire or in-license additional third-party intellectual property rights on which we may similarly rely. We face risks with respect to such reliance, including the risk that we could lose these rights that are important to our business if we fail to comply with our obligations under these licenses or that we may be unable to acquire or in-license third-party intellectual property that may be necessary or important to our business operations.

We rely on third-party license agreements pursuant to which we have non-exclusive and exclusive rights to technology that is incorporated into our development programs and product candidates. For example, under our license agreement with City of Hope, we have exclusively in-licensed certain patent rights that cover our anti-CTLA-4 antibody. We also have a license agreement with WuXi Biologics pursuant to which we received an exclusive worldwide license to specified mAbs and patent rights and know-how controlled by WuXi Biologics, including certain patent rights related to our anti-CTLA-4 mAb program. These license agreements impose diligence, milestone payment, royalty payment and other obligations on us.

Moreover, the growth of our business may depend in part on our ability to acquire, in-license or use additional third-party intellectual property rights. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Licenses to additional third-party intellectual property, technology, processes, and materials that may be required for the development and commercialization of our product candidates or technology may not be available at all or on commercially reasonable terms. In that event, we may be required to expend significant time and resources to redesign our product candidates or manufacturing processes, or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize our future product candidates or technologies, which could materially harm our business, financial condition, results of operations and growth prospects.

In addition, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products, if any, in the event we do in-license third-party intellectual property rights, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability.

Under our agreement with City of Hope, we are responsible for the achievement of certain diligence milestones, and our failure to timely achieve such milestones could result in City of Hope's termination of the agreement or conversion of our exclusive licenses under the licensed patents to non-exclusive licenses. If City of Hope terminates the agreement or converts our licenses to non-exclusive licenses as a result of our failure to meet these diligence milestones, then our ability to commercialize products comprising our anti-CTLA-4 antibody may be impaired or we may face increased competition in the commercialization of anti-CTLA-4 antibody products. Furthermore, our agreement with City of Hope is subject to, and we expect our future license agreements may also be subject to, a reservation of rights by one or more third parties, including the licensor.

Disputes may arise regarding intellectual property subject to our current or any future license agreements, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the amount and timing of payments owed under the license agreements;
- our or our licensor's ability to defend intellectual property and to enforce intellectual property rights against third parties;
- the extent to which our technology, product candidates and processes infringe, misappropriate or otherwise violate any intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under the license agreement;
- 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 any partners of ours; and
- the priority of invention of patented technology.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. We are generally also subject to all of the same risks described in this Quarterly Report on Form 10-Q with respect to protection of intellectual property that we license as we are for intellectual property that we own. If we or our licensors fail to adequately obtain or protect this intellectual property, our ability to commercialize products could suffer.

Our current and any potential future licensors might conclude that we have materially breached our license agreements and might therefore terminate the relevant license agreements, thereby removing our ability to develop and commercialize products and technology covered by such license agreements. If any of our current or future inbound license agreements are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products that are covered by such license agreements and underlying patents, which might be identical or similar to our products or product candidates. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations and growth prospects. Our business also would suffer if any current or future licensors fail to abide by the terms of the license or fail to enforce licensed patents against infringing third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor's rights.

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

If our efforts to protect the proprietary nature of the intellectual property related to our technologies and product candidates are not adequate, we may not be able to compete effectively in our market.

Biotechnology and pharmaceutical companies generally, and we in particular, compete in a crowded competitive space characterized by rapidly evolving technologies and aggressive development of intellectual property.

We rely upon a combination of patents, confidentiality agreements, trade secret protection and license agreements to protect the intellectual property related to our technologies and our product candidates. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements and product candidates, thus eroding our competitive position in our market. We, or any future partners, collaborators, or licensees, may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position.

It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If we or our partners, collaborators, licensees or licensors fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our partners, collaborators, licensees or licensors are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of our patents or patent applications, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. We cannot be certain that the claims in any of our issued patents will be considered valid by courts in the U.S. or foreign countries. Third parties may challenge the validity, enforceability or scope thereof. 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, a competitor's technology or product would be found by a court to infringe our patents. Various post-grant review proceedings, such as *inter partes* review, post-grant review and derivation proceedings, are available and may be pursued by any interested third party in the USPTO to challenge the patentability of claims issued in patents to us or our licensors. No assurance can be given as to the outcome of any such post-grant review proceedings. If the breadth or strength of protection provided by the patents and patent applications we hold with respect to our product

candidates or technology 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 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 achieve 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. On the other hand, 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 we have had issued 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. For example, the AIA implemented in March 2013, moved the U.S. 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 AIA 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 USPTO-administered post-grant review system that has affected patent litigation. The AIA 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 polypeptides or nucleic acids that are similar to our product candidates or components of our product candidates but that are not covered by the claims of our patents;
- the active biological ingredients in our current product candidates will eventually become commercially available in biosimilar drug products, and no patent protection may be available with regard to formulation or method of use;
- we or our licensors, as the case may be, may fail to meet our obligations to the U.S. government in regard to any 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;
- 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;
- 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 U.S.;
- the claims of our owned or in-licensed issued patents or patent applications, if and when issued, may not cover our product candidates or technology;
- 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, and 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 technology 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.

Our proprietary position depends upon patents that are manufacturing, formulation or method-of-use patents, which may not prevent a competitor or other third party from designing around or using the same product candidate for another use.

Composition of matter patents for biological and pharmaceutical products are generally considered to be the strongest form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of making or method of use. We cannot be certain, however, that the claims in our pending patent applications, including those claims covering the composition of matter of our product candidates, will be considered patentable by the USPTO or by patent offices in foreign countries, or that the claims in any of our patents that have issued or may issue will be considered valid and enforceable by courts in the U.S. or foreign countries. Furthermore, in some cases, we may not be able to obtain issued claims covering compositions of matter relating to our product candidates, and instead may need to rely on secondary intellectual property, including patents or patent applications with claims covering formulations, methods of use and/or methods of manufacture. Method of use patents protect a specified method of using a product, such as a method of treating a particular medical indication. This type of patent may only be enforced against a competitor through indirect infringement, i.e., inducement or contributory infringement, which is more difficult to prove than direct infringement. A competitor may be able to circumvent this type of patent by skinny labeling. Furthermore, this type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their products for our targeted indications, physicians may prescribe these products "off-label" for those uses that are covered by our method of use patents. Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent by enforcing patent rights or otherwise.

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

In addition to the protection afforded by patents, we seek to rely on trade secret protection, confidentiality agreements, and license and other agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our product discovery and development processes that involve proprietary know-how, information, or technology that is not covered by patents. For example, significant elements of our product candidates, including aspects of sample preparation, methods of manufacturing, cell culturing conditions and related processes are based on unpatented trade secrets that are not publicly disclosed. 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 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. However, we cannot provide assurance that these agreements and policies will not be breached by our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors and that our trade secrets and other proprietary and confidential

information will not be disclosed to publicly or to competitors. We cannot be certain that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques.

Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the U.S. As a result, we may encounter significant problems in protecting and defending our trade secrets and other confidential proprietary know-how, information, or technology both in the U.S. and abroad. If we are unable to prevent unauthorized material disclosure of our trade secrets and other confidential information to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results and financial condition.

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.

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

Our commercial success depends in part on our avoiding infringement of the patents and violation of other proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, reexamination, and post-grant review proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We may be exposed to, or threatened with, future litigation or other adversarial proceedings 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 pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents may ultimately issue because many patent filings 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
- redesigning our product candidates or processes so they do not infringe third-party intellectual property rights, which may not be possible or may require substantial monetary expenditures and time.

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

Third parties may assert that we are employing their proprietary technology without authorization. Generally, conducting preclinical and clinical trials and other development activities in the U.S. is not considered an act of infringement. If any of our product candidates is approved by the FDA, a third party may then seek to enforce its patent by filing a patent infringement lawsuit against us. While we do not believe that any claims that could otherwise have a materially adverse effect on the commercialization of our product candidates are valid and enforceable, we may be incorrect in this belief, or we may not be able to prove it in litigation. In this regard, patents issued

in the U.S. by law enjoy a presumption of validity that can be rebutted only with evidence that is "clear and convincing," a heightened standard of proof. There may be issued third-party patents of which we are currently unaware with claims to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Patent applications can take many years to issue.

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents or patent applications, the scope of pending or issued patent claims, or the expiration of relevant patents are complete, nor can we be certain that we have identified each and every third-party patent and pending application in the U.S. and abroad that is relevant to or necessary to commercialization of our product candidates in any jurisdiction. There may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Moreover, we may fail to identify relevant third-party patents or incorrectly interpret the relevance, scope, or expiration of a third-party patent or incorrectly conclude that a patent is invalid, not enforceable, exhausted, or not infringed by our activities. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, constructs or molecules used in or formed during the manufacturing process, or any final product itself, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, 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, could involve substantial litigation expense and would be a substantial diversion of 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 on commercially reasonable terms or at all. Furthermore, even in the absence of litigation, we may need or may choose 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.

We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and in-licenses.

Currently, we have certain intellectual property rights under patents and patent applications that we own or have rights to under our inbound license agreements related to our product candidates. Our development of additional product candidates may require the use of proprietary rights held by third parties, and the growth of our business will likely 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 rights to such formulation technology may be held by others. Similarly, efficient production or delivery of our product candidates may also require specific compositions or methods, and the rights to these may be owned by third parties. Moreover, the specific components, such as linkers and antibody fragments, that will be used with our product candidates may be covered by the intellectual property rights of others. We may be unable to acquire or in-license any compositions, methods of use, formulations, 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 may collaborate with or sponsor research at academic institutions to accelerate our preclinical research or development under written agreements with these institutions. In certain cases, these institutions may provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration or sponsorship. 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.

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 licensors. To counter infringement or unauthorized use, we may be required to file lawsuits with 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. 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. 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.

Third parties may initiate post-grant proceedings and the Patent Trial and Appeal Board of the USPTO may institute such proceedings to determine the validity or 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. Litigation or post-grant 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, infringement of our patents or 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.

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

We generally enter into confidentiality and intellectual property assignment agreements with our employees, consultants, and contractors. These agreements generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, those agreements may not be honored and may not effectively assign intellectual property rights to us. Moreover, there may be some circumstances, where we are unable to negotiate for such ownership rights. Disputes regarding ownership or inventorship of intellectual property can also arise in other contexts, such as collaborations and sponsored research. If we

are subject to a dispute challenging our rights in or to patents or other intellectual property, such a dispute could be expensive and time consuming. If we were unsuccessful, we could lose valuable rights in intellectual property that we regard as our own.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed confidential information of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors.

Many of our employees, consultants and advisers were previously employed at other pharmaceutical companies, including our competitors or potential competitors, in some cases until recently. Some of these employees, consultants, advisers, and members of management executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we take steps to ensure that our employees 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, advisers, and members of management have inadvertently or otherwise used or disclosed trade secrets or other confidential information of these former employers or competitors. In addition, we may in the future be subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. 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 these claims, litigation could result in substantial costs and could be a distraction to management. If our defense to those claims fails, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Any litigation or the threat thereof may adversely affect our ability to hire employees. A loss of key personnel or their work product could hamper or prevent our ability to commercialize product candidates, which could have an adverse effect on our business, results of operations and financial condition.

In the future, we may in-license intellectual property that may have been discovered through government funded programs and thus may be subject to federal regulations and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non-U.S. manufacturers.

Any of the intellectual property rights that we have licensed or may license in the future and that have been generated through the use of U.S. government funding are subject to certain federal regulations. As a result, the U.S. government may have certain rights to intellectual property embodied in our product candidates pursuant to the Bayh-Dole Act of 1980, or the Bayh-Dole Act. These U.S. government rights in certain inventions developed under a government-funded program include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose, generally referred to as "march-in rights." To our knowledge, none of our current product candidates are subject to march-in rights. However, intellectual property rights that we license in the future could be subject to such limitations. The U.S. government also has the right to take title to such intellectual property rights if we, or the applicable licensor, fail to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us or the applicable licensor to expend substantial resources. We cannot be certain that our current or future licensors will comply with the disclosure or reporting requirements of the Bayh-Dole Act at all times or be able to rectify any lapse in compliance with these requirements.

In addition, the U.S. government requires that any products embodying the subject invention or produced using the subject invention be manufactured substantially in the U.S. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the U.S. or that, under the circumstances, domestic manufacture is not commercially feasible. This preference for U.S. manufacturers may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. To the extent any of our current or future intellectual property is generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply.

If we do not obtain patent term extension for any of our current or future product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any of our current or future product candidates, 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 Act of 1984, or the Hatch-Waxman Act. The Hatch-Waxman Act permits 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 for each marketing approval 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. If we are unable to obtain patent term extension or term of any such extension is less than we request, 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.

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

Our trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks. We rely on both registration and common law protection for our trademarks. 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. During the trademark registration process, we may receive Office Actions from the USPTO objecting to the registration of our trademark. Although we would be given an opportunity to respond to those objections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and/or to seek the cancellation of registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. 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.

Numerous factors may limit any potential competitive advantage provided by our intellectual property rights.

The degree of future protection afforded by our intellectual property rights, whether owned or in-licensed, is uncertain because intellectual property rights have limitations, and may not adequately protect our business, provide a barrier to entry against our competitors or potential competitors, or permit us to maintain our competitive advantage. Moreover, if a third party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The factors that may limit any potential competitive advantage provided by our intellectual property rights include:

- pending patent applications that we own or license may not lead to issued patents;
- patents, should they issue, that we own or license, may not provide us with any competitive advantages, or may be challenged and held invalid or unenforceable;
- others may be able to develop and/or practice technology that is similar to our technology or aspects of our technology but that is not covered by the claims of any of our owned or in-licensed patents, should any such patents issue;
- third parties may compete with us in jurisdictions where we do not pursue and obtain patent protection;
- we (or our licensors) might not have been the first to make the inventions covered by a pending patent application that we own or license;
- we (or our licensors) might not have been the first to file patent applications covering a particular invention;
- others may independently develop similar or alternative technologies without infringing our intellectual property rights;
- we may not be able to obtain and/or maintain necessary licenses on reasonable terms or at all;
- third parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights, or any rights at all, over that intellectual property;
- we may not be able to maintain the confidentiality of our trade secrets or other proprietary information;
- we may not develop or in-license additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business and results of operation.

Risks Related to Regulatory Approval and Other Legal Compliance Matters

Even if we complete the necessary preclinical studies and clinical trials, the regulatory approval process is expensive, time consuming and uncertain and may prevent us from obtaining approvals for the commercialization of some or all of our product candidates. As a result, we cannot predict when or if, and in which territories, we will obtain marketing approval to commercialize a product candidate.

The research, testing, manufacturing, labeling, approval, selling, marketing, promotion and distribution of drug and biologic products are subject to extensive regulation by the FDA and comparable foreign regulatory authorities. We are not permitted to market our product candidates in the U.S. or in other countries until we receive approval of a BLA from the FDA or marketing approval from applicable regulatory authorities outside the U.S. Our product candidates are in various stages of development and are subject to the risks of failure inherent in development. We have not submitted an application for or received marketing approval for any of our product candidates in the U.S. or in any other jurisdiction. We have no experience as a company in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party CROs to assist us in this process.

The process of obtaining marketing approvals, both in the U.S. and abroad, is lengthy, expensive and uncertain. It may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information, including manufacturing information, to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. The FDA or other regulatory authorities may determine that our product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use.

Further, the FDA may determine that we must provide additional evidence and data before approving a BLA for our product candidates. For example, the FDA reviews an application to determine whether there is "substantial evidence" to support a finding of effectiveness for the proposed product for its intended use(s). The FDA has interpreted this evidentiary standard to generally require at least two adequate and well-controlled clinical trials to establish effectiveness of a new product. Under certain circumstances, however, the FDA has indicated that a single trial with certain characteristics and additional confirmatory evidence may satisfy this standard. The FDA issued draft guidance in September 2023 that outlines considerations for relying on confirmatory evidence in lieu of a second clinical trial to demonstrate effectiveness. In the event that we submit a BLA on the basis of one clinical trial and confirmatory evidence, the FDA could determine that such information is not sufficient to support approval of the application and the agency could require us to conduct an additional trial in support of the BLA.

Further, under the Pediatric Research Equity Act, or PREA, a BLA or supplement to a BLA for certain biological products must contain data to assess the safety and effectiveness of the biological product in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective, unless the sponsor receives a deferral or waiver from the FDA. A deferral may be granted for several reasons, including a finding that the product or therapeutic candidate is ready for approval for use in adults before pediatric trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric trials begin. The applicable legislation in the EU also requires sponsors to either conduct clinical trials in a pediatric population in accordance with a Pediatric Investigation Plan approved by the Pediatric Committee of the EMA or to obtain a waiver or deferral from the conduct of these studies by this Committee. For any of our product candidates for which we are seeking regulatory approval in the U.S. or the EU, we cannot guarantee that we will be able to obtain a waiver or alternatively complete any required studies and other requirements in a timely manner, or at all, which could result in associated reputational harm and subject us to enforcement action.

In addition, changes in marketing approval policies during the development period, changes in or the enactment or promulgation of additional statutes, regulations or guidance or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

Moreover, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA, or a comparable foreign regulatory authority, may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA, or comparable foreign regulatory authority, may

therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA, or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

For example, in December 2022, with the passage of Food and Drug Omnibus Reform Act, or FDORA, Congress required sponsors to develop and submit a diversity action plan for each Phase 3 clinical trial or any other "pivotal study" of a new drug or biological product. These plans are meant to encourage the enrollment of more diverse patient populations in late-stage clinical trials of FDA-regulated products. In June 2024, as mandated by FDORA, the FDA issued draft guidance outlining the general requirements for diversity action plans, or DAPs. Unlike most guidance documents issued by the FDA, the DAP guidance, when finalized, will have the force of law, because FDORA specifically dictates that the form and manner for submission of DAPs are specified in FDA guidance.

Further, in January 2022, the new Clinical Trials Regulation (EU) No 536/2014 became effective in the EU and replaced the prior Clinical Trials Directive 2001/20/EC. This regulation aims at simplifying and streamlining the authorization, conduct and transparency of clinical trials in the EU. Under the coordinated procedure for the approval of clinical trials, the sponsor of a clinical trial to be conducted in more than one EU Member State will only be required to submit a single application for approval. The submission will be made through the Clinical Trials Information System, a clinical trials portal overseen by the EMA and available to clinical trial sponsors, competent authorities of the EU Member States and the public.

Accordingly, any delay in obtaining or failure to obtain required approvals could negatively affect our ability or that of any future collaborators to generate revenue from the particular product candidate, which likely would result in significant harm to our financial position and adversely impact our stock price.

Disruptions at the FDA and other government agencies from funding cuts, personnel losses, regulatory reform, government shutdowns or other developments could hinder their ability to provide guidance or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.

The FDA plays an important role in the development of our product candidates by providing guidance on our clinical and preclinical development programs and reviewing our regulatory submissions. If these oversight and review activities are disrupted, then correspondingly our ability to develop and secure timely approval of our product candidates could be impacted in a negative manner. For example, the loss of FDA leadership and personnel could lead to disruptions and delays in FDA guidance, review, and approval of our product candidates. While the FDA's review of marketing applications and other activities for new drugs and biologics is largely funded through the user fee program established under the Prescription Drug User Fee Act, it remains unclear how the reduction in force and budget cuts will impact this program and the ability of the FDA to provide guidance and review our product candidates in a timely manner. There is also substantial uncertainty as to how regulatory reform measures being implemented by the new presidential administration across the government will impact the FDA and other federal agencies with jurisdiction over our activities. In addition, government funding of the SEC and other government agencies on which our operations may rely is subject to the political process, which is inherently fluid and unpredictable.

Over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC, and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions and the ability of the SEC to timely review our public filings, to the extent such review is necessary, and our ability to access the public markets.

For example, as a result of the prolonged the federal government shut down from October 1, 2025 through November 12, 2025, the FDA issued a public notice on October 1, 2025 stating that agency operations would continue to the extent permitted by law, such as activities necessary to address imminent threats to the safety of human life and activities funded by carryover user fee funds. At the same time, the FDA declared that, during the shutdown period, it did not have legal authority to accept user fees assessed for fiscal year 2026 until a fiscal year 2026 appropriation or continuing resolution for the FDA is enacted. As a result, during the prolonged shut down, the FDA could not accept any regulatory submissions for fiscal year 2026 that required a fee payment and that were submitted during the lapse period.

At the same time, disruptions at the FDA and other government agencies may result from public health events similar to the COVID-19 pandemic. During the pandemic, a number of companies announced receipt of complete response letters due to the FDA's inability to

complete required inspections for their applications. In the event of a similar public health emergency in the future, the FDA may not be able to continue its current pace and review timelines could be extended. Regulatory authorities outside the U.S. facing similar circumstances may adopt similar restrictions or other policy measures in response to a similar public health emergency and may also experience delays in their regulatory activities.

Accordingly, if any of the foregoing developments and others impact the ability of the FDA to provide us with guidance regarding our clinical development programs or delay the FDA's review and processing of our regulatory submissions, including INDs or BLAs, our business would be negatively impacted. Further, any future government shutdown could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Failure to obtain marketing approval in foreign jurisdictions would prevent our product candidates from being marketed abroad. Any approval we may be granted for our product candidates in the U.S. would not assure approval of our product candidates in foreign jurisdictions and any of our product candidates that may be approved for marketing in a foreign jurisdiction will be subject to risks associated with foreign operations.

In order to market and sell our products in the EU and other foreign jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The marketing approval process outside the U.S. generally includes all of the risks associated with obtaining FDA approval. We may not obtain approvals from regulatory authorities outside the U.S. on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the U.S. does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may file for marketing approvals but not receive necessary approvals to commercialize our products in any market.

In many countries outside the U.S., a product candidate must also be approved for reimbursement before it can be sold in that country. In some cases, the price that we intend to charge for our products, if approved, is also subject to approval. Obtaining non-U.S. regulatory approvals and compliance with non-U.S. regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our product candidates in certain countries. In addition, if we fail to obtain the non-U.S. approvals required to market our product candidates outside the U.S. or if we fail to comply with applicable non-U.S. regulatory requirements, our target markets will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business, financial condition, results of operations and prospects may be adversely affected.

Additionally, we could face heightened risks with respect to obtaining marketing authorization in the United Kingdom, or the U.K., as a result of the withdrawal of the U.K. from the EU, commonly referred to as Brexit. The U.K. is no longer part of the European Single Market and EU Customs Union.

As of January 1, 2025, the Medicines and Healthcare Products Regulatory Agency, or MHRA, is responsible for approving all medicinal products destined for the U.K. market (i.e., Great Britain and Northern Ireland). At the same time, a new international recognition procedure, or IRP, will apply, which intends to facilitate approval of pharmaceutical products in the U.K. The IRP is open to applicants that have already received an authorization for the same product from one of the MHRA's specified Reference Regulators. The Reference Regulators notably include EMA and regulators in the EU/European Economic Area, or EEA, member states for approvals in the EU centralized procedure and mutual recognition procedure as well as the FDA for product approvals granted in the United States. However, the concrete functioning of the IRP is currently unclear. Any delay in obtaining, or an inability to obtain, any marketing approvals may force us or our collaborators to restrict or delay efforts to seek regulatory approval in the U.K. for our product candidates, which could significantly and materially harm our business.

In addition, foreign regulatory authorities may change their approval policies and new regulations may be enacted. For instance, the EU pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission's proposal for revision of several legislative instruments related to medicinal products (potentially reducing the duration of regulatory data protection, revising the eligibility for expedited pathways, etc.) was published on April 26, 2023. The proposed revisions remain to be agreed and adopted by the European Parliament and European Council and the proposals may therefore be substantially revised before adoption, which is not anticipated before early 2026. The revisions may however have a significant impact on the pharmaceutical industry and our business in the long term.

Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, may force us to restrict or delay efforts to seek regulatory approval in the United Kingdom for our product candidates, which could significantly and materially harm our business. We expect that we will be subject to additional risks in commercializing any of our product candidates that receive marketing approval outside the U.S., including tariffs, trade barriers and regulatory requirements; economic weakness, including inflation, or political instability in particular foreign economies and markets; compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country; and workforce uncertainty in countries where labor unrest is more common than in the U.S.

We may not be able to obtain orphan drug designation or orphan drug exclusivity for our product candidates and, even if we do, that exclusivity may not prevent the FDA or the EMA from approving competing products.

Regulatory authorities in some jurisdictions, including the U.S. and the EU, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the U.S. Generally, a product with orphan drug designation only becomes entitled to orphan drug exclusivity if it receives the first marketing approval for the indication for which it has such designation, in which case the FDA or the EMA will be precluded from approving another marketing application for the same product for that indication for the applicable exclusivity period. The applicable exclusivity period is seven years in the U.S. and ten years in the EU. The European exclusivity period can be reduced to six years if a product no longer meets the criteria for orphan drug designation or if the product is sufficiently profitable so that market exclusivity is no longer justified.

We may seek orphan drug designations for our product candidates and may be unable to obtain such designations. Even if we do secure such designations and orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different products can be approved for the same condition. Further, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later product is clinically superior in that it is shown to be safer, to be more effective or to make a major contribution to patient care. Finally, orphan drug exclusivity may be lost if the FDA or the EMA 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.

The FDA may further reevaluate the Orphan Drug Act and its regulations and policies. This may be particularly true in light of a decision from the Court of Appeals for the 11th Circuit in September 2021 finding that, for the purpose of determining the scope of exclusivity, the term "same disease or condition" means the designated "rare disease or condition" and could not be interpreted by the FDA to mean the "indication or use." Thus, the court concluded, orphan drug exclusivity applies to the entire designated disease or condition rather than the "indication or use." Although there have been legislative proposals to overrule this decision, they have not been enacted into law. On January 23, 2023, the FDA announced that, in matters beyond the scope of that court order, the FDA will continue to apply its existing regulations tying orphan-drug exclusivity to the uses or indications for which the orphan drug was approved. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

Any product candidate for which we obtain marketing approval is subject to ongoing regulation and could be subject to restrictions or withdrawal from the market, and we may be subject to substantial penalties if we fail to comply with regulatory requirements, when and if any of our product candidates are approved.

Any product candidate for which we obtain marketing approval will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to quality control and manufacturing, quality assurance and corresponding maintenance of records and documents, and requirements regarding the distribution of samples to physicians and recordkeeping. In addition, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the medicine, including the requirement to implement a risk evaluation and mitigation strategy. Accordingly, if we receive marketing approval for one or more of our product candidates, we will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we fail to comply with these requirements, we could have the marketing approvals for our products withdrawn by regulatory authorities and our ability to market any products could be limited, which could adversely affect our ability to achieve or sustain profitability.

Failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on distribution or use of a product;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- damage to relationships with collaborators;
- unfavorable press coverage and damage to our reputation;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure;
- injunctions or the imposition of civil or criminal penalties; and
- litigation involving patients using our products.

Non-compliance with EU requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with the EU's requirements regarding the protection of personal information can also lead to significant penalties and sanctions. Further, the marketing and promotion of authorized drugs, including industry-sponsored continuing medical education and advertising directed toward the prescribers of drugs and/or the general public, are strictly regulated in the EU notably under Directive 2001/83EC, as amended, and are also subject to EU Member State laws. Direct-to-consumer advertising of prescription medicines is prohibited across the EU.

Accordingly, assuming we, or our collaborators, receive marketing approval for one or more of our product candidates, we, and our collaborators, and our and their contract manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we, and our collaborators, are not able to comply with post-approval regulatory requirements, our or our collaborators' ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

Any regulatory approval to market any of our products candidates for which we obtain approval will be limited by indication. If we fail to comply or are found to be in violation of FDA regulations restricting the promotion of any of our product candidates for unapproved uses, we could be subject to criminal penalties, substantial fines or other sanctions and damage awards.

The regulations relating to the promotion of products for unapproved uses are complex and subject to substantial interpretation by the FDA, EMA, MHRA and other government agencies. In September 2021, the FDA published final regulations which describe the types of evidence that the agency will consider in determining the intended use of a drug product. Physicians may nevertheless prescribe products off-label to their patients in a manner that is inconsistent with the approved label. Prior to the approval of any of our product candidates, we intend to implement compliance and training programs designed to ensure that any future sales and marketing practices comply with applicable regulations. Notwithstanding these programs, the FDA or other government agencies may allege or find that our practices constitute prohibited promotion of our products for unapproved uses. We also cannot be sure that our employees will comply with company policies and applicable regulations regarding the promotion of products for unapproved uses.

Notwithstanding the regulatory restrictions on off-label promotion, the FDA and other regulatory authorities allow companies to engage in truthful, non-misleading, and non-promotional scientific communications concerning their products in certain circumstances. For example, in January 2025, the FDA published final guidance outlining its policies governing the distribution of scientific information to healthcare providers about unapproved uses of approved products. The final guidance calls for such communications to be truthful, non-misleading, and scientifically sound and to include all information necessary for healthcare providers to interpret the strengths and weaknesses and validity and utility of the information about the unapproved use of the approved product. If a company engages in such communications consistent with the guidance's recommendations, the FDA indicated that it will not treat such communications as evidence of unlawful promotion of a new intended use for the approved product. We will need to carefully navigate the FDA's various regulations, guidance and policies, along with recently enacted legislation, to ensure compliance with restrictions governing promotion of our products.

In recent years, a significant number of pharmaceutical and biotechnology companies have been the target of inquiries and investigations by various federal and state regulatory, investigative, prosecutorial and administrative entities in connection with the promotion of products for unapproved uses and other sales practices, including the Department of Justice and various U.S. Attorneys' Offices, the Office of Inspector General of the Department of Health and Human Services, the FDA, the Federal Trade Commission, or the FTC, and various state Attorneys General offices. These investigations have alleged violations of various federal and state laws and regulations, including claims asserting antitrust violations, violations of the FDCA, the False Claims Act, the Prescription Drug Marketing Act and anti-kickback laws and other alleged violations in connection with the promotion of products for unapproved uses, pricing and Medicare and/or Medicaid reimbursement. Many of these investigations originate as "qui tam" actions under the False Claims Act. Under the False Claims Act, any individual can bring a claim on behalf of the government alleging that a person or entity has presented a false claim or caused a false claim to be submitted to the government for payment. The person bringing a qui tam suit is entitled to a share of any recovery or settlement. Qui tam suits, also commonly referred to as "whistleblower suits," are often brought by current or former employees. In a qui tam suit, the government must decide whether to intervene and prosecute the case. If it declines, the individual may pursue the case alone.

If the FDA or any other governmental agency initiates an enforcement action against us or if we are the subject of a qui tam suit and it is determined that we violated prohibitions relating to the promotion of products for unapproved uses, we could be subject to substantial civil or criminal fines or damage awards and other sanctions such as consent decrees and corporate integrity agreements pursuant to which our activities would be subject to ongoing scrutiny and monitoring to ensure compliance with applicable laws and regulations. Any such fines, awards or other sanctions would have an adverse effect on our revenue, business, financial prospects and reputation.

We may seek certain designations for our product candidates, including Breakthrough Therapy, Fast Track and Priority Review designations in the U.S. and PRIME Designation in the EU, but we might not receive such designations, and even if we do, such designations may not lead to a faster development or regulatory review or approval process.

We may seek certain designations for one or more of our product candidates that could expedite review and approval by the FDA. A Breakthrough Therapy product is defined as a product that is intended, alone or in combination with one or more other products, to treat a serious condition, and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For products that have been designated as Breakthrough Therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens.

The FDA may also designate a product for Fast Track review if it is intended, whether alone or in combination with one or more other products, 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. For Fast Track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a Fast Track product's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a Fast Track product may be effective.

We may also seek a priority review designation for one or more of our product candidates. If the FDA determines that a product candidate is intended to treat a serious condition and, if approved, offers a significant improvement in safety or effectiveness, the FDA may designate the product candidate for priority review. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting product reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, and evidence of safety and effectiveness in a new

subpopulation. A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months.

These designations are within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for these designations, the FDA may disagree and instead determine not to make such designation. Further, even if we receive a designation, the receipt of such designation for a product candidate may not result in a faster development or regulatory review or approval process compared to products considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualifies for these designations, the FDA may later decide that the product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

In the EU, we may seek PRIME designation for some of our product candidates in the future. PRIME is a voluntary program aimed at enhancing the EMA's role to reinforce scientific and regulatory support in order to optimize development and enable accelerated assessment of new medicines that are of major public health interest with the potential to address unmet medical needs. The program focuses on medicines that target conditions for which there exists no satisfactory method of treatment in the EU or even if such a method exists, it may offer a major therapeutic advantage over existing treatments. PRIME is limited to medicines under development and not authorized in the EU and the applicant intends to apply for an initial marketing authorization application through the centralized procedure. To be accepted for PRIME, a product candidate must meet the eligibility criteria in respect of its major public health interest and therapeutic innovation based on information that is capable of substantiating the claims. The benefits of a PRIME designation include the appointment of a CHMP rapporteur to provide continued support and help to build knowledge ahead of a marketing authorization application, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review, meaning reduction in the review time for an opinion on approvability to be issued earlier in the application process. PRIME enables an applicant to request parallel EMA scientific advice and health technology assessment advice to facilitate timely market access. Even if we receive PRIME designation for any of our product candidates, the designation may not result in a materially faster development process, review or approval compared to conventional EMA procedures. Further, obtaining PRIME designation does not assure or increase the likelihood of EMA's grant of a marketing authorization.

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

We may seek approval of any of our current and future product candidates using the FDA's accelerated approval pathway. A product may be eligible for accelerated approval if it treats a serious or life-threatening condition, generally provides a meaningful advantage over available therapies, and demonstrates an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA or other applicable regulatory agency makes the determination regarding whether a surrogate endpoint is reasonably likely to predict long-term clinical benefit.

Prior to seeking such accelerated approval, we will seek feedback from the FDA and otherwise evaluate our ability to seek and receive such accelerated approval. As a condition of approval, the FDA requires that a sponsor of a product receiving accelerated approval perform an adequate and well-controlled post-marketing confirmatory clinical trial or trials. These confirmatory trials must be completed with due diligence and we may be required to evaluate different or additional endpoints in these post-marketing confirmatory trials. These confirmatory trials may require enrollment of more patients than we currently anticipate and will result in additional costs, which may be greater than the estimated costs we currently anticipate. In addition, the FDA currently requires as a condition for accelerated approval preapproval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

There can be no assurance that the FDA will agree with any proposed surrogate endpoints or that we will decide to pursue or submit a BLA for accelerated approval or any other form of expedited development, review or approval for any of our current or future product candidates. Similarly, there can be no assurance that, after feedback from FDA, we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval or under another expedited regulatory designation, there can be no assurance that such submission or application will be accepted or that any expedited review or approval will be granted on a timely basis, or at all.

The FDA may withdraw approval of a product candidate approved under the accelerated approval pathway if, for example, the trial required to verify the predicted clinical benefit of our product candidate fails to verify such benefit or does not demonstrate sufficient

clinical benefit to justify the risks associated with the drug. The FDA may also withdraw approval if other evidence demonstrates that our product candidate is not shown to be safe or effective under the conditions of use, we fail to conduct any required post approval trial of our product candidate with due diligence or we disseminate false or misleading promotional materials relating to our product candidate. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidates, or withdrawal of a product candidate, would result in a longer time period for commercialization of such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

Further, there can be no assurance that we will satisfy all FDA requirements, including new provisions that govern accelerated approval. For example, with the passage of FDORA in December 2022, Congress modified certain provisions governing accelerated approval of drug and biologic products. Specifically, the new legislation authorized the FDA to require a sponsor to have its confirmatory clinical trial underway before accelerated approval is awarded and to submit progress reports on its post-approval studies to the FDA every six months until the study is completed. Moreover, FDORA established expedited procedures authorizing FDA to withdraw an accelerated approval if certain conditions are met, including where a required confirmatory trial fails to verify and describe the product's predicted clinical benefit or where evidence demonstrates the product is not shown to be safe or effective under the conditions of use. The FDA may also use such procedures to withdraw an accelerated approval if a sponsor fails to conduct any required post-approval study of the product with due diligence, including with respect to "conditions specified by the Secretary." The new procedures include the provision of due notice and an explanation for a proposed withdrawal, and opportunities for a meeting with the FDA commissioner or the FDA commissioner's designee and a written appeal, among other things. We will need to fully comply with these and other requirements in connection with the development and approval of any product candidate that qualifies for accelerated approval.

More recently, in March 2023, the FDA issued draft guidance that outlines its current thinking and approach to accelerated approval. The FDA indicated that the accelerated approval pathway is commonly used for approval of oncology drugs due to the serious and life-threatening nature of cancer. Although single-arm trials have been commonly used to support accelerated approval, a randomized controlled trial is the preferred approach as it provides a more robust efficacy and safety assessment and allows for direct comparisons to an available therapy. To that end, the FDA outlined considerations for designing, conducting, and analyzing data for trials intended to support accelerated approvals of oncology therapeutics. Subsequently, in December 2024 and January 2025, the FDA issued additional draft guidance relating to accelerated approval. The guidance describes the FDA's views on what it means to conduct a confirmatory trial with due diligence and how the agency plans to interpret whether such a study needs to be underway at the time of approval. While the guidance is currently only in draft form and will ultimately not be legally binding even when finalized, sponsors typically observe the FDA's guidance closely to ensure that their investigational products qualify for accelerated approval.

In the EU, a "conditional" marketing authorization may be granted in cases where all the required safety and efficacy data are not yet available. A conditional marketing authorization is subject to conditions to be fulfilled for generating missing data or ensuring increased safety measures. A conditional marketing authorization is valid for one year and has to be renewed annually until fulfillment of all relevant conditions. Once the applicable pending studies are provided, a conditional marketing authorization can become a "standard" marketing authorization. However, if the conditions are not fulfilled within the timeframe set by the EMA, the marketing authorization will cease to be renewed.

Current and future legislation may increase the difficulty and cost for us to obtain reimbursement for any of our candidate products that do receive marketing approval.

In the U.S. and foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we may receive for any approved products. If reimbursement of our products is unavailable or limited in scope, our business could be materially harmed.

In March 2010, President Obama signed into law the ACA. In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2031 under the CARES Act. The American Taxpayer Relief

Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

Since enactment of the ACA, there have been, and continue to be, numerous legal challenges and Congressional actions to repeal and replace provisions of the law. For example, with enactment of the Tax Act, which was signed by the current president on December 22, 2017, Congress repealed the "individual mandate." The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, became effective in 2019. Further, on June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

During the 2016-2020 presidential administration, Congress and the administration sought to overturn the ACA and related measures. Shortly after taking office in January 2025, the current president revoked numerous executive orders issued by President Biden, including at least two executive orders, E.O. 14009, Strengthening Medicaid and the Affordable Care Act, and E.O. 14070, Continuing to Strengthen Americans' Access to Affordable, Quality Health Coverage, which were designed to further implement the ACA. We anticipate similar efforts to undermine the ACA, and the accompanying uncertainty, for the foreseeable future.

In the EU, on December 13, 2021, Regulation No 2021/2282 on Health Technology Assessment, or HTA, amending Directive 2011/24/EU, was adopted. While the Regulation entered into force in January 2022, it will only begin to apply from January 2025 onwards, with preparatory and implementation-related steps to take place in the interim. Once applicable, it will have a phased implementation depending on the concerned products. The Regulation intends to boost cooperation among EU member states in assessing health technologies, including new medicinal products as well as certain high-risk medical devices, and provide the basis for cooperation at the EU level for joint clinical assessments in these areas. It will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the highest potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement.

We expect that these healthcare reforms, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product and/or the level of reimbursement physicians receive for administering any approved product we might bring to market. Reductions in reimbursement levels may negatively impact the prices we receive or the frequency with which our products are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. Accordingly, such reforms, if enacted, could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain marketing approval and may affect our overall financial condition and ability to develop or commercialize product candidates.

Current and future legislative efforts may limit the prices for our products, if and when they are licensed for marketing, and that could materially impact our ability to generate revenues.

The prices of prescription pharmaceuticals have also been the subject of considerable discussion in the United States. There have been several U.S. congressional inquiries, as well as proposed and enacted state and federal legislation designed to, among other things, bring more transparency to pharmaceutical pricing, review the relationship between pricing and manufacturer patient programs, and reduce the costs of pharmaceuticals under Medicare and Medicaid.

In addition, in October 2020, HHS and the FDA published a final rule allowing states and other entities to develop a Section 804 Importation Program, or SIP, to import certain prescription drugs from Canada into the U.S. That regulation was challenged in a lawsuit by the Pharmaceutical Research and Manufacturers of America, or PhRMA, but the case was dismissed by a federal district court in February 2023 after the court found that PhRMA did not have standing to sue HHS. Seven states (Colorado, Florida, Maine, New Hampshire, New Mexico, Texas and Vermont) have passed laws allowing for the importation of drugs from Canada. North Dakota and Virginia have passed legislation establishing working groups to examine the impact of a state importation program. As of May 2024,

five states (Colorado, Florida, Maine, New Hampshire and New Mexico) had submitted Section 804 Importation Program proposals to the FDA, and on January 5, 2023, the FDA approved Florida's plan for Canadian drug importation. Florida now has authority to import certain drugs from Canada for a period of two years once certain conditions are met, but it will first need to submit a pre-import request for each drug selected for importation, which must be approved by the FDA. Florida will also need to relabel the drugs and perform quality testing of the products to meet FDA standards.

Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration until January 1, 2026 by the Infrastructure Investment and Jobs Act. The final rule would eliminate the current safe harbor for Medicare drug rebates and create new safe harbors for beneficiary point-of-sale discounts and pharmacy benefit manager service fees. It originally was set to go into effect on January 1, 2022, but with the passage of the Inflation Reduction Act of 2022, or the IRA, has been delayed by Congress to January 1, 2032.

On August 16, 2022, the IRA was signed into law by President Biden. The new legislation has implications for Medicare Part D, which is a program available to individuals who are entitled to Medicare Part A or enrolled in Medicare Part B, to give them the option of paying a monthly premium for outpatient prescription drug coverage. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years.

Specifically, with respect to price negotiations, Congress authorized Medicare to negotiate lower prices for certain costly single-source drug and biologic products that do not have competing generics or biosimilars and are reimbursed under Medicare Part B and Part D. CMS may negotiate prices for ten high-cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Part D drugs in 2027, 15 Part B or Part D drugs in 2028, and 20 Part B or Part D drugs in 2029 and beyond. This provision applies to drug products that have been approved for at least 9 years and biologics that have been licensed for 13 years, but it does not apply to drugs and biologics that have been approved for a single rare disease or condition. Nonetheless, since CMS may establish a maximum price for these products in price negotiations, we would be fully at risk of government action if our products are the subject of Medicare price negotiations. Moreover, given the risk that could be the case, these provisions of the IRA may also further heighten the risk that we would not be able to achieve the expected return on our drug products or full value of our patents protecting our products if prices are set after such products have been on the market for nine years. Further, the legislation subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering a price that is not equal to or less than the negotiated "maximum fair price" under the law or for taking price increases that exceed inflation. The legislation also requires manufacturers to pay rebates for drugs in Medicare Part D whose price increases exceed inflation. The new law also caps Medicare out-of-pocket drug costs at an estimated $4,000 a year in 2024 and, thereafter beginning in 2025, at $2,000 a year.

The first cycle of negotiations for the Medicare Drug Price Negotiation Program commenced in the summer of 2023. On August 15, 2024, the HHS published the results of the first Medicare drug price negotiations for ten selected drugs that treat a range of conditions, including diabetes, chronic kidney disease, and rheumatoid arthritis. The prices of these ten drugs will become effective January 1, 2026. On January 17, 2025, CMS announced its selection of 15 additional drugs covered by Part D for the second cycle of negotiations. Thereafter, following the change in U.S. presidential administrations, CMS issued a public statement on January 29, 2025, declaring that lowering the cost of prescription drugs is a top priority of the new presidential administration and CMS is committed to considering opportunities to bring greater transparency in the negotiation program. The second cycle of negotiations with participating drug companies will occur during 2025, and any negotiated prices for this second set of drugs will be effective starting January 1, 2027.

In addition, the IRA potentially raises legal risks with respect to individuals participating in a Medicare Part D prescription drug plan who may experience a gap in coverage if they required coverage above their initial annual coverage limit before they reached the higher threshold, or "catastrophic period" of the plan. Individuals requiring services exceeding the initial annual coverage limit and below the catastrophic period must pay 100% of the cost of their prescriptions until they reach the catastrophic period. Among other things, the IRA contains many provisions aimed at reducing this financial burden on individuals by reducing the co-insurance and co-payment costs, expanding eligibility for lower income subsidy plans, and price caps on annual out-of-pocket expenses, each of which could have potential pricing and reporting implications.

We expect that current or future litigation involving provisions of the IRA will have unpredictable and uncertain results on the implementation and impact of the IRA on biotechnology industry generally, as well as our business and current or future products. For example, on June 6, 2023, Merck & Co., or Merck, filed a lawsuit against the HHS and CMS asserting that, among other things, the IRA's Drug Price Negotiation Program for Medicare constitutes an uncompensated taking in violation of the Fifth Amendment of the Constitution. Subsequently, a number of other parties, including the U.S. Chamber of Commerce, Bristol Myers Squibb Company, the PhRMA, Astellas, Novo Nordisk, Janssen Pharmaceuticals, Novartis, AstraZeneca and Boehringer Ingelheim, also filed lawsuits in various courts with similar constitutional claims against the HHS and CMS. There have been various decisions by the courts considering these cases since they were filed. The HHS has generally won the substantive disputes in these cases, and various federal district court judges have expressed skepticism regarding the merits of the legal arguments being pursued by the pharmaceutical industry. Certain of these cases are now on appeal, and oral arguments took place on October 30, 2024. We expect that litigation involving these and other provisions of the IRA will continue, with unpredictable and uncertain results.

Accordingly, while it is currently unclear how the IRA will be effectuated, we cannot predict with certainty what impact any federal or state health reforms will have on us, but such changes could impose new or more stringent regulatory requirements on our activities or result in reduced reimbursement for our products, any of which could adversely affect our business, results of operations and financial condition.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare organizations and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures. This may be increasingly true with respect to products approved pursuant to the accelerated approval pathway. State Medicaid programs and other payers are developing strategies and implementing significant coverage barriers, or refusing to cover these products outright, arguing that accelerated approval drugs have insufficient or limited evidence despite meeting the FDA's standards for accelerated approval.

Finally, outside the U.S., in some nations, including those of the EU, the pricing of prescription pharmaceuticals is subject to governmental control and access. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we or our collaborators may be required to conduct a clinical trial that compares the cost-effectiveness of our product to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.

We may be subject to certain healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, fines, disgorgement, exclusion from participation in government healthcare programs, curtailment or restricting of our operations, and diminished future profits and earnings, if any.

Healthcare providers, third-party payors and others will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our current and future arrangements with healthcare providers and third-party payors will expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research as well as market, sell and distribute any products for which we obtain marketing approval. Potentially applicable U.S. federal and state healthcare laws and regulations include the following:

- *Anti-Kickback Statute*. The federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid.
- *False Claims Laws*. The federal false claims laws and civil monetary penalties laws, including the civil False Claims Act and the Civil Monetary Penalty Law, impose criminal and civil penalties, including those from civil whistleblower or qui tam actions against individuals or entities for knowingly presenting, or causing to be presented to the federal government,

claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government.

- *HIPAA*. The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program.
- *HIPAA and HITECH*. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or the HITECH Act, also imposes obligations on certain types of individuals and entities, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information.
- *False Statements Statute*. The federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services.
- *Transparency Requirements*. The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the Department of Health and Human Services information related to payments and other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), other healthcare providers, and ownership and investment interests by physicians and their immediate family members. As of January 1, 2022, applicable manufacturers are also required to report such information regarding its payments and other transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year.
- *Analogous State and Foreign Laws*. Analogous state laws and regulations, such as state anti-kickback and false claims laws, and transparency laws, may apply to sales or marketing arrangements, and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, in addition to requiring manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures. Many state laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Foreign laws also govern the privacy and security of health information in many circumstances.

The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the EU. Payments made to physicians in certain EU Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization 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.

Efforts to ensure that our business arrangements with third parties, and our business generally, will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, disgorgement, contractual damages, and reputational harm, any of which could substantially disrupt our operations. If any of the physicians or other providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

We are subject to stringent privacy laws, information security laws, regulations, policies and contractual obligations related to data privacy and security and changes in such laws, regulations, policies, contractual obligations and failure to comply with such requirements could subject us to significant fines and penalties, which may have a material adverse effect on our business, financial condition or results of operations.

We are subject to data privacy and protection laws and regulations that apply to the collection, transmission, storage and use of personally identifiable information, which among other things, impose certain requirements relating to the privacy, security and transmission of personal information, including comprehensive regulatory systems in the U.S., EU and United Kingdom. The legislative and regulatory landscape for privacy and data protection continues to evolve in jurisdictions worldwide, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. Failure to comply with any of these laws and regulations could result in enforcement action against us, including fines, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

There are numerous U.S. federal and state laws and regulations related to the privacy and security of personal information. In particular, regulations promulgated pursuant to HIPAA establish privacy and security standards that limit the use and disclosure of individually identifiable health information, or protected health information, and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. Determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and may be subject to changing interpretation. These obligations may be applicable to some or all of our business activities now or in the future.

If we are unable to properly protect the privacy and security of protected health information, we could be found to have breached our contracts. Further, if we fail to comply with applicable privacy laws, including applicable HIPAA privacy and security standards, we could face civil and criminal penalties. HHS enforcement activity can result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal resources. In addition, state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy of state residents. We cannot be sure how these regulations will be interpreted, enforced or applied to our operations. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies, procedures and systems.

There are a broad variety of data protection laws that are applicable to our activities, and a wide range of enforcement agencies at both the state and federal levels that can review companies for privacy and data security concerns based on general consumer protection laws. The Federal Trade Commission, or FTC, and state attorneys general all are aggressive in reviewing privacy and data security protections for consumers. In addition, new laws have been enacted or are considered at both the federal and state levels. As a result, we will need to seek to ensure our business practices comply with evolving rules and guidance at the federal and state level related to privacy and data security in order to mitigate our risk for any potential enforcement action, which may be costly. In addition, if we are subject to an enforcement action and settlement order, we may be required to adhere to very specific privacy and data security practices or pay fines and adhere to specified compliance requirements, all of which could be costly and adversely impact our business.

For example, the FTC has been particularly focused on the unpermitted processing of health and genetic data through its recent enforcement actions and is expanding the types of privacy violations that it interprets to be "unfair" under Section 5 of the FTC Act, as well as the types of activities it views to trigger the Health Breach Notification Rule, which the FTC also has the authority to enforce, and is in the process of developing rules related to commercial surveillance and data security.

Similarly, in 2018, California passed into law the California Consumer Privacy Act, or the CCPA, which took effect on January 1, 2020 and imposed many requirements on businesses that process the personal information of California residents. Many of the CCPA's requirements are similar to those found in the General Data Protection Regulation, or the GDPR, including requiring businesses to provide notice to data subjects regarding the information collected about them and how such information is used and shared, and providing data subjects the right to request access to such personal information and, in certain cases, request the erasure of such personal information. The CCPA also affords California residents the right to opt-out of "sales" of their personal information. The CCPA contains significant penalties for companies that violate its requirements. In addition, the California Privacy Rights Act, or the CPRA, went into effect on January 1, 2023 and significantly expanded the CCPA to incorporate additional GDPR-like provisions including requiring that the use, retention, and sharing of personal information of California residents be reasonably necessary and proportionate to the purposes of collection or processing, granting additional protections for sensitive personal information, and requiring greater disclosures related to notice to residents regarding retention of information. The CPRA also created the California Privacy Protection Agency, a new enforcement agency whose sole responsibility is to enforce the CPRA.

In addition to California, at least 18 other states have passed comprehensive privacy laws similar to the CCPA and CPRA. These laws are either in effect now or will go into effect in the future. Like the CCPA and CPRA, these laws create obligations related to the

processing of personal information, as well as special obligations for the processing of "sensitive" data (which includes health data in some cases). Some of the provisions of these laws may apply to our business activities. There are also states that are specifically regulating health information that may affect our business. For example, Washington state recently passed a health privacy law that will regulate the collection and sharing of health information, and the law also has a private right of action, which further increases the relevant compliance risk. Other states have also passed similar laws regulating consumer health data and additional states are considering similar laws. A similar health privacy law has passed the New York state legislature and could be signed into law by the governor in the near future. These laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products.

Plaintiffs' lawyers are also increasingly using privacy-related statutes at both the state and federal level to bring lawsuits against companies for their data-related practices. In particular, there have been a significant number of cases filed against companies for their use of pixels and other web trackers. These cases often allege violations of the California Invasion of Privacy Act and other state laws regulating wiretapping, as well as the federal Video Privacy Protection Act. The rise in these types of lawsuits creates potential risk for our business.

Similar to the laws in the United States, there are significant privacy and data security laws that apply in Europe and other countries. The collection, use, disclosure, transfer, or other processing of personal data, including personal health data, regarding individuals who are located in the European Economic Area, or the EEA, and the processing of personal data that takes place in the EEA, is regulated by the GDPR, which went into effect in May 2018 and which imposes obligations on companies that operate in our industry with respect to the processing of personal data and the cross-border transfer of such data. The GDPR imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and policies. If our or our partners' or service providers' privacy or data security measures fail to comply with the GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices requiring us to change the way we use personal data and/or fines of up to 20 million Euros or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, as well as compensation claims by affected individuals, negative publicity, reputational harm and a potential loss of business and goodwill.

The GDPR places restrictions on the cross-border transfer of personal data from the EU to countries that have not been found by the European Commission, or EC, to offer adequate data protection legislation, such as the U.S. There are ongoing concerns about the ability of companies to transfer personal data from the EU to other countries. In July 2020, the Court of Justice of the European Union, or the CJEU, invalidated the EU-U.S. Privacy Shield, one of the mechanisms used to legitimize the transfer of personal data from the EEA to the U.S. The CJEU decision also drew into question the long-term viability of an alternative means of data transfer, the standard contractual clauses, for transfers of personal data from the EEA to the U.S. While we were not self-certified under the Privacy Shield, this CJEU decision may lead to increased scrutiny on data transfers from the EEA to the U.S. generally and increase our costs of compliance with data privacy legislation, as well as our costs of negotiating appropriate privacy and security agreements with our vendors and business partners.

Additionally, in October 2022, President Biden signed an executive order to implement the EU-U.S. Data Privacy Framework, which serves as a replacement to the EU-U.S. Privacy Shield. The EU initiated the process to adopt an adequacy decision for the EU-U.S. Data Privacy Framework in December 2022 and the European Commission adopted the adequacy decision on July 10, 2023. The adequacy decision permits U.S. companies who self-certify to the EU-U.S. Data Privacy Framework to rely on it as a valid data transfer mechanism for data transfers from the EU to the U.S.. However, some privacy advocacy groups have already suggested that they will be challenging the EU-U.S. Data Privacy Framework. If these challenges are successful, they may not only impact the EU-U.S. Data Privacy Framework, but also further limit the viability of the standard contractual clauses and other data transfer mechanisms. The uncertainty around this issue has the potential to impact our business at the international level.

Following the withdrawal of the U.K. from the EU, the United Kingdom Data Protection Act 2018 applies to the processing of personal data that takes place in the U.K. and includes parallel obligations to those set forth by GDPR. In relation to data transfers, both the U.K. and the EU have determined, through separate "adequacy" decisions, that data transfers between the two jurisdictions are in compliance with the United Kingdom Data Protection Act and the GDPR, respectively. The U.K. and the U.S. have also agreed to a to develop a U.S.-U.K. "Data Bridge", which functions similarly to the EU-U.S. Data Privacy Framework and provides an additional legal mechanism for companies to transfer data from the U.K. to the U.S. In addition to the U.K., Switzerland is also in the process of approving an adequacy decision in relation to the Swiss-U.S. Data Privacy Framework (which would function similarly to the EU-U.S. Data Privacy Framework and the U.S.-U.K. Data Bridge in relation to data transfers from Switzerland to the U.S.). Any changes or updates to these developments have the potential to impact our business.

Beyond GDPR, there are privacy and data security laws in a growing number of countries around the world. While many loosely follow GDPR as a model, other laws contain different or conflicting provisions. These laws will impact our ability to conduct our business activities, including both our clinical trials and the sale and distribution of commercial products, through increased compliance costs, costs associated with contracting and potential enforcement actions.

While we continue to address the implications of the recent changes to data privacy regulations, data privacy remains an evolving landscape at both the domestic and international level, with new regulations coming into effect and continued legal challenges, and our efforts to comply with the evolving data protection rules may be unsuccessful. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. We must devote significant resources to understanding and complying with this changing landscape. Failure to comply with laws regarding data protection would expose us to risk of enforcement actions taken by data protection authorities in the EEA and elsewhere and carries with it the potential for significant penalties if we are found to be non-compliant. Similarly, failure to comply with federal and state laws in the U.S. regarding privacy and security of personal information could expose us to penalties under such laws. Any such failure to comply with data protection and privacy laws could result in government-imposed fines or orders requiring that we change our practices, claims for damages or other liabilities, regulatory investigations and enforcement action, litigation and significant costs for remediation, any of which could adversely affect our business. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our business, financial condition, results of operations or prospects.

We are subject to U.S. and certain foreign export control, import, sanctions, anti-corruption, and anti-money laundering laws and regulations with respect to our operations and non-compliance with such laws can subject us to criminal and/or civil liability and harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Control, the U.S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, third-party intermediaries, joint venture partners and collaborators from authorizing, promising, offering or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector. We may have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. In addition, we may engage third-party intermediaries to promote our clinical research activities abroad and/or to obtain necessary permits, licenses, and other regulatory approvals. We can be held liable for the corrupt or other illegal activities of these third-party intermediaries, our employees, representatives, contractors, partners and agents, even if we do not explicitly authorize or have actual knowledge of such activities.

Noncompliance with the laws and regulations described above could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension and/or debarment from contracting with certain persons, the loss of export privileges, reputational harm, adverse media coverage and other collateral consequences. If any subpoenas, investigations or other enforcement actions are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, results of operations and financial condition could be materially harmed. In addition, responding to any such action will likely result in a materially significant diversion of management's attention and resources and significant defense and compliance costs and other professional fees. In certain cases, enforcement authorities may even cause us to appoint an independent compliance monitor which can result in added costs and administrative burdens.

Changes in U.S. and international trade policies and the imposition of tariffs, or threat of tariffs, particularly with respect to China, may adversely impact our business and operating results.

The new presidential administration has imposed or threatened to impose a series of tariffs on goods imported to the U.S. from non-U.S. countries. The imposition of new tariffs or increases in existing tariffs on goods imported from countries where our suppliers or other third party vendors operate or rely upon third parties to provide certain goods or components of goods necessary for the research and development of our product candidates, could result in increased costs, including without limitation for raw materials, components, animal testing, assays or finished goods used in the research or development of our product candidates.

On April 2, 2025, an executive order issued by the new presidential administration announced a "baseline" reciprocal tariff of 10% on all U.S. trading partners effective April 5, 2025, and higher individualized reciprocal tariffs on 57 countries (with certain product exemptions for pharmaceutical-related imports, among others), including China. To date, we have relied upon third party suppliers and vendors located in China for a significant amount of goods or components of goods necessary for the research and development of our product candidates. Earlier the administration imposed a 25% tariff on Canada and Mexico for goods not covered by the U.S.-Mexico-Canada Agreement, or the USMCA, and tariffs equaling 20% on China. In response, several countries, including China, have threatened retaliatory measures and imposed retaliatory tariffs that would impact goods or components of goods historically imported by us. Prior to when the country-specific reciprocal tariffs were scheduled to take effect, the U.S. delayed the effective date of such tariffs for all countries except China to allow for negotiations. Later, the U.S. and China reached a framework agreement that resulted in the suspension of the higher reciprocal tariffs on China until November 10, 2025. Since the April announcement, several other countries have also reached deals with the U.S. that include reduced tariff rates and other measures. On July 31, 2025, the administration issued an executive order detailing new reciprocal tariff rates for individual countries that took effect on August 7, 2025. The new rates range between 10% and 41%. The revised rates reflect the deals that have been announced during the suspension period. China, Canada and Mexico were not included in the July 31, 2025 announcement. Imports from these countries are subject to additional tariffs imposed under separate executive orders. For China, the 10% baseline reciprocal tariff announced in April remains in effect, in addition to a minimum of an additional 20% tariff. The tariff rate on Mexican imports that are not covered by the USMCA remains at 25%. And, while the U.S. and Canada continue to engage in discussions, the U.S. announced an increase in Canada's tariff rate for goods not covered by the USMCA from 25% to 35%, effective August 1, 2025. Certain countries have reached agreements with the U.S. that cap pharmaceutical tariffs at 15%. These include the EU, Japan, South Korea and the U.K. The extent and duration of increased tariffs or retaliatory tariffs, and the resulting impact on general economic conditions and on our business, are uncertain and depend on various factors, such as negotiations between the U.S. and affected countries, the responses of other countries or regions, exemptions or exclusions that may be granted, availability and cost of alternative sources of supply.

The U.S. government has also recently made statements and taken certain actions that may lead to potential changes to U.S. and international trade policies, including imposing several rounds of tariffs and export control restrictions affecting certain products manufactured in China, and most recently, proposing legislation that, if enacted would restrict trade with certain Chinese companies that provide biopharmaceutical research, development, and manufacturing services. Recently both China and the U.S. have each imposed tariffs indicating the potential from further trade barriers. In addition, the U.S. Commerce Department has significantly expanded export controls for goods and technology destined for China, including adding numerous Chinese entities to its "entity list" and "unverified list" and imposing expanded restrictions on certain end users and end uses in China or by entities based in China, which require U.S. exporters to pursue export licenses that might not be approved, or to complete more procedures and diligence review before exporting goods to such entities. It is unknown whether and to what extent new tariffs, export controls, trade restrictions, or other new laws or regulations will be adopted, or the effect that any such actions would have on us or our industry. Sustained uncertainty about, or the further escalation of, trade and political tensions between the U.S. and China could result in a disadvantageous research and manufacturing environment in China, particularly for U.S. based companies, including retaliatory restrictions that hinder or potentially inhibit our ability to rely on CDMOs and other service providers that operate in China. For example, proposed legislation has been introduced in Congress that could prohibit, among other things, the use of U.S. government executive agency contract, grant, or loan funding to procure or obtain, or enter into, extend or renew contracts involving the use of certain equipment or services produced or provided by certain Chinese companies, including our current CDMO, WuXi Biologics, which could cause us to reevaluate our relationship with our current CDMO.

Separately, in April 2025, the Department of Commerce initiated an investigation under Section 232 of the Trade Expansion Act of 1962 into the impact on U.S. national security of the imports of pharmaceuticals and pharmaceutical ingredients, including finished drug products, medical countermeasures, critical inputs such as active pharmaceutical ingredients, and key starting materials, and derivative products of those items. On September 25, 2025, the U.S. administration announced that, beginning October 1, 2025, all branded or patented drugs imported in the U.S. would face a 100% tariff. At the same time, the administration indicated that these tariffs could be avoided by building pharmaceutical manufacturing facilities in the U.S. Thereafter, the administration delayed the October 1, 2025 effective date of the tariffs on branded or patented pharmaceutical products announcing that the administration had now "begun preparing" tariffs on manufacturers that don't build in the Untied States or enter into a most-favored-nation drug pricing agreement with the administration.

In addition to our CDMO, WuXi Biologics, some of our other suppliers, vendors and service providers are located in China or other countries, or rely on third parties located in China or other countries, impacted by tariffs imposed or threatened to be imposed by the U.S. Trade tensions and conflicts between the U.S. and China have been escalated in recent years and, as such, we are exposed to the

possibility of supply disruptions and increased costs and expenses in the event of changes to the laws, rules, regulations and policies of the governments of the U.S. or China, or due to geopolitical unrest and unstable economic conditions. Certain Chinese biotechnology companies may become subject to trade restrictions, sanctions, other regulatory requirements or proposed legislation by the U.S. government, which could restrict or even prohibit our ability to work with such entities, thereby potentially disrupting their supply of material to us. For example, in February 2024, U.S. lawmakers called for investigations into and the imposition of possible economic sanctions against certain Chinese biotechnology companies including WuXi AppTec and WuXi Biologics, or collectively WuXi, over alleged ties to the Chinese military. Escalating tensions between the U.S. and China may prevent or hinder the export of materials or technical information between us and our CDMO and third parties, such as pharmaceutical partners. Additionally, third parties may voluntarily require compliance or supply chain requirements that go above and beyond potential legislation to address perceived risk of "pass through," which would make it difficult for us to operate our business.

In addition, in 2024, the U.S. Congress considered, but did not pass, a bill widely referred to as the BIOSECURE Act. If this legislation had been enacted into law, it would have prohibited, subject to limited exceptions, the direct or indirect use of U.S. federal government contract, grant, and loan funds for purchasing biotechnology equipment and services from certain Chinese biotechnology companies, possibly including WuXi entities. On October 9, 2025, the U.S. Senate passed a revised version of the BIOSECURE legislation as part of its National Defense Authorization Act for fiscal year 2026. Instead of specifying particular Chinese entities for restrictions, the Senate bill would initially target biotechnology companies that have been identified on the so-called 1260H List by the U.S. Department of Defense as Chinese Military Companies Operating in the U.S. This list currently includes BGI Group, BGI Genomics Co., Ltd., Forensic Genomics International, and MGI Tech Co., Ltd., but does not include WuXi entities. The legislation would allow for other biotechnology companies, possibly including WuXi entities, to be added to the federal funding prohibitions at a later time. The U.S. House of Representatives has passed a version of the bill that does not contain similar biotechnology provisions, so it is not currently known whether the House or Senate language or other language or neither may become law.

Any unfavorable government policies on international trade, such as export controls, capital controls or tariffs, may increase the cost of manufacturing our product candidates and platform materials, affect the demand for our drug products (if and once approved), the competitive position of our product candidates, and import or export of raw materials and finished product candidate used in our and our collaborators' preclinical studies and clinical trials, particularly with respect to any product candidates and materials that we import from China, including pursuant to our manufacturing service arrangements with WuXi. If we are unable to obtain goods or components of goods necessary for the research and development of our product candidates, including without limitation, raw materials, components, animal testing, assays or finished goods, in sufficient quantity and in a timely manner due to disruptions in the global supply chain caused by macroeconomic events and conditions, the research, development, testing and clinical trials of our product candidates may be delayed or infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business. We cannot yet predict the effect of the recently imposed U.S. tariffs on imports, or the extent to which other countries, in particular, China, will impose and maintain quotas, duties, tariffs, taxes or other similar restrictions upon imports or exports in the future, nor can we predict future trade policy or the terms of any renegotiated trade agreements and their impact on our business.

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

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

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

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

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

We are exposed to the risk of fraud or other misconduct by our employees, independent contractors, CROs, consultants, commercial partners, vendors and our principal investigators. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in the EU and other jurisdictions, provide accurate information to the FDA, the EC and other regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately, or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements.

Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. Even with appropriate policies and procedures, it is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent such activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition, results of operations and prospects, including the imposition of significant fines or other sanctions.

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

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

We are highly dependent on the management, research and development, clinical, financial and business development expertise of our executive officers, as well as the other members of our scientific and clinical teams. Although we have employment agreements that outline the terms of employment with each of our executive officers, each of them may terminate their employment with us at any time. As such, these employment agreements do not guarantee our retention of our executive officers for any period of time. In addition, at our 2025 annual meeting of stockholders, our stockholders approved a certificate of amendment to our restated certificate of incorporation to provide for the exculpation of our executive officers, as permitted under Delaware law, which amendment became effective on June 10, 2025. Despite this, we may have difficulty retaining key personnel, which could adversely affect our business and further development of our product candidates. Furthermore, the cost of directors' and officers' liability insurance, or D&O insurance, is subject to change, which could result in D&O insurance becoming significantly more expensive for us to maintain or require us to accept coverage terms or policy limits that are less favorable. Accordingly, there is no guarantee that we will be able to maintain D&O insurance at a reasonable cost or in an amount adequate to satisfy any liability that may arise. An inability to secure and maintain D&O insurance may make it difficult for us to retain and attract talented and skilled directors and officers to serve our company, which could adversely affect our business. We do not maintain "key person" insurance for any of our employees.

Recruiting and retaining qualified scientific and clinical personnel and, if we are successful in obtaining marketing approval for our product candidates, sales and marketing personnel, is and will be critical to our success. The loss of the services of our executive officers or other key employees could impede, delay or prevent the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and other key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval for and commercialize products in the life sciences industry, and specifically our product candidates. We are based in Massachusetts, a state that is home to many other biopharmaceutical companies as well as many academic and research institutions, resulting in fierce competition for qualified personnel. Furthermore, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their research output. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we

rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. Additionally, the biotechnology industry generally has continued to experience a competitive wage environment, which is likely to further exacerbate the foregoing risks and may impact our ability to retain our executive officers or other key employees. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited and could adversely affect our business, prospects, financial condition and results of operations.

We depend on our information technology systems and those of our third-party service providers, and any failure of these systems could harm our business. Security breaches, loss of data, inability to access systems, and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability or competitive or reputational harm, which could adversely affect our business, results of operations and financial condition.

We collect and maintain information in digital and other forms that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. It is critical that we do so in a secure manner to maintain the privacy, security, confidentiality, availability and integrity of such confidential information. Our internal information technology systems and infrastructure, and those of our contractors, consultants, vendors, service providers and other third parties on which we rely, are vulnerable to damage or unauthorized access or use resulting from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, denial or degradation of service attacks, ransomware, hacking, phishing and other social engineering attacks, attachments to emails, intentional or accidental actions or inactions by persons inside our organization or by persons with access to systems inside our organization.

The risk of a security breach or disruption or data loss, particularly through cyber-attacks or cyber intrusion, including by computer hackers, supply chain attacks, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. Additionally, attackers may use artificial intelligence and machine learning to launch more automated, targeted and coordinated attacks against targets. In addition, the prevalent use of mobile devices that access confidential information increases the risk of lost or stolen devices, security incidents and data security breaches, which could lead to the loss of confidential information or other intellectual property. We also may face increased risks of a security breach or disruption due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. The costs to us to mitigate network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service, negative publicity and other harm to our business and our competitive position. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs.

Any security compromise affecting us, our partners, our service providers or our industry, whether real or perceived, could harm our reputation, erode confidence in the effectiveness of our security measures and lead to regulatory scrutiny. If such an event were to occur and cause interruptions in our operations or result in the unauthorized acquisition of or access to personally identifiable information or individually identifiable health information (violating certain privacy laws, as applicable, such as HIPAA, CCPA, HITECH and GDPR), it could result in a material disruption of our discovery and development programs and our business operations, whether due to a loss of our trade secrets or other similar disruptions. Some of the federal, state and foreign government requirements include obligations of companies to notify individuals of security breaches involving particular personally identifiable information, which could result from breaches experienced by us or by our vendors, contractors, or organizations with which we have formed strategic relationships. Notifications and follow-up actions related to a security breach could impact our reputation, cause us to incur significant costs, including legal expenses and remediation costs. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the lost data. We would also be exposed to a risk of loss, governmental investigations or enforcement, or litigation and potential liability, any of which could materially adversely affect our business, results of operations and financial condition. While we do maintain cyber liability insurance, our insurance coverages may not be sufficient in type or amount to cover us against any such losses, claims, or liabilities related to security breaches, cyber-attacks, cyber intrusion, or other related breaches or disruptions.

A variety of risks associated with marketing our product candidates internationally, if approved, could materially adversely affect our business.

We also plan to seek regulatory approval of our product candidates outside of the U.S. and, accordingly, we expect that we will be subject to additional risks related to operating, including conducting marketing and sales activities, in international jurisdictions if we obtain the necessary approvals, including:

- regulatory requirements in foreign countries that differ from those in the U.S.;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.;
- potential liability under the FCPA or other comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the U.S.;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war, armed conflicts and terrorism or natural disasters, including pandemics or other outbreaks of infectious disease, earthquakes, typhoons, floods and fires.

Any of these factors, along with other risks associated with international operations, could materially adversely affect our future international expansion and operations and, consequently, our results of operations.

We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

From time to time, we may consider strategic transactions, such as acquisitions of companies, asset purchases and out-licensing or in-licensing of intellectual property, products or technologies. Additional potential transactions that we may consider in the future include a variety of business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any future transactions could increase our near and long-term expenditures, result in potentially dilutive issuances of our equity securities, including our common stock, or the incurrence of debt, contingent liabilities, amortization expenses or acquired in-process research and development expenses, any of which could affect our financial condition, liquidity and results of operations. Future acquisitions may also require us to obtain sufficient additional capital, which may not be available on favorable terms or at all. These transactions may not be successful and may require significant time and attention of management. In addition, the integration of any business that we may acquire in the future may disrupt our existing business and may be a complex, risky and costly endeavor for which we may never realize any or all potential benefits of the acquisition. Accordingly, although there can be no assurance that we will undertake or successfully complete any additional transactions of the nature described above, any additional transactions that we do complete could have a material adverse effect on our business, results of operations, financial condition and prospects.

Our operations or those of the third parties upon whom we depend might be affected by the occurrence of a catastrophic event, such as a terrorist attack, war or other armed conflict, geopolitical tensions or trade wars, pandemic or natural disaster.

We depend on our employees, consultants, CDMOs, CROs, as well as regulatory agencies and other parties, for the continued operation of our business. While we maintain disaster recovery plans, they might not adequately protect us. Despite any precautions that we or any third parties on whom we depend take for catastrophic events, including terrorist attacks, wars or other armed conflicts, geopolitical tensions or trade wars, pandemics or natural disasters, these events could result in significant disruptions to our research and development, manufacturing, preclinical studies, clinical trials, and, ultimately, if approved, the commercialization of our products. Long-term disruptions in the infrastructure caused by these types of events, such as natural disasters, which are increasing in frequency due to the impacts of climate change, the outbreak of wars or other armed conflicts, the escalation of hostilities, geopolitical tensions or trade wars, acts of terrorism or "acts of God," particularly involving geographies in which we or third parties on whom we depend have offices, manufacturing or clinical trial sites, could adversely affect our businesses. Although we carry business interruption insurance policies and typically have provisions in our contracts that protect us in certain events, our coverage might not include or be adequate to compensate us for all losses that may occur. Any catastrophic event affecting us, our CDMOs, our CROs, regulatory agencies or other parties with which we are engaged could have a material adverse effect on our operations and financial performance.

Risks Related to Ownership of Our Common Stock and Our Status as a Public Company

Our common stock may be subject to a low trading volume and volatile market price related or unrelated to our operations and purchasers of our common stock could have difficulty selling their shares or could suffer a decline in value.

The trading volume and market price of our common stock has been, and may continue to be, subject to significant fluctuations in response to numerous factors, many of which are beyond our control. The stock market in general and the market for biotechnology and pharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price paid for the shares. The trading volume and market price for our common stock may be influenced by many factors, including:

- the results from our preclinical studies and clinical trials;
- the commencement, enrollment or results of any current or future clinical trials we may conduct, or changes in the development status of our product candidates;
- adverse results from, delays in initiating or completing, or termination of clinical trials;
- unanticipated serious safety concerns related to the use of our product candidates;
- clinical trial results from, or regulatory developments regarding, a competitor's product candidate;
- adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;
- regulatory or legal developments in the U.S. and foreign countries;
- 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;
- the public's response to press releases or other public announcements by us or third parties, including our filings with the SEC, and announcements relating to acquisitions, strategic transactions, licenses, joint ventures, collaborations, capital commitments, intellectual property, litigation or other disputes impacting us or our business;
- lower than expected market acceptance of our product candidates, if approved;
- adverse developments concerning our manufacturers;
- our inability to obtain adequate product supply for any product candidate, or approved product or inability to do so at acceptable prices;
- variations in the level of expenses related to our preclinical and clinical development programs, including relating to the timing of invoices from, and other billing practices of, our CROs and clinical trial sites;
- variations in the level of expenses related to our commercialization activities, if any product candidates are approved;

- the clinical results of our competitors or potential competitors;
- introduction of new products or services by our competitors;
- changes in financial estimates by us or by any securities analysts who might cover our common stock;
- conditions or trends in our industry;
- our cash position;
- sales of our common stock by us or our stockholders in the future, including the common stock that may be issuable upon the exercise of outstanding prefunded warrants and common stock warrants, or the perception that such sales could occur;
- adoption of new, or changes to current accounting standards;
- ineffectiveness of our internal controls;
- changes in the market valuations of similar companies;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biotechnology and pharmaceutical industry;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- changes in the structure of healthcare payment systems;
- investors' general perception of our company and our business;
- overall performance of the equity markets;
- potential inclusion or exclusion of our common stock in exchange, industry, or other tracking indices;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies and product candidates;
- significant lawsuits, including patent or stockholder litigation;
- proposed changes to healthcare laws, intellectual property laws or pharmaceutical pricing in the U.S. or foreign jurisdictions, or speculation regarding such changes;
- future sales of our common stock by our officers, directors and significant stockholders;
- recruitment or departure of key personnel;
- public health epidemics or pandemics, such as the COVID-19 pandemic, and any recession, depression, or other sustained adverse market event or economic impact resulting from such epidemics or pandemics;
- general political, economic, industry and market conditions; and
- other events or factors described in this "Risk Factors" section, many of which are beyond our control.

In addition, in the past, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' stock. This risk is especially relevant for us, because biopharmaceutical companies have experienced significant stock price volatility in recent years. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources from our business.

If securities or industry analysts do not publish research or reports about our company, or if they issue unfavorable or inaccurate research regarding our business, or if they publish negative evaluations of our stock, the price and trading volume of our stock could decline.

The trading market for our common stock relies, in part, on the research and reports that securities or industry analysts publish about us or our business. A limited number of securities and industry analysts currently publish research on our company. There can be no assurance that existing analysts will continue to cover us or that new analysts will begin to cover us. There is also no assurance that any covering analyst will provide favorable coverage. Although we have obtained analyst coverage, if one or more of the analysts covering our business downgrade their evaluations of our stock or publish inaccurate or unfavorable research about our business, or provides more favorable relative recommendations about our competitors, the price of our stock could decline. In the past, analysts have ceased to cover our stock and others may cease to do so in the future. As a result, we could lose visibility in the market for our stock, which in turn could cause our stock price and trading volume to decline.

Unstable global economic and political conditions, including economic uncertainty tied to interest rates and heightened inflation, credit and financial market instability, and uncertainty related to ongoing geopolitical conflicts, could adversely affect our business, financial condition, stock price and ability to raise capital.

Unstable global economic and political conditions, including economic uncertainty tied to interest rates and heightened inflation, credit and financial market instability, and uncertainty related to ongoing geopolitical conflicts, could adversely affect our business, financial condition, stock price and ability to raise capital. The global economy, in particular the financial markets, have recently experienced significant disruption and volatility, including without limitation, as a result of heightened inflation, capital market volatility, interest rate and currency rate fluctuations, volatility in commodity prices, decline in consumer confidence and economic growth, supply chain disruptions, banking disruptions, and uncertainty resulting from geopolitical events, including trade wars, civil and political unrest, wars and other armed conflicts. In addition, market volatility, high levels of inflation and high interest rates may increase our cost of financing or restrict our access to potential sources of future capital. Furthermore, our stock price may further decline due in part to the volatility of the stock market and any general economic downturn. If the disruption and volatility persist or deepen, we may be unable to raise sufficient additional capital on acceptable terms, or at all. If we are unable to raise sufficient additional capital, our business, financial condition, stock price and results of operations could be adversely affected, and we may need to implement cost reduction strategies, which could include delaying, reducing or altogether terminating both internal and external costs related to our operations and research and development programs. In addition, political developments impacting government spending and international trade, including changes in trade agreements, trade disputes, tariffs and investment restrictions, such as the ongoing trade dispute between the United States and China, may negatively impact markets and cause weaker macroeconomic conditions. These global economic and political factors could also strain certain of our suppliers and manufacturers, including our primary CDMO, possibly resulting in supply disruptions or increased raw material or manufacturing costs, or adversely impacting their ability to manufacture clinical trial materials for our product candidates. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic and geopolitical climate and financial market conditions could adversely impact our business.

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

As of September 30, 2025, our executive officers, directors, holders of 5% or more of our common stock and their respective affiliates beneficially owned shares in the aggregate representing a majority of our outstanding common stock. As a result of their share ownership, these stockholders, if they act together, would have the ability to influence our management and policies and would be able to significantly affect the outcome of matters requiring stockholder approval, such as elections of directors, amendments of our organizational documents or approvals 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 our stockholders may feel are in their best interest.

Some of these persons or entities may have interests different than our unaffiliated stockholders, or they may want us to pursue strategies that deviate from the interests of other stockholders. In addition, this concentration of ownership might adversely affect the market price of our common stock by:

- delaying, deferring or preventing a change of control of us;
- entrench our management and board of directors;
- impeding a merger, consolidation, takeover or other business combination involving us; or

- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

We have broad discretion regarding use of our cash and cash equivalents, and we may not use them effectively.

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

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

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any determination to pay dividends in the future will be at the sole discretion of our board of directors. In addition, the terms of any future debt agreements may preclude us from paying dividends. Any return to stockholders will therefore be limited in the foreseeable future to the appreciation of their stock.

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

We are an "emerging growth company," or EGC, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. We may remain an EGC until December 31, 2026, although if the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of any June 30 before that time or if we have annual gross revenues of $1.235 billion or more in any fiscal year, we would cease to be an EGC as of December 31 of the applicable year. We also would cease to be an EGC if we issue more than $1.0 billion of non-convertible debt over a three-year period. For so long as we remain an EGC, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not EGCs. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of financial Condition and Results of Operations" disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

Even after we no longer qualify as an emerging growth company, we may continue to qualify as a smaller reporting company, which would allow us to take advantage of many of the same exemptions from disclosure requirements, including reduced disclosure obligations regarding executive compensation. In addition, if we are a smaller reporting company with less than $100 million in annual revenue, we would not be required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404.

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

In addition, the JOBS Act permits an EGC to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected not to "opt out" of such extended transition period, which means that when a standard is issued or revised and it has different application dates for

public or private companies, we can adopt the new or revised standard at the time private companies adopt the new or revised standard and may do so until such time that we either (1) irrevocably elect to "opt out" of such extended transition period or (2) no longer qualify as an EGC or a smaller reporting company. We may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for private companies.

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

As a public company, we have incurred and will continue to incur substantial legal, accounting and other expenses. The Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, Nasdaq listing requirements, and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

We evaluate developments in these rules and regulations as they are promulgated and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to continue to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us and our business may be materially adversely effected.

Pursuant to Section 404, we are required to furnish a report by our management on our internal control over financial reporting. However, while we remain an EGC or a smaller reporting company with less than $100 million in annual revenue, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To comply with Section 404, we are engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses in our internal control over financial reporting, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

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 control over financial reporting is necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, is 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 control over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also subject us to regulatory scrutiny and sanctions, impair our ability to raise revenue and cause investors to lose confidence in our reported financial information, which could harm our business and have a negative effect on the trading price of our common stock and adversely affect our results of operations and financial condition.

We are required to disclose changes made in our internal controls and procedures on a quarterly basis and our management is required to assess the effectiveness of these controls annually. However, for as long as we are an EGC or a smaller reporting company with less than $100 million in annual revenue, our independent registered public accounting firm will not be required to attest to the effectiveness

of our internal control over financial reporting pursuant to Section 404. An independent assessment of the effectiveness of our internal control over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal control over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation, which could have a negative effect on the trading price of our common stock and adversely affect our results of operations and financial condition.

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

As a public company, we are subject to certain reporting requirements of the Securities Exchange Act of 1934, as amended, or 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 control over financial reporting, 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.

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

Income, sales, use or other tax laws, statutes, rules, or regulations could be enacted or amended at any time, which could affect our business or financial condition, including causing potentially adverse impacts to our effective tax rate, tax liabilities, cash tax obligations. For example, the Inflation Reduction Act, or the IRA, was signed into law in August 2022, and the One Big Beautiful Bill Act, or OBBBA, was signed into law in July 2025. The IRA introduced new tax provisions, including a one percent excise tax imposed on certain stock repurchases by publicly traded companies. The one percent excise tax generally applies to any acquisition of stock by the publicly traded company (or certain of its affiliates) from a stockholder of the company in exchange for money or other property (other than stock of the company itself), subject to a de minimis exception. Thus, the excise tax could apply to certain transactions that are not traditional stock repurchases. The OBBBA contains numerous tax provisions that we are currently in the process of evaluating the impact to our business or financial condition. The recent changes under the OBBBA include tax rate extensions, changes to the business interest deduction limitation, immediate expensing of domestic research and development expenditures (in contrast to the continued capitalization and amortization of foreign research and development expenditures), changes to the bonus depreciation deduction rules, and changes to the international tax framework. Regulatory guidance under the OBBBA and other tax-related legislation is and continues to be forthcoming, and we will utilize such guidance to analyze the impact on our business and financial condition. In addition, it is uncertain if and to what extent various states will conform to federal tax legislation.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current directors and members of management.

Provisions in our restated certificate of incorporation and our second amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that only one of three classes of directors is elected each year;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from our board of directors;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;

- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least two-thirds of the votes that all our stockholders would be entitled to cast to amend or repeal specified provisions of our certificate of incorporation or bylaws.

In addition, these provisions would apply even if we were to receive an offer that some stockholders may consider beneficial. Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, or the DGCL, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Our restated certificate of incorporation designates the Court of Chancery of the State of Delaware and the federal district courts of the United States of America as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers and employees and increase the costs to our stockholders of bringing such claims.

Our restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware does not have jurisdiction, the federal district court for the District of Delaware) will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, employees or stockholders to our company or our stockholders;
- any action asserting a claim arising pursuant to any provision of the DGCL or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware; or
- any action asserting a claim arising pursuant to any provision of our certificate of incorporation or bylaws (in each case, as they may be amended from time to time) or governed by the internal affairs doctrine.

The choice of forum provisions will not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions, and investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall, to the fullest extent permitted by law, be the sole and exclusive forum for the resolution of any claims arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

These exclusive forum provisions may limit the ability of our stockholders to bring a claim in a judicial forum that such stockholders find favorable for disputes with us or our directors, officers or employees, and increase the costs to such stockholders of bringing such a claim, either of which may discourage such lawsuits against us and our directors, officers and employees. If a court were to find that either exclusive forum provision contained in our restated certificate of incorporation to be inapplicable or unenforceable in an action,

we may incur further significant additional costs associated with resolving such action in other jurisdictions, all of which could materially adversely affect our business, financial condition and operating results.

Item 5. Other Information

(c)

Director and Officer Trading Arrangements

None of our directors or officers adopted or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement (as such terms are defined in Items 408(a) and 408(c) of Regulation S-K, respectively) during the quarterly period covered by this Quarterly Report on Form 10-Q.

Item 6. Exhibits

EXHIBIT INDEX

Exhibit Number	Description
3.1	Restated Certificate of Incorporation of the Registrant, as amended (incorporated by reference to Exhibit 3.1 to the Registrant's Form 10-Q (File No. 001-40925), filed with the Securities and Exchange Commission on August 14, 2025)
3.2	Second Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-40925), filed with the Securities and Exchange Commission on April 3, 2023)
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1+	Certifications of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS*	XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH*	Inline XBRL Taxonomy Extension Schema with Embedded Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL with applicable taxonomy extension information contained in Exhibits 101)

* Filed herewith.

\+ The certifications attached as Exhibit 32.1 are being furnished solely to accompany this Quarterly Report on Form 10-Q and will not be deemed to be "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that section. Such certifications will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent that the Registrant specifically incorporates it by reference into such filing.

SIGNATURES

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

XILIO THERAPEUTICS, INC.

Date: November 13, 2025

By: /s/ René Russo
René Russo, Pharm.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 13, 2025

By: /s/ Christopher Frankenfield
Christopher Frankenfield
Chief Financial Officer and Chief Operating Officer
(Principal Financial Officer)

EXHIBIT 31.1

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

I, René Russo, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Xilio 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2025

/s/ René Russo
Name: René Russo
Title: President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

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

I, Christopher Frankenfield, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Xilio 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2025

/s/ Christopher Frankenfield
Name: Christopher Frankenfield
Title: Chief Financial Officer and Chief Operating Officer
(Principal Financial Officer)

EXHIBIT 32.1

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

In connection with this Quarterly Report on Form 10-Q of Xilio Therapeutics, Inc. (the "Company") for the three months ended September 30, 2025, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, René Russo, President and Chief Executive Officer of the Company, and Christopher Frankenfield, Chief Financial Officer and Chief Operating Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to our knowledge that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

/s/ René Russo
Name: René Russo
Title: President and Chief Executive Officer
(Principal Executive Officer)

Date: November 13, 2025

/s/ Christopher Frankenfield
Name: Christopher Frankenfield
Title: Chief Financial Officer and Chief Operating Officer
(Principal Financial Officer)

Date: November 13, 2025