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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, 2026

or

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

For the transition period from_____to

Commission File Number: 001-40925

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 6, 2026: 7,063,982

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, and our license agreement with Gilead Sciences, Inc., or Gilead;
- 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 $36.2 million in additional gross proceeds in the fourth quarter of 2026 if all outstanding Series C common stock warrants issued in connection with our June 2025 follow-on offering are exercised at their current exercise price of $10.50 per warrant;
- our ability to secure additional capital in the future;
- 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;
- 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:

- We will need to obtain substantial additional capital in the future to finance our operations and complete the development of any current or future product candidates.
- We have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future.
- 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 third-party drugs.
- Manufacturing biologics is complex, and we may experience manufacturing problems that result in delays in our development or commercialization programs.
- 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 expect to rely on third parties to conduct, supervise and monitor investigational new drug application enabling studies and clinical trials, and to perform other functions for us, 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, 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.

- 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.
- 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.

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, 2026	December 31, 2025
ASSETS		
Current assets		
Cash and cash equivalents	$ 122,182	$ 137,531
Collaboration and license agreement receivable	—	5,000
Prepaid expenses and other current assets	4,316	2,496
Total current assets	126,498	145,027
Restricted cash	1,825	1,807
Property and equipment, net	3,086	3,892
Operating lease right-of-use asset	3,423	3,959
Total assets	$ 134,832	$ 154,685
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 753	$ 3,168
Accrued expenses	9,171	11,739
Deferred revenue, current portion	15,407	40,023
Operating lease liability, current portion	1,468	1,343
Total current liabilities	26,799	56,273
Deferred revenue, net of current portion	9,927	20,635
Operating lease liability, net of current portion	4,492	5,611
Common stock warrant liabilities	25,380	29,560
Liabilities to issue common stock	—	7,333
Total liabilities	66,598	119,412
Commitments and contingencies (Note 7)		
Stockholders' 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; 6,587,811 shares issued and outstanding at September 30, 2026; 4,530,641 shares issued and outstanding at December 31, 2025	1	—
Additional paid-in capital	508,872	454,062
Accumulated deficit	(440,639)	(418,789)
Total stockholders' equity	68,234	35,273
Total liabilities and stockholders' equity	$ 134,832	$ 154,685

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,	
	2026	2025	2026	2025
Revenue				
Collaboration and license revenue	$ 9,984	$ 19,066	$ 41,324	$ 30,080
Total revenue	9,984	19,066	41,324	30,080
Operating expenses				
Research and development	$ 14,805	$ 14,321	$ 49,196	$ 37,917
General and administrative	6,928	6,674	21,480	22,309
Total operating expenses	21,733	20,995	70,676	60,226
Loss from operations	(11,749)	(1,929)	(29,352)	(30,146)
Other income (expense), net				
Change in fair value of common stock warrant liabilities	4,820	(15,380)	4,180	(15,430)
Other income, net	981	1,022	3,322	180
Total other income (expense), net	5,801	(14,358)	7,502	(15,250)
Net loss and comprehensive loss	$ (5,948)	$ (16,287)	$ (21,850)	$ (45,396)
Net loss per share, basic and diluted	$ (0.30)	$ (1.58)	$ (1.18)	$ (6.03)
Weighted average common shares outstanding, basic and diluted	19,687,818	10,293,347	18,492,240	7,524,228

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

XILIO THERAPEUTICS, INC.
Condensed Consolidated Statements of Stockholders' Equity (Deficit)
For the three months ended September 30, 2026 and 2025
(In thousands, except share data)
(Unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at June 30, 2026	6,580,149	$ 1	$ 506,954	$ (434,691)	$ 72,264
Issuance of common stock in connection with the exercise of prefunded warrants	7,501	—	—	—	—
Exercise of stock options	161	—	—	—	—
Stock-based compensation expense	—	—	1,918	—	1,918
Net loss	—	—	—	(5,948)	(5,948)
Balance at September 30, 2026	6,587,811	$ 1	$ 508,872	$ (440,639)	$ 68,234

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount			
Balance at June 30, 2025	3,701,952	$ —	$ 419,931	$ (412,862)	$ 7,069
Exercise of stock options	78	—	—	—	—
Stock-based compensation expense	—	—	1,123	—	1,123
Net loss	—	—	—	(16,287)	(16,287)
Balance at September 30, 2025	3,702,030	$ —	$ 421,054	$ (429,149)	$ (8,095)

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

XILIO THERAPEUTICS, INC.
Condensed Consolidated Statements of Stockholders' Equity (Deficit)
For the nine months ended September 30, 2026 and 2025
(In thousands, except share data)
(Unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2025	4,530,641	$ —	$ 454,062	$ (418,789)	$ 35,273
Issuance of prefunded warrants in connection with a follow-on offering, net of issuance costs	—	—	37,256	—	37,256
Issuance of common stock to settle the liabilities to issue common stock	708,223	1	7,332	—	7,333
Issuance of common stock in connection with the exercise of prefunded warrants	743,410	—	—	—	—
Issuance of common stock in connection with at-the-market offerings, net of issuance costs	592,300	—	4,458	—	4,458
Issuance of common stock under employee stock purchase plan	4,973	—	36	—	36
Vesting of restricted stock units	7,952	—	—	—	—
Exercise of stock options	312	—	1	—	1
Stock-based compensation expense	—	—	5,727	—	5,727
Net loss	—	—	—	(21,850)	(21,850)
Balance at September 30, 2026	6,587,811	$ 1	$ 508,872	$ (440,639)	$ 68,234

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount			
Balance at December 31, 2024	3,268,299	$ —	$ 401,351	$ (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	310,559	—	2,810	—	2,810
Issuance of common stock in connection with at-the-market offerings, net of issuance costs	110,747	—	2,017	—	2,017
Issuance of common stock under employee stock purchase plan	3,240	—	40	—	40
Vesting of restricted stock units	7,952	—	—	—	—
Exercise of stock options	1,233	—	9	—	9
Stock-based compensation expense	—	—	4,009	—	4,009
Net loss	—	—	—	(45,396)	(45,396)
Balance at September 30, 2025	3,702,030	$ —	$ 421,054	$ (429,149)	$ (8,095)

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,	
	2026	2025
Cash flows from operating activities:		
Net loss	$ (21,850)	$ (45,396)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	996	1,218
Stock-based compensation expense	5,727	4,009
Change in fair value of common stock warrant liabilities	(4,180)	15,430
Issuance costs allocated to common stock warrant liabilities	—	2,284
Changes in operating assets and liabilities:		
Collaboration and license agreement receivable	5,000	(17,500)
Prepaid and other assets	(1,283)	2,580
Accounts payable	(1,973)	(276)
Accrued expenses and other liabilities	(2,012)	(1,907)
Deferred revenue	(35,324)	36,564
Net cash used in operating activities	(54,899)	(2,994)
Cash flows from investing activities:		
Purchases of property and equipment	(633)	(423)
Net cash used in investing activities	(633)	(423)
Cash flows from financing activities:		
Proceeds from issuance of prefunded warrants in connection with a follow-on offering, net of issuance costs	37,256	—
Proceeds from issuance of common stock in connection with at-the-market offerings, net of issuance costs	4,458	2,017
Proceeds from issuance of prefunded warrants and common stock warrants in connection with a follow-on 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 under employee stock purchase plan	36	40
Proceeds from exercise of stock options	1	9
Payments of issuance costs included in accounts payable or accrued expenses at prior year end	(1,550)	—
Net cash provided by financing activities	40,201	51,909
(Decrease) increase in cash, cash equivalents and restricted cash	(15,331)	48,492
Cash, cash equivalents and restricted cash, beginning of period	139,338	57,073
Cash, cash equivalents and restricted cash, end of period	$ 124,007	$ 105,565
Supplemental disclosure of non-cash activities:		
Settlement of liabilities to issue common stock by issuing common stock	$ 7,332	$ —
Reconciliation to amounts within the consolidated balance sheets:		
Cash and cash equivalents	$ 122,182	$ 103,764
Restricted cash	1,825	1,801
Cash, cash equivalents and restricted cash, end of period	$ 124,007	$ 105,565

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 and Liquidity

Xilio Therapeutics, Inc. ("Xilio" or the "Company") is a clinical-stage biotechnology company dedicated to discovering and developing masked 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.

Since its inception, the Company has devoted substantially all of its financial resources and efforts to research and development activities. As of September 30, 2026, the Company had an accumulated deficit of $440.6 million and has incurred significant operating losses, including net losses of $21.9 million and $45.4 million for the nine months ended September 30, 2026 and 2025, respectively. The Company expects its operating losses and negative operating cash flows to continue for the foreseeable future as it continues to advance its product candidates through clinical trials, maintains the infrastructure necessary to support these activities and continues to incur costs associated with operating as a public company.

As of September 30, 2026, the Company had cash and cash equivalents of $122.2 million. Based on its current operating plans, the Company anticipates that its existing cash and cash equivalents as of September 30, 2026 will be sufficient to enable it to fund its operating expenses and capital expenditure requirements for at least twelve months from the date of the issuance of these condensed consolidated financial statements.

However, the Company has based its estimates on assumptions that may prove to be wrong. If actual results differ from the Company's estimates, the Company could exhaust its available capital resources sooner than it anticipates, in which case, the Company would be required to seek additional capital sooner or curtail planned activities to reduce operating expenses, which may have an adverse impact on the Company's ability to achieve its business objectives.

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, 2025 and notes thereto, included in the Company's Annual Report on Form 10-K filed with the SEC on March 23, 2026. 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, 2026 and the results of its operations for the three and nine months ended September 30, 2026 and 2025 and cash flows for the nine months ended September 30, 2026 and 2025. Such adjustments are of a normal and recurring nature. The results for the three and nine months ended September 30, 2026 are not necessarily indicative of the results for the year ending December 31, 2026 or for any future period.

On March 13, 2026, the Company effected a reverse stock split of its common stock at a ratio of 1-for-14. The reverse stock split did not impact the number of authorized shares of common stock or preferred stock or the par value per share of the common stock or preferred stock. All share and per share amounts in these condensed consolidated financial statements and notes thereto have been adjusted retroactively to reflect the reverse stock split for all periods presented.

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, 2025. 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, 2025.

Use of Estimates

The preparation of financial statements in accordance with U.S. 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 masked 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 condensed 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 November 2024, the FASB issued Accounting Standards Update No. 2024-03, Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses ("ASU 2024-03"), which requires disclosure, in the notes to financial statements, of specified information about certain costs and expenses. The guidance is effective for annual reporting 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 consolidated financial statements and related disclosures.

In December 2025, the FASB issued Accounting Standards Update No. 2025-12, Codification Improvements ("ASU 2025-12"), to clarify ambiguities and improve consistency across multiple topics in the ASC). Key provisions of ASU 2025-12 include amendments to ASC 260, *Earnings Per Share* ("EPS"), to refine the treatment of anti-dilutive shares in year-to-date diluted EPS calculations when an entity experiences a loss from continuing operations. The amendments in ASU 2025-12 are effective for all entities for annual reporting periods beginning after December 15, 2026, and interim reporting periods within those annual reporting periods. Early adoption is permitted in both interim and annual reporting periods in which financial statements have not yet been issued or made available for issuance. If an entity adopts the amendments in ASU 2025-12 in an interim period, it must adopt them as of the beginning of the annual reporting period that includes that interim reporting period. An entity may elect to early adopt the amendments on an issue-by-issue basis. An entity should apply the amendments in ASU 2025-12 (except for the amendments to ASC 260, *Earnings Per Share*) using one of the following transition methods: (i) prospectively to all transactions recognized on or after the date that the entity first applies the amendments, or (ii) retrospectively to the beginning of the earliest comparative period presented. An entity should adjust the opening balance of retained earnings as of the beginning of the earliest comparative period presented. An entity should apply the amendments in ASU 2025-12 related to ASC 260, *Earnings Per Share* on a retrospective basis for all periods presented. The Company is currently evaluating the potential impact of adopting ASU 2025-12 on its consolidated financial statements and related disclosures.

3. Fair Value Measurements

Liabilities measured at fair value on a recurring basis consist of the following as of September 30, 2026:

	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 warrants	$ —	$ —	$ 21,820	$ 21,820
Series C warrants	—	—	3,560	3,560
Total financial liabilities at September 30, 2026	$ —	$ —	$ 25,380	$ 25,380

Liabilities measured at fair value on a recurring basis consist of the following as of December 31, 2025:

	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 warrants	$ —	$ —	$ 23,100	$ 23,100
Series C warrants	—	—	6,460	6,460
Total financial liabilities at December 31, 2025	$ —	$ —	$ 29,560	$ 29,560

See Note 8 to these condensed consolidated financial statements for more information on the Series A warrants and Series C warrants. The fair value of the common stock warrant liabilities is calculated utilizing a Black-Scholes option pricing model for the Series A warrants and a Monte Carlo simulation model for 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 term of the warrant, the current price of the Company's common stock, expected volatility, the risk-free interest rate for the expected term of the warrant and expected dividend yield. The Monte Carlo simulation assumptions also include the potential impacts of the warrant strike price reset feature in the Series C warrants.

The following assumptions were used in determining the fair value of the Company's common stock warrant liabilities as of September 30, 2026 and December 31, 2025:

	September 30, 2026	December 31, 2025
Closing price of common stock	$ 9.05	$ 8.96
Warrant exercise price	$ 10.50	$ 10.50
Expected volatility	70 %	70 %
Risk free interest rate	4.91 %	3.62 %
Expected dividend yield	—	—
Expected term (in years)	0.17 - 3.68	0.92 - 4.43

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 C	Total level 3 financial liabilities
Balance at December 31, 2025	$ 23,100	$ 6,460	$ 29,560
Change in fair value of common stock warrant liabilities	(1,280)	(2,900)	(4,180)
Balance at September 30, 2026	$ 21,820	$ 3,560	$ 25,380

4. Property and Equipment, Net

Property and equipment, net consists of the following as of September 30, 2026 and December 31, 2025:

	September 30, 2026	December 31, 2025
Laboratory equipment	$ 6,975	$ 6,381
Furniture and fixtures	681	681
Leasehold improvements	5,160	5,124
Construction in process	—	459
Total property and equipment	12,816	12,645
Less: accumulated depreciation	(9,730)	(8,753)
Property and equipment, net	$ 3,086	$ 3,892

The Company recognized depreciation and amortization expense related to property and equipment of $0.3 million and $0.3 million for the three months ended September 30, 2026 and 2025, respectively. The Company recognized depreciation and amortization expense related to property and equipment of $1.0 million and $1.2 million for the nine months ended September 30, 2026 and 2025, respectively.

5. Accrued Expenses

Accrued expenses consist of the following as of September 30, 2026 and December 31, 2025:

	September 30, 2026	December 31, 2025
External research and development	$ 3,648	$ 3,767
Personnel-related	4,740	5,733
Professional and consulting fees	634	2,156
Other	149	83
Total accrued expenses	$ 9,171	$ 11,739

6. Collaboration, License and Option 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 Group Holdings Limited ("AbbVie") for up to four programs leveraging the Company's proprietary masking 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 310,559 shares of its common stock to AbbVie Inc. in a private placement at a purchase price of $32.20 per share for an aggregate purchase price of $10.0 million.

As of September 30, 2026, the Company has received $63.0 million in payments under the AbbVie agreements, consisting of a $42.0 million upfront cash payment under the Collaboration Agreement, $10.0 million in gross proceeds from the private placement under the stock purchase agreement and $11.0 million in development milestones related to the Collaboration Program. 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 each of the Option Programs 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 masked 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. During the year ended December 31, 2025, the overall transaction price was adjusted to include the achievement of a $5.0 million development milestone related to the Collaboration Program in the fourth quarter of 2025. During the nine months ended September 30, 2026, the overall transaction price was adjusted to include the achievement of a $6.0 million development milestone related to the Collaboration Program in the second quarter of 2026. All additional contingent payments are fully constrained as of September 30, 2026, as the achievement of the milestones underlying such contingent payments is based on either the Company or AbbVie's ability to execute under the development plan which is not certain at contract 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 at the outset of the arrangements 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.

For the three months ended September 30, 2026 and 2025, the Company recognized collaboration and license revenue of $7.2 million and $8.3 million, respectively, under the Collaboration Agreement and the stock purchase agreement with AbbVie. For the nine months ended September 30, 2026 and 2025, the Company recognized collaboration and license revenue of $27.9 million and $13.9 million, respectively, under the Collaboration Agreement and the stock purchase agreement with AbbVie. As of September 30, 2026, the Company recorded deferred revenue of $12.1 million, of which $2.2 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 (the "License Agreement") with Gilead Sciences, Inc. ("Gilead"), pursuant to which it granted Gilead an exclusive global license to develop and commercialize efarindodekin alfa, the Company's masked 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 650,387 shares of common stock and prefunded warrants to purchase up to an aggregate of 712,514 shares of its common stock. The prefunded warrants are exercisable any time at an exercise price of $0.0014 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.

The Company has received $72.5 million in payments under the Gilead agreements, consisting of the $30.0 million upfront cash payment under the License Agreement, $25.0 million in gross proceeds from private placements under the stock purchase agreement and a $17.5 million development milestone. As of September 30, 2026, the Company is eligible to receive up to $575.0 million in additional contingent payments, which consist of 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. 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 masked 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 year ended December 31, 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, 2026, 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.

For the three months ended September 30, 2026 and 2025, the Company recognized collaboration and license revenue of $2.8 million and $10.7 million, respectively, under the License Agreement and the stock purchase agreement with Gilead. For the nine months ended September 30, 2026 and 2025, the Company recognized collaboration and license revenue of $13.4 million and $16.2 million, respectively, under the License Agreement and the stock purchase agreement with Gilead. As of September 30, 2026, the Company recorded deferred revenue under the License Agreement and the stock purchase agreement of $13.2 million, all of which 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, 2025	$ 26,651	$ 34,007	$ 60,658
Additions	—	6,000	6,000
Collaboration and license revenue recognized	(13,407)	(27,917)	(41,324)
Deferred revenue as of September 30, 2026	$ 13,244	$ 12,090	$ 25,334

7. Commitments and Contingencies

The Company has an operating lease for its headquarters. 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, 2026 and December 31, 2025, 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, 2026 and December 31, 2025, 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, 2026 and December 31, 2025, there were no shares of preferred stock issued or outstanding.

Common Stock

As of September 30, 2026 and December 31, 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.

The following table presents information about prefunded warrants and common stock warrants that were outstanding as of September 30, 2026:

	Underlying Equity Instrument	Number Outstanding	Exercise Price per Share	Expiration Date
Prefunded warrants	Common Stock	13,100,119	$ 0.0014	— (1)
Series A warrants	Common Stock	4,762,533	10.50	6/5/2030
Series C warrants	Common Stock	3,443,388	10.50 (2)	12/2/2026 (2)
Total warrants outstanding		21,306,040		

(1) Prefunded warrants do not expire. Each prefunded warrant is exercisable at any time from the date of issuance until fully exercised, subject to beneficial ownership limitations for each holder.

(2) Each Series C warrant became exercisable on June 1, 2026, and will expire on December 2, 2026; provided that, 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 date will be extended to December 31, 2026.

February 2026 Follow-On Offering

In February 2026, the Company closed a follow-on offering of prefunded warrants and received net proceeds of $37.3 million. In connection with the offering, the Company issued prefunded warrants to purchase 5,341,404 shares of its common stock. Each prefunded warrant is exercisable for one share of the Company's common stock. The purchase price of each prefunded warrant was $7.4886.

June 2025 Follow-On Offering

In June 2025, the Company closed a follow-on offering of prefunded warrants and accompanying common stock warrants and received net proceeds of $47.0 million. In connection with the offering, the Company issued prefunded warrants to purchase 4,762,533 shares of common stock, accompanied by Series A warrants to purchase 4,762,533 shares of common stock (or prefunded warrants in lieu of common stock) (the "Series A warrants"), Series B warrants to purchase 4,762,533 shares of common stock (or prefunded warrants in lieu of common stock) (the "Series B warrants"), and Series C warrants to purchase 4,762,533 shares of common stock (or prefunded warrants in lieu of common stock) (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 $10.4986, which was equal to the combined offering price of the prefunded warrants, Series A warrants, Series B warrants and Series C warrants, less the $0.0014 per share exercise price of the prefunded warrants.

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 remaining outstanding Series C warrants, the Company may elect to cancel a number of warrant shares equal to $14.00 divided by the $10.50 warrant exercise price (or one and one-third warrants) without any compensation paid by the Company to the warrant holders. 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 $21.00.

At the June 2025 issuance date, 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 B warrants that were exercised for common stock and prefunded warrants in lieu of shares of common stock were reclassified to equity on the later of the date of each exercise, or December 2, 2025, the date the remaining outstanding Series B warrants qualified for equity classification due to the settlement of the exercise price reset feature. The Series A warrants and the remaining outstanding 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 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.

For the three and nine months ended September 30, 2026, the Company recognized a gain of $4.8 million and $4.2 million, respectively, related to the change in fair value of the common stock warrants. For 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.

The exercisability of the prefunded warrants and outstanding 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.

The Series B warrants were exercisable through December 31, 2025. During the exercise period, 3,443,388 of the Series B warrants were exercised and 1,319,145 Series B warrants expired unexercised on December 31, 2025. The prefunded warrants and Series A warrants may be exercised for cash or on a net exercise or "cashless" basis, and the 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 C warrants and shares of common stock issuable upon exercise of the Series C warrants. There can be no assurance that any of the warrants that remain outstanding as of September 30, 2026 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 outstanding Series C warrants are exercised in cash at their current exercise price of $10.50 per warrant, the Company will receive up to $36.2 million in additional total gross proceeds by the end of 2026, before deducting underwriting discounts and commissions and any offering expenses.

Sales Agreement and "At-The-Market" Facility

In March 2025, the Company entered into an "at-the-market" ("ATM") facility with Leerink Partners, LLC ("Leerink") pursuant to which the Company could initially issue and sell shares of its common stock from time to time at an aggregate offering price of up to $50.0 million through Leerink as sales agent. In May 2026, the Company filed a prospectus supplement to cover the offering, issuance and sale of up to a maximum of $14.5 million of the Company's common stock that may be issued and sold from time to time under the sales agreement with Leerink. During the second quarter of 2026, the Company issued and sold 592,300 shares of its common stock pursuant to the sales agreement with Leerink at a weighted average price of $7.76 per share for aggregate gross proceeds of $4.6 million, before deducting underwriting discounts and commissions and any offering expenses. The Company did not issue any shares of its common stock pursuant to the sales agreement with Leerink during the third quarter of 2026.

Shares Reserved for Future Issuance

Shares of common stock reserved for future issuance consists of the following as of September 30, 2026 and December 31, 2025:

	September 30, 2026	December 31, 2025
Stock options and unvested restricted stock units	3,348,718	2,963,086
Employee stock purchase plan	136,294	89,603
Common stock in process of settlement at period end	—	708,215
Prefunded warrants	13,100,119	8,502,224
Common stock warrants	8,205,921	8,206,109
Total shares reserved for future issuance	24,791,052	20,469,237

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 469,929 shares of common stock under the 2021 Plan. The 2021 Plan initially provided that the number of shares reserved and available for issuance under the 2021 Plan would 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. In June 2026, the Company's stockholders approved an amendment to the 2021 Plan (as amended, the "Amended and Restated 2021 Plan"), which had previously been adopted by the Company's board of directors subject to stockholder approval, to provide that, beginning on January 1, 2027 and continuing for each calendar year through January 1, 2031, the number of shares reserved and available for issuance under the Amended and Restated 2021 Plan will be cumulatively increased on January 1 of each calendar year in an amount equal to 5% of the sum of (i) the total number of shares of common stock outstanding and (ii) the total number of shares of common stock subject to prefunded warrants issued by the Company and outstanding on such date, or such lesser amount determined by the Company's board of directors. As of September 30, 2026, there were 390,911 shares of common stock available for future issuance under the Amended and Restated 2021 Plan.

2025 Stock Incentive Plan

In November 2025, the Company's stockholders adopted the 2025 Stock Incentive Plan (the "2025 Plan"), which had previously been adopted by the Company's board of directors subject to stockholder approval. The 2025 Plan provides for the grant of stock options to employees for 2,285,592 shares of common stock, divided into four equal tranches of 571,398 total shares per tranche, with the vesting of each tranche of stock options tied to a tranche of the June 2025 warrants, which are further described in Note 8.

The stock options granted under the 2025 Plan vest as follows:

- The first tranche of stock options vests in equal monthly installments over a period of three years, subject to the employee continuing to provide services to the Company on each vesting date.
- The second tranche of stock options ("Tranche 2 Stock Options") will become eligible to vest based on the portion of such stock options that equals the percentage of the Series A warrants that are exercised by December 31 of each of 2025, 2026, 2027, 2028, and 2029 and on June 30, 2030 (each, a "measurement date"). Any Tranche 2 Stock Options will vest in three equal installments with one-third vesting on the applicable measurement date and the remaining two-thirds vesting in equal annual installments on each of the subsequent two anniversaries thereafter.
- The third tranche of stock options ("Tranche 3 Stock Options") became eligible to vest based on the portion of such stock options that equaled the percentage of Series B warrants that were exercised by December 31, 2025. The Tranche 3 Stock Options vest in three equal installments with one-third vesting on December 31, 2025 and the remaining two-thirds vesting in equal annual installments on each of the subsequent two anniversaries thereafter.
- The fourth tranche of stock options ("Tranche 4 Stock Options") will become eligible to vest based on the portion of such stock options that equals the percentage of the Series C warrants that are exercised or are cancelled due to the Company's receipt of non-dilutive capital by December 31, 2026. Any Tranche 4 Stock Options that become eligible for vesting will vest in three equal installments with one-third vesting on December 31, 2026 and the remaining two-thirds vesting in equal annual installments on each of the subsequent two anniversaries thereafter.

As of September 30, 2026, there were 365,778 shares of common stock available for future issuance under the 2025 Plan.

As of September 30, 2026, the Tranche 2 and Tranche 4 Stock Options contain outstanding performance conditions for which the likelihood of satisfying each of the performance conditions is considered probable.

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 Nasdaq 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 19,642 shares of common stock for issuance

under the 2022 Inducement Plan. The Company's board of directors approved amendments to the 2022 Inducement Plan to increase the number of shares of common stock reserved for issuance under the 2022 Inducement Plan by 35,714 shares in each of November 2024 and March 2025, by an additional 32,485 shares in January 2026, and by an additional 250,000 shares in each of June 2026 and September 2026. As of September 30, 2026, there were 454,191 shares of common stock available for future issuance under the 2022 Inducement Plan, as amended.

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 20,859 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 41,718 shares of common stock per year). On January 1, 2026, the number of shares reserved for issuance under the 2021 ESPP was increased by 41,718 shares. During the three and nine months ended September 30, 2026 and 2025, the Company issued 4,973 and 3,240 shares of common stock, respectively, under the 2021 ESPP. As of September 30, 2026, there were 136,294 shares available for future issuance under the 2021 ESPP.

Stock-Based Compensation Expense

During the three and nine months ended September 30, 2026 and 2025, 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,	
	2026	2025	2026	2025
Research and development expense	$ 632	$ 319	$ 1,947	$ 1,054
General and administrative expense	1,286	804	3,780	2,955
Total stock-based compensation expense	$ 1,918	$ 1,123	$ 5,727	$ 4,009

Stock Options

A summary of stock option activity under the Company's 2020 Plan, Amended and Restated 2021 Plan, 2025 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, 2025	2,785,102	$ 14.40	9.1	$ 27
Granted	188,969	$ 8.85		
Exercised	(312)	$ 7.70		
Forfeited	(482,967)	$ 15.16		
Outstanding as of September 30, 2026 [2]	2,490,792	$ 13.83	8.5	$ 85
Exercisable as of September 30, 2026 [2]	771,244	$ 18.83	7.3	$ 19

(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.

(2) The weighted-average exercise price per share of the options outstanding and exercisable as of September 30, 2026 includes the impact of the stock option repricing described below.

As of September 30, 2026, the Company had unrecognized stock-based compensation expense of $11.6 million related to stock options issued to employees and directors, including $5.3 million of unrecognized stock-based compensation expense related to awards with performance conditions for which the likelihood of satisfying such performance conditions is considered probable, which is expected to be recognized over a weighted-average period of 2.6 years.

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, 2026 and 2025 was $7.17 per share and $9.94 per share, respectively. The following assumptions were used in determining the fair value of options granted during the nine months ended September 30, 2026 and 2025:

	Nine Months Ended September 30,	
	2026	2025
Risk-free interest rate	3.62 - 4.61 %	3.9 - 4.4 %
Expected dividend yield	0 %	0 %
Expected term (in years)	5.5 - 6.1	5.5 - 6.1
Expected volatility	99.4 - 103.0 %	94.5 - 100.8 %

Stock Option Repricing

In October 2025, the Company's board of directors approved a stock option repricing (the “Option Repricing”), which was effective upon stockholder approval on November 21, 2025 (the “Repricing Date”). The Option Repricing applied to all outstanding options to purchase shares of common stock of the Company granted to employees under the Company’s 2020 Plan, Amended and Restated 2021 Plan and 2022 Inducement Plan with an exercise price greater than $21.00 for members of the Company's executive team and $14.00 for all other employees (the “underwater options”) with grant dates prior to January 1, 2025 (the “Eligible Options”). The total number of shares of common stock underlying all Eligible Options was 354,200. Non-employee members of the Company’s board of directors were not eligible to participate in the Option Repricing. If such Eligible Options are exercised prior to the one-year anniversary of the Repricing Date (the "Retention Period"), the original exercise price must be paid.

The repricing of the Eligible Options was accounted for as a modification under ASC 718. Accordingly, the Company calculated incremental compensation cost on the modification date in an amount equal to the difference between the fair value of the awards before and after modification. The total amount of the incremental compensation expense to be recognized was determined to be $0.6 million, which is being recognized over the Retention Period.

Restricted Stock Units

In January 2024, the Company awarded 34,389 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, 2025	23,866	$ 7.70
Granted	—	$ —
Vested	(7,952)	$ 7.70
Forfeited	(3,090)	$ 7.70
Unvested as of September 30, 2026	12,824	$ 7.70

For each of the nine months ended September 30, 2026 and 2025, the Company recognized less than $0.1 million of stock-based compensation expense related to these awards. As of September 30, 2026, the Company had unrecognized stock-based compensation expense of $0.1 million related to these restricted stock units, which is expected to be recognized over 1.25 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 prefunded warrants to purchase common stock, as the prefunded warrants are exercisable at any time for nominal cash consideration.

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,	
	2026	2025
Unvested restricted stock units	12,824	23,866
Outstanding stock options	2,490,792	822,371
Common stock warrants	8,205,921	14,287,599
Unvested employee stock purchase plan shares	5,254	4,453
Total common stock equivalents	10,714,791	15,138,289

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, 2025.

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 masked immuno-oncology, or I-O, therapies with the goal of significantly improving outcomes for people living with cancer. Leveraging our clinically-validated masking technology and capabilities, we are developing I-O therapies designed to selectively activate within the tumor microenvironment to achieve durable efficacy without the severe side effects associated with systemically active I-O agents. Our integrated biology and protein engineering approach enables us to design and develop highly potent, masked biologics that are activated, or unmasked, by tumor-specific proteases within the tumor microenvironment. We are currently advancing multiple programs in preclinical and clinical development, including: XTX501, a PD-1/masked IL-2 bispecific; masked, multi-specific T cell engagers, or TCEs; and efarindodekin alfa, a masked IL-12. Our clinically-validated masking technology has enabled us to establish top-tier strategic partnerships, including with AbbVie Group Holdings Limited, or AbbVie, and Gilead Sciences, Inc., or Gilead.

XTX501: PD-1/masked IL-2 bispecific

XTX501 is a novel, investigational PD-1/masked IL-2 (alpha-optimized) bispecific antibody fusion protein that combines two complementary mechanisms in a single molecule: selective inhibition of the PD-1/PD-L1 pathway and potent IL-2-driven expansion of T cells. The PD-1 binding arm is designed to selectively direct IL-2 activity to PD-1 positive, antigen-experienced T cells and enhance their function. The IL-2 binding arm incorporates a masked, high potency IL-2 variant with an alpha-optimized receptor binding profile. By leveraging our proprietary masking technology, XTX501 aims to overcome IL-2 receptor-mediated clearance, peripheral activity, and tolerability challenges associated with non-masked IL-2 therapies. We are currently evaluating XTX501 as a monotherapy in patients with metastatic non-small cell lung cancer, or NSCLC, and select advanced solid tumors who have previously received anti-PD(L)-1 therapy in a first-in-human, multi-center, open-label Phase 1/2 clinical trial at multiple sites in the United States. We recently initiated patient dosing in the trial, and we plan to report initial Phase 1 data in patients with metastatic NSCLC in the fourth quarter of 2027.

Masked T Cell Engager Programs

We are leveraging our proprietary, clinically-validated masking technology and modular TCE architecture to advance two wholly-owned masked TCE programs, as well as an additional masked TCE program in collaboration with AbbVie. As part of the core design, our TCEs incorporate a masked CD3 binding domain, a tumor-associated antigen, or TAA, binding domain and built-in co-stimulation. Our modular architecture enables the flexibility to incorporate additional TAA binding domains and mask the TAA binding domain(s) and/or co-stimulatory signaling domain. Upon tumor-selective activation, the molecules are designed to release the mask(s) and deliver a potent TCE with a short half-life in the tumor microenvironment.

XTX602: dual-masked CLDN18.2-targeting multi-specific TCE with co-stimulation

XTX602 is a potential first-in-class, dual-masked CLDN18.2-targeting multi-specific TCE with built-in CD2 co-stimulation. CLDN18.2 is a TAA expressed in gastrointestinal cancers (gastric, pancreatic and esophageal). By incorporating masks for both the CLDN18.2 and the CD3 binding domain, XTX602 is designed to overcome potential gastrointestinal toxicity associated with non-masked CLDN18.2 targeting molecules. In addition, the CD2 co-stimulatory domain is built directly into the molecule to enable enhanced T cell activation, expansion and durability of T cell response. Investigational new drug application, or IND, enabling studies for XTX602 are ongoing, and we plan to submit an IND for XTX602 in the fourth quarter of 2027.

XTX701: masked PSMAxSTEAP1 targeting multi-specific TCE with co-stimulation

XTX701 is a potential first-in-class, masked PSMAxSTEAP1-targeting multi-specific TCE with built-in CD2 co-stimulation. PSMA and STEAP1 are TAAs collectively expressed in approximately 95% of metastatic castration-resistant prostate cancer. Targeting these two TAAs is intended to address heterogeneity of expression of PSMA and STEAP1 across prostate tumors and limit resistance and lack of durability of response due to antigen escape. By incorporating a mask for the CD3 binding domain, XTX701 is designed to minimize toxicity due to peripheral T cell activation and on-target, off-tumor engagement associated with non-masked molecules. In addition, the CD2 co-stimulatory domain is built directly into the molecule to enable enhanced T cell activation, expansion and durability of T cell response. IND-enabling studies for XTX701 are ongoing, and we plan to submit an IND for XTX701 in the fourth quarter of 2027.

Efarindodekin alfa: masked IL-12

We are evaluating efarindodekin alfa as a monotherapy in an ongoing Phase 2 clinical trial in patients with advanced solid tumors under our license agreement with Gilead and expect to deliver an option data package to Gilead in the first half of 2027.

Liquidity Overview

To date, we have financed our operations primarily from proceeds raised through private placements of equity securities; sales of common stock in our initial public offering, or IPO, and through "at-the-market" offerings; the sale of prefunded warrants in our June 2025 and February 2026 follow-on offerings; the exercise of certain common stock warrants issued in connection with our June 2025 follow-on offering; development event payments under our co-funded clinical trial collaboration with F. Hoffmann-La Roche Ltd., or Roche; and upfront payments and milestone payments under our collaboration and license agreements with AbbVie and Gilead. All of our programs are in early 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 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.

Since inception, we have incurred significant operating losses, including net losses of $21.9 million and $45.4 million for the nine months ended September 30, 2026 and 2025, respectively, and a net loss of $35.0 million for the year ended December 31, 2025. As of September 30, 2026, we had an accumulated deficit of $440.6 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, 2026, we had cash and cash equivalents of $122.2 million. Based on our current operating plans, we anticipate that our existing cash and cash equivalents as of September 30, 2026 will be sufficient to enable us to fund our operating expenses and capital expenditure requirements into the first quarter of 2028. This estimate excludes up to $36.2 million in additional gross proceeds in the fourth quarter of 2026 if all outstanding Series C warrants are exercised at their current exercise price and any potential additional milestone payments, option-related fees or other contingent payments under our collaboration and license agreements with AbbVie and Gilead, including up to $31.0 million in near-term milestones and option extension fees that could be achieved under the AbbVie collaboration through the first half of 2027.

In addition, 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. 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, masked 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.

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. Non-refundable 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 in the future, 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 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 in the future, 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.

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 gain or loss recorded upon the revaluation at each reporting period of the common stock warrant liabilities in connection with the June 2025 follow-on offering.

Other Income (Expense), Net

Other income (expense), net consists primarily of interest income earned from our cash and cash equivalents, and for the three and nine months ended September 30, 2025 also consists of the portion of the issuance costs we incurred in connection with the June 2025 follow-on offering, which were allocated to the common stock warrant liabilities.

Results of Operations

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

The following table summarizes our results of operations for the three months ended September 30, 2026 and 2025 (in thousands):

	Three Months Ended September 30,		
	2026	2025	Change
Revenue			
Collaboration and license revenue	$ 9,984	$ 19,066	$ (9,082)
Total revenue	9,984	19,066	(9,082)
Operating expenses			
Research and development	$ 14,805	$ 14,321	$ 484
General and administrative	6,928	6,674	254
Total operating expenses	21,733	20,995	738
Loss from operations	(11,749)	(1,929)	(9,820)
Other income (expense), net			
Change in fair value of common stock warrant liabilities	4,820	(15,380)	20,200
Other income, net	981	1,022	(41)
Total other income (expense), net	5,801	(14,358)	20,159
Net loss	$ (5,948)	$ (16,287)	$ 10,339

Collaboration and License Revenue

Collaboration and license revenue decreased by $9.1 million from $19.1 million for the three months ended September 30, 2025 to $10.0 million for the three months ended September 30, 2026 due to a decrease in collaboration and license revenue recognized under our collaboration and license agreements with AbbVie and Gilead.

Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended September 30, 2026 and 2025 (in thousands):

	Three Months Ended September 30,		
	2026	2025	Change
XTX501	$ 1,571	$ 2,189	$ (618)
efarindodekin alfa	1,189	2,065	(876)
vilastobart	885	1,677	(792)
Other early programs and indirect research and development	5,489	3,474	2,015
Personnel-related	5,671	4,916	755
Total research and development expenses	$ 14,805	$ 14,321	$ 484

Research and development expenses increased by $0.5 million from $14.3 million for the three months ended September 30, 2025 to $14.8 million for the three months ended September 30, 2026. The changes in research and development expenses were primarily due to the following:

- other early programs and indirect research and development costs increased by $2.0 million, primarily driven by an increase in preclinical research and development activities related to our masked TCE programs, partially offset by a decrease in preclinical research and development activities related to our AbbVie collaboration;

- personnel-related costs increased by $0.8 million, primarily driven by a $0.6 million increase in salaries, bonuses and benefits due to higher research and development headcount and a $0.3 million increase in stock-based compensation;

- XTX501 costs decreased by $0.6 million, primarily driven by a $0.9 million decrease in preclinical development activities and a $0.9 million decrease in manufacturing activities related to IND-enabling studies, partially offset by a $1.1 million increase in clinical trial startup activities related to our Phase 1/2 clinical trial for XTX501;
- vilastobart costs decreased by $0.8 million, primarily driven by a decrease in clinical development activities related to our Phase 1/2 clinical trial evaluating vilastobart in combination with atezolizumab; and
- efarindodekin alfa costs decreased by $0.9 million, primarily driven by a decrease in clinical development activities related to our ongoing Phase 2 clinical trial.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the three months ended September 30, 2026 and 2025 (in thousands):

	Three Months Ended September 30,		
	2026	2025	Change
Personnel-related	$ 3,962	$ 3,414	$ 548
Professional and consulting fees	2,275	2,374	(99)
Facility-related and other general and administrative expenses	691	886	(195)
Total general and administrative expenses	$ 6,928	$ 6,674	$ 254

General and administrative expenses increased by $0.3 million from $6.7 million for the three months ended September 30, 2025 to $6.9 million for the three months ended September 30, 2026. The changes in general and administrative expenses were primarily due to an increase in stock-based compensation and recruiting costs.

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, 2026 was due to a gain of $4.8 million resulting from the decrease in the fair value of the common stock warrant liabilities between June 30, 2026 and September 30, 2026, which was primarily driven by a decrease in the price per share of our common stock.

Other Income (Expense), Net

Other income (expense), net, was $1.0 million in other income for each of the three months ended September 30, 2026 and 2025, which primarily consisted of interest income on our cash balance for both periods.

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

The following table summarizes our results of operations for the nine months ended September 30, 2026 and 2025 (in thousands):

	Nine Months Ended September 30,		
	2026	2025	Change
Revenue			
Collaboration and license revenue	$ 41,324	$ 30,080	$ 11,244
Total revenue	41,324	30,080	11,244
Operating expenses			
Research and development	$ 49,196	$ 37,917	$ 11,279
General and administrative	21,480	22,309	(829)
Total operating expenses	70,676	60,226	10,450
Loss from operations	(29,352)	(30,146)	794
Other income (expense), net			
Change in fair value of common stock warrant liabilities	4,180	(15,430)	19,610
Other income, net	3,322	180	3,142
Total other income (expense), net	7,502	(15,250)	22,752
Net loss	$ (21,850)	$ (45,396)	$ 23,546

Collaboration and License Revenue

Collaboration and license revenue increased by $11.2 million from $30.1 million for the nine months ended September 30, 2025 to $41.3 million for the nine months ended September 30, 2026 due to an increase in collaboration and license revenue recognized under our collaboration and license agreement with AbbVie, partially offset by a decrease in collaboration and license revenue recognized under our license agreement with Gilead.

Research and Development Expenses

The following table summarizes our research and development expenses for the nine months ended September 30, 2026 and 2025 (in thousands):

	Nine Months Ended September 30,		
	2026	2025	Change
XTX501	$ 9,003	$ 4,253	$ 4,750
efarindodekin alfa	4,223	4,869	(646)
vilastobart	3,320	5,587	(2,267)
Other early programs and indirect research and development	15,426	8,905	6,521
Personnel-related	17,224	14,303	2,921
Total research and development expenses	$ 49,196	$ 37,917	$ 11,279

Research and development expenses increased by $11.3 million from $37.9 million for the nine months ended September 30, 2025 to $49.2 million for the nine months ended September 30, 2026. The changes in research and development expenses were primarily due to the following:

- other early programs and indirect research and development costs increased by $6.5 million, primarily driven by an increase in preclinical research and development activities related to our masked TCE programs, partially offset by a decrease in preclinical research and development activities related to our AbbVie collaboration;
- XTX501 costs increased by $4.8 million, primarily driven by a $2.7 million increase related to clinical trial startup activities for our Phase 1/2 clinical trial for XTX501 and a $1.8 million increase in manufacturing activities related to IND-enabling studies;

- personnel-related costs increased by $2.9 million, primarily driven by a $2.2 million increase in salaries, bonuses and benefits due to higher research and development headcount and a $0.9 million increase in stock-based compensation;
- efarindodekin alfa costs decreased by $0.6 million, primarily driven by a decrease in clinical development activities related to our ongoing Phase 2 clinical trial; and
- vilastobart costs decreased by $2.3 million, primarily driven by a decrease in clinical development activities related to our Phase 1/2 clinical trial evaluating vilastobart in combination with atezolizumab.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the nine months ended September 30, 2026 and 2025 (in thousands):

	Nine Months Ended September 30,		
	2026	2025	Change
Personnel-related	$ 12,546	$ 11,985	$ 561
Professional and consulting fees	6,673	7,799	(1,126)
Facility-related and other general and administrative expenses	2,261	2,525	(264)
Total general and administrative expenses	$ 21,480	$ 22,309	$ (829)

General and administrative expenses decreased by $0.8 million from $22.3 million for the nine months ended September 30, 2025 to $21.5 million for the nine months ended September 30, 2026. The changes in general and administrative expenses were primarily due to:

- personnel-related costs increased by $0.6 million, primarily driven by a $0.8 million increase in stock-based compensation, partially offset by a $0.2 million decrease in salaries, bonuses and benefits; and
- professional and consulting fees decreased by $1.1 million, primarily driven by a $1.6 million decrease in legal fees, partially offset by a $0.6 million increase in consulting and other professional 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, 2026 was due to a gain of $4.2 million resulting from a decrease in the fair value of the common stock warrant liabilities between December 31, 2025 and September 30, 2026, which was primarily driven by a decrease in the remaining term of the common stock warrants.

Other Income (Expense), Net

Other income (expense), net, increased by $3.1 million from other income of $0.2 million for the nine months ended September 30, 2025 to other income of $3.3 million for the nine months ended September 30, 2026. The increase in other income was primarily due to an increase in interest income due to a higher average cash balance, partially offset by the $2.3 million in issuance costs we incurred in connection with the June 2025 follow-on offering, which were allocated to the common stock warrant liabilities, for which there was no comparable cost for the nine months ended September 30, 2026.

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 equity securities; sales of common stock in our IPO and through “at-the-market” offerings; the sale of prefunded warrants in our June 2025 and February 2026 follow-on offerings; the exercise of certain common stock warrants issued in connection with our June 2025 follow-on offering; development event payments under our co-funded clinical trial collaboration with Roche for vilastobart; and upfront and milestone payments under our collaboration and license agreements with AbbVie and Gilead. All

of our programs are in early 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 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.

At-the-Market Offering Program

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). In March 2025, we entered into a sales agreement with Leerink Partners, LLC, or Leerink, under which we could initially issue and sell shares of our common stock from time to time at an aggregate offering price of up to $50.0 million. In February 2026, we filed a prospectus supplement to our prospectus dated May 8, 2025 (333-285703) to reduce the amount of common stock we may offer and sell under the sales agreement to an aggregate offering price of up to $9.5 million.

In May 2026, 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 29, 2026 (333-295785), or the 2026 Form S-3. In May 2026, we filed a prospectus supplement to our prospectus in the 2026 Form S-3 to cover the offering, issuance and sale by us of up to a maximum of $14.5 million of our common stock that may be issued and sold from time to time under our sales agreement with Leerink.

During the second quarter of 2026, we issued and sold 592,300 shares of our common stock pursuant to the sales agreement with Leerink at a weighted average price of $7.76 per share for aggregate gross proceeds of $4.6 million, before deducting underwriting discounts and commissions and any offering expenses. We did not issue any shares of our common stock pursuant to the sales agreement with Leerink during the third quarter of 2026.

Cash Flows

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

	Nine Months Ended September 30,	
	2026	2025
Net cash (used in) provided by:		
Operating activities	$ (54,899)	$ (2,994)
Investing activities	(633)	(423)
Financing activities	40,201	51,909
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (15,331)	$ 48,492

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, 2026, net cash used in operating activities of $54.9 million was primarily driven by net changes in operating assets and liabilities of $35.6 million, our net loss of $21.9 million and the $4.2 million gain recorded on the change in fair value of our common stock warrant liabilities, partially offset by $5.7 million of stock-based compensation expense and $1.0 million of depreciation and amortization expense.

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.

Investing Activities

During the nine months ended September 30, 2026 and 2025, net cash used in investing activities consisted of purchases of property and equipment.

Financing Activities

During the nine months ended September 30, 2026, net cash provided by financing activities of $40.2 million primarily consisted of proceeds from the sale of prefunded warrants through a follow-on offering and proceeds from the sale and issuance of common stock through our ATM program.

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 our June 2025 follow-on 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 our ATM program.

Capital Requirements

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, 2026, we had cash and cash equivalents of $122.2 million. Based on our current operating plans, we anticipate that our existing cash and cash equivalents as of September 30, 2026 will be sufficient to enable us to fund our operating expenses and capital expenditure requirements into the first quarter of 2028. This estimate excludes up to $36.2 million in additional gross proceeds in the fourth quarter of 2026 if all outstanding Series C warrants are exercised at their current exercise price and any potential additional milestone payments, option-related fees or other contingent payments under our collaboration and license agreements with AbbVie and Gilead, including up to $31.0 million in near-term milestones and option extension fees that could be achieved under the AbbVie collaboration through the first half of 2027.

In addition, 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, masked 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.

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, efarindodekin alfa and XTX501, 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 masked 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;
- the potential receipt of up to $36.2 million in additional gross proceeds in the fourth quarter of 2026 if all of the outstanding Series C common stock warrants issued in connection with our June 2025 follow-on offering are exercised at their current exercise price of $10.50 per warrant;
- our ability to secure additional capital in the future;
- 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, 2026, 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, 2025.

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, 2025.

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 expect to remain classified as an EGC until December 31, 2026.

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, 2026. Based upon such evaluation, our principal executive officer and principal financial officer have concluded that, as of September 30, 2026, 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

We will need to obtain substantial additional capital in the future to finance our operations and complete the development of any current or future product candidates.

As of September 30, 2026, we had cash and cash equivalents of $122.2 million. Based on our current operating plans, we anticipate that our existing cash and cash equivalents as of September 30, 2026 will be sufficient to enable us to fund our operating expenses and capital expenditure requirements into the first quarter of 2028. This estimate excludes up to $36.2 million in additional gross proceeds in the fourth quarter of 2026 if all outstanding Series C warrants are exercised at their current exercise price and any potential additional milestone payments, option-related fees or other contingent payments under our collaboration and license agreements with AbbVie Group Holdings Limited, or AbbVie, and Gilead Sciences, Inc., or Gilead, including up to $31.0 million in near-term milestones and option extension fees that could be achieved under the AbbVie collaboration through the first half of 2027. In addition, 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 and may need to seek additional capital sooner than anticipated.

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, efarindodekin alfa and XTX501, 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 masked 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;
- the potential receipt of up to $36.2 million in additional gross proceeds in the fourth quarter of 2026 if all of the outstanding Series C common stock warrants issued in connection with our June 2025 follow-on offering are exercised at their current exercise price of $10.50 per warrant;
- our ability to secure additional capital in the future;
- 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.

Our existing cash and cash equivalents will not be sufficient to complete development of any current or future product candidates, and we will require additional capital in the future to sustain our operations. We currently do not have any committed external sources of funds and will be required to obtain further funding in the future through public or private equity offerings, debt, collaborations, licensing arrangements, the conversion of common stock warrants for cash, or other sources. However, adequate additional capital may not be available to us in the future 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, 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. Our failure to raise additional capital in the future as and when needed to support our operations would have a material adverse effect on our financial condition, our ability to develop and commercialize our current and any future product candidates or otherwise pursue our business strategy.

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 $21.9 million and $45.4 million for the nine months ended September 30, 2026 and 2025, respectively, and $35.0 million for the year ended December 31, 2025. As of September 30, 2026, we had an accumulated deficit of $440.6 million. 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, masked 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. 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.

To date, we have financed our operations primarily from proceeds raised through private placements of equity securities; sales of common stock in our initial public offering, or IPO, and through “at-the-market” offerings; the sale of prefunded warrants in our June 2025 and February 2026 follow-on offerings; the exercise of certain common stock warrants issued in connection with our June 2025 follow-on offering; development event payments under our co-funded clinical trial collaboration with F. Hoffmann-La Roche Ltd, or Roche; and upfront and milestone 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.

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, masked I-O molecules through development. 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.

Raising additional capital in the future 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. 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.

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 masked I-O 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, 2025, we had federal and state net operating loss, or NOL, carryforwards of $263.5 million and $234.6 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.

Even if we generate taxable income in the future, our ability to use our NOL carryforwards and tax attributes may nevertheless be limited. 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. We have experienced ownership changes as defined by Sections 382 and 383 of the Code. As a result of these changes and any future ownership changes, 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 and Our Status as a Public Company—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 or future product candidates, including our current clinical-stage product candidates, efarindodekin alfa and XTX501. We are currently evaluating efarindodekin alfa as a monotherapy in an ongoing Phase 2 clinical trial in patients with certain advanced solid tumors and XTX501 as a monotherapy in an ongoing Phase 1/2 clinical trial in patients with metastatic non-small cell lung cancer, or NSCLC, and select advanced solid tumors. We also have a portfolio of programs that are in preclinical development and may never advance to clinical-stage development, including XTX602 and XTX701, our wholly-owned masked, multi-specific T cell engagers targeting CLDN18.2 and PSMAxSTEAP1, respectively, 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.

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, including without limitation, the planned INDs for XTX602 and XTX701, our masked, multi-specific T cell engagers targeting CLDN18.2 and PSMAxSTEAP1, respectively, 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 data reported to date for our Phase 1 clinical trial for efarindodekin alfa. 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 efarindodekin alfa as a monotherapy and our Phase 1/2 clinical trial to evaluate XTX501 in patients with NSCLC and select advanced solid tumors, 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 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 data from our Phase 1 clinical trial for efarindodekin alfa in November 2025 at the Society for Immunotherapy of Cancer 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. 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 masked I-O product candidates.

A key element of our strategy is to use our novel platform technology to engineer and develop masked I-O 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 certain of our clinical-stage product candidates, 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, and other tumor-specific proteases to activate our molecules within the tumor microenvironment. If protease 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 our CDMOs, 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 a CDMO, WuXi Biologics (Hong Kong) Limited, or WuXi Biologics, for developing the manufacturing processes required to supply our product candidates. We cannot ensure that WuXi Biologics will remain in business or have sufficient capacity or supply to meet our needs. Our use of a single third-party 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 develop the processes to manufacture our product candidates, and to manufacture and supply our product candidates and 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. For example, in December 2025, the BIOSECURE Act was signed into law as part of the Fiscal Year 2026 National Defense Authorization Act. Under the BIOSECURE Act, U.S. government agencies cannot (i) buy or obtain biotechnology equipment or services provided by biotechnology companies of concern, or BCCs; (ii) enter into, extend, or renew a contract with any entity using biotechnology equipment or services provided by a BCC to perform a government contract; or (iii) expend loan or grant funds for biotechnology equipment or services provided by a BCC, whether directly or through a loan or grant recipient. The BIOSECURE Act does not name specific companies as BCCs but treats any company on the Department of Defense/War 1260H list of "Chinese military companies" as a BCC. The 1260H list was updated by the Department of Defense in January 2024 and January 2025. Subsequently, on June 8, 2026, the Department of Defense/War released an updated version of the 1260H list, which included WuXi AppTec, along with two other biotechnology companies (Complete Genomics and Novogene). WuXi AppTec challenged its

designation as a Chinese military company and was removed from the 1260H list in November 2026. Nonetheless, the U.S. government has authority to add additional entities of concern to the 1260H list, and there is a risk that such a future listing could include the re-listing of WuXi AppTec or the listing of WuXi Biologics. Entities on the 1260H list are covered under a grandfather clause that allows any contracts signed before their effective date of listing to be protected for five years from their listing. Moreover, while WuXi Biologics was originally the biologics division of WuXi AppTec, they are now operationally independent companies. As a result, we do not expect a re-listing of WuXi AppTec to impact WuXi Biologics and the services it currently provides to us.

Separately from our reliance on WuXi Biologics for manufacturing, we engage WuXi AppTec to perform a significant portion of the nonclinical and IND-enabling studies for our product candidates. However, we do not use WuXi AppTec's services in the performance of any U.S. government contract and do not rely on U.S. government grant or loan funds for such services and we believe we could transition these services to alternative providers in a timely manner, if necessary. Nonetheless, if we were to seek or rely on U.S. government contracts, grants, or loans in the future, or if the U.S. government were to expand the restrictions applicable to entities on the 1260H list (including through WuXi AppTec's potential designation under other U.S. restricted party regimes) and we were unable to transition these services on a timely and cost-effective basis, such developments could adversely affect our business.

Any disruption in China or the U.S. that significantly impacts WuXi Biologics, WuXi AppTec or other third parties with whom we conduct business now or in the future, including CROs that provide services for our research and development programs, or manufacturers that 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 to perform other functions for us, and if these third parties perform in an unsatisfactory manner, it may harm our business, reputation and results of operations.

We rely, and expect to continue to rely, on third parties, including but not limited to, 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 third-party vendors for additional research programs as well as other functions. 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 third-party vendors' 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 third-party vendors 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 and other third-party vendors 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 or other functions. These third-party vendors 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 third-party vendors 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 masked 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, develop with third parties or acquire 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 "Risk Factors" section 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 clinical-stage product candidates for the treatment of cancer and have not completed clinical development or received marketing approval for any of our product candidates. 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.

- With respect to XTX501, currently there are no PD-1/IL-2 bispecific therapies approved for the treatment of cancer. However, we are aware of several companies that have PD-1/IL-2 bispecific programs in development, including but not limited to Anaveon AG, Anwita Biosciences, Inc., Boan Biotech Co. Ltd., Bright Peak Therapeutics, Inc., Innovent Biologics, Inc. (co-development with Takeda Pharmaceutical Company Limited), Medicenna Therapeutics Corp., Proviva Therapeutics, Inc., Regeneron Pharmaceuticals, Inc., Roche, Shandong Boan Biotechnology Co., Ltd. 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. However, we are aware of 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. To our knowledge, there are no companies currently developing a masked T cell engager program targeting both PSMA and STEAP1 or 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 AstraZeneca PLC, Qilu Pharmaceutical Co. and Xencor, Inc. (licensed to Astellas Pharma Inc.), for PSMA, including but not limited to Regeneron Pharmaceuticals, Inc. and Xencor, Inc. (licensed to Johnson & Johnson), for STEAP1, including but not limited to Xencor, Inc. (licensed to Amgen Inc.) and Shanghai Henlius Biotech, Inc., and for PSMA and STEAP1, including but not limited to Qilu Pharmaceutical Co., Ltd.
- With respect to efarindodekin alfa, currently there are no IL-12 therapies approved for the treatment of cancer. However, we are aware of several companies that have systemically delivered IL-12 programs in development, including but not limited to PDS Biotechnology Corporation, Philogen S.p.A. and Shanghai KangaBio Co., Ltd.

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, the submission of a regulatory filing, 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. Further, the FDA may revise the standards governing approval of biosimilars so as to bring such products to the market more quickly. For example, in October 2025, the FDA issued draft guidance which proposes to eliminate the need for sponsors of biosimilar products to conduct comparative human clinical efficacy studies, allowing them to rely instead on analytical testing to demonstrate product differences from a reference product.

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 U.S. Court of Appeals for the Federal Circuit held claims reciting broad antibody genus based on function invalid for lack of written description. In 2023 and 2024, respectively, 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. Recently, the Federal Circuit in *Teva Pharmaceuticals v. Eli Lilly* held that method-of-treatment claims reciting a genus of antibodies for a new therapeutic use satisfied the written description and enablement requirements if the claimed antibody genus was well-known in the art. Additionally, the U.S. Supreme Court in *Hikma Pharmaceuticals USA, Inc. v. Amarin Pharma, Inc.* held that induced infringement of pharmaceutical method-of-use patents generally requires affirmative acts encouraging infringement, and that the mere marketing of a product with a "skinny label" is insufficient. 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. 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.

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 "Risk Factors" section 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). In most cases, the default requirement for FDA approval of a new product is one adequate and well-controlled pivotal clinical trial plus confirmatory evidence. However, 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 FDA 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 certain 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, 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. On January 27, 2025, in response to an executive order regarding diversity, equity and inclusion programs, the FDA removed this draft guidance from its website. That action, along with similar actions by the current administration to remove many other healthcare webpages, is the subject of ongoing litigation. In late July 2025, pursuant to a court order, the FDA restored the draft DAP guidance to its website with a statement that

"information on this page may be modified and/or removed in the future subject to the terms of the court's order and implemented consistent with applicable law." Accordingly, in light of these ongoing actions, there is considerable uncertainty surrounding the draft DAP guidance and how the FDA will consider DAPs in connection with its review of BLAs.

Further, for our new clinical activities in the EU, we will need to navigate the Clinical Trials Regulation (EU) No 536/2014, which 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 and other developments could hinder our ability to obtain guidance from the FDA regarding our clinical development program, progress development efficiently, and secure approval of our product candidates in a timely manner, which would negatively impact our business.

The FDA and comparable regulatory agencies in foreign jurisdictions, such as the EMA and Committee for Medicinal Products for Human Use, play an important role in the development of our product candidates by providing guidance on our clinical development programs and reviewing our regulatory submissions, including INDs, requests for special designations and marketing applications. 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, on July 14, 2025, following litigation reaching the U.S. Supreme Court, the current administration began to carry out layoffs across HHS, including at the FDA. The loss of FDA leadership and personnel could lead to disruptions and delays in FDA guidance, review, and approval of our product candidates. In November 2025, Congress agreed to provide full-year funding for the FDA through September 30, 2026, at a slight decrease compared to previous spending levels. On September 2, 2026, the President signed into law a continuing resolution that provides funding for the federal government, including the FDA, at current levels, through December 11, 2026. There were several reports in 2025 of the FDA failing to meet its Prescription Drug User Fee Act, or PDUFA, goal dates for approval of a new drug application, or NDA, or BLA due to heavy workload and limited resources.

There is also substantial uncertainty as to how regulatory reform measures being implemented by the current administration across the government will impact the FDA and other federal agencies with jurisdiction over our activities. For example, the administration has issued a number of executive orders that could have a significant impact on the manner in which the FDA conducts its operations and engages in regulatory and oversight activities. If these or other orders or executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

Similarly, actions by the U.S. government have significantly disrupted the operations of government agencies, such as the National Institutes of Health, the National Science Foundation, the Centers for Disease Control and Prevention, and the FDA, which have traditionally provided funding for basic research, research and development, and clinical testing. These government actions have included, among other things, suspending, terminating and withholding of disbursements of funds owed under ongoing contracts, grants, and other financial assistance agreements; declining to continue multi-year research projects for additional annual budget periods; canceling or delaying solicitations for new contract, grant and other financial assistance awards; canceling or delaying proposal evaluation processes and issuance of such new awards; substantially reducing federal agency staff responsible for managing contract and financial assistance programs; eliminating agency information and resources for facilitating research activity; delaying or terminating federal agency procedures for authorizing international transactions; initiating aggressive enforcement actions that may disrupt the operations of major research universities that are significant contributors to life sciences research in the United States, and threatening access to federal agency contracts and other funding awards based on companies' otherwise lawful corporate policies and choice of counsel. These actions could, directly or indirectly, significantly disrupt, delay, prevent, or increase the costs of our research and product commercialization programs, including our ability to develop new product candidates, conduct clinical trials, implement research collaborations with other companies or institutions, and obtain approvals to market and sell new products.

In addition, government funding of government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. For example, the federal government shut down on October 1, 2025 and did not reopen for 43 days. With the shutdown, the FDA issued a public notice stating that FDA 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. 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 was enacted. As a result, the FDA was not able to accept any regulatory submissions for fiscal year 2026 that required a fee payment and that was submitted during the lapse period. In addition, the FDA indicated that some of its regulatory science research, crucial for advancing product innovation, safety, and quality, would be curtailed 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. For example, during the COVID-19 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 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 and 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). The U.K. Parliament adopted amendments to improve and strengthen the U.K.'s clinical trials regulatory regime, which took effect on April 28, 2026. These changes were needed since the prior U.K. requirements were based upon the now-repealed EU Clinical Trials Directive (2001/20/EC), which has been replaced by the European Clinical Trials Regulation (Regulation EU No 536/2014). Since the U.K. left the EU prior to the date on which the EU Clinical Trials Regulation took effect, the U.K. legal framework did not benefit from the same revisions as occurred at EU level.

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, which may reduce the duration of regulatory data protection and exclusivity periods for orphan drugs, and revise the eligibility for expedited pathways in addition to other changes, was published on April 26, 2023. On June 4, 2025, after almost two years of negotiations among the EU member states, the Council of the European Union adopted its position on the proposed overhaul of the EU general pharmaceutical legislative framework. Thereafter, on December 11, 2025, the European Parliament and Council reached a provisional political agreement on the legislation. The Council formally adopted these new measures on September 28, 2026. The new provisions are expected to be approved by the Parliament and to enter into force by December 2026, and to become applicable in late 2028. If the new measures are finalized in line with the provisional political agreement, they will have a significant impact on the EU pharmaceutical industry, which could have a significant impact on our business.

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 and Congress may further reevaluate the Orphan Drug Act and its regulations and policies. For example, in September 2021, the U.S. Court of Appeals for the 11th Circuit held that, for the purpose of determining the scope of orphan drug exclusivity, the term "same disease or condition" in the statute 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 approved "indication or use." Subsequently, in another case, a federal district court in Washington, D.C., followed the reasoning of the 11th Circuit decision and that decision was appealed to the U.S. Court of Appeals for the D.C. Circuit. On February 3,

2026, the Consolidated Appropriations Act of 2026 was enacted into law. It overruled these court decisions and codified the FDA's longstanding interpretation of the scope of orphan drug exclusivity to apply to "the same drug for the same approved use or indication within such designated rare disease or condition." This change, which applies retroactively, expressly authorizes the FDA to approve multiple versions of the same orphan drug for different sub-indications and subpopulations, such as adult and pediatric patients or multiple variations of the same disease that are caused by different genetic variants.

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.

For example, on September 9, 2025, the current administration issued a memorandum directing HHS to "ensure transparency and accuracy in direct-to-consumer, or DTC, prescription drug advertising, including by increasing the amount of information regarding any risks associated with the use of any such prescription drug required to be provided in prescription drug advertisements." To that end, the FDA announced that it is initiating a rulemaking process "to eliminate the 'adequate provision' loophole that allows pharmaceutical advertisements to hide safety information by placing it in another format or location." In this context, the FDA declared that it will no longer tolerate what it characterized as "deceptive practices" in prescription drug advertising and that the FDA would "aggressively deploy" its available enforcement tools, with "heightened scrutiny" of fair balance and disclosures in social media promotions. The FDA also issued a generic "notice letter" directing companies to "remove any noncompliant advertising and bring all promotional communications into compliance."

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 non-promotional, 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.

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.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our drug product candidates and affect the prices we may obtain for any products that are approved in the United States or foreign jurisdictions.

In the U.S. and some 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 drug product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any drug product candidates for which we obtain marketing approval. The pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by legislative initiatives. 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 receive for any FDA approved product.

In the U.S., the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

In March 2010, the PPACA was signed into law. In addition, other legislative changes have been proposed and adopted since the PPACA 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 pursuant to 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 drug product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used. For example, under current legislation, the actual reductions in Medicare payments may vary by up to 4%.

Since enactment of the PPACA, 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 Cuts and Jobs Act of 2017, or the TCJA, Congress repealed the "individual mandate." The repeal of this provision, which required 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 an action challenging the PPACA after finding that the plaintiffs did not have standing to challenge the constitutionality of the law. Litigation and legislation over the PPACA are likely to continue, with unpredictable and uncertain results.

In the EU, on December 13, 2021, Regulation No 2021/2282 on Health Technology Assessment, or HTA, amending Directive 2011/24/EU, was adopted. The HTA entered into force in January 2022 and began to apply in January 2025, with a phased implementation depending on the concerned products. The HTA 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 permits 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 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 been the subject of considerable legislative and executive actions in the United States. There have been 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.

For example, 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. Several states have passed laws allowing for the importation of drugs from Canada. On May 21, 2025, the FDA announced that it would offer individual states the opportunity to submit a draft proposal for pre-review and meet with the FDA to obtain its initial feedback prior to formally submitting SIP proposals. The intent of these meetings is to assist states in developing their proposals by further clarifying requirements, enhancing the quality of proposals submitted to the FDA and ultimately shortening the review timeline.

On August 16, 2022, the Inflation Reduction Act of 2022, or the IRA, was signed into law. The 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 now requires manufacturers of certain drugs to engage in price negotiations with Medicare, 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; and replaces the Part D coverage gap discount program with a new discounting program. The IRA permits the Secretary 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 nine years and biologics that have been licensed for 13 years, but it did not originally apply to drugs and biologics that had been approved for a single rare disease or condition. With passage of the One Big Beautiful Bill Act, or OBBBA, on July 3, 2025, which was signed into law on July 4, 2025, Congress extended this exemption to drugs and biologics with multiple orphan drug designations. 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.

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 placing price caps on annual out-of-pocket expenses, each of which could have potential pricing and reporting implications.

The first cycle of negotiations for the Medicare Drug Price Negotiation Program commenced in the summer of 2023, with the negotiated prices for ten selected drug products becoming effective on January 1, 2026. The second cycle of negotiations with participating drug companies occurred during 2025, and the negotiated prices for this second set of fifteen drugs will become effective on January 1, 2027. On January 27, 2026, CMS published the list of fifteen drugs selected for the third cycle of negotiations. These negotiated prices will become effective on January 1, 2028.

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. Every court that has thus far considered substantive challenges to the Medicare drug price negotiation program has ruled against the pharmaceutical industry, dismissing both constitutional and statutory arguments. 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 the biotechnology industry generally, as well as our business and current or future products.

In addition, since adoption of the IRA, the current administration has taken a number of actions to reduce the costs of pharmaceutical products. For example, an April 2025 executive order directed HHS to take steps to reduce the prices of pharmaceutical products, and a May 2025 executive order called on pharmaceutical manufacturers to voluntarily reduce the prices of medicines in the United States. The May 2025 executive order provides that if such actions do not lower the costs of pharmaceuticals, the Secretary of HHS would pursue other actions, including proposing a rulemaking that imposes most favored nation, or MFN, pricing in the United States. Thereafter, on July 31, 2025, 17 pharmaceutical companies were issued letters reiterating the requirements of the May 2025 executive order and demanding that such companies extend MFN pricing to Medicaid patients. Virtually all of these pharmaceutical companies have entered into agreements with the administration to provide for lower prices on certain pharmaceuticals. On February 5, 2026, the administration launched a website that directs individuals to pharmaceutical manufacturer websites that are offering price discounts based on the administration's pricing agreements with pharmaceutical manufacturers.

Separately, on December 23, 2025, CMS, through its Center for Medicare and Medicaid Innovation, or CMMI, proposed two five-year pilot programs to implement a "reference pricing" regime for drugs paid for under Medicare for 25% of covered beneficiaries. The

programs are referred to as the Global Benchmark for Efficient Drug Pricing Model for Medicare Part B drugs, or GLOBE, and the Guarding U.S. Medicare Against Rising Drug Costs for Medicare Part D drugs, or GUARD. Under the proposed pilot programs, a manufacturer would owe rebates to Medicare if prices for its drugs exceeded the prices paid by other economically comparable reference countries, defined in the proposed regulations as Organisation for Economic Co-Operation and Development countries with a gross domestic product, or GDP, of $400 billion and a per capita GDP that is at least 60% of the U.S. per capita GDP (an initial list of 19 reference countries is included in the proposed rule). On September 20, 2026, CMS issued a final rule for the GLOBE model. Although we cannot predict whether, when, or to what extent any of our product candidates, if approved, would become subject to these or future pricing and reimbursement programs, such measures could reduce reimbursement for pharmaceutical products, place downward pressure on pricing, increase rebate, discount, or other payment obligations, limit commercial flexibility, and adversely affect demand for pharmaceutical products.

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:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, paying, 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, in whole or in part, under a federal healthcare program such as Medicare and Medicaid;
- the federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false, fictitious, or fraudulent or knowingly making, using, or causing to made or used a false record or statement to avoid, decrease, or conceal an obligation to pay money to the federal government;
- the federal civil monetary penalty and false statement laws and regulations relating to pricing and submission of pricing information for government programs, including penalties for knowingly and intentionally overcharging 340b eligible entities and the submission of false or fraudulent pricing information to government entities

- HIPAA, which created additional federal criminal laws that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information;
- the federal false statements statute, which 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 health care benefits, items or services;
- the Foreign Corrupt Practices Act, which prohibits companies and their intermediaries from making, or offering or promising to make, improper payments to non-U.S. officials for the purpose of obtaining or retaining business or otherwise seeking favorable treatment;
- the federal transparency requirements known as the federal Physician Payments Sunshine Act, under the Patient Protection and Affordable Care Act, or PPACA, as amended by the Health Care Education Reconciliation Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services, or CMS, within HHS, information related to payments and other transfers of value made by that entity to physicians, other healthcare providers and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to healthcare items or services that are reimbursed by non-governmental third-party payors, including private insurers.

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. There are also increased restrictions at the federal level relating to transferring sensitive data outside of the United States to certain foreign countries. For example, in 2024, Congress passed H.B. 815, which included the Protecting Americans' Data from Foreign Adversaries Act of 2024. This law creates certain restrictions for entities that disclose sensitive data, including potential health data, to countries such as China. Failure to comply with these rules can lead to a potential FTC enforcement action. Additionally, the Department of Justice recently finalized a rule implementing Executive Order 14117, which creates similar restrictions related to the transfer of sensitive U.S. data to countries such as China. These data protection laws and transfer restrictions, and others that may pass in the future, may create operational challenges and legal risks for our business. 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, which will further increase compliance risk.

In addition to California, a number of other states have passed comprehensive privacy laws similar to the CCPA and CPRA. These laws are either in effect or will go into effect sometime before the end of 2026, with other states likely to consider or pass similar laws 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. Congress has also been debating passing a federal privacy law. There are also states that are specifically

regulating health information that may affect our business. For example, the State of Washington passed the My Health My Data Act in 2023 which specifically regulated health information that is not otherwise regulated by the HIPAA rules, and the law also has a private right of action, which further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data, and more states are considering such legislation. 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.

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.

Given the breadth and depth of changes in data protection obligations, complying with the GDPR's requirements is rigorous and time intensive and requires significant resources and a review of our technologies, systems and practices, as well as those of any third-party collaborators, service providers, contractors or consultants that process or transfer personal data collected in the European Union. The GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of sensitive data, such as healthcare data or other personal information from our clinical trials, could require us to change our business practices and put in place additional compliance mechanisms, may interrupt or delay our development, regulatory and commercialization activities, and could lead to government enforcement actions, private litigation and significant fines and penalties against us, all of which could increase our cost of doing business and have a material adverse effect on our business, financial condition or results of operations. Similarly, failure to comply with federal and state laws regarding privacy and security of personal information could expose us to fines and penalties under such laws. 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 reputation and our business.

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.

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. Further, we cannot assure you that our third-party service providers with access to our or our customers', suppliers', trial patients' and employees' personally identifiable and other sensitive or confidential information in relation to which we are responsible will not breach contractual obligations imposed by us, or that they will not experience data security breaches or attempts thereof, which could have a corresponding effect on our business, including putting us in breach of our obligations under privacy laws and regulations and/or which could in turn adversely affect our business, results of operations and financial condition. We cannot assure you that our contractual measures and our own privacy and security-related safeguards will protect us from the risks associated with the third-party processing, storage and transmission of such information.

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 and uncertainty surrounding U.S. and international trade policies may adversely impact our business and operating results.

In 2025, the U.S. government initiated a series of tariff-related actions against U.S. trading partners, which included a number of reciprocal and country-specific tariffs under the International Emergency Economic Powers Act, or the IEEPA. In February 2026, the U.S. Supreme Court held that the IEEPA does not authorize the President to impose tariffs, invalidating both the "reciprocal" tariffs and certain country-specific tariffs. The President subsequently invoked Section 122 of the Trade Act of 1974, or the Trade Act, to impose a 10% tariff, which could be raised to 15%, on nearly all foreign imports. The tariffs imposed under Section 122 are temporary and valid for 150 days without congressional approval. On May 7, 2026, the U.S. Court of International Trade ruled that these tariffs were unlawful and issued a permanent injunction for certain named private party plaintiffs and the State of Washington. The U.S. government appealed to the U.S. Court of Appeals for the Federal Circuit and, on June 11, 2026, the Federal Circuit stayed enforcement of the lower court's permanent injunction pending further appeals.

In addition, the U.S. Trade Representative is currently conducting two investigations under Section 301 of the Trade Act, which may also result in additional tariffs. In June 2026, in one such investigation, it proposed additional tariffs of 10% to 12.5% on products of 60 economies determined to have failed to impose and effectively enforce a prohibition on the importation of goods produced with forced

labor. These proposed tariffs remain subject to an ongoing notice-and-comment process and have not yet taken effect, and the second investigation into structural excess capacity and production in manufacturing sectors remains ongoing.

Separately, in 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 April 2, 2026, the administration issued a proclamation invoking Section 232 of the Trade Expansion Act of 1962 to impose tariffs on imports of patented pharmaceuticals, biologics, and associated ingredients into the U.S. Specifically, as of July 31, 2026, a 100% tariff applies to pharmaceutical articles classified in certain 10-digit harmonized tariff, or HTS, codes that are subject to a valid, unexpired U.S. patent and are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, or the Orange Book, or are listed in the FDA's Lists of Licensed Biological Products, or the Purple Book, unless a relevant exemption applies. The 100% tariff also applies to active pharmaceutical ingredients, or APIs, and key starting materials for such articles. For companies like ours that are not listed in the annexes to the proclamation (i.e., those that have not concluded qualifying onshoring plans and MFN pharmaceutical pricing agreements with the U.S. government), the Section 232 tariffs became effective on September 29, 2026. Preferential tariff rates are provided for imports of covered pharmaceuticals from Japan, the EU, Korea, Switzerland, Liechtenstein and the U.K. Certain categories of products are exempt from these tariffs, including, but not limited to, generic pharmaceuticals and biosimilars; specified U.S.-origin pharmaceutical products; and products classified in certain HTS codes, listed in Annex IV of the proclamation. Other products likely to be exempt from the tariffs include drugs and associated ingredients for all approved indications that are designated as orphan pursuant to the Orphan Drug Act; drugs for certain specific uses, including nuclear medicines; plasma-derived therapies; fertility treatments; cell and gene therapies; antibody drug conjugates; medical countermeasures related to chemical, biological, radiological, and nuclear threats; animal health; and other specialty pharmaceutical products to be later identified by the Secretary of Commerce.

The changes in tariffs that have been announced and/or implemented and the underlying uncertainty currently surrounding international trade, could have a negative impact on our costs of materials and production processes, or could cause supply chain disruptions and delays due to new tariff policies or trade restrictions. If we are unable to obtain necessary raw materials or product components in sufficient quantities and in a timely manner, 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. Further, 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 CMOs and other service providers that operate in China. We cannot yet predict the effect of the U.S. tariffs on imports, or the extent to which other countries will impose 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. In addition, artificial intelligence, or AI, presents emerging risks and challenges that may impact our business.

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 AI and machine learning to launch more automated, targeted and coordinated attacks against targets, and other third parties may use AI to probe information technology systems without authorization. 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.

We also face additional emerging risks associated with the use of generative AI and related technologies, which we have implemented, and may further expand, into our operations. The development and use of AI, combined with an uncertain regulatory environment, introduce risks and challenges that may result in reputational harm, liability, or other adverse consequences to our business operations. In addition, we may face competitive risks if we fail to adopt AI or other machine learning technologies in a timely fashion. AI algorithms may be flawed, datasets may be insufficient or biased and overreliance on AI or dependence on a specific model or vendor may limit our flexibility, increase costs, or expose us to operational risks if the AI provider modifies or discontinues its services or increases its costs. AI use could lead to noncompliance with applicable laws and regulations, threats to intellectual property rights, including the leakage of our proprietary information and the risk that AI-generated outputs may infringe third-party intellectual property rights. In addition, the providers of these AI tools may not meet existing or future regulatory or industry standards with respect to privacy and data protection. All of these risks also apply to our vendors who use AI and who may incorporate AI tools into their offerings without disclosing this use to us. If we, our vendors, or our third-party partners experience an actual or perceived breach or other privacy or security incident because of the use of AI, we may lose valuable intellectual property and confidential information, and our reputation and the public perception of the effectiveness of our security measures could be harmed. Further, bad actors around the world use increasingly sophisticated methods, including AI, to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. Additionally, several states have passed laws to regulate the use of AI and the regulatory environment is rapidly evolving at the state, federal, and international levels, which creates potential compliance and enforcement risk. Any of these developments in AI could damage our reputation, result in the loss of valuable property and information, and adversely impact our business.

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 reverse stock split of our common stock, which became effective March 13, 2026;
- 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 in the future, we fail to comply 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.

Our common stock is listed on the Nasdaq Capital Market and we must satisfy continued listing requirements, including minimum stock price, public float, stockholders' equity and other corporate governance standards. 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 our business. We have previously received deficiency letters from the Listing Qualifications Department of Nasdaq informing us that we were not in compliance with the continued listing requirements for minimum stock price and stockholders' equity. While we have regained compliance with respect to each of these deficiencies, there can be no assurance that we will be able to continue to maintain compliance with the Nasdaq continued listing requirements in the future. Any potential delisting of our common stock 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.

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. Currently, one securities and industry analyst publishes research on our company. There can be no assurance that the existing analyst will continue to cover us or that new analysts will begin to cover us. There is also no assurance that the covering analyst will provide favorable coverage. Although we have obtained analyst coverage, if the analyst covering our business downgrades her evaluation of our stock or publishes 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, 2026, 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 expect to remain an EGC until December 31, 2026. 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, and cash tax obligations. For example, the IRA was signed into law in August 2022 and 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 certain exceptions. Thus, the excise tax could apply to certain transactions that are not traditional stock repurchases. The OBBBA contains numerous tax provisions that may significantly affect our business or financial condition. The recent changes under the OBBBA include tax rate extensions, changes to the business interest deduction limitation, the election to either fully deduct or continue to capitalize and amortize 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 of such legislation 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 Annual Report on Form 10-K (File No. 001-40925), filed with the Securities and Exchange Commission on March 23, 2026)
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)
10.1	Third Amended and Restated 2022 Inducement Stock Incentive Plan (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-40925), filed with the Securities and Exchange Commission on August 12, 2026)
10.2*	Amendment No. 1 to the Third Amended and Restated 2022 Inducement Stock Incentive Plan
10.3*	Employment Agreement, dated August 13, 2026, by and between the Registrant and Yariv Houvras
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 10, 2026

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

Date: November 10, 2026

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

EXHIBIT 10.2

AMENDMENT NO. 1 TO
THIRD AMENDED AND RESTATED 2022 INDUCEMENT STOCK INCENTIVE PLAN

The Third Amended and Restated 2022 Inducement Stock Incentive Plan (the "***Plan***") of Xilio Therapeutics, Inc. (the "***Company***") is hereby amended as follows, in accordance with Section 11(d) of the Plan (capitalized terms used but not defined herein have the meanings ascribed to such terms in the Plan):

1. Section 4(a) of the Plan be, and hereby is, deleted in its entirety and replaced with the following:

> "(a) Authorized Number of Shares. Subject to adjustment under Section 9, Awards may be made under the Plan for up to 623,555 shares of common stock, $0.0001 par value per share, of the Company (the "***Common Stock***"). Shares issued under the Plan may consist in whole or in part of authorized but unissued shares or treasury shares."

2. Except as amended hereby, the Plan shall remain in full force and effect.

Adopted by the Board of Directors: September 29, 2026

EXHIBIT 10.3

EMPLOYMENT AGREEMENT

This Employment Agreement (the "Agreement") is entered into as of the Effective Date (as defined below) by and between Xilio Therapeutics, Inc. (the "Company") and Yariv Houvras (the "Executive") (together, the "Parties").

RECITALS

WHEREAS, the Company desires to employ the Executive as its Chief Medical Officer; and

WHEREAS, the Executive has agreed to accept employment on the terms and conditions set forth in this Agreement;

NOW, THEREFORE, in consideration of the foregoing and of the respective covenants and agreements of the Parties herein contained, the Parties hereto agree as follows:

1. *Agreement*. This Agreement shall be effective as of the date on which it is fully executed by the Parties (the "Effective Date"). As of the first date of Executive's employment with the Company (the "Employment Commencement Date"), the Executive shall be an employee of the Company until such employment relationship is terminated in accordance with Section 7 hereof (the "Term of Employment"). The Company and Executive anticipate that the Employment Commencement Date will be September 28, 2026.

2. *Position*. During the Term of Employment, the Executive shall serve as the Chief Medical Officer of the Company. The Executive's principal work location shall be the Executive's residence in New York, provided that the Executive shall also work regularly from the Company's headquarters, currently located in Waltham, Massachusetts, and shall travel as reasonably necessary to perform the Executive's duties and responsibilities hereunder.

3. *Scope of Employment*. During the Term of Employment, the Executive shall be responsible for the performance of those duties consistent with the Executive's position as Chief Medical Officer of the Company. The Executive shall report to the Chief Executive Officer of the Company and shall perform and discharge faithfully, diligently, and to the best of the Executive's ability, the Executive's duties and responsibilities hereunder. The Executive shall devote substantially all of the Executive's business time, loyalty, attention and efforts to the business and affairs of the Company and its affiliates. During the Term of Employment, the Executive will not engage in any other employment, occupation, consulting, or other business activity directly related to the business in which the Company is now involved or becomes involved during the Term of Employment without the prior written consent of the Chief Executive Officer of the Company. Notwithstanding the foregoing, the Executive may serve on other boards of directors with the approval of the Chair of the Board of Directors of the Company (the "Board"), and the Executive may engage in religious, charitable or other community activities as long as such services and activities are disclosed to the Chief Executive Officer of the Company and do not materially interfere with the Executive's performance of duties to the Company or the Executive's obligations pursuant to the Restrictive Covenants Agreement (as defined below). The Executive agrees to abide by the rules, regulations, instructions, personnel practices and policies of the Company and any changes therein that may be adopted from time to time by the Company.

4. *Compensation*. As full compensation for all services rendered by the Executive to the Company and any affiliate thereof, during the Term of Employment, the Company will provide to the Executive the following:

(a) *Base Salary*. Effective as of the Employment Commencement Date, the Executive shall receive a base salary at the annualized rate of $525,000 (the "Base Salary"). The Executive's Base Salary shall be paid in equal installments in accordance with the Company's regularly established payroll procedures. The Executive's Base Salary will be reviewed on an annual or more frequent basis by the Board and, except as set forth in Section

7(c)(i), is subject to increase (but not decrease) in the discretion of the Board. Upon any such adjustment, the adjusted amount shall thereafter be deemed to be the Base Salary for purposes of this Agreement.

(b) *Annual Discretionary Bonus*. Following the end of each calendar year beginning with the 2026 calendar year, the Executive will be considered for an annual incentive bonus with respect to each fiscal year of the Executive's employment with the Company. The amount, terms and conditions of such bonus (if any) are to be determined at the sole discretion of the Board. The Executive's target incentive bonus (the "Target Bonus") shall be 40.0% of the Executive's annualized base salary. The actual payout amount for any calendar year is discretionary and will be subject to the Board's assessment of the Executive's performance, business conditions at the Company, and the terms of any applicable bonus plan. No amount of annual bonus is guaranteed, and the Executive must be an employee in good standing on the last day of the applicable bonus year in order to be eligible for any annual bonus for such year, except as specifically set forth in Section 8 below. Any annual bonus hereunder will be paid by no later than March 15 of the calendar year after the bonus year to which it relates. With respect to the Executive's bonus, if any, to be paid following the end of the 2026 calendar year, the Executive shall be eligible to earn a prorated annual incentive bonus based upon the number of days the Executive is employed by the Company during the 2026 calendar year.

(c) *Equity Awards*. In connection with Executive's commencement of employment and subject to the approval of the Board or an authorized committee or delegate thereof, the Executive will be granted a stock option to purchase 105,000 shares of common stock, $0.0001 par value per share, of the Company (the "Stock Option Award") at an exercise price per share equal to the closing price per share of the common stock on the Nasdaq Global Select Market on the date of grant (or, if no closing market price is reported for such date, the closing market price on the immediately preceding date for which a closing market price is reported). The date of grant for the Stock Option Award is anticipated to be the first day of the month after the Employment Commencement Date. The Stock Option Award will vest with respect to 25% of the shares of common stock underlying the Stock Option Award on the first anniversary of the Employment Commencement Date (the "Vesting Commencement Date"), and the remaining 75% of the shares of common stock underlying the Stock Option Award shall vest in 36 equal monthly installments following the Vesting Commencement Date, subject to the Executive's continued service to the Company through each applicable vesting date. The Stock Option Award shall be issued as an "inducement grant" within the meaning of Nasdaq Listing Rules 5635(c)(4) and will be subject to all terms and conditions and other provisions set forth in the Company's 2022 Inducement Stock Incentive Plan (as amended and/or restated from time to time) and a separate agreement for the Stock Option Award, which the Executive will be required to sign as a condition to receiving the Stock Option Award. The Executive will also be eligible to receive future equity awards, if any, at such times and on such terms and conditions as the Board or an authorized committee thereof shall determine, in its or their sole discretion.

(d) *Sign-on Bonus.* The Company will provide the Executive with a sign-on bonus in the amount of $75,000 (the "Sign-On Bonus"). The Sign-On Bonus will be paid to the Executive, less applicable taxes and withholdings, in the first regularly scheduled payroll cycle following the Employment Commencement Date. If the Executive resigns from employment other than for Good Reason or the Company terminates the Executive's employment for Cause, in either case before the first anniversary of the Employment Commencement Date, the Executive shall repay to the Company the gross amount of the Sign-On Bonus within thirty (30) days following the Date of Termination (as defined in Section 8). If the Executive resigns from employment other than for Good Reason or the Company terminates the Executive's employment for Cause, in either case on or after the first anniversary of the Employment Commencement Date but before the second anniversary of the Employment Commencement Date, the Executive shall repay to the Company fifty percent (50%) of the gross amount of the Sign-On Bonus within thirty (30) days following the Date of Termination.

(e) *Retention Bonus.* In recognition of the Executive's anticipated contributions to the Company and as an incentive for the Executive's continued employment, the Company shall provide the Executive with an opportunity to earn a retention bonus of up to $150,000 (the "Retention Bonus"), payable in two installments as follows: (i) $75,000 shall be earned if the Executive remains continuously employed by the Company through December 31, 2027; and (ii) $75,000 shall be earned if the Executive remains continuously employed by the Company through December 31, 2028. Each earned installment of the Retention Bonus shall be paid in a lump sum during the first regularly scheduled payroll cycle following the applicable vesting date, less applicable taxes and

withholdings. Notwithstanding the foregoing, if, prior to the applicable vesting date, the Executive's employment is terminated by the Company without Cause or the Executive resigns for Good Reason, then, subject to the Executive's satisfaction of the release and other conditions applicable to the receipt of severance benefits under Section 8(d), any unpaid portion of the Retention Bonus that has not previously been earned and paid shall become fully vested and nonforfeitable as of the Date of Termination. In such event, the Company shall pay any such unpaid portion of the Retention Bonus in accordance with Section 8(d).

(f) *Benefits*. Subject to eligibility requirements and the Company's policies, the Executive shall have the right, on the same basis as other similarly-situated employees of the Company, to participate in, and to receive benefits under, all employee health, disability, insurance, fringe, welfare benefit and retirement plans, arrangements, practices and programs the Company provides to its senior executives in accordance with the terms thereof as in effect from time to time. The Company reserves the right to modify, amend or terminate any and all of its benefits plans at its discretion.

(g) *Paid Time Off*. During the Term of Employment, the Executive shall be entitled to vacation and holidays in accordance with the Company's applicable policy.

(h) *Withholdings*. All compensation payable to the Executive shall be subject to applicable taxes and withholdings.

5. *Expenses*. The Executive will be reimbursed for the Executive's actual, necessary and reasonable business expenses pursuant to Company policy, subject to the provisions of Section 3 of Exhibit A attached hereto.

6. *Restrictive Covenants Agreement*. As a condition of the Executive's employment pursuant to the terms hereof, the Executive shall execute the Employee Restrictive Covenants Agreement (the "Restrictive Covenants Agreement") attached hereto as Exhibit B. The Executive acknowledges that the Executive's receipt of the grant of stock options set forth in Section 4(c) of this Agreement is contingent upon the Executive's agreement to the non-competition provisions set forth in the Restrictive Covenants Agreement, and that such consideration is fair and reasonable in exchange for the Executive's compliance with such non-competition obligations.

7. *Employment Termination*. This Agreement and the employment of the Executive shall terminate upon the occurrence of any of the following:

(a) Upon the death or Disability of the Executive. As used in this Agreement, the term "Disability" shall mean a physical or mental illness or disability that prevents the Executive from performing the duties of the Executive's position for a period of more than any three (3) consecutive months or for periods aggregating more than twenty-six (26) weeks in any twelve-month period. The Company shall determine in good faith and in its sole discretion whether the Executive is unable to perform the services provided for herein.

(b) At the election of the Company, with or without Cause (as defined below), immediately upon written notice by the Company to the Executive. As used in this Agreement, "Cause" shall mean, as determined in good faith by the Company:

(i) conduct by the Executive constituting a material act of misconduct in connection with the performance of the Executive's duties, including, without limitation, misappropriation of funds or property of the Company or any of its subsidiaries or affiliates other than the occasional, customary and de minimis use of company property for personal purposes;

(ii) the Executive's commission of acts satisfying the elements of (A) any felony or (B) a misdemeanor involving moral turpitude, deceit, dishonesty or fraud;

(iii) any misconduct by the Executive, regardless of whether or not in the course of the Executive's employment, that would reasonably be expected to result in material injury or substantial reputational harm to the Company or any of its subsidiaries or affiliates if the Executive were to continue to be employed in the

same position; for the avoidance of doubt, a violation of the Company's anti-discrimination or anti-harassment policies shall constitute Cause pursuant to this (iii);

(iv) the Executive's continued non-performance of the Executive's duties hereunder (other than by reason of the Executive's Disability) which has continued for more than 30 days following written notice of such non-performance from the Board;

(v) the Executive's material breach of any of the provisions contained in this Agreement or the Restrictive Covenants Agreement; or

(vi) the Executive's failure to reasonably cooperate with a bona fide internal investigation or an investigation by regulatory or law enforcement authorities, after being instructed by the Company to cooperate, or the willful destruction or failure to preserve documents or other materials known to be relevant to such investigation or the inducement of others to fail to cooperate or to produce documents or other materials in connection with such investigation.

(c) At the election of the Executive, with or without Good Reason (as defined below), upon written notice by the Executive to the Company (subject, if it is with Good Reason, to the timing provisions set forth in the definition of Good Reason). As used in this Agreement, "Good Reason" shall mean that the Executive has completed all steps of the Good Reason Process (hereinafter defined) following the occurrence of any of the following events without the Executive's consent (each, a "Good Reason Condition"):

(i) a material diminution of the Executive's Base Salary, other than in connection with, and substantially proportionate to, reductions by the Company of the base salaries of all or substantially all senior management employees of the Company;

(ii) a material diminution in the Executive's role, duties, authority or responsibilities; provided, however, that a reduction in authority, duties or responsibilities primarily by virtue of the Company being acquired and made part of a larger entity (whether as a subsidiary, business unit or otherwise) will not constitute Good Reason;

(iii) a relocation of the Company's headquarters outside of Massachusetts; or

(iv) any material breach by the Company of this Agreement (to the extent not otherwise covered by this paragraph) or any other written agreement between the Company and the Executive;

"Good Reason Process" consists of the following steps: (i) the Executive reasonably determines in good faith that a Good Reason Condition has occurred; (ii) the Executive notifies the Company in writing of the first occurrence of the Good Reason Condition within 90 days of the first occurrence of such condition; (iii) the Executive cooperates in good faith with the Company's efforts, for a period of not less than 30 days following such notice (the "Cure Period"), to remedy the Good Reason Condition; (iv) notwithstanding such efforts, the Good Reason Condition continues to exist; and (v) the Executive terminates employment within 90 days after the end of the Cure Period. If the Company cures the Good Reason Condition during the Cure Period, Good Reason shall be deemed not to have occurred.

8. *Effect of Termination*.

(a) *All Terminations Other Than by the Company Without Cause or by the Executive With Good Reason*. If the Executive's employment is terminated under any circumstances other than a termination by the Company without Cause or a termination by the Executive with Good Reason (including a voluntary termination by the Executive without Good Reason or a termination by the Company for Cause or, except as expressly set forth in this Agreement, due to the Executive's death or Disability), the Company's obligations under this Agreement shall immediately cease and the Executive shall only be entitled to receive (i) the Base Salary that has accrued and to which the Executive is entitled as of the effective date of such termination (the "Date of Termination") and to the extent consistent with general Company policy, to be paid in accordance with the Company's established payroll

procedure and applicable law but no later than the next regularly scheduled pay period, (ii) unreimbursed business expenses for which expenses the Executive has timely submitted appropriate documentation in accordance with Section 5 hereof, and (iii) any amounts or benefits to which the Executive is then entitled under the terms of the benefit plans then-sponsored by the Company in accordance with their terms (and not accelerated to the extent acceleration does not satisfy Section 409A of the Internal Revenue Code of 1986, as amended, (the "Code")) (the payments described in this sentence, the "Accrued Obligations").

(b) *Termination by the Company Without Cause or by the Executive With Good Reason Prior to or More Than Twelve Months Following a Change in Control.* If the Executive's employment is terminated by the Company without Cause or by the Executive with Good Reason, in each case prior to, or more than twelve (12) months following, a Change in Control (as defined below), then the Executive shall be entitled to the Accrued Obligations. In addition, and subject to the conditions of Section 8(d), the Company shall:

(i) pay the Executive an amount equal to (x) nine (9) months (the "Severance Period") of the Executive's Base Salary, and (y) the Executive's Target Bonus for the year in which the Date of Termination occurs, without regard to whether the metrics have been established or achieved for such year (such bonus amount prorated to reflect the period during such year that the Executive was employed prior to the Date of Termination);

(ii) provided the Executive is eligible for and timely elects to continue receiving group medical insurance pursuant to the "COBRA" law, continue to pay for nine (9)months following the Executive's termination date or until the Executive has secured other employment or is no longer eligible for coverage under COBRA, whichever occurs first, the share of the premium for health coverage that is paid by the Company for active and similarly-situated employees who receive the same type of coverage, unless the Company's provision of such COBRA payments will violate the nondiscrimination requirements of applicable law, in which case the Company shall convert such payments to payroll payments directly to the Executive for the time period specified above. Such payments, if to the Executive, shall be subject to tax-related deductions and withholdings and paid on the Company's regular payroll dates. For the avoidance of doubt, the taxable payments described above may be used for any purpose, including, but not limited to, continuation coverage under COBRA; and

(iii) If applicable, the Executive shall be entitled to any accelerated Retention Bonus payment provided for in Section 4(e) (collectively, the benefits set forth in Sections 8(b)(i)-(iii), the "Severance Benefits").

(c) *Termination by the Company Without Cause or by the Executive With Good Reason Within Twelve Months Following a Change in Control.* If, within twelve (12) months following a Change in Control, the Executive's employment is either terminated by the Company without Cause or by the Executive with Good Reason, then the Executive shall be entitled to the Accrued Obligations. In addition, in lieu of the Severance Benefits set forth in Section 8(b) above, and subject to the conditions of Section 8(d), the Company shall:

(i) pay the Executive an amount equal to (x) twelve (12) months (the "Change in Control Severance Period") of the Executive's Base Salary (or the Executive's Base Salary in effect immediately prior to the Change in Control, if higher), and (y) an amount equal to the Executive's Target Bonus for the year in which the Date of Termination occurs, without regard to whether the metrics have been established or achieved for such year;

(ii) provided the Executive is eligible for and timely elects to continue receiving group medical insurance pursuant to the "COBRA" law, continue to pay for twelve (12) months following the Executive's termination date or until the Executive has secured other employment or is no longer eligible for coverage under COBRA, whichever occurs first, the share of the premium for health coverage that is paid by the Company for active and similarly-situated employees who receive the same type of coverage, unless the Company's provision of such COBRA payments will violate the nondiscrimination requirements of applicable law, in which case the Company shall convert such payments to payroll payments directly to the Executive for the time period specified above. Such payments, if to the Executive, shall be subject to

tax-related deductions and withholdings and paid on the Company's regular payroll dates. For the avoidance of doubt, the taxable payments described above may be used for any purpose, including, but not limited to, continuation coverage under COBRA;

(iii) notwithstanding anything to the contrary in any applicable equity incentive award agreement, stock option agreement or other stock-based award agreement, all equity incentive awards, stock options and other stock-based awards subject to time-based vesting held by the Executive shall be accelerated, such that all then-unvested equity awards that vest based solely on the passage of time immediately vest and become fully exercisable or non-forfeitable as of the Executive's Date of Termination; and

(iv) If applicable, the Executive shall be entitled to any accelerated Retention Bonus payment provided for in Section 4(e) (collectively, the benefits set forth in Sections 8(c)(i)-(iv) referred to as the "Change in Control Severance Benefits").

(d) *Release and Timing of Payments*. As a condition of the Executive's receipt of the Severance Benefits or the Change in Control Severance Benefits, as applicable, the Executive must execute and deliver to the Company a severance and release of claims agreement in a form to be provided by the Company (the "Severance Agreement"), which Severance Agreement will include, at a minimum, a release of all releasable claims, non-disparagement, confidentiality, and cooperation obligations, a reaffirmation of the Executive's continuing obligations under the Restrictive Covenants Agreement, and an agreement not to compete with the Company (but not to infringe upon Executive's ability to practice law) for twelve (12) months following the Date of Termination. The Severance Agreement must become irrevocable within sixty (60) days following the date of the Executive's Date of Termination (or such shorter period as may be directed by the Company). The Severance Benefits or the Change in Control Severance Benefits, as applicable, are subject to Exhibit A and, to the extent taxable, shall be paid out in substantially equal installments in accordance with the Company's payroll practice over the Severance Period or the Change in Control Severance Period, as applicable, commencing within 60 days after the Date of Termination; provided, however, that if the 60-day period begins in one calendar year and ends in a second calendar year, any payments due under Section 8(b) or 8(c) above, to the extent they qualify as "non-qualified deferred compensation" within the meaning of Section 409A of the Code, shall begin to be paid in the second calendar year by the last day of such 60-day period; provided, further, that the initial payment shall include a catch-up payment to cover amounts retroactive to the day immediately following the Date of Termination. The Executive must continue to comply with the Severance Agreement, the Restrictive Covenants Agreement and any similar agreement with the Company in order to be eligible to receive or continue receiving the Severance Benefits or Change in Control Severance Benefits, as applicable.

(e) *Change in Control Definition*. For purposes of this Agreement, "Change in Control" shall mean the occurrence of any of the following events, provided that such event or occurrence constitutes a change in the ownership or effective control of the Company, or a change in the ownership of a substantial portion of the assets of the Company, as defined in Treasury Regulation §§ 1.409A-3(i)(5)(v), (vi) and (vii): (i) the acquisition by an individual, entity or group (within the meaning of Section 13(d)(3) or 14(d)(2) of the Securities Exchange Act of 1934 (the "Exchange Act")) (a "Person") of beneficial ownership of any capital stock of the Company if, after such acquisition, such Person beneficially owns (within the meaning of Rule 13d-3 under the Exchange Act) fifty percent (50%) or more of either (x) the then-outstanding shares of common stock of the Company (the "Outstanding Company Common Stock") or (y) the combined voting power of the then-outstanding securities of the Company entitled to vote generally in the election of directors (the "Outstanding Company Voting Securities"); provided, however, that for purposes of this subsection (i), the following acquisitions shall not constitute a Change in Control: (1) any acquisition of capital stock of the Company directly from the Company or (2) any acquisition of capital stock of the Company by any entity pursuant to a Business Combination (as defined below) which complies with clauses (x) and (y) of subsection (iii) of this definition; or (ii) a change in the composition of the Board that results in the Continuing Directors (as defined below) no longer constituting a majority of the Board (or, if applicable, the Board of Directors of a successor corporation to the Company), where the term "Continuing Director" means at any date a member of the Board (x) who was a member of the Board on the Employment Commencement Date or (y) who was nominated or elected subsequent to such date by at least a majority of the directors who were Continuing Directors at the time of such nomination or election or whose election to the Board was recommended or endorsed by at least a majority of the directors who were Continuing Directors at the time of such nomination or election;

provided, however, that there shall be excluded from this clause (y) any individual whose initial assumption of office occurred as a result of an actual or threatened election contest with respect to the election or removal of directors or other actual or threatened solicitation of proxies or consents, by or on behalf of a person other than the Board; or (iii) the consummation of a merger, consolidation, reorganization, recapitalization or share exchange involving the Company, or a sale or other disposition of all or substantially all of the assets of the Company (a "Business Combination"), unless, immediately following such Business Combination, each of the following two (2) conditions is satisfied: (x) all or substantially all of the individuals and entities who were the beneficial owners of the Outstanding Company Common Stock and Outstanding Company Voting Securities immediately prior to such Business Combination beneficially own, directly or indirectly, more than fifty percent (50%) of the then-outstanding shares of common stock and the combined voting power of the then-outstanding securities entitled to vote generally in the election of directors, respectively, of the resulting or acquiring corporation in such Business Combination (which shall include, without limitation, a corporation which as a result of such transaction owns the Company or substantially all of the Company's assets either directly or through one (1) or more subsidiaries) (such resulting or acquiring corporation is referred to herein as the "Acquiring Corporation") in substantially the same proportions as their ownership of the Outstanding Company Common Stock and Outstanding Company Voting Securities, respectively, immediately prior to such Business Combination and (y) no Person (excluding any employee benefit plan (or related trust) maintained or sponsored by the Company or by the Acquiring Corporation) beneficially owns, directly or indirectly, fifty percent (50%) or more of the then-outstanding shares of common stock of the Acquiring Corporation, or of the combined voting power of the then-outstanding securities of such corporation entitled to vote generally in the election of directors (except to the extent that such ownership existed prior to the Business Combination); or (iv) the liquidation or dissolution of the Company.

9. *Modified Section 280G Cutback*. Notwithstanding any other provision of this Agreement, except as set forth in Section 9(b), in the event that the Company undergoes a "Change in Ownership or Control" (as defined below), the following provisions shall apply:

(a) The Company shall not be obligated to provide to the Executive any portion of any "Contingent Compensation Payments" (as defined below) that the Executive would otherwise be entitled to receive to the extent necessary to eliminate any "excess parachute payments" (as defined in Section 280G(b)(1) of the Code) for the Executive. For purposes of this Section 9, the Contingent Compensation Payments so eliminated shall be referred to as the "Eliminated Payments" and the aggregate amount (determined in accordance with Treasury Regulation Section 1.280G-1, Q/A-30 or any successor provision) of the Contingent Compensation Payments so eliminated shall be referred to as the "Eliminated Amount."

(b) Notwithstanding the provisions of Section 9(a), no such reduction in Contingent Compensation Payments shall be made if (1) the Eliminated Amount (computed without regard to this sentence) exceeds (2) one hundred percent (100%) of the aggregate present value (determined in accordance with Treasury Regulation Section 1.280G-1, Q/A-31 and Q/A-32 or any successor provisions) of the amount of any additional taxes that would be incurred by the Executive if the Eliminated Payments (determined without regard to this sentence) were paid to the Executive (including state and federal income taxes on the Eliminated Payments, the excise tax imposed by Section 4999 of the Code payable with respect to all of the Contingent Compensation Payments in excess of the Executive's "base amount" (as defined in Section 280G(b)(3) of the Code), and any withholding taxes). The override of such reduction in Contingent Compensation Payments pursuant to this Section 9(b) shall be referred to as a "Section 9(b) Override." For purpose of this paragraph, if any federal or state income taxes would be attributable to the receipt of any Eliminated Payment, the amount of such taxes shall be computed by multiplying the amount of the Eliminated Payment by the maximum combined federal and state income tax rate provided by law.

(c) For purposes of this Section 9 the following terms shall have the following respective meanings:

(i) "Change in Ownership or Control" shall mean a change in the ownership or effective control of the Company or in the ownership of a substantial portion of the assets of the Company determined in accordance with Section 280G(b)(2) of the Code.

(ii) "Contingent Compensation Payment" shall mean any payment (or benefit) in the nature of compensation that is made or made available (under this Agreement or otherwise) to or for the benefit of a

"disqualified individual" (as defined in Section 280G(c) of the Code) and that is contingent (within the meaning of Section 280G(b)(2)(A)(i) of the Code) on a Change in Ownership or Control of the Company.

(d) Any payments or other benefits otherwise due to the Executive following a Change in Ownership or Control that could reasonably be characterized (as determined by the Company) as Contingent Compensation Payments (the "Potential Payments") shall not be made until the dates provided for in this Section 9(d). Within thirty (30) days after each date on which the Executive first becomes entitled to receive (whether or not then due) a Contingent Compensation Payment relating to such Change in Ownership or Control, the Company shall determine and notify the Executive (with reasonable detail regarding the basis for its determinations) (1) which Potential Payments constitute Contingent Compensation Payments, (2) the Eliminated Amount and (3) whether the Section 9(b) Override is applicable. Within thirty (30) days after delivery of such notice to the Executive, the Executive shall deliver a response to the Company (the "Executive Response") stating either (A) that the Executive agrees with the Company's determination pursuant to the preceding sentence or (B) that the Executive disagrees with such determination, in which case the Executive shall set forth (x) which Potential Payments should be characterized as Contingent Compensation Payments, (y) the Eliminated Amount, and (z) whether the Section 9(b) Override is applicable. In the event that the Executive fails to deliver an Executive Response on or before the required date, the Company's initial determination shall be final. If and to the extent that any Contingent Compensation Payments are required to be treated as Eliminated Payments pursuant to this Section 9, then the payments shall be reduced or eliminated, as determined by the Company, in the following order: (i) any cash payments, (ii) any taxable benefits, (iii) any nontaxable benefits, and (iv) any vesting of equity awards in each case in reverse order beginning with payments or benefits that are to be paid the farthest in time from the date that triggers the applicability of the excise tax, to the extent necessary to maximize the Eliminated Payments. If the Executive states in the Executive Response that the Executive agrees with the Company's determination, the Company shall make the Potential Payments to the Executive within three (3) business days following delivery to the Company of the Executive Response (except for any Potential Payments which are not due to be made until after such date, which Potential Payments shall be made on the date on which they are due). If the Executive states in the Executive Response that the Executive disagrees with the Company's determination, then, for a period of sixty (60) days following delivery of the Executive Response, the Executive and the Company shall use good faith efforts to resolve such dispute. If such dispute is not resolved within such 60-day period, such dispute shall be settled exclusively by arbitration in Boston, Massachusetts, in accordance with the rules of the American Arbitration Association then in effect. Judgment may be entered on the arbitrator's award in any court having jurisdiction. The Company shall, within three (3) business days following delivery to the Company of the Executive Response, make to the Executive those Potential Payments as to which there is no dispute between the Company and the Executive regarding whether they should be made (except for any such Potential Payments which are not due to be made until after such date, which Potential Payments shall be made on the date on which they are due). The balance of the Potential Payments shall be made within three (3) business days following the resolution of such dispute. Subject to the limitations contained in Sections 9(a) and 9(b) hereof, the amount of any payments to be made to the Executive following the resolution of such dispute shall be increased by the amount of the accrued interest thereon computed at the prime rate announced from time to time by The Wall Street Journal, compounded monthly from the date that such payments originally were due.

The provisions of this Section 9 are intended to apply to any and all payments or benefits available to the Executive under this Agreement or any other agreement or plan under which the Executive may receive Contingent Compensation Payments.

10. *Absence of Restrictions*. The Executive represents and warrants that the Executive is not bound by any employment contracts, restrictive covenants or other restrictions that prevent the Executive from carrying out the Executive's responsibilities for the Company, or which are in any way inconsistent with any of the terms of this Agreement.

11. *Notice*. Any notice delivered under this Agreement shall be deemed duly delivered three (3) business days after it is sent by registered or certified mail, return receipt requested, postage prepaid, one (1) business day after it is sent for next-business day delivery via a reputable nationwide overnight courier service, immediately upon hand delivery, or, with respect to email transmission, immediately if sent during normal business hours, and if not sent

during normal business hours, then on the next business day; in each case to the address of the recipient set forth below.

To the Executive: At the address set forth in the Executive's personnel file and/or the Executive's Company email address

To Company:

Xilio Therapeutics, Inc.
828 Winter Street, Suite 300
Waltham, MA 02451
Attention: Chief Executive Officer
(*and/or if sent by electronic mail, to the Chief Executive Officer's Company email address*)

Either Party may change the address to which notices are to be delivered by giving notice of such change to the other Party in the manner set forth in this Section 11.

12. *Company Property, Electronic Communications and Monitoring*. The Executive acknowledges and agrees that the Company's premises, including all workspaces, furniture, documents and other tangible materials, and all information technology resources of the Company (including computers, data and other electronic files, and all internet, Teams, Slack, Google, chat and email usage) are subject to oversight, access and inspection by the Company at any time, to the fullest extent permitted by applicable law. The Executive acknowledges that the Executive has no expectation of privacy with respect to any Company premises, materials, resources, systems, communications or information. The Executive further acknowledges that, during the course of the Executive's employment, any telephone conversations or transmissions, electronic mail or other electronic communications, internet access or usage, and other activities conducted using any Company electronic device, system or network, or any electronic device or system used for Company business, including any computer, telephone, wire, radio, electromagnetic, photoelectronic or photo-optical system, may be monitored, accessed, reviewed, recorded or disclosed by the Company at any time and by any lawful means, subject to applicable law.

13. *Governing Law; Enforcement*. The terms of this Agreement and the resolution of any disputes as to the meaning, effect, performance or validity of this Agreement or arising out of, related to, or in any way connected with this Agreement, the Executive's employment with the Company or any other relationship between the Executive and the Company (the "Disputes") will be governed by Massachusetts law, excluding laws relating to conflicts or choice of law. The Executive and the Company submit to the exclusive personal jurisdiction of the federal and state courts located in the Commonwealth of Massachusetts in connection with any Dispute or any claim related to any Dispute.

14. *Successors and Assigns*. This Agreement shall be binding upon and inure to the benefit of both Parties and their respective successors and assigns, including any corporation with which or into which the Company may be merged or which may succeed to its assets or business; provided, however, that the obligations of the Executive are personal and shall not be assigned by the Executive.

15. *At-Will Employment*. During the Term of Employment, the Executive will continue to be an at-will employee of the Company, which means that, notwithstanding any provision set forth herein, the employment relationship can be terminated by either Party for any reason, at any time, with or without prior notice and with or without Cause.

16. *Acknowledgment*. The Executive states and represents that the Executive has had an opportunity to fully discuss and review the terms of this Agreement with an attorney. The Executive further states and represents that the Executive has carefully read this Agreement, understands the contents herein, freely and voluntarily assents to all of the terms and conditions hereof, and signs the Executive's name of the Executive's own free act.

17. *No Oral Modification, Waiver, Cancellation or Discharge*. This Agreement may be amended or modified only by a written instrument executed by both the Company and the Executive. No delay or omission by the Company in exercising any right under this Agreement shall operate as a waiver of that or any other right. A waiver or consent given by the Company on any one occasion shall be effective only in that instance and shall not be construed as a bar to or waiver of any right on any other occasion.

18. *Captions and Pronouns*. The captions of the sections of this Agreement are for convenience of reference only and in no way define, limit or affect the scope or substance of any section of this Agreement. Whenever the context may require, any pronouns used in this Agreement shall include the corresponding masculine, feminine or neuter forms, and the singular forms of nouns and pronouns shall include the plural, and vice versa.

19. *Interpretation*. The Parties agree that this Agreement will be construed without regard to any presumption or rule requiring construction or interpretation against the drafting Party. References in this Agreement to "include" or "including" should be read as though they said "without limitation" or equivalent forms. References in this Agreement to the "Board" shall include any authorized committee thereof.

20. *Severability*. Each provision of this Agreement must be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be prohibited by or invalid under applicable law, such provision will be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of such provision or the remaining provisions of this Agreement. Moreover, if a court of competent jurisdiction determines any of the provisions contained in this Agreement to be unenforceable because the provision is excessively broad in scope, whether as to duration, activity, geographic application, subject or otherwise, it will be construed, by limiting or reducing it to the extent legally permitted, so as to be enforceable to the extent compatible with then applicable law to achieve the intent of the Parties.

21. *Entire Agreement*. This Agreement, including the exhibits hereto, constitutes the entire agreement between the Parties with respect to the subject matter hereof and supersedes all prior agreements and understandings, whether written or oral, relating to the subject matter of this Agreement.

[Signature page follows.]

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement as of the date indicated below.

XILIO THERAPEUTICS, INC.

By: /s/ René Russo Date: August 13, 2026
Name: René Russo
Title: President and Chief Executive Officer

EXECUTIVE:

/s/ Yariv Houvras Date: August 7, 2026
Yariv Houvras

EXHIBIT A

Payments Subject to Section 409A

1. Subject to this Exhibit A, any severance payments that may be due under the Agreement shall begin only upon the date of the Executive's "separation from service" (determined as set forth below) which occurs on or after the termination of the Executive's employment. The following rules shall apply with respect to distribution of the severance payments, if any, to be provided to the Executive under the Agreement, as applicable:

(a) It is intended that each installment of the severance payments provided under the Agreement shall be treated as a separate "payment" for purposes of Section 409A of the Internal Revenue Code ("Section 409A"). Neither the Company nor the Executive shall have the right to accelerate or defer the delivery of any such payments except to the extent specifically permitted or required by Section 409A.

(b) If, as of the date of the Executive's "separation from service" from the Company, the Executive is not a "specified employee" (within the meaning of Section 409A), then each installment of the severance payments shall be made on the dates and terms set forth in the letter agreement.

(c) If, as of the date of the Executive's "separation from service" from the Company, the Executive is a "specified employee" (within the meaning of Section 409A), then:

(i) Each installment of the severance payments due under the Agreement that, in accordance with the dates and terms set forth herein, will in all circumstances, regardless of when the Executive's separation from service occurs, be paid within the short-term deferral period (as defined under Section 409A) shall be treated as a short-term deferral within the meaning of Treasury Regulation Section 1.409A-1(b)(4) to the maximum extent permissible under Section 409A and shall be paid on the dates and terms set forth in the Agreement; and

(ii) Each installment of the severance payments due under the Agreement that is not described in this Exhibit A, Section 1(c)(i) and that would, absent this subsection, be paid within the six-month period following the Executive's "separation from service" from the Company shall not be paid until the date that is six months and one day after such separation from service (or, if earlier, the Executive's death), with any such installments that are required to be delayed being accumulated during the six-month period and paid in a lump sum on the date that is six months and one day following the Executive's separation from service and any subsequent installments, if any, being paid in accordance with the dates and terms set forth herein; provided, however, that the preceding provisions of this sentence shall not apply to any installment of payments if and to the maximum extent that that such installment is deemed to be paid under a separation pay plan that does not provide for a deferral of compensation by reason of the application of Treasury Regulation 1.409A-1(b)(9)(iii) (relating to separation pay upon an involuntary separation from service). Any installments that qualify for the exception under Treasury Regulation Section 1.409A-1(b)(9)(iii) must be paid no later than the last day of the Executive's second taxable year following the taxable year in which the separation from service occurs.

2. The determination of whether and when the Executive's separation from service from the Company has occurred shall be made and in a manner consistent with, and based on the presumptions set forth in, Treasury Regulation Section 1.409A-1(h). Solely for purposes of Section 2 of this Exhibit A, "Company" shall include all persons with whom the Company would be considered a single employer under Section 414(b) and 414(c) of the Code.

3. All reimbursements and in-kind benefits provided under the Agreement shall be made or provided in accordance with the requirements of Section 409A to the extent that such reimbursements or in-kind benefits are subject to Section 409A, including, where applicable, the requirements that (i) any reimbursement is for expenses

incurred during the Executive's lifetime (or during a shorter period of time specified in the Agreement), (ii) the amount of expenses eligible for reimbursement during a calendar year may not affect the expenses eligible for reimbursement in any other calendar year, (iii) the reimbursement of an eligible expense will be made on or before the last day of the calendar year following the year in which the expense is incurred and (iv) the right to reimbursement is not subject to set off or liquidation or exchange for any other benefit.

4. The Company makes no representation or warranty and shall have no liability to the Executive or to any other person if any of the provisions of the Agreement (including this Exhibit A) are determined to constitute deferred compensation subject to Section 409A but that do not satisfy an exemption from, or the conditions of, that section.

5. The Agreement is intended to comply with, or be exempt from, Section 409A and shall be interpreted accordingly.

[Remainder of page intentionally left blank.]

EXHIBIT B

Restrictive Covenants Agreement

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 10, 2026

/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 10, 2026

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

EXHIBIT 32.1

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

In connection with this Quarterly Report on Form 10-Q of Xilio Therapeutics, Inc. (the "Company") for the three months ended September 30, 2026, 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 10, 2026

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

Date: November 10, 2026