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 June 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: 001-40407

Vera Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware **(State or other jurisdiction of incorporation or organization)**	**81-2744449** **(I.R.S. Employer Identification No.)**
2000 Sierra Point Parkway, Suite 1200 **Brisbane, California** **(Address of principal executive offices)**	**94005** **(Zip Code)**

Registrant's telephone number, including area code: (650) 770-0077

Not Applicable
(Former name, former address and former fiscal year, if changed since last report)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Class A common stock, $0.001 par value per share	**VERA**	**The Nasdaq Stock Market LLC**

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

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

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

As of July 29, 2026, the registrant had 72,063,335 shares of common stock, $0.001 par value per share, outstanding, consisting solely of Class A common stock, $0.001 par value per share.

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In this Quarterly Report on Form 10-Q, unless otherwise stated or as the context otherwise requires, references to "Vera," "the Company," "we," "us," "our" and similar references refer to Vera Therapeutics, Inc. In addition, references to "common stock" refer to our Class A common stock, unless otherwise stated or as the context otherwise requires.

This Quarterly Report on Form 10-Q also contains registered marks, trademarks and trade names of other companies. All other trademarks, registered marks and trade names appearing in this report are the property of their respective holders. We do not intend our use or display of other companies' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, these other companies.

SUMMARY OF RISKS ASSOCIATED WITH OUR BUSINESS

An investment in shares of our common stock involves a high degree of risk. Below is a list of some of the material risks associated with our business. This summary does not address all of the risks that we face. Additional discussion of the risks listed in this summary, as well as other risks that we face, is set forth under Part II, Item 1A, "Risk Factors" in this Quarterly Report on Form 10-Q:

- We have completed a limited number of clinical trials for our lead product, TRUTAKNA™, which received accelerated approval for commercial sale in the United States in July 2026, and it may be difficult to evaluate our current business and predict our future success and viability.
- We will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs of our product candidates or commercialization efforts.
- We have incurred net losses since inception, and expect to record limited revenue from product sales during the third quarter of 2026. We expect to continue to incur net losses at least until we have one or more approved products that achieve commercial success.
- The terms of our loan agreement place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.
- TRUTAKNA is our only FDA-approved product and the success of our business depends, in part, on its successful commercialization.
- We have never successfully commercialized a product before and may lack the necessary expertise, personnel and resources to successfully commercialize any product on our own or together with potential collaborators.
- TRUTAKNA may fail to achieve the broad degree of physician and patient adoption and use necessary for commercial success.
- We depend, in part, on the success of our product candidates. If we are unable to complete development of, obtain regulatory approval for and successfully commercialize our product candidates in one or more indications and in a timely manner, our business, financial condition, results of operations and prospects will be significantly harmed.
- Enrollment and retention of participants in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control, due in part to the availability of competitive products and significant competition for recruiting participants in clinical trials.
- The incidence and prevalence for target patient populations of our product candidates in specific indications are based on estimates and third-party sources. If the market opportunities for our product candidates, if and when approved, are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability might be materially and adversely affected.
- Interim, initial, "top-line" and preliminary data from our clinical trials that we announce or publish from time to time may change as more participant data become available and are subject to audit and verification procedures that could result in material changes in the final data.
- We face significant competition, which may result in others discovering, developing or commercializing products before or more successfully than us.
- Changes in methods of manufacturing or formulation of our product candidates may result in additional costs or delays.
- Our product candidates may cause significant adverse events, toxicities or other undesirable side effects when used alone or in combination with other approved products or investigational new drugs that may result in a safety profile that could inhibit regulatory approval, prevent market acceptance, limit their commercial potential or result in significant negative consequences.
- Our lead product is subject to continued regulatory oversight and failure to comply with applicable regulatory requirements could have a material adverse impact on our business.
- Disruptions at the FDA and other government agencies caused by funding shortages, staffing limitations, or policy changes could hinder their ability to hire, retain or deploy key leadership and other personnel, and prevent new or modified products from being developed, reviewed, approved or commercialized in a timely manner or at all, which could negatively impact our business.
- Biosimilars may provide competition sooner than anticipated.

- Unfavorable geopolitical and global economic conditions, including tariffs and trade tensions, could adversely affect our business, financial condition and results of operations.
- Our success is highly dependent on our ability to attract and retain highly skilled executive officers, employees and key consultants.
- Our success depends on our ability to protect our intellectual property and our proprietary technologies.
- If we breach our license agreement (Ares Agreement) with Ares Trading S.A. (Ares), an affiliate of Merck KGaA (Merck), Darmstadt, Germany, related to atacicept, the license agreement (Novartis Agreement) with Novartis International Pharmaceutical AG (Novartis) related to MAU868, or the license agreement (Stanford Agreement) with the Board of Trustees of Leland Stanford Junior University (Stanford) related to VT-109, we could lose the ability to continue the development and commercialization of atacicept, MAU868, or VT-109, respectively.
- We may be required to make significant payments under our license agreements related to our lead product and product candidates.
- If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical product candidates would be adversely affected.
- Patent terms may be inadequate to protect our competitive position on our lead product or product candidates for an adequate amount of time.
- We rely, and expect to continue to rely, on third parties, including independent clinical investigators and contract research organizations (CROs), to conduct certain aspects of our nonclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business, financial condition, results of operations and prospects could be significantly harmed.
- The manufacture of drugs is complex and our third-party manufacturers may encounter difficulties in production. If any of our third-party manufacturers encounter such difficulties, our ability to provide adequate supply of our product candidates for clinical trials or our lead product for patients could be delayed or prevented.
- If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.
- The price of our common stock may be volatile, and you could lose all or part of your investment.
- If we experience material weaknesses in internal control over financial reporting in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.
- Provisions in our amended and restated certificate of incorporation and amended and restated bylaws and Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.
- We may be subject to securities litigation, which is expensive and could divert management attention.

PART I. FINANCIAL INFORMATION

Item 1. Unaudited Condensed Financial Statements

VERA THERAPEUTICS, INC.
Condensed Balance Sheets
(in thousands, except share amounts)
(unaudited)

	June 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 48,876	$ 354,725
Marketable securities	450,285	359,864
Prepaid expenses and other assets, current	28,332	14,294
Total current assets	527,493	728,883
Other assets, noncurrent	5,491	5,850
Total assets	$ 532,984	$ 734,733
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 14,573	$ 21,898
Accrued expenses and other liabilities, current	33,748	31,557
Total current liabilities	48,321	53,455
Long-term debt	75,228	74,838
Other liabilities, noncurrent	1,677	1,919
Total liabilities	125,226	130,212
Stockholders' equity		
Class A common stock, $0.001 par value; 500,000,000 shares authorized as of June 30, 2026 and December 31, 2025; 71,955,885 and 71,267,429 shares issued and outstanding as of June 30, 2026 and December 31, 2025, respectively	72	71
Additional paid-in capital	1,399,459	1,364,529
Accumulated other comprehensive (loss) income	(403)	786
Accumulated deficit	(991,370)	(760,865)
Total stockholders' equity	407,758	604,521
Total liabilities and stockholders' equity	$ 532,984	$ 734,733

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

VERA THERAPEUTICS, INC.
Condensed Statements of Operations and Comprehensive Loss
(unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Operating expenses:				
Research and development	$ 60,080	$ 58,195	$ 146,091	$ 99,473
General and administrative	52,410	21,946	91,531	37,862
Total operating expenses	112,490	80,141	237,622	137,335
Loss from operations	(112,490)	(80,141)	(237,622)	(137,335)
Other income (expense):				
Interest income	5,348	6,320	11,703	13,226
Interest expense	(1,848)	(1,874)	(3,671)	(3,667)
Other expense, net	(483)	(836)	(915)	(449)
Total other income, net	3,017	3,610	7,117	9,110
Net loss	$ (109,473)	$ (76,531)	$ (230,505)	$ (128,225)
Other comprehensive loss:				
Change in unrealized gains and losses on marketable securities	(247)	(127)	(1,189)	134
Comprehensive loss	$ (109,720)	$ (76,658)	$ (231,694)	$ (128,091)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.52)	$ (1.20)	$ (3.22)	$ (2.01)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	71,838,008	63,789,303	71,658,300	63,730,756

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

VERA THERAPEUTICS, INC.
Condensed Statements of Stockholders' Equity
(unaudited)
(in thousands, except share amounts)

	Class A Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances as of December 31, 2025	**71,267,429**	**$ 71**	**$ 1,364,529**	**$ 786**	**$ (760,865)**	**$ 604,521**
Issuance of common stock pursuant to exercise of options	155,639	1	2,500	—	—	2,501
Issuance of common stock upon vesting of restricted stock units	237,070	—	—	—	—	—
Issuance of common stock pursuant to employee stock purchase plan	69,952	—	1,441	—	—	1,441
Stock-based compensation	—	—	13,208	—	—	13,208
Change in unrealized gains and losses on marketable securities	—	—	—	(942)	—	(942)
Net loss	—	—	—	—	(121,032)	(121,032)
Balances as of March 31, 2026	**71,730,090**	**$ 72**	**$ 1,381,678**	**$ (156)**	**$ (881,897)**	**$ 499,697**
Issuance of common stock pursuant to exercise of options	166,995	—	1,918	—	—	1,918
Issuance of common stock upon vesting of restricted stock units	58,800	—	—	—	—	—
Stock-based compensation	—	—	15,863	—	—	15,863
Change in unrealized gains and losses on marketable securities	—	—	—	(247)	—	(247)
Net loss	—	—	—	—	(109,473)	(109,473)
Balances as of June 30, 2026	**71,955,885**	**$ 72**	**$ 1,399,459**	**$ (403)**	**$ (991,370)**	**$ 407,758**

	Class A Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances as of December 31, 2024	**63,559,858**	**$ 64**	**$ 1,037,948**	**$ 393**	**$ (461,250)**	**$ 577,155**
Issuance of common stock pursuant to exercise of options	100,587	—	982	—	—	982
Issuance of common stock upon vesting of restricted stock units	90,283	—	—	—	—	—
Issuance of common stock pursuant to employee stock purchase plan	23,430	—	551	—	—	551
Stock-based compensation	—	—	7,744	—	—	7,744
Change in unrealized gains and losses on marketable securities	—	—	—	261	—	261
Net loss	—	—	—	—	(51,694)	(51,694)
Balances as of March 31, 2025	**63,774,158**	**$ 64**	**$ 1,047,225**	**$ 654**	**$ (512,944)**	**$ 534,999**
Issuance of common stock pursuant to exercise of options	45,162	—	464	—	—	464
Issuance of common stock upon vesting of restricted stock units	4,345	—	—	—	—	—
Stock-based compensation	—	—	9,472	—	—	9,472
Change in unrealized gains and losses on marketable securities	—	—	—	(127)	—	(127)
Net loss	—	—	—	—	(76,531)	(76,531)
Balances as of June 30, 2025	**63,823,665**	**$ 64**	**$ 1,057,161**	**$ 527**	**$ (589,475)**	**$ 468,277**

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

VERA THERAPEUTICS, INC.
Condensed Statements of Cash Flows
(unaudited)
(in thousands)

	Six Months Ended June 30,	
	2026	**2025**
Cash flows from operating activities		
Net loss	$ (230,505)	$ (128,225)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	272	204
Accretion of discount and amortization of premium on purchase of debt securities	(1,941)	(4,421)
Accretion of loan exit fee and amortization of loan costs	1,285	377
Reduction in the carrying amount of operating lease right-of-use assets	236	901
Stock-based compensation	29,071	17,216
Upfront and milestone obligations under license agreements	15,000	800
Changes in operating assets and liabilities:		
Prepaid expense and other current assets	(14,571)	(4,162)
Other assets	—	158
Accounts payable	(7,302)	5,492
Accrued and other liabilities	2,071	3,319
Operating lease liabilities	(369)	(863)
Net cash used in operating activities	(206,753)	(109,204)
Cash flows from investing activities		
Upfront and milestone payments under license agreements	(15,000)	(800)
Purchase of internal use software license	(264)	—
Purchase of property and equipment	(23)	(395)
Purchase of marketable securities	(308,617)	(187,251)
Proceeds from maturities of marketable securities	218,948	232,307
Net cash provided by (used in) investing activities	(104,956)	43,861
Cash flows from financing activities		
Proceeds from exercise of stock options and employee stock purchase plan	5,860	1,997
Proceeds from refinancing under loan and security agreement, net	—	23,338
Payment of deferred issuance costs related to unfunded loan commitments	—	(3,517)
Net cash provided by financing activities	5,860	21,818
Net decrease in cash and cash equivalents	(305,849)	(43,525)
Cash and cash equivalents, beginning of period	354,725	92,646
Cash and cash equivalents, end of period	$ 48,876	$ 49,121
Supplemental disclosure of cash flow information		
Cash paid for interest expense	$ 3,280	$ 3,238
Internal-use software license acquired through accrued liabilities	247	—

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

1. ORGANIZATION AND DESCRIPTION OF THE BUSINESS

Description of Business

Vera Therapeutics, Inc. (the Company) is a commercial-stage biotechnology company focused on developing and commercializing treatments for patients with serious immunological diseases. The Company was incorporated in May 2016 in Delaware. The Company's headquarters are in Brisbane, California. The Company operates in one segment, Therapeutics, focused on developing and commercializing transformative treatments for patients with serious immunological diseases. On July 7, 2026, the U.S. Food and Drug Administration (FDA) granted accelerated approval to TRUTAKNA™ (atacicept-vymj) to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk for disease progression.

Liquidity

Since inception, the Company has devoted substantially all of its resources to its research and development efforts, pre-clinical studies and clinical trials, building a sales, marketing and distribution infrastructure to support commercial launch activities, establishing and maintaining its intellectual property portfolio, hiring personnel, raising capital, and providing general and administrative support for these operations. The Company has incurred recurring net operating losses and has not generated positive cash flows from operations since its inception and had an accumulated deficit of $991.4 million as of June 30, 2026. The Company had cash, cash equivalents and marketable securities of $499.2 million as of June 30, 2026. The Company has funded its operations primarily through the issuance of common stock, redeemable convertible preferred stock, debt financing and convertible notes. Management expects to continue to incur losses and negative cash flows from operations in the near term.

Management believes that the Company's cash, cash equivalents and marketable securities as of June 30, 2026 will be sufficient to fund its planned operations and capital expenditure requirements for at least the next 12 months subsequent to the issuance date of these financial statements. The Company intends to raise additional capital through public or private equity offerings, debt financing, or other capital sources, which may include strategic collaborations or other arrangements with third parties in order to achieve its long-term business objectives. If the Company fails to obtain necessary capital when needed on acceptable terms, or at all, it could force the Company to delay, limit, reduce or terminate its product development programs, commercialization efforts or other operations.

2. BASIS OF PRESENTATION AND SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (GAAP) and applicable rules and regulations of the Securities and Exchange Commission (SEC) regarding interim financial reporting. The U.S. dollar is the Company's functional and reporting currency.

Unaudited Condensed Financial Statements

In the opinion of management, the unaudited condensed financial statements reflect all adjustments of a normal recurring nature that are necessary for a fair presentation of the results for the periods presented. Interim results are not necessarily indicative of results for a full year or any other period. The information included in this Form 10-Q should be read in conjunction with the audited financial statements and related notes in the Company's Annual Report on Form 10-K for the year ended December 31, 2025, filed with the SEC on February 26, 2026.

Use of Estimates

The preparation of the Company's financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the unaudited condensed financial statements and the reported amounts of expenses during the reporting period. Management estimates that affect the reported amounts of assets and liabilities include the accrual of research and development expenses, valuation of equity awards for stock-based compensation, determination of incremental borrowing rate for operating leases, the valuation allowance for deferred tax assets and fair value of marketable securities. The Company evaluates and adjusts its estimates and assumptions on an ongoing basis using historical experience and other factors. Actual results could differ from those estimates.

Reclassifications

Certain prior period amounts have been reclassified to conform to the current period presentation, with no impact on previously reported net income or total assets.

Concentrations of Credit Risk and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash, cash equivalents and marketable securities. The Company maintains bank deposits in federally insured financial institutions and these deposits may exceed federally insured limits. The Company is exposed to credit risk in the event of default by any of the financial institutions holding its cash, cash equivalents, and marketable securities to the extent recorded in the balance sheet. The Company has not experienced any losses to date related to these concentrations.

The Company's future results of operations involve a number of other risks and uncertainties. Factors that could affect the Company's future operating results and cause actual results to vary materially from expectations include, but are not limited to, uncertainty of results of clinical trials and reaching milestones, uncertainty of regulatory approval of the Company's current and potential future product candidates, uncertainty of market acceptance of the Company's lead product or product candidates, competition from substitute products and larger companies, securing and protecting proprietary technology, strategic relationships and dependence on key individuals or sole-source suppliers. The Company relies on single-source suppliers for some components of its supply chain. If any of the single source suppliers fails to satisfy the Company's requirements on a timely basis, it could suffer delays in its clinical development programs and commercial launch activities, which could adversely affect operating results.

TRUTAKNA is the Company's only FDA-approved product and the success of its business depends, in part, on successful commercialization. In addition, the Company's product candidates require approvals from the U.S. Food and Drug Administration and comparable foreign regulatory authorities prior to commercial sales in their respective jurisdictions. There can be no assurance that any product candidates will receive the necessary approvals. If the Company was denied approval, approval was delayed, or the Company was unable to maintain approval for any approved product, it could have a materially adverse impact on the Company.

Significant Accounting Policies

There have been no material changes to the Company's significant accounting policies disclosed in the Company's Annual Report on Form 10-K for the year ended December 31, 2025.

Recently Adopted Accounting Pronouncements

In July 2025, the FASB issued ASU 2025-05, Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses for Accounts Receivable and Contract Assets. This update will provide all entities with a practical expedient in developing reasonable and supportable forecasts as part of estimating expected credit losses by assuming that current conditions as of the balance sheet date do not change for the remaining life of the asset. The ASU is effective for annual reporting periods beginning after December 15, 2025, and interim reporting periods within those annual reporting periods. The Company adopted this standard on January 1, 2026, and it did not have a material impact on the Company's condensed financial statements or related disclosures.

Recently Issued Accounting Pronouncements Not Yet Adopted

In November 2024, the FASB issued ASU 2024-03, Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses. This update will improve disclosures about a public business entity's expenses and address requests from investors for more detailed information about the types of expenses (including purchases of inventory, employee compensation, depreciation, amortization, and depletion) in commonly presented expense captions (such as cost of sales, selling, general, and administrative expenses, and research and development). The ASU is effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027, with early adoption permitted. The Company will adopt the standard as of and for the year ending December 31, 2027 and for the interim reporting periods within the year ending December 31, 2028. This ASU will result in the required additional disclosures being included in the Company's financial statements upon adoption.

In September 2025, the FASB issued ASU 2025-06, Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40): Targeted Improvements to the Accounting for Internal-Use Software. This update will introduce changes to the timing of software cost capitalization based on likelihood of completion for all entities subject to the internal-use software guidance in Subtopic 350-40 and the guidance on website development costs in Subtopic 350-50. The ASU will be effective for annual reporting periods beginning after December 15, 2027, and interim reporting periods within those annual reporting periods, with early adoption permitted as of the beginning of an annual reporting period. The Company is currently evaluating the timing of adoption and the impact of adoption on its financial statements and related disclosures.

In December 2025, the FASB issued ASU 2025-11, Interim Reporting (Topic 270): Narrow Scope Improvements. This update will improve the navigability of required interim disclosures and clarify when that guidance is applicable, and will require entities to

disclose events since the end of the last annual reporting period that have a material impact on the entity. The ASU is effective for interim periods within annual reporting periods beginning after December 15, 2027, with early adoption permitted. The Company will adopt the standard for the interim periods within the year ending December 31, 2028. The Company is currently evaluating the impact of the adoption on its financial statements and related disclosures.

In December 2025, the FASB issued ASU 2025-12, Codification Improvements. This update will make a number of amendments to the Accounting Standards Codification and improvements to GAAP arising from technical corrections, unintended application of the Codification, clarifications, and other minor improvements. The ASU is effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods within those annual reporting periods, with early adoption permitted in both interim and annual reporting periods for which financial statements have not yet been issued or made available for issuance. Entities may elect to early adopt the amendments on an issue-by-issue basis. The Company is currently evaluating the timing of adoption and the impact of adoption on its financial statements and related disclosures.

3. OTHER FINANCIAL STATEMENT INFORMATION

Prepaid Expenses and Other Current Assets

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

	June 30, 2026	December 31, 2025
Prepaid drug manufacturing costs	$ 9,978	$ 1,637
Interest income receivable	3,928	3,285
Prepaid clinical trial costs	2,930	3,435
Prepaid commercial planning costs	2,562	359
Prepaid software costs	2,448	1,669
Prepaid medical affairs costs	2,277	486
Other	4,209	3,423
Total prepaid expenses and other current assets	$ 28,332	$ 14,294

Other Noncurrent Assets

Other noncurrent assets consist of the following (*in thousands*):

	June 30, 2026	December 31, 2025
Operating lease right-of-use assets	$ 1,687	$ 1,923
Deferred debt issuance costs	1,578	2,473
Property and equipment, net	813	1,374
Internal-use software	800	—
Other	613	80
Total other noncurrent assets	$ 5,491	$ 5,850

Accrued Expenses and Other Current Liabilities

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

	June 30, 2026	December 31, 2025
Accrued payroll	$ 12,151	$ 18,700
Accrued drug manufacturing costs	10,283	8,427
Accrued commercial planning expenses	4,452	1,181
Accrued clinical trial costs	4,131	1,333
Other	2,731	1,916
Total accrued expenses and other current liabilities	$ 33,748	$ 31,557

4. CASH, CASH EQUIVALENTS AND MARKETABLE SECURITIES

The Company's cash equivalents and available-for-sale investment securities are classified within the fair value hierarchy as defined by authoritative guidance. Level 1 securities consist of highly liquid money market funds for which the carrying amount approximates the fair value of identical assets as quoted in the active markets. Level 2 securities, consisting of U.S. Treasuries, U.S. agency securities and corporate debt securities, are measured based on other observable inputs, including broker or dealer quotations or other valuations using observable market data. The Company's debt securities are accounted for as available-for-sale securities.

Unrealized gains and losses are reported as a component of other comprehensive income (loss). Fair value of the debt securities was $450.3 million and $367.1 million as of June 30, 2026 and December 31, 2025, respectively.

The following table presents the Company's financial assets measured at fair value on a recurring basis by level within the fair value hierarchy (*in thousands*):

	June 30, 2026						
	Fair Value Hierarchy Level	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents	Marketable Securities
Money market funds	Level 1	$ 47,652	$ —	$ —	$ 47,652	$ 47,652	$ —
U.S. Government bonds	Level 2	206,439	25	(144)	206,320	—	206,320
U.S. Government agency securities	Level 2	16,995	—	(66)	16,929	—	16,929
Corporate debt securities	Level 2	227,254	28	(246)	227,036	—	227,036
Total cash equivalents and marketable securities		498,340	53	(456)	497,937	47,652	450,285
Cash		1,224	—	—	1,224	1,224	—
Total		$ 499,564	$ 53	$ (456)	$ 499,161	$ 48,876	$ 450,285

	December 31, 2025						
	Fair Value Hierarchy Level	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents	Marketable Securities
Money market funds	Level 1	$ 342,915	$ —	$ —	$ 342,915	$ 342,915	$ —
U.S. Government bonds	Level 2	166,736	480	—	167,216	—	167,216
U.S. Government agency securities	Level 2	9,997	1	(23)	9,975	—	9,975
Corporate debt securities	Level 2	189,536	329	(1)	189,864	7,191	182,673
Total cash equivalents and marketable securities		709,184	810	(24)	709,970	350,106	359,864
Cash		4,619	—	—	4,619	4,619	—
Total		$ 713,803	$ 810	$ (24)	$ 714,589	$ 354,725	$ 359,864

Marketable debt securities that had been in unrealized loss positions as of June 30, 2026, and December 31, 2025 were in an unrealized loss position for less than 12 months. Unrealized losses from marketable debt securities are primarily attributable to changes in interest rates and not due to credit-related factors. Management does not believe any remaining unrealized losses represent impairments or credit-related losses based on evaluation of available evidence.

The following table classifies the estimated fair value of investments in available-for-sale marketable debt securities by effective contractual maturity dates (*in thousands*):

	June 30, 2026
Due within one year	$ 407,480
Due after one year to two years	42,805
Total marketable securities	$ 450,285

5. NOTES PAYABLE

Notes payable consist of the following (in thousands):

		June 30, 2026		December 31, 2025	
	Maturity	Effective Interest Rate	Amount	Effective Interest Rate	Amount
Collateralized note 2025-06	2030	9.74%	$ 75,000	9.85%	$ 75,000
Total borrowings			75,000		75,000
Accrued exit fees net of unamortized issuance costs			228		(162)
Net carrying amount of debt			$ 75,228		$ 74,838

2021 Loan Agreement

In June 2025, the Company refinanced its debt under the non-revolving loan and security agreement (2021 Loan Agreement) with a loan syndicate involving Oxford Finance LLC (Oxford Finance), Oxford Finance Credit Fund II LP (OFCF II), and Oxford Finance Credit Fund III LP (OFCF III) entered into in December 2021, by entering into a new non-revolving loan and security agreement, the proceeds of which were partially used to prepay the outstanding principal balance of the 2021 Loan Agreement in full. The Company paid an exit fee of $3.0 million, equal to 6% on the aggregate principal amount of the loan, as 1% of the original 7% exit fee was waived in connection with the refinancing. The entirety of the 2% prepayment fee that would have applied to the prepayment of the $25.0 million of debt drawn in December 2023 was also waived in connection with the refinancing.

2025 Loan Agreement

On June 2, 2025, the Company entered into a new non-revolving loan and security agreement (2025 Loan Agreement) with a loan syndicate involving Oxford Finance, OFCF II, OFCF III, and Oxford Finance Credit Fund IV LP (OFCF IV) (collectively, Oxford). The 2025 Loan Agreement has a total borrowing capacity of up to $500.0 million, of which $75.0 million was funded at closing and $50.0 million remains available for draw at the Company's discretion until December 31, 2026. Following accelerated approval of TRUTAKNA by the FDA in July 2026, an additional $75.0 million is available for draw at the Company's discretion until November 4, 2026. The Company also has the option to draw two tranches, each of a maximum of $50.0 million, upon achievement of certain commercial milestones related to TRUTAKNA once approved, and up to $200.0 million available at the mutual discretion of the Company and Oxford. As of June 30, 2026, the Company's outstanding borrowing under the 2025 Loan Agreement was $75.0 million.

The Company accounted for the loan syndicate on a creditor-by-creditor basis. With respect to the continuing creditors, Oxford Finance, OFCF II, and OFCF III, the Company accounted for this transaction as a loan modification, and with respect to the new lender, OFCF IV, the Company accounted for this transaction as an issuance of debt. Of the $3.7 million in exit fees on the 2021 Loan Agreement and fees paid to creditors as part of the refinancing, $1.6 million was recorded as a reduction to the net carrying amount of the debt drawn under the 2025 Loan Agreement at close, and $2.0 million was recorded as noncurrent deferred debt issuance costs. Of the $2.3 million in fees paid by the Company to third parties in connection with the refinancing, $0.8 million was recorded as other expense, and $1.4 million was recorded as noncurrent deferred debt issuance costs. Deferred debt issuance costs will be amortized over the respective draw periods of each of the loan commitment tranches on a straight-line basis.

The 2025 Loan Agreement is scheduled to mature in June 2030, provided that the Company has not achieved a revenue-based interest-only extension milestone as of the end of the initial interest-only period in August 2029. If the Company achieves this interest-only extension milestone, the maturity date and end of the interest-only period will be extended to June 2031 and August 2030, respectively. The Company is permitted to prepay the loan, subject to certain conditions, and will incur prepayment fees of 2% if the loan is prepaid prior to June 4, 2027, or 1% if the loan is prepaid between June 5, 2027, and June 4, 2028. No prepayment fee shall be applicable after June 4, 2028. Additionally, upon maturity date, acceleration of the loan in the event of default, or prepayment of the loan, the Company is required to pay an exit fee equal to 5% of the aggregate principal amount of the loan. The Company will accrue for this exit fee over the life of the loan as an increase to the net carrying amount of debt using the effective interest rate method.

The variable interest rate on the drawn amount is 1-Month CME Term SOFR (subject to a per annum floor rate of 3.75%) plus 4.95% per annum. At the initial funding of the 2025 Loan Agreement on June 4, 2025, the nominal interest rate was 9.27%. There are two financial covenants: (i) commencing on March 31, 2027, the Company is required to maintain certain levels of unrestricted cash subject to control agreements provided that such liquidity covenant shall not apply at any given time if the market capitalization of the Company is at least $1.0 billion on the measurement date, and (ii) commencing with the last day of the month in which the aggregate amount of Term Loans funded exceeds $200.0 million, the Company will be required to maintain a loan coverage ratio, which will replace the minimum cash covenant. The loan coverage ratio should not apply at any given time if the market capitalization of the Company is at least $1.25 billion on the measurement date. The loan is secured by substantially all of the Company's assets. The

proceeds from the 2025 Loan Agreement were partially used to prepay the outstanding principal balance of the 2021 Loan Agreement in full, with the remaining proceeds available for working capital, capital expenditures, and other general corporate purposes.

Principal installments due on the notes are as follows (*in thousands*):

2026 (remaining)	$	—
2027		—
2028		—
2029		34,091
2030		40,909
Total long-term debt	$	75,000

6. STOCKHOLDERS' EQUITY

As of June 30, 2026 and December 31, 2025, the Company's amended and restated certificate of incorporation authorized the Company to issue 500,000,000 shares of Class A common stock and 14,600,000 shares of Class B common stock, and 10,000,000 shares of preferred stock, each with a par value of $0.001 per share. Each share of Class A common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. There were no shares of Class B common stock or preferred stock outstanding as of June 30, 2026 and December 31, 2025. Common stockholders are entitled to receive dividends, as may be declared by the board of directors. Through June 30, 2026, no cash dividends have been declared or paid.

In December 2025, the Company completed a follow-on public offering pursuant to which the Company issued and sold 7,058,824 shares of its Class A common stock at a public offering of $42.50 per share, including 920,716 shares of Class A common stock pursuant to the full exercise of the underwriters' option to purchase additional shares. Net proceeds from this follow-on public offering were $281.3 million, after deducting underwriting fees and offering-related expenses.

7. STOCK COMPENSATION

Equity Plans

2024 Inducement Plan

In February 2024, the Company adopted the 2024 Inducement Plan (Inducement Plan). The Inducement Plan was adopted by the compensation committee of the Company's board of directors without stockholder approval pursuant to Nasdaq Listing Rule 5635(c)(4) and subsequently amended in August 2024, January 2025, September 2025, and March 2026. In accordance with Rule 5635(c)(4), awards made under the Inducement Plan, including stock options and restricted stock units, may only be granted to newly hired employees as a material inducement to accept employment with the Company. Stock options granted under the Inducement Plan expire no later than ten years from the date of grant.

2021 Equity Incentive Plan and 2017 Equity Incentive Plan

The 2021 Equity Incentive Plan (2021 EIP) and the 2017 Equity Incentive Plan (2017 EIP) became effective in May 2021 and February 2017, respectively. The Company may not grant any additional awards under the 2017 EIP. The 2017 EIP will continue to govern outstanding equity awards granted thereunder. Stock options granted under the 2021 EIP and 2017 EIP expire no later than 10 years from the date of grant.

2021 Employee Stock Purchase Plan

The 2021 Employee Stock Purchase Plan (ESPP) became effective in May 2021. As of June 30, 2026, 220,042 shares have been issued pursuant to the ESPP. The ESPP generally provides for six-month consecutive offering periods beginning every September 14 and March 14. The ESPP is a compensatory plan as defined by the authoritative guidance for stock compensation.

The table below summarizes the Company's equity plans as of June 30, 2026:

Plan	Maximum Number of Shares Authorized	Shares Available for Future Issuance
2024 Inducement Plan	4,390,000	655,797
2021 Equity Incentive Plan	13,614,767	3,978,065
2017 Equity Incentive Plan	2,275,305	—
2021 Employee Stock Purchase Plan	2,029,448	1,809,406

Option Activity

Stock option activity under the 2017 EIP, 2021 EIP, and 2024 Inducement Plan for the period ended June 30, 2026 is summarized as follows:

	Number of Options	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (000s)
Outstanding as of December 31, 2025	8,395,290	$ 19.59	7.58	$ 260,696
Granted	2,155,339	$ 41.93		
Exercised	(322,634)	$ 13.70		
Cancelled and forfeited	(312,144)	$ 32.41		
Outstanding as of June 30, 2026	9,915,851	$ 24.23	7.59	$ 187,146
Options exercisable as of June 30, 2026	5,019,619	$ 16.62	6.43	$ 132,361
Vested and expected to vest as of June 30, 2026	9,915,851	$ 24.23	7.59	$ 187,146

The aggregate intrinsic value of stock options exercised during the three months ended June 30, 2026 and 2025 was $4.3 million and $1.0 million, respectively. The aggregate intrinsic value of stock options exercised during the six months ended June 30, 2026 and 2025 was $8.7 million and $3.7 million, respectively. The weighted-average grant date fair value of options granted during the three months ended June 30, 2026 and 2025 was $30.02 per share and $20.20 per share, respectively. The weighted-average grant date fair value of options granted during the six months ended June 30, 2026 and 2025 was $34.73 per share and $23.43 per share, respectively.

Award Activity

The Company grants restricted stock units (RSU) pursuant to the 2021 EIP and satisfies such grants through the issuance of the Company's Class A common stock. The following table shows RSU activity for the period ended June 30, 2026:

	Number of Shares	Weighted Average Grant Date Fair Value per Share
Unvested balance as of December 31, 2025	1,599,840	$ 28.67
Granted	1,031,465	42.46
Vested	(295,870)	27.12
Cancelled and forfeited	(144,673)	29.99
Unvested balance as of June 30, 2026	2,190,762	$ 35.28

Stock-Based Compensation Expense

The following tables summarize the stock-based compensation expense for stock options and restricted stock units granted to employees and non-employees and for ESPP stock-based compensation that was recorded in the Company's condensed statements of operations and comprehensive loss for the three and six months ended June 30, 2026 and 2025 (*in thousands*):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Research and development	$ 6,977	$ 4,328	$ 13,406	$ 7,753
General and administrative	8,886	5,144	15,665	9,463
Total stock-based compensation expense	$ 15,863	$ 9,472	$ 29,071	$ 17,216

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Employees	$ 15,155	$ 8,847	$ 27,834	$ 15,836
Non-employees	708	625	1,237	1,380
Total stock-based compensation expense	$ 15,863	$ 9,472	$ 29,071	$ 17,216

As of June 30, 2026, the Company had $107.8 million of unrecognized stock-based compensation expense related to unvested stock options, which is expected to be recognized over a weighted-average period of approximately 2.7 years. For the three months ended June 30, 2026 and 2025, the Company recognized $10.4 million and $6.9 million of stock-based compensation expense for stock options, respectively. For the six months ended June 30, 2026 and 2025, the Company recognized $19.3 million and $12.8 million of stock-based compensation expense for stock options, respectively.

As of June 30, 2026, the Company had $68.4 million of unrecognized stock-based compensation expense related to unvested RSUs, which is expected to be recognized over a weighted-average period of approximately 3.1 years. For the three months ended June 30, 2026 and 2025, the Company recognized $5.1 million and $2.4 million of stock-based compensation expense for restricted stock units, respectively. For the six months ended June 30, 2026 and 2025, the Company recognized $9.1 million and $4.1 million of stock-based compensation expense for restricted stock units, respectively.

Stock-based compensation expense related to the ESPP for the three months ended June 30, 2026 and 2025 was $0.3 million and $0.2 million, respectively. Stock-based compensation expense related to the ESPP for the six months ended June 30, 2026 and 2025 was $0.7 million and $0.3 million, respectively.

The fair value of stock options granted during the three and six months ended June 30, 2026 and 2025 was estimated using the Black-Scholes option pricing model based on the following assumptions:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Expected term (in years)	5.5 – 6.1	5.5 – 6.1	5.5 – 6.1	5.5 – 6.1
Expected volatility	78.1% – 82.5%	81.8% – 83.9%	78.1% – 87.6%	81.8% – 83.9%
Risk-free rate	4.0% – 4.3%	3.8% – 4.3%	3.7% – 4.3%	3.8% – 4.5%
Dividend yield	—	—	—	—

8. LICENSES

Ares Trading S.A.

The Company has a license agreement with Ares Trading S.A. (Ares), pursuant to which the Company maintains an exclusive worldwide license to certain patents and related know-how to research, develop, manufacture, use and commercialize therapeutic products containing atacicept, a recombinant fusion protein used to inhibit B cell growth and differentiation.

In January 2026, the Company achieved a specified regulatory milestone and paid $15.0 million to Ares upon acceptance of the Company's Biologics License Application for treatment of IgAN by the FDA. This was recorded as research and development expense. In July 2026, the Company achieved a specified regulatory milestone and is obligated to pay $20.0 million to Ares upon accelerated approval of the Company's Biologics License Application for treatment of IgAN by the FDA.

The Company is obligated to pay Ares additional milestone payments, including $10.0 million upon the first filing of an approval application in the European Union, and other potential milestone payments of up to $131.5 million in aggregate upon the achievement of regulatory filing and approval milestones for other geographic regions and indications, and up to $515.0 million upon the achievement of specified worldwide aggregate annual net sales milestones, beginning with $15.0 million if net sales reach $250.0 million and $50.0 million if net sales reach $500.0 million.

9. COMMITMENTS AND CONTINGENCIES

Legal Proceedings

The Company believes that there are no actions pending which would have a material adverse effect on its financial statements.

Indemnification

As of June 30, 2026, the Company did not have any material indemnification claims that were probable and consequently no related liabilities have been recorded.

Employee Agreements

The Company has signed employment agreements with certain key employees pursuant to which, if their employment is terminated following a change of control of the Company, the employees are entitled to receive certain benefits, including severance and accelerated vesting of equity incentives.

Development and Manufacturing Services Agreements

The Company enters into development and manufacturing contracts with vendors in the conduct of its business. Contracts with these vendors may be terminated at the Company's option, with varying provisions regarding termination. If a contract with a specific vendor were to be terminated, the Company would be obligated to pay for the products or services that had been provided or received at the time the termination became effective and potentially additional compensation based upon the period of time remaining between the date of notice of cancellation and the scheduled manufacturing.

10. NET LOSS PER SHARE ATTRIBUTABLE TO COMMON STOCKHOLDERS

The following outstanding potentially dilutive shares were excluded from the computation of diluted net loss per share attributable to common stockholders for the periods presented, because including them would have been anti-dilutive (on an as-converted basis):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Class A common stock options issued and outstanding	9,915,851	8,104,871	9,915,851	8,104,871
Unvested restricted stock units	2,190,762	1,379,915	2,190,762	1,379,915
Shares reserved for ESPP purchases	5,550	6,929	5,550	6,929
Total	12,112,163	9,491,715	12,112,163	9,491,715

11. RELATED PARTY TRANSACTIONS

A member of the Company's board of directors also serves as chairman of the board of directors of IntegriChain. The Company entered into an agreement with IntegriChain to procure software and services for government pricing, contracting, policy development, and rebate operations related to commercialization and market access with expected fees and expenses of up to $0.3 million. The Company recorded related party expense of $0.1 million and $0.1 million to IntegriChain for these services in the three and six months ended June 30, 2026, respectively. This amount is included in general and administrative expenses on the Company's condensed statements of operations and comprehensive loss. As of June 30, 2026, the Company recorded related party payable amounts of $0.1 million to IntegriChain, which were included in accounts payable and other current liabilities on the Company's condensed balance sheet.

12. SEGMENT REPORTING

The Company has one reportable segment: Therapeutics. This segment is dedicated to developing and commercializing medical treatments for patients with serious immunological diseases. The Company's lead product, TRUTAKNA, was granted accelerated approval by the FDA for the treatment of IgAN in the U.S. in July 2026. TRUTAKNA is a native human TACI-Fc fusion protein that binds both the B-cell activating factor (BAFF) and A proliferation-inducing ligand (APRIL) cytokines and is self-administered subcutaneously at home. Atacicept is also being evaluated for the treatment of other autoimmune kidney diseases and the Company

intends to seek marketing approval of atacicept for the treatment of IgAN in regions outside of the U.S. in the future. The Company also holds worldwide, exclusive development and commercial rights to MAU868, a monoclonal antibody to treat BK virus infections for which the Company completed a Phase 2 clinical trial in 2022, and worldwide, exclusive development and commercial rights to VT-109, a novel, next generation dual BAFF/APRIL inhibitor that is in preclinical development.

Since inception, the Company has devoted substantially all its resources to research and development efforts, pre-clinical studies and clinical trials, building a sales, marketing and distribution infrastructure to support commercial activities, establishing and maintaining intellectual property portfolio, hiring personnel, raising capital, and providing general and administrative support for these operations. As of June 30, 2026, the Company did not have any product candidates approved for commercial sale and had not generated any revenue from product sales.

The accounting policies used in the segment reporting are the same as those disclosed in the summary of significant accounting policies in the Company's Annual Report on Form 10-K for the year ended December 31, 2025. The Company's Chief Operating Decision Maker (CODM) is the Chief Executive Officer. The CODM assesses performance for the single reportable segment and decides how to allocate resources based on net loss and total operating expenses. As the Company has not generated any revenue as of June 30, 2026, total operating expenses is equivalent to loss from operations on the statements of operations and comprehensive loss. The measure of segment assets is reported on the balance sheet as total assets.

The CODM uses net loss as the reportable segment's primary measure of profit or loss to evaluate the segment's financial position and to determine the need for additional financing or equity offerings. The CODM also uses total operating expenses as a measure to evaluate controllable spend from total current assets in deciding how to allocate resources within the Therapeutics segment.

The Company's reportable segment total operating expenses, including significant segment expenses, and net loss for the three and six months ended June 30, 2026 and 2025, consisted of the following (*in thousands*):

	Therapeutics			
	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Operating expenses:				
Payroll and related	$ 48,543	$ 25,193	$ 90,584	$ 45,950
Direct research and development - clinical trials	15,633	12,636	44,329	24,630
Direct research and development - contract drug manufacturing	15,742	23,498	46,197	33,040
Commercial planning	15,057	3,822	23,040	6,986
Depreciation and amortization	132	119	272	204
Other segment items*	17,383	14,873	33,200	26,525
Total operating expenses	112,490	80,141	237,622	137,335
Loss from operations	(112,490)	(80,141)	(237,622)	(137,335)
Other income (expense):				
Interest income	5,348	6,320	11,702	13,226
Interest expense	(1,848)	(1,874)	(3,671)	(3,667)
Other segment items**	(483)	(836)	(914)	(449)
Segment and consolidated net loss	$ (109,473)	$ (76,531)	$ (230,505)	$ (128,225)

**Other segment items included in total operating expenses primarily consist of consulting and contractors, professional services, equipment and software, travel and entertainment, facilities, medical affairs, and corporate communications.*

***Other segment items included in net loss consist of currency exchange gains and losses and other income/expense.*

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 unaudited condensed financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q and our audited financial statements and notes thereto and the related Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the year ended December 31, 2025, filed with the U.S. Securities and Exchange Commission on February 26, 2026 (the Annual Report).

Forward-Looking Statements

In addition to historical financial information, this discussion contains forward-looking statements based upon current expectations that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth in the section titled "Risk Factors" under Part II, Item 1A below. In some cases, you can identify forward-looking statements by terminology such as "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potentially," "predict," "should," "will" or the negative of these terms or other similar expressions.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report on Form 10-Q, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

Overview

We are a commercial-stage biotechnology company focused on the pursuit of truth in science to transform medicine in autoimmune disease, starting with the kidney. Our flagship commercial product is TRUTAKNA™ (atacicept-vymj), an inhibitor of B-cell activating factor (BAFF) and A Proliferation-Inducing Ligand (APRIL) indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk for disease progression. Beyond IgAN, we are evaluating additional diseases where the reduction of autoantibodies through inhibition of BAFF and APRIL may prove clinically meaningful.

On July 7, 2026, the U.S. Food and Drug Administration (FDA) granted accelerated approval to TRUTAKNA. The accelerated approval is based on a prespecified interim analysis of the ongoing ORIGIN Phase 3 trial (ORIGIN 3) in which participants treated with TRUTAKNA achieved a 46% reduction in proteinuria from baseline, with a statistically significant and clinically meaningful 42% reduction compared to placebo ($p < 0.0001$) at 36 weeks. In this registrational program, TRUTAKNA was generally well-tolerated. The final efficacy analysis from ORIGIN 3 is expected in the third quarter of 2026, followed by an anticipated supplemental Biologics License Application submission to the FDA expected in the fourth quarter of 2026 which could lead to potential full FDA approval of TRUTAKNA in 2027.

TRUTAKNA is a soluble recombinant fusion protein containing the human transmembrane activator and calcium-modulating cyclophilin ligand interactor (TACI) receptor that binds to BAFF and APRIL, the two key cytokines that activate B cells and drive IgAN pathophysiology. In IgAN, activated B cells produce both the antigen and associated antibodies that result in the production of damaging IgA immune complexes. The overlapping roles of BAFF and APRIL in activating B cells support the potential for TRUTAKNA as a disease-modifying therapy. TRUTAKNA is self-administered as an at home, small-volume (1 ml), 150 mg once-weekly autoinjector.

We believe that atacicept has pipeline-in-a-molecule potential, with potential application in multiple diseases. In the Phase 2 PIONEER clinical trial, for which we expect to report additional results in the fourth quarter of 2026, we are evaluating atacicept in a broader population of IgAN patients as well as other autoimmune kidney diseases, including primary membranous nephropathy (pMN), focal segmental glomerulosclerosis (FSGS) and minimal change disease (MCD), in patients with anti-phospholipase A2 receptor or anti-nephrin autoantibodies. Potential future indications include anti-neutrophil cytoplasmic antibody-associated vasculitis, lupus nephritis, Sjogren's disease, systemic lupus erythematosus, systemic sclerosis, generalized myasthenia gravis, and idiopathic thrombocytopenic purpura.

We also hold worldwide, exclusive development and commercial rights to MAU868, a potentially first-in-class monoclonal antibody to treat reactivated BK virus infections, for which we completed a Phase 2 clinical trial in 2022. In January 2025, we acquired worldwide, exclusive development and commercial rights to VT-109, a novel, next-generation BAFF and APRIL inhibitor that is in preclinical development. We believe that our current pipeline programs leverage the deep expertise of our team and have strong potential commercial synergies.

We currently have only one product approved for commercial sale and expect to record limited revenue from product sales during the third quarter of 2026. Our ability to generate revenue sufficient to achieve profitability, if ever, will depend on the

successful commercialization of our lead product and development of our product candidates, which we expect will take a number of years. We also do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of our lead product and product candidates. We believe that this strategy allows us to maintain a more efficient infrastructure by eliminating the need for us to invest in our own manufacturing facilities, equipment, and personnel while also enabling us to focus our expertise and resources on the successful commercialization of our lead product and development of our product candidates.

To date, we have funded our operations primarily through proceeds from the sale of shares of our common stock, redeemable convertible preferred stock, debt financing and convertible promissory notes. As of June 30, 2026, we had $499.2 million in cash, cash equivalents and marketable securities, compared to $714.6 million as of December 31, 2025.

We have incurred significant operating losses since the commencement of our operations. Our net losses were $109.5 million and $76.5 million for the three months ended June 30, 2026 and 2025, respectively, and we expect to incur significant and increasing losses for the foreseeable future as we commercialize our lead product and continue to advance our product candidates toward commercialization. Our net losses may fluctuate significantly from period to period, depending on the timing of expenditures on our research and development activities. As of June 30, 2026, we had an accumulated deficit of $991.4 million, compared to $760.9 million as of December 31, 2025. Our primary use of cash is to fund operating expenses, which consist of research and development and general and administrative expenditures. Cash used to fund operating expenses depends on the timing of when we pay these expenses, as reflected in the changes in our working capital balances.

We expect to continue to incur net operating losses in the near term, and we expect our research and development expenses, general and administrative expenses, and capital expenditures will continue to increase. We expect our expenses and capital requirements will increase significantly in connection with our ongoing activities as we:

- initiate or continue nonclinical studies and clinical trials for our lead product and product candidates;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- continue to scale up external manufacturing capacity with the aim of securing sufficient quantities to meet our capacity requirements for clinical trials and potential commercialization;
- establish a sales, marketing and distribution infrastructure to commercialize approved product candidates and related additional commercial manufacturing costs;
- develop, maintain, expand, protect and enforce our intellectual property portfolio, including patents, trade secrets, and know-how;
- acquire, develop or in-license other product candidates and technologies and further expand our clinical product pipeline;
- attract, develop and retain additional clinical, scientific, quality control, commercial, and manufacturing management and administrative personnel; and
- add clinical, operational, financial and management information systems and personnel, including personnel to support our product development and commercialization efforts.

We also expect to increase the size of our administrative function to support the growth of our business. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and our expenditures on other research and development activities.

We will require substantial additional funding to successfully commercialize our lead product, develop our product candidates and support our continuing operations. Until such time that we can generate significant revenue from product sales or other sources, if ever, we expect to finance our operations through the sale of equity, debt financings, or other capital sources, which could include income from collaborations, strategic partnerships, or marketing, distribution, licensing or other strategic arrangements with third parties, or from grants. We may be unable to raise additional funds or to enter into such agreements or arrangements on favorable terms, or at all. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the disruptions to, and volatility in, the credit and financial markets in the United States and worldwide. Our failure to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on our business, results of operations or financial condition, including requiring us to have to delay, reduce or eliminate our product development or commercialization efforts. Insufficient liquidity may also require us to relinquish rights to our lead product or product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our development efforts. We cannot provide assurance that we will ever be profitable or generate positive cash flow from operating activities.

Geopolitical and Macroeconomic Developments

Due to geopolitical and macroeconomic events, including bank failures, tariffs and trade tensions, supply chain challenges, ongoing military conflicts, related sanctions, changes in U.S.-China relations, elevated inflation rates and the responses by central banking authorities to control such inflation, the U.S. and global financial markets experienced volatility, which has led to disruptions to trade, commerce, pricing stability, credit availability and supply chain continuity globally. As a result of these factors and other geopolitical and macroeconomic developments described in this Quarterly Report on Form 10-Q, our business and results of operations may be adversely affected.

Although we did not see a significant financial impact to our business operations as a result of recent geopolitical and macroeconomic developments during the three months ended June 30, 2026, there may be potential impacts to our business in the future that are highly uncertain and difficult to predict such as disruptions or restrictions in our supply chain, disruption or restrictions on our employees' ability to travel, disruptions to or delays in ongoing non-clinical trials, clinical trials, third-party manufacturing supply and other operations, interruptions or delays in the operations of the FDA or other regulatory authorities, and continued elevated inflation and interest rates which may increase the cost of conducting business activities or cause changes in availability and cost of credit and impact our ability to raise capital and conduct business development activities. The ultimate impact of these geopolitical and macroeconomic developments, as well as any lasting effects on our business, is highly uncertain and subject to continued change, and we recognize that macroeconomic and geopolitical factors may continue to present unique challenges for us.

We believe that our existing cash, cash equivalents and marketable securities held as of June 30, 2026, will be sufficient to fund our planned operations and capital expenditure requirements for at least the next 12 months from the date of this Quarterly Report on Form 10-Q. However, should adverse geopolitical or macroeconomic events, such as those discussed above, any recession or depression associated with those events or other events described herein, continue for a prolonged period, our results of operations, financial condition, liquidity and cash flows could be materially impacted as a result of a lower likelihood of successfully commercializing our lead product and effectively developing our product candidates.

Results of Operations

Comparison of the Three and Six Months Ended June 30, 2026 and 2025

The following table summarizes our results of operations for the periods presented:

	Three Months Ended June 30,			Six Months Ended June 30,		
(dollars in thousands)	2026	2025	Change	2026	2025	Change
Operating expenses:						
Research and development	$ 60,080	$ 58,195	$ 1,885	$ 146,091	$ 99,473	$ 46,618
General and administrative	52,410	21,946	30,464	91,531	37,862	53,669
Total operating expenses	112,490	80,141	32,349	237,622	137,335	100,287
Loss from operations	(112,490)	(80,141)	(32,349)	(237,622)	(137,335)	(100,287)
Other income (expense):						
Interest income	5,348	6,320	(972)	11,703	13,226	(1,523)
Interest expense	(1,848)	(1,874)	26	(3,671)	(3,667)	(4)
Other (expense) income, net	(483)	(836)	353	(915)	(449)	(466)
Total other income	3,017	3,610	(593)	7,117	9,110	(1,993)
Net loss	$ (109,473)	$ (76,531)	$ (32,942)	$ (230,505)	$ (128,225)	$ (102,280)

Research and Development Expenses

Research and development expenses represent a substantial portion of our operating expenses. Our research and development expenses consist primarily of direct and indirect expenses incurred in connection with the research and development of our lead product and product candidates. Direct expenses include costs incurred under agreements with third parties, including contract research organizations, contract drug manufacturing organizations and consultants directly related to our research and development of our lead product and product candidates, and license and milestone fees incurred as a result of our contractual obligations for our development candidates. Until we receive marketing approval for a product candidate, all drug manufacturing costs are expensed as research and development. Indirect expenses include employee compensation and other personnel-related expenses, including stock-based compensation, facilities and depreciation related to buildings and equipment used by research and development personnel and activities and other expenses.

Research and development expenses are recorded as expense in the period in which the related activities occurred, and payments we make prior to the receipt of goods or services to be used in research and development efforts are deferred as prepaid expenses until

the goods or services are received and used. We accrue expenses for contract research and development as the related services are performed by monitoring the status of specified activities and billings received from our external service providers. These expenses are accrued based on estimates and are adjusted as actual expenses become known. The cost incurred in obtaining technology licenses, including initial and subsequent milestone payments incurred under our licensing agreements, are recorded as expense in the period in which they are incurred, as the licensed technology, method or process has no alternative future uses other than for our research and development activities. Where contingent milestone payments related to development-stage programs are due to third parties under license or other agreements, the milestone payment obligations are recognized as expense when achievement of the contingent milestone is probable, which is generally upon achievement of the milestone.

The following table summarizes our research and development expenses incurred during the respective periods:

	Three Months Ended June 30,			Six Months Ended June 30,		
(dollars in thousands)	2026	2025	Change	2026	2025	Change
Direct research and development expenses						
Contract drug manufacturing	$ 15,742	$ 23,498	$ (7,756)	46,197	$ 33,040	$ 13,157
Clinical trial expenses	15,633	12,636	2,997	29,229	23,880	5,349
Consulting and professional services	5,571	6,613	(1,042)	9,889	12,772	(2,883)
License and milestone obligations	—	—	—	15,100	750	14,350
Indirect research and development expenses						
Employee compensation and related benefits	21,390	14,191	7,199	42,318	26,562	15,756
Facilities and other	1,744	1,257	487	3,358	2,469	889
Research and development expenses	$ 60,080	$ 58,195	$ 1,885	$ 146,091	$ 99,473	$ 46,618

Research and development expenses increased by $1.9 million, or 3%, to $60.1 million in the three months ended June 30, 2026, from $58.2 million in the three months ended June 30, 2025, due to an increase of $7.2 million for employee compensation and related benefit expenses, including a $2.7 million increase in stock-based compensation expense, as a result of growth in research and development employee headcount, an increase of $3.0 million in clinical trial expenses mainly due to increased expenses for the PIONEER and ORIGIN EXTEND trials, and an increase of $0.5 million in facilities and other, including a $0.3 million increase in travel expenses supporting research and development activities, partially offset by a decrease of $7.8 million in contract drug manufacturing costs for clinical and potential commercial use and a decrease of $1.0 million in consulting and professional services, primarily related to advisory board and expert forum activities incurred in 2025.

Research and development expenses increased by $46.6 million, or 47%, to $146.1 million in the six months ended June 30, 2026, from $99.5 million in the six months ended June 30, 2025, due to an increase of $15.8 million for employee compensation and related benefit expenses, including a $5.7 million increase in stock-based compensation expense, as a result of growth in research and development employee headcount, an increase of $14.4 million in license and milestone expense related to current period recognition of a $15.0 million milestone payment due upon filing of the BLA, an increase of $13.2 million in contract drug manufacturing costs for clinical and potential commercial use, an increase of $5.3 million in clinical trial expenses mainly due to increased expenses for the PIONEER and ORIGIN EXTEND trials, and an increase of $0.9 million in facilities and other, including a $0.6 million increase in travel expenses supporting research and development activities, partially offset by a decrease of $2.9 million in consulting and professional services, primarily related to advisory board and expert forum activities incurred in 2025.

Prior to receiving accelerated approval from the FDA for TRUTAKNA on July 7, 2026, we recorded all manufacturing costs as research and development expenses as incurred, including costs for materials and work in process that we intend to use for commercial supply. From July 7, 2026 and onward, manufacturing costs incurred for commercial inventory will be capitalized as current assets and later recorded to expense as cost of sales in the periods in which sales of the related inventory are recognized.

We expect our research and development expenses to increase in future periods as we seek full regulatory approval of atacicept in IgAN in the U.S. and regulatory approval in other non-U.S. markets, conduct additional clinical trials of atacicept, and if we expand development of atacicept in other indications or product configurations, or advance other product candidates.

General and Administrative Expenses

General and administrative expenses consist primarily of compensation and personnel-related expenses, including stock-based compensation, for our personnel in executive management, legal, finance, human resources, corporate communications, sales and marketing and other administrative functions. General and administrative expenses also include professional fees paid for accounting, auditing, legal, tax and consulting services, and other general overhead costs to support our operations. General and administrative expenses are recorded as expense in the period in which they are incurred, and payments we make prior to the receipt of goods or

services to be used for general and administrative purposes are deferred as prepaid expenses until the goods or services are received and used.

The following table summarizes our general and administrative expenses incurred during the respective periods:

(dollars in thousands)	Three Months Ended June 30, 2026	2025	Change	Six Months Ended June 30, 2026	2025	Change
Employee compensation and related benefits	$ 27,153	$ 11,002	$ 16,151	$ 48,266	$ 19,387	$ 28,879
Commercial planning and medical affairs	15,297	3,811	11,486	23,924	5,147	18,777
Legal, accounting and audit fees	1,841	1,883	(42)	4,009	3,668	341
Software	1,520	868	652	2,764	1,191	1,573
Consultants, including non-employee director compensation	1,410	1,142	268	2,593	2,654	(61)
Other	5,189	3,240	1,949	9,975	5,815	4,160
General and administrative expenses	$ 52,410	$ 21,946	$ 30,464	$ 91,531	$ 37,862	$ 53,669

General and administrative expenses increased by $30.5 million, or 139%, to $52.4 million in the three months ended June 30, 2026, from $21.9 million in the three months ended June 30, 2025, primarily due to an increase of $16.2 million in employee compensation and related benefits expenses, including stock-based compensation, as a result of increased general and administrative employee headcount including sales personnel, an increase of $11.5 million in commercial planning and medical affairs expenses related to marketing, market research, market access, medical information, and health economics activities in preparation for the anticipated commercial launch of TRUTAKNA, an increase of $0.7 million in software expenses primarily supporting anticipated commercial operations, and an increase of $0.3 million in consulting expenses. The $1.9 million increase in other general and administrative expenses was primarily driven by increases of $1.2 million in corporate communications expenses and $0.9 million in business travel expenses, partially offset by decreases of $0.3 million in recruiting and placement expenses and $0.2 million in rent and facilities expenses.

General and administrative expenses increased by $53.7 million, or 142%, to $91.5 million in the six months ended June 30, 2026, from $37.9 million in the six months ended June 30, 2025, primarily due to an increase of $28.9 million in employee compensation and related benefits expenses, including stock-based compensation, as a result of increased general and administrative employee headcount including sales personnel, an increase of $18.8 million in commercial planning and medical affairs expenses related to marketing, market research, market access, medical information, and health economics activities in preparation for the anticipated commercial launch of TRUTAKNA, an increase of $1.6 million in software expenses to support scaling operations, and an increase of $0.3 million in legal, accounting, and audit expenses, partially offset by a decrease of $0.1 million in consulting expenses. The $4.2 million increase in other general and administrative expenses was primarily driven by increases of $1.9 million in corporate communications expenses, $1.6 million in business travel expenses, $0.6 million in recruiting and placement expenses, and $0.4 million in information technology expenses.

We expect our general and administrative expenses to increase in future periods as we scale up commercial manufacturing capacity, continue to build out a sales, marketing, and distribution infrastructure to support TRUTAKNA and any other approved product candidates, and provide general and administrative support for our operations.

Other Income, Net

(dollars in thousands)	Three Months Ended June 30, 2026	2025	Change	Six Months Ended June 30, 2026	2025	Change
Other income (expense):						
Interest income	$ 5,348	$ 6,320	$ (972)	$ 11,703	$ 13,226	$ (1,523)
Interest expense	(1,848)	(1,874)	26	(3,671)	(3,667)	(4)
Other (expense) income, net	(483)	(836)	353	(915)	(449)	(466)
Total other income, net	$ 3,017	$ 3,610	$ (593)	$ 7,117	$ 9,110	$ (1,993)

Other income, net, decreased by $0.6 million, or 16%, to $3.0 million for the three months ended June 30, 2026, from $3.6 million in the three months ended June 30, 2025, primarily due to a decrease of $1.0 million in interest income resulting from lower average balances of marketable securities held during the three months ended June 30, 2026, as compared to the three months ended June 30, 2025, and a decrease in sublease income of $0.5 million due to the expiration of a sublease to a third-party in September 2025, partially offset by a decrease of $0.5 million in amortization of deferred debt issuance costs for unfunded loan commitments relating to the refinancing of the Oxford credit facility in June 2025.

Other income, net, decreased by $2.0 million, or 22%, to $7.1 million for the six months ended June 30, 2026, from $9.1 million in the six months ended June 30, 2025, primarily due to a decrease of $1.5 million in interest income resulting from lower average balances of marketable securities held during the three months ended June 30, 2026, as compared to the three months ended June 30, 2025 and a decrease in sublease income of $1.0 million due to the expiration of a sublease to a third-party in September 2025, partially offset by an increase of $0.2 million in currency exchange gains and losses and an increase of $0.3 million in unrealized gains and losses.

Liquidity and Capital Resources

To date, we have funded our operations primarily through proceeds from the sale of shares of our common stock, redeemable convertible preferred stock, debt financing and convertible notes. From our inception through June 30, 2026, we have raised aggregate net cash proceeds of approximately $1.3 billion from the issuance and sale of redeemable convertible preferred stock, convertible notes and common stock, and proceeds from our Loan Agreements with Oxford. Since the date of our incorporation, we have not generated any revenue from product sales and have incurred substantial operating losses and negative cash flows from operations.

In June 2025, we entered into an agreement to refinance our existing debt by replacing the existing $50.0 million in notes payable with $75.0 million in new notes payable. We received aggregate net proceeds of approximately $23.3 million, after deducting debt issuance costs.

In December 2025, we completed a follow-on public offering and issued 7,058,824 shares of common stock for net proceeds of approximately $281.3 million, after deducting underwriting fees and offering-related expenses.

In August 2025, we entered into a Sales Agreement (the Sales Agreement) with TD Securities (USA) LLC (TD Cowen). Under the Sales Agreement, we may offer and sell, from time to time, through TD Cowen as our sales agent and/or principal, shares of our common stock, having an aggregate offering amount of up to $200 million (the Shares). We are not obligated to sell Shares under the Sales Agreement. We will pay TD Cowen a commission of up to 3.0% of the gross sales proceeds of any Shares sold through TD Cowen under the Sales Agreement. As of June 30, 2026, there have been no sales under the Sales Agreement.

We use our cash to fund operations, primarily to fund our research and development efforts, including clinical trials, build a sales, marketing and distribution infrastructure to support commercial activities, establish and maintain our intellectual property portfolio, hire personnel, raise capital, and provide general and administrative support for these operations. Cash used to fund operating expenses is affected by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable, accrued expenses and prepaid assets.

We anticipate that we will continue to incur net losses for the foreseeable future as we continue research and development activities for our lead product and product candidates, hire additional staff, including clinical, commercial, operational, administrative and management personnel, and incur additional expenses associated with operating as a public company. We expect to incur significant expenses and operating losses for the foreseeable future as we continue to commercialize TRUTAKNA and advance our clinical development activities and our product candidate portfolio. We expect that our research and development and selling, general and administrative costs will increase substantially in connection with conducting additional clinical trials for our research programs, lead product, and product candidates, contracting with third parties to support nonclinical studies and clinical trials, expanding our intellectual property portfolio, scaling up external commercial manufacturing capacity, continuing to build a sales, marketing and distribution infrastructure to successfully commercialize TRUTAKNA and any other approved product candidates, and providing general and administrative support for our operations. As a result, we will need additional capital to fund our operations, which we may obtain from additional equity or debt financings, collaborations, licensing arrangements, or other sources.

As of June 30, 2026, we had cash, cash equivalents and marketable securities of $499.2 million, as compared to $714.6 million as of December 31, 2025. We believe, based on our current operating plan, that our cash, cash equivalents and marketable securities as of June 30, 2026 will be sufficient to fund our planned operations and capital expenditure requirements for at least the next 12 months from the date of this Quarterly Report on Form 10-Q.

Cash Flows

The following table summarizes our cash flows for the periods indicated:

	Six Months Ended June 30,	
(dollars in thousands)	**2026**	**2025**
Net cash used in operating activities	$ (206,753)	$ (109,204)
Net cash provided by (used in) investing activities	(104,956)	43,861
Net cash provided by financing activities	5,860	21,818
Net decrease in cash and cash equivalents	$ (305,849)	$ (43,525)

Operating Activities

In the six months ended June 30, 2026, we used $206.8 million of cash in operating activities, attributable to a net loss of $230.5 million and an increase in our net operating assets and liabilities of $20.2 million, partially offset by $15.0 million in license fees attributable to investing activities and adjustments for non-cash charges of $28.9 million. Non-cash charges primarily consisted of $29.1 million of stock-based compensation and $1.3 million net in accretion and amortization of loan exit fees and costs, partially offset by non-cash interest income of $1.9 million related to amortization of discount on purchases of marketable securities. The change in our net operating assets and liabilities was primarily due to a decrease of $7.3 million in accounts payable, an increase of $14.6 million in prepaid expense and other current assets, and a decrease of $0.4 million in operating lease liabilities, partially offset by an increase of $2.1 million in accrued and other current liabilities.

In the six months ended June 30, 2025, we used $109.2 million of cash in operating activities, attributable to a net loss of $128.2 million, partially offset by adjustments for non-cash charges of $14.3 million, $0.8 million in license fees attributable to investing activities, and a decrease in our net operating assets and liabilities of $3.9 million. Non-cash charges primarily consisted of $17.2 million of stock-based compensation, non-cash interest income of $4.4 million related to amortization of discount on purchases of marketable securities, and a $0.9 million reduction in the carrying amount of operating lease right-of-use assets. The change in our net operating assets and liabilities was primarily due to an increase of $3.3 million in accrued and other current liabilities and an increase of $5.5 million in accounts payable, partially offset by an increase of $4.2 million in prepaid expense and other current assets and a decrease of $0.9 million in operating lease liabilities.

The increase in cash used in operating activities from the six months ended June 30, 2025 to the six months ended June 30, 2026 was primarily attributable to increased research and development and general and administrative expenses.

Investing Activities

In the six months ended June 30, 2026, our investing activities used $104.9 million of cash, primarily resulting from $308.6 million used for purchases of marketable securities and $15.0 million paid in license fees, partially offset by $218.9 million provided by maturities of marketable securities.

In the six months ended June 30, 2025, our investing activities provided $43.9 million of cash, primarily resulting from $232.3 million provided by maturities of marketable securities, partially offset by $187.3 million used for purchases of marketable securities.

Financing Activities

In the six months ended June 30, 2026, our financing activities provided $5.9 million of cash, resulting from proceeds from exercise of stock options and issuance of shares under our employee stock purchase plan.

In the six months ended June 30, 2025, our financing activities provided $21.8 million of cash, resulting from $23.3 million in net proceeds from borrowings from the initial funding under the 2025 Loan Agreement in June 2025, after repayment of borrowings under the 2021 Loan Agreement, $2.0 million in proceeds from exercise of stock options and issuance of shares under our employee stock purchase plan, and $3.5 million in payment of deferred issuance costs related to unfunded loan commitments under the 2025 Loan Agreement.

Material Cash Requirements

During the six months ended June 30, 2026, there were no material changes to our contractual obligations and commitments from those described under “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in the Annual Report.

2021 Loan Agreement

On December 17, 2021, we entered into a Loan and Security Agreement (the 2021 Loan Agreement) with a loan syndicate involving Oxford Finance LLC, Oxford Finance Credit Fund II LP (OFCF II), and Oxford Finance Credit Fund III LP (OFCF III). The 2021 Loan Agreement provided for term loans (collectively, the Loan) in an aggregate maximum principal amount of $50.0 million, of which $5.0 million was funded on December 17, 2021, $20.0 million was funded on November 4, 2022, and the remaining $25.0 million was funded in December 2023.

In March 2023, we opted to extend the final maturity date of the Loan from December 2026 to December 2027, based on positive Phase 2b clinical trial data of atacicept in IgAN, as provided in the 2021 Loan Agreement. We were required to make monthly interest-only payments for 60 months followed by full amortization through maturity.

In June 2025, we refinanced our debt under the 2021 Loan Agreement by entering into a new non-revolving loan and security agreement, the proceeds of which were partially used to prepay the outstanding principal balance of the 2021 Loan Agreement in full. As a result, we no longer have any contractual obligations and commitments under the 2021 Loan Agreement.

2025 Loan Agreement

On June 2, 2025, we entered into a Loan and Security Agreement (the 2025 Loan Agreement) with a loan syndicate involving Oxford Finance, OFCF II, OFCF III, and Oxford Finance Credit Fund IV LP (OFCF IV) (collectively, Oxford). The 2025 Loan Agreement provides for term loans (collectively, the 2025 Loan) in an aggregate maximum principal amount of $500.0 million, of which $75.0 million was funded on June 4, 2025.

The 2025 Loan Agreement is scheduled to mature in June 2030, but the maturity date can be extended based on achievement of a revenue-based interest-only extension milestone as of the end of the initial interest-only period in August 2029. If the Company achieves this interest-only extension milestone, the maturity date and the end of the interest-only period will be extended to June 2031 and August 2030, respectively. We are required to make monthly interest-only payments for 49 months (or 61 months upon achievement of the revenue-based interest-only extension milestone mentioned above) followed by full amortization through maturity.

The 2025 Loan incurs interest at a floating per annum rate (based on the actual number of days elapsed divided by a year of 360 days) equal to the sum of (a) the greater of (i) the 1-Month CME Term Secured Overnight Financing Rate (SOFR) and (ii) 3.75%, plus (b) 4.95%.

We are permitted to prepay the 2025 Loan in full or in part at any time upon 10 business days' written notice to Oxford, subject to payment of the applicable Prepayment Fee (as defined in (c) below). Upon the earliest to occur of the maturity date, acceleration of the 2025 Loan or prepayment of the 2025 Loan, we are required to make a final payment equal to 5.0% of the aggregate principal amount of the 2025 Loan (the Final Fee). Any prepayments of the 2025 Loan must be accompanied by (a) accrued and unpaid interest thereon, (b) the Final Fee and (c) prepayment fee of (i) 2.0% of the portion of the 2025 Loan being prepaid if the repayment is on or before June 4, 2027 or (ii) 1.0% of the portion of the 2025 Loan being prepaid if the repayment is after June 4, 2027 through June 4, 2028 (the Prepayment Fee). There is no Prepayment Fee for any prepayments occurring after June 4, 2028.

Our obligations under the 2025 Loan Agreement are secured by a security interest in substantially all of our assets, other than our intellectual property, which is subject to a negative pledge. The 2025 Loan Agreement contains two financial related covenants. Also included in the 2025 Loan Agreement are customary representations and covenants that, subject to exceptions, restrict our ability to, among other things: declare dividends or redeem or repurchase equity interests; incur additional liens; make loans and investments; incur additional indebtedness; engage in mergers, acquisitions, and asset sales; transact with affiliates; undergo a change in control; add or change business locations; and engage in businesses that are not related to our existing business.

Upon the occurrence of an event of default, a default interest rate of an additional 4.0% may be applied to the outstanding loan balances, and Oxford may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the 2025 Loan Agreement. Events of default under the 2025 Loan Agreement include customary events of default, including, but not limited to: (i) non-payment; (ii) failure to perform any obligation under the 2025 Loan Agreement and related documents; (iii) the occurrence of a material adverse change; (iv) bankruptcy and other insolvency events; (v) cross-defaults; and (vi) judgment defaults.

Critical Accounting Policies and Significant Judgments and Estimates

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

Our critical accounting policies are described in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Policies and Significant Judgments and Estimates" in the Annual Report and the notes to our unaudited condensed financial statements appearing elsewhere in this Quarterly Report on Form 10-Q. During the six months ended June 30, 2026, there were no material changes to our critical accounting policies and estimates from those discussed in the Annual Report.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest rate risk

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities. As of December 31, 2025 and June 30, 2026, we had cash, cash equivalents, and marketable securities of $714.6 million and $499.2 million, respectively, consisting primarily of money market funds, U.S. government bonds, and corporate debt securities.

Our primary exposure to market risk is interest rate sensitivity in our fixed income portfolio, which is affected by changes in the general level of U.S. interest rates. Due to the short-term duration of our investment portfolio and the low risk profile of our investment portfolio, an immediate 100 basis point change in interest rates as of December 31, 2025 and June 30, 2026 would not have a material effect on the fair market value of our cash, cash equivalents, and marketable securities. We have the ability to hold our investments until maturity, and therefore, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on our investment portfolio.

We are also exposed to interest rate risk in connection to our borrowings under our 2025 Loan Agreement with Oxford. As of June 30, 2026, we had $75.0 million of outstanding borrowings under the 2025 Loan Agreement. Pursuant to the 2025 Loan Agreement, outstanding indebtedness under the term loan bears interest at a per annum rate equal to the sum of (a) the greater of (i) the 1-Month CME Term SOFR (Term SOFR) and (ii) 3.75%, plus (b) 4.95%. We currently do not engage in any interest rate hedging activity, and we have no intention to do so in the foreseeable future. Based on the current interest rate of the term loan and the scheduled payments thereunder, we do not believe a 1.0% increase in the Term SOFR would have a material impact on our financial condition or results of operations. For more information regarding the 2025 Loan Agreement, see Note 5, Notes Payable, to our unaudited condensed financial statements.

Financial institution risk

Substantially all of our cash is held with a single financial institution. Due to its size, this financial institution represents a minimal credit risk. Cash amounts held at financial institutions are insured by the Federal Deposit Insurance Corporation up to $250,000 per depositor, per financial institution.

Foreign currency exchange risk

We are also exposed to market risk related to changes in foreign currency exchange rates, including recent changes resulting from monetary policies set by the U.S. and international central banks, inflationary pressures, and geopolitical developments, or instability or volatility in the global markets. From time to time, we contract with vendors that are located in Asia and Europe and whose balances due are denominated in foreign currencies. We are subject to fluctuations in foreign currency rates in connection with these agreements. We do not currently hedge our foreign currency exchange rate risk. As of June 30, 2026 and December 31, 2025, we held limited funds and future obligations denominated in foreign currencies. As such, a 10.0% increase or decrease in current exchange rates would not have a material effect on our financial results.

Effects of inflation

Inflation generally affects us by increasing our cost of labor, pricing of contracts for clinical trial and manufacturing costs, and indirectly, interest rates. We do not believe that inflation has had a material effect on our business, financial condition, or results of operations during the periods presented.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer (CEO) and chief financial officer (CFO), evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (Exchange Act)). 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 management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Based upon such evaluation, our CEO and CFO concluded that, as of June 30, 2026, our disclosure controls and procedures are effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC, and that such information is accumulated and communicated to our management, including our CEO and CFO, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

We identified no changes in our internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) during the quarter ended June 30, 2026, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are not currently a party to any material legal proceedings. Regardless of outcome, such proceedings or claims can have an adverse impact on us because of defense and settlement costs, diversion of resources and other factors, and there can be no assurances that favorable outcomes will be obtained.

Item 1A. Risk Factors.

An investment in shares of our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Quarterly Report on Form 10-Q, including our unaudited condensed financial statements and the related notes and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" before deciding whether to purchase, hold or sell shares of our common stock. The occurrence of any of the risks described below could harm our business, financial condition, results of operations, growth prospects, and/or stock price or 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 consider all of the risk factors described when evaluating our business.

Risks related to our financial position and need for additional capital

We have completed a limited number of clinical trials for our lead product, TRUTAKNA, and have only recently received accelerated approval for commercial sale in the United States, which may make it difficult to evaluate our current business and predict our future success and viability.

We are a commercial-stage biotechnology company and, until July 7, 2026, we had no products approved for commercial sale. At this time, we expect to record limited revenue from product sales during the third quarter of 2026 and have incurred losses since inception. To date, we have devoted substantially all of our resources to our research and development efforts, pre-clinical studies and clinical trials, preparing for commercialization, establishing and maintaining our intellectual property portfolio, hiring personnel, raising capital and providing general and administrative support for these operations. We have not yet demonstrated over an extended period of time our ability to successfully conduct sales and marketing activities necessary for successful product commercialization. As a result, it may be more difficult to accurately predict our future success or viability than it would be if we had a longer operating history.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by biotechnology companies in rapidly evolving fields. We may face difficulty transitioning from a company with a clinical development focus to a company capable of supporting successful commercial operations. If we do not adequately address these risks and difficulties or successfully make such a transition, our business, financial condition, results of operations and prospects will be significantly harmed.

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

Developing treatments for immunological and rare diseases, including conducting nonclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception, and we expect our expenses will increase in connection with our ongoing activities, particularly as we continue our commercialization efforts for our lead product and continue to conduct clinical trials of, and seek marketing approval for, our product candidates. We anticipate incurring significant commercialization expenses related to drug sales, marketing, manufacturing, and distribution costs associated with our commercialization efforts for our lead product. In addition, we expect to incur significant costs associated with the development of our product candidates. Our expenses could increase beyond expectations if we are required by the FDA, or any comparable foreign regulatory authority, to perform clinical trials or nonclinical studies in addition to those that we currently anticipate. Other unanticipated costs may also arise. We cannot reasonably estimate the actual amounts necessary to successfully commercialize our lead product or to complete the development of our product candidates. We also will continue to incur costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to maintain our continuing operations.

As of June 30, 2026, we had $499.2 million in cash, cash equivalents and marketable securities. We expect that our existing cash, cash equivalents and marketable securities will be sufficient to fund our planned operations and capital expenditure requirements beyond the next 12 months from the date of this Quarterly Report on Form 10-Q. Our estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of

which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned. Moreover, it is particularly difficult to estimate with certainty our future expenses given the dynamic nature of our business and the macroeconomic and geopolitical environment generally. We anticipate that our expenses will increase substantially if, and as, we:

- initiate or continue nonclinical studies and clinical trials for our lead product and product candidates;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- continue to scale up external manufacturing capacity with the aim of securing sufficient quantities to meet our capacity requirements for clinical trials and potential commercialization;
- establish and continue to build a sales, marketing and distribution infrastructure to commercialize any approved products and related additional commercial manufacturing costs;
- develop, maintain, expand, protect and enforce our intellectual property portfolio, including patents, trade secrets, and know-how;
- acquire, develop or in-license other product candidates and technologies and further expand our clinical product pipeline;
- attract, develop and retain additional clinical, scientific, quality control, commercial, and manufacturing management and administrative personnel; and
- add clinical, operational, financial and management information systems and personnel, including personnel to support our product development and ongoing and future commercialization efforts.

Successfully commercializing our lead product and advancing the development of our product candidates will require a significant amount of capital. Our working capital and available credit will not be sufficient to fund all of the activities that are necessary to successfully commercialize our lead product and complete the development of our product candidates through approval and commercial launch.

We will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources, which may dilute our stockholders or restrict our operating activities. Adequate additional financing may not be available to us on acceptable terms, or at all. Adverse geopolitical and macroeconomic developments, such as potential disruptions in access to bank deposits and lending commitments due to bank failures, ongoing military conflicts, related sanctions, actual and anticipated changes in interest rates, economic inflation and the responses by central banking authorities to control such inflation, could affect our ability to access capital as and when needed. Our failure to raise capital as and when needed, or on acceptable terms, would have a negative impact on our financial condition and our ability to pursue our business strategy, and we may have to delay, reduce the scope of, suspend or eliminate one or more of our research-stage programs, clinical trials, or ongoing or future commercialization efforts.

We have incurred net losses since inception and expect to record limited revenue from product sales during the third quarter of 2026. We expect to continue to incur net losses at least until we have one or more approved products that achieve commercial success.

We have incurred net losses in each reporting period since the commencement of our operations and expect to record limited revenue from product sales during the third quarter of 2026. We had net losses of $109.5 million and $76.5 million for the three months ended June 30, 2026 and 2025, respectively. We had an accumulated deficit of $991.4 million as of June 30, 2026. Our losses have resulted principally from expenses incurred in research and development and from general and administrative costs and other expenses that we have incurred while building our business infrastructure. Our product candidates are in clinical and pre-clinical development. Even though TRUTAKNA received accelerated approval by the FDA for the treatment of IgAN in the U.S. in July 2026, we expect that it will be years, if ever, before revenue from product sales will result in net income. In addition, we expect that we will continue to incur substantial research and development and other expenses as we continue the clinical development programs for our lead product and product candidates in other indications.

We expect to continue to incur increased expenses and operating losses for the foreseeable future as we continue to commercialize our lead product, continue our research and development efforts and seek to obtain regulatory approval for our product candidates. The net losses we incur may fluctuate significantly from quarter to quarter such that a period-to-period comparison of our results of operations may not be an indication of our future performance. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had, and will continue to have, an adverse effect on our working capital. In any particular period, our operating results could be below the expectations of securities analysts or investors, which could cause our stock price to decline.

We have incurred losses and negative cash flows from operations. As a company which received its first FDA accelerated approval for a product in July 2026, we expect to continue to incur significant losses at least until we successfully commercialize a

product. Successful commercialization of a product is not guaranteed and may never be achieved. As a result, there is a possibility that the company may never be profitable.

Our ability to generate revenue from product sales and achieve profitability depends on our ability, alone or with our collaboration partners, to successfully commercialize our lead product and complete the development of, and obtain the regulatory approvals necessary to commercialize our product candidates. Our ability to generate revenue from product sales depends heavily on our and our potential future collaborators' success in:

- completing clinical development of product candidates and programs and identifying and developing new product candidates;
- seeking and obtaining marketing approvals for any product candidates that we develop;
- launching and commercializing approved products by establishing a sales force, marketing, medical affairs and distribution infrastructure or, alternatively, collaborating with a commercialization partner;
- achieving adequate access and reimbursement by government and third-party payors for our lead product and product candidates that we develop;
- establishing and maintaining supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development of our product candidates and the market demand for our lead product and product candidates that we develop, if approved;
- obtaining market acceptance of our lead product and any product candidates that we develop as viable treatment options;
- addressing any competing technological and market developments;
- maintaining our rights under our existing license agreements and any similar agreements we may enter into in the future;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter and performing our obligations in such collaborations;
- maintaining, protecting, enforcing and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how;
- defending against third-party interference, infringement or other intellectual property-related claims, if any; and
- attracting, developing and retaining qualified personnel.

Even if a product candidate that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing such approved product candidate, including our lead product. Our expenses could increase beyond expectations if we are required by the FDA or comparable foreign regulatory authorities to perform clinical trials or nonclinical studies in addition to those that we currently anticipate. Even if we are able to generate revenue from the sale of any approved products, we may not be able to reach or sustain profitability, and may need to obtain additional funding to continue operations.

The terms of our loan agreement place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.

In June 2025, we entered into a Loan and Security Agreement (2025 Loan Agreement) with a loan syndicate involving Oxford Finance LLC, Oxford Finance Credit Fund II LP, Oxford Finance Credit Fund III LP, and Oxford Finance Credit Fund IV LP (collectively, Oxford) providing for borrowing capacity of up to $500.0 million. As of June 30, 2026, our outstanding debt balance under the 2025 Loan Agreement was $75.0 million. Our overall leverage and certain obligations and affirmative and negative covenants contained in the related documentation could adversely affect our financial health and business and future operations by limiting our ability to, among other things, satisfy our obligations under the 2025 Loan Agreement, refinance our debt on terms acceptable to us or at all, plan for and adjust to changing business, industry and market conditions, use our available cash flow to fund future acquisitions and make dividend payments, and obtain additional financing for working capital, to fund growth or for general corporate purposes, even when necessary to maintain adequate liquidity.

If we default under the 2025 Loan Agreement, Oxford may accelerate all of our repayment obligations and exercise all of their rights and remedies under the 2025 Loan Agreement and applicable law, potentially requiring us to renegotiate our agreement on terms less favorable to us. Further, if we are liquidated, the lenders' right to repayment would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation. Oxford could declare a default upon the occurrence of customary events of default, including events that they interpret as a material adverse change as delineated in the 2025 Loan Agreement, payment defaults or breaches of certain affirmative or negative covenants, thereby requiring us to repay the loan immediately. Any declaration by the lender of an event of default could significantly harm our business and prospects and could cause the price of our common

stock to decline. Additionally, if we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

Risks related to the successful commercialization of our lead product and the development of our product candidates

TRUTAKNA is our only FDA-approved product and the success of our business depends, in part, on its successful commercialization.

TRUTAKNA was recently approved by the FDA for the treatment of IgAN. The success of our business will depend, in part, on the successful commercialization of TRUTAKNA. The commercial success of TRUTAKNA will depend on a number of factors, including the following:

- our ability to maintain our sales team and scale our distribution capabilities;
- the availability of adequate reimbursement for TRUTAKNA;
- acceptance by physicians, payors and patients of the benefits, safety and efficacy of TRUTAKNA, including relative to alternative and competing treatments;
- a continued acceptable safety profile of TRUTAKNA;
- our ability to successfully obtain the substances and materials from third parties and to have finished product manufactured by third parties in accordance with regulatory requirements and in sufficient quantities for our commercial needs; and
- our ability to establish and enforce intellectual property rights in and to TRUTAKNA and avoid third-party patent interference or intellectual property infringement claims.

If we do not achieve one or more of these factors, many of which are beyond our control, in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize TRUTAKNA, which would harm our business, financial condition, operating results and prospects.

We have never successfully commercialized a product before and may lack the necessary expertise, personnel and resources to successfully commercialize any product on our own or together with suitable collaborators.

As an organization, we have never successfully commercialized a product, and we are currently building and strengthening marketing, sales force, market access, and distribution capabilities. To achieve commercial success for a product, which we may license to others, we will rely on the assistance and guidance of those collaborators. For any products for which we retain commercialization rights, we will have to develop and maintain our own sales, marketing and supply organization or outsource these activities to a third party.

Factors that may affect our ability to successfully commercialize TRUTAKNA include recruiting and retaining adequate numbers of effective sales and marketing personnel, obtaining access to or educating adequate numbers of physicians on its benefits and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization has been and will continue to be expensive and time-consuming. We may not be able to maintain an effective sales and marketing organization. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the successful commercialization of TRUTAKNA, we may not generate revenues or be able to achieve or sustain profitability.

TRUTAKNA may fail to achieve the broad degree of physician and patient adoption and use necessary for commercial success.

The commercial success of TRUTAKNA will depend significantly on its broad adoption and use by physicians and patients for the approved indication. The degree and rate of physician and patient adoption will depend on a number of factors, including:

- the efficacy and safety profile as demonstrated in clinical trials compared to alternative treatments;
- the clinical indications for which TRUTAKNA is approved;
- restrictions on use, such as warnings or precautions in labeling, which may not be required of alternative treatments and competitor products;
- the potential and perceived advantages of TRUTAKNA over alternative treatments;
- the cost of treatment in relation to alternative treatments;
- our pricing and the availability of coverage and adequate reimbursement by third-party payors, including government authorities;

- the availability of TRUTAKNA for use in combination therapy;
- relative convenience and ease of administration;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the effectiveness of sales and marketing efforts;
- inclusion or exclusion of TRUTAKNA from treatment guidelines established by various physician groups;
- unfavorable publicity relating to TRUTAKNA or similar approved products or product candidates in development by third parties; and
- the approval of other new therapies for the same indications.

Sales of medical products also depend on the willingness of physicians to prescribe the treatment, which is likely to be based on a determination by these physicians that the products are safe, therapeutically effective and accessible to patients. In addition, the inclusion or exclusion of products from treatment guidelines established by various physician groups and the viewpoints of influential physicians can affect the willingness of other physicians to prescribe the treatment. We cannot predict whether physicians, physicians' organizations, hospitals, other healthcare professionals, government agencies, regulatory authorities or private insurers will determine that TRUTAKNA is safe, therapeutically effective and cost effective as compared with competing treatments. If our lead product does not achieve an adequate level of acceptance by such parties, we may not generate or derive sufficient revenue and may not be able to achieve or sustain profitability.

We depend, in part, on the success of our product candidates. If we are unable to complete development of, obtain regulatory approval for and successfully commercialize our product candidates in one or more indications and in a timely manner, our business, financial condition, results of operations and prospects will be significantly harmed.

Our future success depends, in part, on our ability to timely complete clinical trials, obtain marketing approval for and successfully commercialize our product candidates. We expect that a substantial portion of our efforts and expenses over the next several years will continue to be devoted to the development of our product candidates.

We plan to invest significant efforts and financial resources in the research and development of our product candidates, which will require additional clinical development, evaluation of clinical, nonclinical and manufacturing activities, marketing approval from regulatory authorities, and significant marketing efforts before we can generate any revenues from product sales. We are not permitted to market or promote our product candidates before we receive marketing approval from the FDA and comparable foreign regulatory authorities, and we may never receive such marketing approvals. We cannot assure you that our planned clinical development programs for our product candidates will be completed in a timely manner, or at all, or that we will be able to obtain approval for our product candidates from the FDA or comparable foreign regulatory authorities. If we are unable to complete development of, obtain regulatory approval for and successfully commercialize our product candidates in one or more indications and in a timely manner, our business, financial condition, results of operations and prospects will be harmed.

Clinical development is a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Failure can occur at any stage of clinical development. If we are ultimately unable to obtain regulatory approval for our product candidates, our business, financial condition, results of operations and prospects will be significantly harmed.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of nonclinical studies and early clinical trials may not be predictive of the results of subsequent clinical trials. We have limited experience in conducting large scale clinical trials.

Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through nonclinical studies and initial clinical trials. For example, atacicept has been the subject of clinical trials by prior sponsors, including a Phase 2 trial in systemic lupus erythematosus, that missed its primary endpoint in the overall study population. In the future, clinical trial failures may result from a multitude of factors including flaws in trial design, dose selection, placebo effect and patient enrollment criteria. A number of companies in the biotechnology industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Based upon negative or inconclusive results, we or any potential future collaborator may decide to conduct additional clinical trials or nonclinical studies. Any future delays or abandonment could harm our business, financial condition, results of operations and prospects. Even if our clinical trials are completed as planned, we cannot be certain that their results will support our proposed indications.

Our future clinical trials may not be successful. If any product candidate is found to be unsafe or lack efficacy, we will not be able to obtain regulatory approval for it and our business, financial condition, results of operations and prospects may be significantly harmed. In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in composition of the patient populations,

adherence to the dosing regimen and other trial protocols and the dropout rate among clinical trial participants. As a result, assessments of efficacy can vary widely for a particular patient, and from patient to patient and site to site within a clinical trial. This subjectivity can increase the uncertainty of, and adversely impact, our clinical trial outcomes.

We do not know whether our clinical trials will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization. If we are unable to bring our product candidates to market, our ability to create long-term shareholder value will be limited.

In addition, we rely, in part, on nonclinical, clinical and quality data generated by CROs and other third parties in connection with our planned regulatory submissions. While we have or will have agreements governing these third parties' services, we have limited influence over their actual performance. If these third parties do not make data available to us, or, if applicable, make regulatory submissions in a timely manner, our development programs may be significantly delayed, and we may need to conduct additional studies or collect additional data independently. In either case, our development costs would increase.

Moreover, nonclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in nonclinical studies and clinical trials nonetheless failed to obtain FDA or comparable foreign regulatory authority approval. We cannot guarantee that the FDA or foreign regulatory authorities will interpret trial results as we do, and more trials could be required before we are able to submit an application seeking approval of our product candidates. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. Even if regulatory approval is secured for a product candidate, the terms of such approval may limit the scope and use, which may also limit commercial potential. Furthermore, the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval, which may lead to the FDA or comparable foreign regulatory authorities delaying, limiting or denying approval of a product candidate.

Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and jeopardize or delay our ability to obtain regulatory approval and commence product sales.

We may experience delays in clinical trials of our product candidates. Our planned clinical trials may not begin on time, have an effective design, enroll a sufficient number of participants, or be completed on schedule, if at all. Our clinical trials can be delayed for a variety of reasons, including delays related to:

- obtaining regulatory authorizations to commence a clinical trial or reaching a consensus with regulatory authorities on trial design;
- any failure or delay in reaching an agreement with CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining approval from one or more institutional review boards (IRBs) or positive ethics committee opinions;
- IRBs refusing to approve or ethics committees issuing negative opinions, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- changes to clinical trial protocols;
- clinical sites deviating from trial protocol or dropping out of a trial;
- study conduct issues, which could confound the clinical endpoints and/or data;
- manufacturing sufficient quantities of clinical trial material to supply the clinical trials;
- subjects failing to enroll or remain in our trial at the rate we expect, or failing to return for post-treatment follow-up;
- delays in enrollment due to low prevalence or incidence rates of subjects with the applicable disease;
- delays in enrollment due to a shift in our prioritization and dedication of resources towards other product candidates or indications;
- subjects choosing an alternative treatment or participating in competing clinical trials;
- lack of adequate funding to continue the clinical trial;
- subjects experiencing severe or unexpected drug-related adverse effects;
- regulatory authorities imposing a clinical hold;

- occurrence of serious adverse events in trials of the same class of agents conducted by other companies;
- shutdowns, either temporarily or permanently, of any facility manufacturing our product candidates or any of their components, including by order from the FDA or comparable foreign regulatory authorities due to violations of current good manufacturing practice (cGMP) or similar foreign requirements, regulations or other applicable requirements;
- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, good clinical practices (GCP) or other regulatory requirements;
- third-party contractors not performing data collection or analysis in a timely or accurate manner; or
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications.

Further, conducting clinical trials in foreign countries, as we may do for our lead product and product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled participants in foreign countries to adhere to clinical protocol 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.

If we experience delays in the completion of, or termination of, any clinical trial, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues will be delayed. Moreover, any delays in completing our clinical trials will increase our costs, slow down development and approval processes and jeopardize our ability to commence product sales and generate revenues.

In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval.

Any delays in our clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize our product candidates and our competitors may be able to bring products to market before we do, and the commercial viability of such product candidates could be significantly reduced. Any of these occurrences may significantly harm our business, financial condition, results of operations and prospects.

Enrollment and retention of participants in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control, due in part to the availability of competitive products and significant competition for recruiting participants in clinical trials.

Identifying and qualifying patients to participate in our clinical trials is critical to our success. We may encounter delays in enrolling, or be unable to enroll, a sufficient number of participants to complete any of our clinical trials, and even once enrolled we may be unable to retain a sufficient number of participants to complete any of our trials. Although we have engaged certain third-party investigators to assist with participant enrollment, there can be no assurance that we will be able to maintain our relationships with such third parties or that such third parties will be successful in helping us identify patients.

Factors that may generally affect participant enrollment include:

- the size and nature of the patient population;
- the number and location of clinical sites we enroll;
- competition with other companies for clinical sites or patients;
- the drug background and clinical experience (e.g., safety profile, risk/benefit assessment, mechanism of action, known proof of concept);
- the eligibility and exclusion criteria for the trial;
- the design of the clinical trial;
- inability to obtain and maintain participant consents;
- risk that enrolled participants will drop out before completion;
- a shift in our prioritization and dedication of resources towards other product candidates or indications; and

- competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating.

In addition, if any significant adverse events or other side effects are observed in any of our future clinical trials or other sponsor development programs of similar mechanism of action that may result in a drug class effect, it may make it more difficult for us to recruit patients to our clinical trials and participants may drop out of our trials, or we may be required to abandon the trials or our development efforts of one or more product candidates altogether. Our inability to enroll or retain a sufficient number of participants for our clinical trials would result in significant delays, which would increase our costs and have an adverse effect on our company.

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 limited financial and human resources, which has in the past and may in the future cause us to make prioritization and resource allocation decisions. 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 commercially viable products. 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 royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

We may develop our product candidates in combination with other therapies, which exposes us to additional risks.

We may develop our product candidates in combination with one or more currently approved therapies. Even if a product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or similar regulatory authorities outside of the United States could revoke or modify approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. This could result in our own products being removed from the market or being less successful commercially.

We may also evaluate our product candidates in combination with one or more other therapies that have not yet been approved for marketing by the FDA or similar regulatory authorities outside of the United States. We will not be able to market and sell such product candidate we develop in combination with any such unapproved therapies that do not ultimately obtain marketing approval. If the FDA or similar regulatory authorities outside of the United States do not approve these other drugs or revoke their approval of, or if safety, efficacy, manufacturing, or supply issues arise with, the drugs we choose to evaluate in combination with our product candidates, we may be unable to obtain approval of or market our product candidates.

The European Union (EU) regulates medical devices and medicinal products separately, through different legislative instruments, and the applicable requirements will vary depending on the type of drug-device combination product. For instance, drug-delivery products intended to administer a medicinal product where the medicinal product and the device form a single integral product are regulated as medicinal products in the EU. In such a case, the marketing authorization application must include – where available – the results of the assessment of the conformity of the device part with the EU Medical Devices Regulation contained in the manufacturer's EU declaration of conformity of the device or the relevant certificate issued by a notified body. If the marketing authorization application does not include the results of the conformity assessment and where for the conformity assessment of the device, if used separately, the involvement of a notified body is required, the European Medicine Agency or the EU member state competent authority must require the applicant to provide a notified body opinion on the conformity of the device. By contrast, in case of drug-delivery products intended to administer a medicinal product where the device and the medicinal product do not form a single integral product (but are e.g. co-packaged), the medicinal product is regulated in accordance with the rules for medicinal products described above while the device part is regulated as a medical device and will have to comply with all the requirements set forth by the EU Medical Devices Regulation.

The incidence and prevalence for target patient populations of our product candidates in specific indications are based on estimates and third-party sources. If the market opportunities for our product candidates, if and when approved, are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability might be materially and adversely affected.

Periodically, we make estimates regarding the incidence and prevalence of target patient populations for particular diseases based on various third-party sources and internally generated analysis and use such estimates in making decisions regarding our drug development strategy, including acquiring or in-licensing product candidates and determining indications on which to focus in nonclinical or clinical trials. These estimates may be inaccurate or based on imprecise data. For example, the total addressable market opportunity will depend on, among other things, acceptance of our drugs by the medical community and patient access, drug pricing and reimbursement. The number of patients in the addressable markets may turn out to be lower than expected, patients may not be

otherwise amenable to treatment with our drugs, or new patients may become increasingly difficult to identify or gain access to. If the market opportunities for our product candidates, if and when approved, are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve and sustain profitability might be materially and adversely affected.

Interim, initial, "top-line" and preliminary data from our clinical trials that we announce or publish from time to time may change as more participant 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 publicly disclose preliminary or top-line data from our nonclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. 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 we previously published. As a result, top-line data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more participant data become available or as participants from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of our particular program, the approvability or commercialization of our particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If the interim, top-line, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could significantly harm our business, financial condition, results of operations and prospects.

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

The biotechnology industry is intensely competitive and subject to rapid and significant technological change. Our competitors include multinational pharmaceutical companies, specialized biotechnology companies and universities and other research institutions. The current standard-of-care for IgAN consists of treatment with off-label use of renin-angiotensin-aldosterone system inhibitors, including ACE inhibitors and ARBs, to control blood pressure, or steroids with or without other immunosuppressive agents to non-specifically reduce inflammation. SGLT2 inhibitors, including AstraZeneca's FARXIGA®, which is approved for chronic kidney disease, is becoming the standard-of-care in some geographies including the United States. Among emerging therapies, we consider our most direct competitors with respect to TRUTAKNA to be approved products: the reformulated steroid (TARPEYO®) from Asahi Kasei Corp., the anti-APRIL monoclonal antibody (VOYXACT®) from Otsuka Pharmaceuticals, both the complement inhibitor (FABHALTA®) and selective ETA receptor antagonist (VANRAFIA®) from Novartis, and the endothelin and angiotensin II receptor antagonist (FILSPARI®) from Travere Therapeutics, Inc.; and programs in Phase 3 clinical development: Roche/Ionis, Vertex, AstraZeneca, Biogen, Takeda, Novartis, and Biohaven.

There are no FDA-approved therapies for pMN. Companies with pMN trials in Phases 2 or 3 include Vertex, Roche, BeOne Medicines, Biogen, Climb Bio, and Walden Biosciences. Notably, Roche recently reported positive Phase 3 data for obinutuzumab in pMN. On April 13, 2026, Travere's FILSPARI® received full FDA approval for the treatment of FSGS, becoming the first and only therapy approved in this indication. Companies with FSGS trials in Phases 2 or 3 include the following: Sanofi, Eli Lilly, Astellas, Walden Biosciences, Boehringer Ingelheim, Novartis, and Vertex. There are no FDA-approved therapies for MCD. Companies with MCD trials in Ph2/Ph3 include Sanofi, Travere Therapeutics, and Walden Biosciences.

In the kidney transplant or hematopoietic stem cell transplant setting, there are currently no anti-BK Virus (anti-BKV) therapies approved. The standard of care in both settings is to reduce immunosuppression as a first line, and potentially to offer intravenous immune globulin in kidney transplant recipients or antivirals with limited clinical evidence, including leflunomide and cidofovir, in

either setting. There are few industry sponsored programs in development for these indications; we consider our most direct competitor to be Memo Therapeutics AG's Anti-BKV, a neutralizing monoclonal antibody in a Phase 2/3 clinical trial.

The current landscape of B cell modulators primarily includes monoclonal antibodies, or Fc-fusion proteins containing TACI or TACI variants, including TRUTAKNA. VT-109 is a novel BAFF/APRIL dual-inhibitor B cell maturation antigen (BCMA) molecule which, if successfully developed, approved, and commercialized, may compete with the existing approaches to treat B cell mediated autoimmune diseases, many of which are described in the preceding paragraphs on IgAN. We consider the most advanced direct competitor to VT-109 to be the BCMA Fc-fusion protein from Aurinia Pharmaceuticals Inc., which is currently in Phase 1 clinical development.

Many of our competitors have significantly greater financial, technical, human and other resources than we do and may be better equipped to develop, manufacture and market technologically superior products. In addition, many of these competitors have significantly greater experience than we have in undertaking nonclinical studies and human clinical trials of new pharmaceutical products and in obtaining regulatory approvals of human therapeutic products. Accordingly, our competitors may succeed in obtaining FDA or comparable approval for superior products. Many of our competitors have established and in-use distribution channels for the commercialization of their products, whereas our channels and capabilities are less established. In addition, many competitors have greater name recognition and more extensive collaborative relationships. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Our competitors may obtain regulatory approval of their products more rapidly than we do or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates or any future product candidates. Our competitors may also develop drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile than our products and these competitors may also be more successful than we are in manufacturing and marketing their products. If we are unable to compete effectively against these companies, then we may not be able to commercialize our product candidates or any future product candidates or achieve a competitive position in the market. This would adversely affect our ability to generate revenue. Our competitors also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and participant registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Changes in methods of manufacturing or formulation of our product candidates may result in additional costs or delays.

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

Risks related to regulatory approval and other legal compliance matters

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business, financial condition, results of operations and prospects will be significantly harmed.

The time required to obtain approval by the FDA and comparable foreign authorities typically takes many years following the commencement of clinical trials. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions.

Any product candidate we may develop could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials;
- the FDA or comparable foreign regulatory authorities may determine that our product candidates are not safe, pure, and/or potent (or 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;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval, potentially resulting in a restrictive label and limiting commercial use;

- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from nonclinical studies or clinical trials;
- the data collected from clinical trials may not be sufficient to support the submission of a Biologics License Application (BLA), or other submission or to obtain regulatory approval in the United States or elsewhere;
- we may be unable to demonstrate to the FDA or comparable foreign regulatory authorities that the risk-benefit ratio for our proposed indication is acceptable;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval; and
- disruptions at the FDA and other government and regulatory agencies caused by funding shortages, furloughs or other reasons could result in delays in reviewing regulatory submissions or extensions of time necessary for new drugs to be reviewed and/or approved.

This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, financial condition, results of operations and prospects.

In addition, even if we obtain approval of our product candidates for one indication, regulatory authorities may not approve such product candidates for other indications, may impose significant limitations in the form of narrow indications, warnings, or a Risk Evaluation and Mitigation Strategy (REMS). Certain regulatory authorities may grant approval contingent on the performance of costly post-marketing clinical trials or may approve them with a label that does not include the labeling claims necessary or desirable for successful commercialization of our product candidates. In addition, if we are unable to obtain regulatory approval, or if regulatory approval results in a limited label, our business, financial condition, results of operation and prospects will be significantly harmed.

Our business entails a significant risk of product liability and product liability claims could significantly harm our business, financial condition, results of operations and prospects.

Our business exposes us to significant product liability risks inherent in the development, testing, manufacturing and marketing of therapeutic treatments. Product liability claims could delay or prevent completion of our development programs. If we succeed in obtaining regulatory approval of a product, such claims could result in an FDA or other regulatory authority investigation of the safety and effectiveness of our product, our manufacturing processes and facilities or our marketing programs. FDA or other regulatory authority investigations could potentially lead to a recall of our product or more serious enforcement action, limitations on the approved indications for which it may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our product, injury to our reputation, costs to defend the related litigation, a diversion of management's time and our resources and substantial monetary awards to trial participants or patients. We currently have product liability insurance that we believe is appropriate for our stage of development and may need to obtain higher levels at a future date. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities caused by product liability claims, which could significantly harm our business, financial condition, results of operations and prospects.

Our product candidates may cause significant adverse events, toxicities or other undesirable side effects when used alone or in combination with other approved products or investigational new drugs that may result in a safety profile that could inhibit regulatory approval, prevent market acceptance, limit their commercial potential or result in significant negative consequences.

As is the case with pharmaceuticals generally, it is likely that there may be side effects and adverse events associated with the use of our product candidates. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by our product candidates 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. For example, Merck previously conducted APRIL-LN, a Phase 2/3 clinical trial aimed to evaluate the efficacy and safety of atacicept in patients with active lupus nephritis, receiving newly initiated mycophenlate mofetil (MMF) and corticosteroids (CS). Two weeks before the initiation of atacicept, significant decreases in immunoglobulin G levels began unexpectedly with initiation of MMF and high-dose CS, and persisted upon initiation of atacicept, which led to trial termination. Such drug-related side effects could affect participant recruitment or the ability of enrolled participants to complete the trial or result in potential product liability claims. Any of these occurrences may significantly harm our business, financial condition, results of operations and prospects.

If product candidates we develop are associated with undesirable side effects or have unexpected characteristics in nonclinical studies or clinical trials when used alone or in combination with other approved products or investigational drugs, we may need to

interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Treatment-related side effects could also affect participant recruitment or the ability of enrolled subjects to complete a trial, or result in potential product liability claims. Any of these occurrences may prevent us from achieving or maintaining market acceptance of the affected product candidate and may significantly harm our business, financial condition, results of operations and prospects.

Participants in our ongoing and planned clinical trials may in the future suffer significant adverse events or other side effects not observed in our nonclinical studies or previous clinical trials. Our product candidates may be used as chronic therapies or be used in pediatric populations, for which safety concerns may be particularly scrutinized by regulatory authorities. In addition, if our product candidates are used in combination with other therapies, such product candidates may exacerbate adverse events associated with the therapy and it may not be possible to determine whether such adverse events were caused by our product candidate or the agent with which it was combined. The inclusion of patients with advanced disease in our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using or due to the gravity of such patients' illnesses.

If significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting participants to the clinical trials, participants may drop out of our trials, or we may be required to abandon the trials or our development efforts of that product candidate altogether. We, the FDA, other comparable regulatory authorities or an IRB or ethics committee may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance due to its tolerability versus other therapies. Any of these developments could significantly harm our business, financial condition, results of operations and prospects.

Further, toxicities associated with our products not seen during clinical testing may also develop after approval is obtained and lead to a requirement to conduct additional clinical safety trials, additional contraindications, warnings and precautions being added to the drug label, significant restrictions on the use of the product or the withdrawal of the product from the market. We cannot predict whether our lead product or product candidates will cause toxicities in humans that would preclude or lead to the revocation of regulatory approval based on nonclinical studies or early-stage clinical trials.

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

Maintaining regulatory approval of our lead product or obtaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. For example, even though the FDA granted accelerated approval for TRUTAKNA, we must obtain additional marketing approvals from comparable regulatory authorities in foreign jurisdictions. In addition, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional nonclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our product is also subject to approval.

Obtaining foreign regulatory approvals and establishing and maintaining compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our lead product or product candidates in certain countries. If we or any future collaborator fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our lead product or product candidates will be harmed.

Our lead product is subject to continued regulatory oversight and failure to comply with applicable regulatory requirements could have a material adverse impact on our business.

Even though the FDA granted accelerated approval for TRUTAKNA, such regulatory approval and any future regulatory approvals that we may receive for our lead product and product candidates will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of the marketed product, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. For example, in connection with the FDA granting accelerated approval for TRUTAKNA, certain post-approval studies are required to maintain such approval. Furthermore, the FDA may require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or applicable foreign regulatory authorities approve any of our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping will be subject to

extensive and ongoing regulatory requirements, all to which our lead product is currently subject. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as on-going compliance with cGMPs and GCP for any clinical trials that we conduct post-approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and standards. If we or a regulatory authority discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory authority may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. In addition, failure to comply with FDA and other comparable foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions, including:

- delays in or the rejection of product approvals;
- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- restrictions on the products, manufacturers or manufacturing process;
- warning letters;
- civil and criminal penalties;
- injunctions;
- suspension, variation or withdrawal of regulatory approvals;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- total or partial suspension of production; and
- imposition of restrictions on operations, including costly new manufacturing requirements.

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

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of any of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not be able to achieve or sustain profitability.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. If these actions impose constraints on FDA's or foreign regulatory authorities' ability to engage in oversight and implementation activities in the normal course, it may significantly harm our business, financial condition, results of operations and prospects.

We may seek but fail to obtain orphan drug designations from the FDA or other regulatory authorities for our product candidates, and even where we have obtained such designations, we may be unable to receive or maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.

We may seek orphan drug designation for some or all of our product candidates. Under the Orphan Drug Act, the FDA may designate a drug product as an orphan drug if it is intended to treat a rare disease or condition, defined as a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States but where there is no reasonable expectation to recover the costs of developing and marketing a treatment drug in the United States. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and application fee waivers. However, orphan drug designation neither shortens the development time nor regulatory review time of a product candidate nor gives the candidate any advantage in the regulatory review or approval process. We sought orphan drug designation for TRUTAKNA in IgAN in the United States but such designation was not obtained.

If a product receives the first FDA approval for the disease or condition for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same disease or condition for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity for the orphan patient population. Exclusive marketing rights in the United States may also be unavailable if we or our collaborators seek approval for a disease or condition broader than the orphan designated disease or condition and may be lost if the FDA later determines that the request for designation was materially defective. Even if we obtain orphan drug designation, we may not be the first to obtain marketing approval for any particular orphan disease or condition due to the uncertainties associated with developing pharmaceutical

products. Further, even if we obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is safer, more effective, or makes a major contribution to patient care.

We received orphan medicinal product designation for atacicept in the EU in October 2024. In the EU, a medicinal product may receive orphan designation under Article 3 of Regulation (EC) 141/2000 if its sponsor can establish that (i) the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition and (ii) either (1) such condition affects no more than five in 10,000 persons in the EU when the application is made, or (2) the product, without the benefits derived from orphan status, would be unlikely to generate sufficient returns in the EU to justify the necessary investment in its development. Moreover, in order to obtain orphan designation in the EU it is necessary to demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU or, if such a method exists, the product will be of significant benefit to those affected by the condition. The application for orphan designation must be submitted before the application for marketing authorization. Orphan medicinal product designation entitles an applicant to financial incentives such as fee reductions or fee waivers, protocol assistance, and access to the centralized marketing authorization procedure. Moreover, upon grant of a marketing authorization and assuming the requirements for orphan designation are also met at the time the marketing authorization is granted, orphan medicinal product are entitled to a ten-year period of market exclusivity for the approved therapeutic indication, which means that the EMA cannot accept another marketing authorization application or accept an application to extend for a similar product and the European Commission cannot grant a marketing authorization for the same indication for a period of ten years. A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed pediatric investigation plan. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications. Orphan medicinal product designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. This market exclusivity period may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan drug designation, for example because the product is sufficiently profitable not to justify continued market exclusivity. In addition, a marketing authorization may be granted to a similar medicinal product with the same orphan indication during the ten year period of market exclusivity on an individual basis in very select cases, such as with consent from the marketing authorization holder, if the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities of the authorized product or if the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior to the original orphan medicinal product. A company may voluntarily remove a product from the register of orphan products.

We also received orphan drug designation for atacicept in Japan in September 2025. In Japan, drugs can be designated as orphan drugs if they are (1) intended for use in less than 50,000 patients in Japan or, if the usage is for a designated intractable disease, the number of patients is less than approximately one-thousandth of the population; (2) there is a high medical need due to the seriousness of the disease for which there are no sufficient alternative drugs or treatments or high efficacy or safety is expected with the new drug compared with existing products; and (3) the development plan is appropriate and there is reasonable possibility of development success. The benefits of orphan drug designation in Japan include subsidies to reduce the financial burden of product development, guidance and consultation from governmental agencies on development activities with a priority consultation system, tax credits for development costs, eligibility for priority review, and following approval, extension of the exclusivity period for up to ten years as well as premium pricing.

If we do not receive or maintain orphan drug designation for our product candidates, it could limit our ability to realize revenues.

Even though MAU868 has Fast Track designation from the FDA for the prevention of BK viremia in renal transplant and hematopoietic stem cell transplant, it may not lead to a faster development or regulatory review or approval process, and will not increase the likelihood that MAU868 will receive marketing approval.

If a drug or biologic is intended for the treatment of a serious or life-threatening condition or disease, whether alone or in combination with other drugs or biologics, and nonclinical or clinical data demonstrate the potential to address an unmet medical need for such condition or disease, the product candidate may qualify for FDA Fast Track designation, for which sponsors must apply. The FDA has broad discretion whether or not to grant this designation. Fast Track designation allows for more frequent communication with the FDA and the potential for rolling review of a marketing application. Although we have received Fast Track designation for the investigation of MAU868 for the prevention of BK viremia in renal transplant and hematopoietic stem cell transplant recipients, we may not experience a faster development process, review or approval compared to conventional FDA procedures. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program.

We may attempt to secure approval from the FDA or comparable foreign regulatory authorities through the use of accelerated approval pathways. If we are unable to obtain such approval, we may be required to conduct additional nonclinical studies or clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA or comparable foreign regulatory authorities, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA or comparable foreign regulatory authorities may seek to withdraw any accelerated approval.

TRUTAKNA received accelerated approval for the treatment of IgAN from the FDA in July 2026 and we may attempt to secure accelerated approval for our product candidates in the future. Under the accelerated approval program, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. For example, endpoints assessing changes in 24-hour urine protein-to-creatinine ratio (UPCR) have been accepted by FDA as surrogate primary endpoints for clinical trials of drugs targeting patients with IgAN, while assessments of estimated glomerular filtration rate (eGFR) slope have been viewed by regulators as the more conventional endpoint assessing clinical benefit in IgAN patients. We received accelerated approval for TRUTAKNA based on the UPCR endpoint results observed in our ORIGIN 3 trial and are required as a condition of such approval to complete the trial to collect eGFR data to demonstrate improvement in kidney function.

An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to complete ongoing trials and/or conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit and to report regularly to the FDA on progress of such trials. Additionally, unless and until converted to full approval at the time of satisfying the conditions of any accelerated approval letter, the sponsor must submit any promotional materials for the accelerated approval drug to FDA at least 30 days prior to use. Third-party payors may refuse to provide coverage or reimbursement for the drug until the confirmatory studies are complete. Additionally, if such post-approval studies fail to confirm the drug's clinical benefit, or if the product sponsor fails to complete any confirmatory studies in a timely manner, the FDA may withdraw its approval of the drug on an expedited basis.

Prior to seeking accelerated approval for any of our other product candidates, we intend to seek feedback from the FDA and will otherwise evaluate our ability to seek and receive accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit a BLA for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent FDA feedback 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, 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 or comparable foreign regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited review or approval for our product candidates would result in a longer time period to commercialization of such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

We may seek EMA PRIME (PRIority MEdicines) designation or other designations, schemes or tools for one or more of our product candidates. In the EU, innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, some which provide incentives similar to the Breakthrough Therapy designation in the United States. For instance, 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.

Furthermore, marketing authorizations may also be granted "under exceptional circumstances" when the applicant can show that it is unable to provide comprehensive data on the efficacy and safety under normal conditions of use even after the product has been authorized and subject to the introduction of specific procedures. This may arise when the intended indications are very rare and, in the present state of scientific knowledge, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles. This type of marketing authorization is close to a conditional marketing authorization as it is reserved to medicinal products to be approved for severe diseases or unmet medical needs and the applicant does not hold the

complete data set legally required for the grant of a marketing authorization. However, unlike a conditional marketing authorization, the applicant does not have to provide the missing data and will never have to. Although a marketing authorization "under exceptional circumstances" is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually and the marketing authorization may be withdrawn where the risk-benefit ratio is no longer favorable.

The competent regulatory authorities in the EU have broad discretion whether to grant such an accelerated assessment, conditional marketing authorization or marketing authorization under exceptional circumstances, and, even if such assessment or authorization is granted, we may not experience a faster development process, review or authorization compared to conventional procedures. Moreover, the removal or threat of removal of such marketing authorizations may create uncertainty or delay in the clinical development of our product candidates and threaten the commercialization prospects of our products and product candidates, if approved. Such an occurrence could materially impact our business, financial condition and results of operations.

A Breakthrough Therapy Designation from the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that our product candidates will receive FDA approval.

We obtained Breakthrough Therapy Designation from the FDA for TRUTAKNA for the treatment of IgAN, and we may seek additional Breakthrough Therapy Designations for our product candidates where we believe the clinical data support such designation. A "Breakthrough Therapy" is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition, where preliminary clinical evidence indicates that the drug or biologic 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 product candidates that have been designated as Breakthrough Therapies, increased 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. Products designated as Breakthrough Therapies also receive the same benefits associated with Fast Track designation, including eligibility for rolling review of a submitted BLA.

Designation as a Breakthrough Therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy Designation for a product candidate may not result in a faster development process or review and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as Breakthrough Therapies, the FDA may later decide that the product candidate no longer meets the conditions for qualification and rescind the designation.

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

The ability of the FDA and foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's or foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's or foreign regulatory authorities' ability to perform routine functions. Average review times at the FDA and foreign regulatory authorities have fluctuated in recent years as a result. Disruptions at the FDA and other agencies may also prolong the time necessary for new biologics or modifications to approved biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough FDA employees and stop critical activities. In addition, the current U.S. Presidential administration has issued certain policies and Executive Orders directed towards reducing the employee headcount and costs associated with U.S. administrative agencies, including the FDA, and it remains unclear the degree to which these efforts may limit or otherwise adversely affect the FDA's ability to conduct routine activities. If a prolonged government shutdown occurs, or if changes in policy, funding shortages or staffing limitations hinder or prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other such regulatory authorities to timely review and process our planned regulatory submissions, which could have a material adverse effect on our business.

Biosimilars may provide competition sooner than anticipated.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the Affordable Care Act), signed into law on March 23, 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 (BPCIA), which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval 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 market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product.

We believe that any of our product candidates approved 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 our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products will depend on a number of marketplace and regulatory factors that are still developing.

In the EU, upon receiving a marketing authorization, innovative medicinal products are generally entitled to receive eight years of data exclusivity and an additional two years of market exclusivity. Data exclusivity, if granted, prevents regulatory authorities in the EU from referencing the innovator's data to assess a generic or biosimilar application for eight years from the date of authorization of the innovative product, after which a generic or biosimilar marketing authorization application can be submitted, and the innovator's data may be referenced. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until ten years have elapsed from the initial marketing authorization of the reference product in the EU. The overall ten-year period may, occasionally, be extended for a further year to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical/biological entity, and products may not qualify for data exclusivity. In the EU, there is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product. For such products, the results of appropriate preclinical or clinical trials must be provided in support of an application for marketing authorization. Guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product. There are no such guidelines for complex biological products, such as gene or cell therapy medicinal products, and so it is unlikely that biosimilars of those products will currently be approved in the EU. However, guidance from the EMA states that they will be considered in the future in light of the scientific knowledge and regulatory experience gained at the time.

If any approved products are subject to biosimilar competition sooner than we expect, we will face significant pricing pressure and our commercial opportunity will be limited.

The successful commercialization of our lead product and any product candidate we develop will depend in part on the extent to which governmental authorities, private health insurers, and other third-party payors provide coverage and adequate reimbursement. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if any and if approved, could limit our ability to market those products and decrease our ability to generate revenue.

We have received accelerated approval to market our lead product in the United States and intend to seek approval to market our product candidates in the United States, the EU, Japan, and certain foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our lead product or product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the EU, the pricing of drugs is subject to governmental control and other market regulations which could put pressure on the pricing and usage of our product candidates. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, in the United States, the EU, and other jurisdictions, market acceptance and sales of an approved product candidate will depend significantly on the availability of adequate coverage and reimbursement from third-party payors.

The availability and extent of coverage and adequate reimbursement by third-party payors, including government health administration authorities, private health coverage insurers, managed care organizations and other third-party payors is essential for most patients to be able to afford treatments. Sales of our lead product and any product candidates, if approved, will depend substantially, both in the United States and internationally, on the extent to which the costs of the product will be covered and reimbursed by third-party payors. If reimbursement is not available, or is available only at inadequate levels, we may not be able to successfully commercialize our lead product or any product candidates we develop. Even if coverage is provided, the approved reimbursement amount may not be sufficient to allow us to establish or maintain pricing to support an adequate return on our investment. Coverage and reimbursement may impact the demand for, or the price of, our lead product or any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize our lead product or any product candidate for which we obtain marketing approval.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, for example, the Centers for Medicare & Medicaid Services (CMS), an agency within the U.S. Department of Health and Human Services (HHS), determines which new products will be covered and reimbursed under Medicare. Private third-party payors often follow CMS's decisions regarding coverage and reimbursement to a substantial degree. However, one third-party payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product.

Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. As a result, the coverage determination process is often time-consuming and costly. This process will require us to provide scientific and clinical support for the use of our product to each third-party payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Governmental payors, as well as other third-party payors, including pharmacy benefit managers, have attempted to control costs by limiting coverage and the amount of reimbursement for particular products and requiring substitutions of generic products and/or biosimilars. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Further, such payors are increasingly examining the medical necessity and reviewing the cost effectiveness of medical product candidates. There may be especially significant delays in obtaining coverage and reimbursement for newly approved drugs. Third-party payors may limit coverage to specific products on an approved list, known as a formulary, which might not include all FDA-approved drugs for a particular indication. We may need to conduct expensive pharmaco-economic studies to demonstrate the medical necessity and cost effectiveness of our product. Nonetheless, our lead product or any product candidates, if approved, may not be considered medically necessary or cost effective. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, whether the level of reimbursement will be adequate.

Outside the United States, pharmaceutical sales are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of therapeutics such as those we are developing or may develop in the future. In many countries, particularly the countries of the EU, medical product prices are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after a product receives marketing approval. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical study that compares the cost-effectiveness of our product candidates or any future product candidates we may develop to other available therapies. The Health Technology Assessment (HTA) of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States, including those representing the larger markets. The HTA process is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States. In December 2021, Regulation No. 2021/2282 on HTA, amending Directive 2011/24/EU, was adopted in the EU. This Regulation, which entered into force in January 2022 began to apply on January 12, 2025 through a phased implementation. It is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. The Regulation will permit EU Member States to use common HTA tools, methodologies, and procedures across the EU to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU Member States will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement. If we are unable to maintain favorable pricing and reimbursement status in EU Member States for product candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for those products in the EU could be negatively affected. In general, product prices under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for any product that we commercialize may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

If we are unable to establish or sustain coverage and adequate reimbursement for our lead product or for any product candidates that we commercialize from third-party payors, the adoption of those products and potential sales revenue would be adversely affected, which, in turn, could adversely affect the ability to market or sell those product candidates, if approved. Coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for a product for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Current and future healthcare reform legislation or regulation may increase the difficulty and cost for us to successfully commercialize our lead product or product candidates and may adversely affect the prices we may obtain and may have a negative impact on our business and results of operations.

Existing regulatory policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not be able to achieve or sustain profitability.

For example, the Affordable Care Act substantially changed healthcare financing, access, and delivery by both governmental and private insurers. The Affordable Care Act contains a number of provisions of particular import to the pharmaceutical and biotechnology industries, including, but not limited to, those governing enrollment in federal healthcare programs, a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, and annual fees based on pharmaceutical companies' share of sales to federal healthcare programs. Under currently applicable U.S. law, certain products not usually self-administered, including injectable drugs, may be eligible for coverage under Medicare Part B. As a condition of receiving Medicare Part B reimbursement, manufacturers are required to participate in other government healthcare programs, including the Medicaid Drug Rebate Program and the 340B Drug Pricing Program, which requires manufacturers to extend discounts to participating entities. These programs may be subject to change as a result of future health reform measures and may reduce the profitability of our lead product or any successfully commercialized product candidate.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted in 2010. These changes include aggregate reductions to Medicare payments to providers pursuant to the Budget Control Act of 2011, which began in 2013, and due to subsequent legislative amendments to the statute will remain in effect until 2032, unless additional congressional action is taken. Additionally, the American Rescue Plan Act of 2021 eliminated the statutory Medicaid drug rebate cap, previously set at 100% of a drug's average manufacturer price, effective January 1, 2024. These laws may result in additional reductions in Medicare and other healthcare funding, which could have an adverse effect on customers for our lead product or product candidates, if approved, and, accordingly, our financial operations. In addition, Congress is considering additional health reform measures.

Moreover, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. Most significantly, the Inflation Reduction Act of 2022 (IRA) was signed into law in August 2022. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare, with prices that can be negotiated subject to a cap (with resulting prices for the initial ten drugs first effective in 2026), imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023), redesigns the Medicare Part D benefit (starting in 2025), and replaces the Part D coverage gap discount program with a new discounting program (which began on January 1, 2025). CMS has published the negotiated prices for the initial ten drugs, which will first be effective in 2026, and the subsequent 15 drugs, which will first be effective in 2027. Each year thereafter, more Part B and Part D products will become subject to the HHS price negotiation program, although the program is currently subject to legal challenges. HHS has issued and will continue to issue guidance implementing the IRA. While the impact of the IRA on us and the pharmaceutical industry cannot yet be fully determined, it is likely to be significant.

The One Big Beautiful Bill Act, which was enacted in July 2025, imposes significant reductions in the funding of the Medicaid program. Such reductions are expected to decrease the number of persons enrolled in Medicaid and reduce the services covered by Medicaid, which could adversely affect our sales of our lead product or any product candidate that we commercialize.

The Trump administration is pursuing a two-fold strategy to reduce drug costs in the U.S. While it is unclear whether and how the proposals will be implemented, the policies may have a negative impact on the pharmaceutical industry and on our ability to receive adequate revenues for our lead product or any product candidate we commercialize. On the one hand, significant tariffs have been threatened to be imposed on pharmaceutical manufacturers that do not adopt pricing policies such as most favored nation pricing, which would tie the price for drugs in the U.S. to the lowest price in a group of other countries. In response, multiple manufacturers have reportedly entered into confidential pricing agreements with the federal government. On the other hand, the Trump administration is pursuing traditional regulatory pathways to impose drug pricing policies, although proposed regulations have not yet been published. Such regulatory proposals or executive actions could negatively impact the U.S. pharmaceutical sector and our business. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan", to codify and expand Most-Favored Nation pricing, lower government subsidies to private insurance companies, increase healthcare price transparency, expand pharmaceutical drugs available for over-the-counter purchase, and enact restrictions on pharmacy benefit manager payment methodologies, among other things. Pharmaceutical pricing and marketing has long been the subject of considerable

discussion in Congress and among policymakers, and it is possible that Congress could enact additional laws that negatively affect the pharmaceutical industry. If most favored nation pricing was ever to be codified by legislation, it could have a significant financial impact on our company.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement-constraints, discounts, restrictions on certain product access, marketing cost disclosure, drug price reporting and other transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. One state has utilized a so-called prescription drug affordability board to impose an upper payment limit in the state, while another state has enacted legislation that bans price increases that outpace inflation. Other enacted state laws affect the distribution of pharmaceuticals. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition, results of operations and prospects.

Additional health reform measures may continue and affect our business in unknown ways, including proposed policies to reduce regulations and expenditures across government agencies, which could create additional uncertainty for our business. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program created under the IRA.

We expect that the Affordable Care Act, the IRA, as well as other healthcare reform measures that may be adopted in the future, particularly under the Trump administration, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate meaningful revenue and achieve and sustain profitability for our lead product or commercialize our product candidates.

The terms of future potential marketing approvals for our product candidates and ongoing regulation regarding promotional activities and post-market obligations may limit how we manufacture and market products that are approved, and compliance with such requirements may involve substantial resources, which could materially impair our ability to generate revenue.

FDA and comparable foreign regulations and guidance may be revised or reinterpreted by the competent authorities in ways that may significantly affect our business and our products. Any new regulations or guidance, or revisions or reinterpretations of existing regulations or guidance, may impose additional costs or lengthen review times for our product candidates. We cannot determine how changes in regulations, statutes, policies, or interpretations when and if issued, enacted or adopted, may affect our business in the future. Such changes could, among other things, require:

- additional clinical trials to be conducted prior to obtaining approval;
- changes to manufacturing methods;
- recalls, replacements, or discontinuance of one or more of our products; and
- additional recordkeeping.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. As an example, the regulatory landscape related to clinical trials in the EU has evolved. The EU Clinical Trials Regulation (CTR), which was adopted in 2014 and repeals the EU Clinical Trials Directive (CTD), became applicable on January 31, 2022. While the CTD required a separate clinical trial application (CTA), to be submitted in each EU Member State in which the clinical trial takes place, to both the competent national health authority and an independent ethics committee, the CTR introduces a centralized process and only requires the submission of a single application for multi-center trials. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each EU Member State, leading to a single decision for each EU Member State. The assessment procedure for the authorization of clinical trials has been harmonized as well, including a joint assessment by all EU Member States concerned, and a separate assessment by each EU Member State with respect to specific requirements related to its own territory, including ethics rules. Each EU Member State's decision is communicated to the sponsor via the centralized EU portal. Once the clinical trial is approved, clinical study development may proceed. The CTR foresaw a three-year transition period that ended on January 31, 2025. Since this date, all new or ongoing trials (and related applications) are fully subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third-party service providers, such as CROs, may impact our developments plans. In light of the entry into application of the CTR on January 31, 2022, we were required to transition clinical trials for which we have obtained regulatory approvals in accordance with the CTD to the regulatory framework of the CTR. Transition of clinical trials governed by the CTD to the CTR was required for clinical trials which had at least one site active in the EU on January 30, 2025. A timely transitioning application was filed with the competent authorities of EU Member States through the Clinical Trials Information Systems in order to continue the clinical trial past January 30, 2025.

Furthermore, on April 28, 2025, the UK adopted an amendment to the UK Medicines for Human Use (Clinical Trials) Regulations 2004 intended to support a more streamlined and flexible regulation of clinical trials, removing unnecessary

administrative burdens on trial sponsors, whilst protecting the interests of trial participants. It also intends to bring the UK regulatory framework for clinical trials, which is still based on the CTD, into closer alignment with the CTR. The amendment became applicable on April 28, 2026 following a one-year transition period.

In addition, 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. On April 26, 2023, the European Commission published a proposal for a new Directive and Regulation to revise the existing pharmaceutical legislation. The European Parliament and the Council of the EU adopted their respective positions on April 10, 2024 and June 4, 2025. Subsequent inter-institutional trilogue negotiations concluded on December 11, 2025, with a provisional political agreement. The proposed revisions remain to be formally adopted. The new framework is expected to enter into force in 2026 and to be subject to transitional arrangements, with full application not anticipated before 2028.

Such changes would likely require substantial time and impose significant costs, or could reduce the potential commercial value of our lead product or product candidates, and could materially harm our business and our financial results. In addition, delays in receipt of or failure to receive regulatory approvals for any other products would harm our business, financial condition, and results of operations.

Our relationships with healthcare professionals, clinical investigators, CROs and third-party payors in connection with our current and future business activities may be subject to federal, state and foreign healthcare fraud and abuse laws, false claims laws, transparency laws, government price reporting, and health information privacy and security laws, which could expose us to, among other things, criminal sanctions, civil penalties, contractual damages, exclusion from governmental healthcare programs, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare professionals and third-party payors play a primary role in the recommendation and prescription of our lead product or product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, clinical investigators, CROs, third-party payors and customers may 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, market, sell and distribute our lead product or product candidates for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- the federal false claims laws, including the civil False Claims Act, which can be enforced by private citizens through civil whistleblower or qui tam actions, and civil monetary penalties laws 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 or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH) and their implementing regulations, also imposes obligations, including mandatory contractual terms, upon certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates and subcontractors that perform services for them that involve the use, or disclosure of, individually identifiable health information with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Physician Payments Sunshine Act requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to CMS information regarding payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other health care professionals (such as physician assistants and nurse practitioners) and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members; and

- analogous state and foreign laws and regulations, such as state and foreign anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

Some state and local laws require certain regulatory licenses to manufacture and distribute products commercially and/or the registration of pharmaceutical sales representatives. Some state and foreign laws require biotechnology companies to comply with the biotechnology industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare professionals or marketing expenditures. Some state and foreign laws require biotechnology companies to report information on the pricing of certain drug products.

Much like the federal Anti-Kickback Statute prohibition in the United States, the provision of benefits or advantages to physicians and other healthcare professionals to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the EU. Outside the United States, interactions between pharmaceutical companies and health care professionals are also governed by strict laws, such as national anti-bribery laws of European countries, national sunshine rules, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment. Infringement of related laws could result in substantial fines and imprisonment.

Payments made to physicians and other healthcare professionals in certain EU Member States must be publicly disclosed. Moreover, agreements with physicians and other healthcare professionals may require prior notification or approval by the physician's or other health care professional's employer, his or her competent professional organization and/or the regulatory authorities of the individual 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 current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve on-going 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 penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, or comparable foreign programs, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other healthcare professionals or entities with whom we expect to do business is found to be not 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 and evolving U.S. and foreign laws, regulations and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class actions) and mass arbitration demands; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) personal data and other sensitive information, including proprietary and confidential business information, trade secrets, intellectual property, information we collect about trial participants in connection with clinical trials in the U.S. and abroad, and sensitive third-party information (collectively, sensitive information). Our data processing activities subject us to numerous obligations relating to data privacy and security, such as various state, federal, and foreign laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual obligations and other obligations relating to data privacy and security.

Outside the United States, our operations are or may become subject to an increasing number of laws, regulations and industry standards governing data privacy and security. For example, the EU's General Data Protection Regulation (EU GDPR) and the UK's Data Protection Act 2018 (UK GDPR) (collectively, GDPR), Canada's Personal Information Protection and Electronic Documents Act (PIPEDA), Australia's Privacy Act, India's Information Technology Act, China's Personal Information Protection Law (PIPL) and South Korea's Personal Information Protection Act impose strict requirements for processing of personal data, including clinical trials participants and other individuals. For instance, companies that violate the GDPR can face private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests, temporary or definitive prohibitions on data processing and other corrective actions, fines of up to the greater of 20 million Euros under the EU GDPR / 17.5 million pounds under the UK GDPR, or 4% of their worldwide annual revenue, whichever is higher.

Furthermore, China's PIPL imposes a set of specific obligations on covered businesses in connection with their processing and transfer of personal data and imposes fines of up to RMB 50 million or 5% of the prior year's total annual revenue of the violator.

In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area (EEA) and the UK have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt or have already adopted similarly stringent data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework). These mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK, or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as the EEA and/or UK) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data out of the EEA for allegedly violating the EU GDPR's cross-border data transfer limitations. Additionally, companies that transfer personal data out of the EEA and/or UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Other regulators (such as the United States Department of Justice (US DOJ)) are also increasingly scrutinizing data transfers and have enacted certain cross-border data transfer prohibitions and restrictions that impact us. Violations of the relevant US DOJ rule can lead to significant civil and criminal penalties and applies regardless of whether the data is anonymized, key-coded, pseudonymized, de-identified or encrypted.

In the United States federal, state and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g. Section 5 of the Federal Trade Commission Act), other similar laws (e.g. wiretapping laws). For example, HIPAA, as amended by HITECH, imposes, among other things, specific requirements relating to the privacy, security, and transmission and breach reporting of individually identifiable health information.

Additionally, numerous U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act (collectively, the CCPA), requires covered businesses that process the personal data of California residents to, among other things: to (i) provide specific disclosures to California residents in privacy notices; (ii) honor requests of such individuals to exercise certain privacy rights; and (iii) enter into specific contractual provisions with service providers that process California resident personal data on the business's behalf. The CCPA also provides for fines and allows private litigants affected by certain data breaches to recover significant statutory damages. Although there are limited exemptions for clinical trial data under the CCPA, the CCPA increases compliance costs and potential liability with respect to other personal data we maintain about California residents. Similar laws have been enacted or are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. While certain of these laws exempt or may exempt data processed in the context of clinical trials, these developments may further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties with whom we work.

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

We also publish privacy policies, marketing materials, and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and security. Regulators are increasingly scrutinizing these statements, and if these policies, materials, or statements are found to be deficient, lacking in transparency, deceptive, unfair, misleading, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, or other adverse consequences.

Obligations related to data privacy and security (and consumers' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. All of these evolving compliance and operational

requirements impose significant costs that are likely to increase over time, may require us to modify our information processing practices and policies, divert resources from other initiatives and projects, including increased costs related to insurance, cybersecurity and information technology, and could restrict the way products and services involving data are offered, all of which could significantly harm our business, financial condition, results of operations and prospects.

We may at times fail (or be perceived to have failed) in our effort to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third-party partners (such as contract research organizations and clinical trial sites) may fail (or be perceived to have failed) to comply with such obligations, which could negatively impact our business operations. If we or our third-party partners fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences. These consequences may include, but are not limited to, government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class actions) and mass arbitration demands; additional reporting requirements and/or oversight; bans on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: interruptions or stoppages in our business operations (including, as relevant, clinical trials); inability to process sensitive information or to operate in certain jurisdictions; limited ability to develop or commercialize our product candidates; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

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 significantly harm our business, financial condition, results of operations or prospects.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. 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. We also could incur significant costs associated with civil or criminal fines and penalties.

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 maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of hazardous and flammable materials, including chemicals and biological materials.

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

Our business activities may be subject to the U.S. Foreign Corrupt Practices Act (FCPA) and similar anti-bribery and anti-corruption laws of other countries in which we operate, as well as U.S. and certain foreign export controls, trade sanctions, and import laws and regulations. Compliance with these legal requirements could limit our ability to compete in foreign markets and subject us to liability if we violate them.

If we expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. Our business activities may be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. The FCPA generally prohibits companies and their employees and third-party intermediaries from offering, promising, giving or authorizing the provision of anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls.

Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, hospitals owned and operated by the government, and doctors and other hospital employees would be considered foreign officials under the FCPA. Recently the SEC and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents or contractors, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or our employees, disgorgement, and other sanctions and remedial measures, and prohibitions on the conduct

of our business. Any such violations could include prohibitions on our ability to offer our product in one or more countries and could materially damage our reputation, our brand, our international activities, our ability to attract and retain employees and our business.

In addition, our product and activities may be subject to U.S. and foreign export controls, trade sanctions and import laws and regulations. Governmental regulation of the import or export of our product, or our failure to obtain any required import or export authorization for our product, when applicable, could harm our international sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our product may create delays in the introduction of our product in international markets or, in some cases, prevent the export of our product to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments, and persons targeted by U.S. sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and/or denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons, or product targeted by such regulations, could result in decreased use of our product by, or in our decreased ability to export our product to existing or potential customers with international operations. Any decreased use of our product or limitation on our ability to export or sell access to our product would likely significantly harm our business, financial condition, results of operations and prospects.

We are subject to various laws relating to foreign investment and the export of certain technologies, and our failure to comply with these laws or adequately monitor the compliance of our suppliers and others we do business with could subject us to substantial fines, penalties and even injunctions, the imposition of which on us could have a material adverse effect on the success of our business.

We are subject to U.S. laws that regulate foreign investments in U.S. businesses and access by foreign persons to technology developed and produced in the United States. These laws include Section 721 of the Defense Production Act of 1950, as amended by the Foreign Investment Risk Review Modernization Act of 2018, and the regulations at 31 C.F.R. Parts 800 and 801, as amended, administered by the Committee on Foreign Investment in the United States; and the Export Control Reform Act of 2018, which is being implemented in part through Commerce Department rulemakings to impose new export control restrictions on "emerging and foundational technologies" yet to be fully identified. Application of these laws, including as they are implemented through regulations being developed, may negatively impact our business in various ways, including by restricting our access to capital and markets; limiting the collaborations we may pursue; regulating the export of our products, services, and technology from the United States and abroad; increasing our costs and the time necessary to obtain required authorizations and to ensure compliance; and threatening monetary fines and other penalties if we do not.

Risks related to employee matters, managing our growth and other risks related to our business

Unfavorable geopolitical and global economic conditions, including tariffs and trade tensions, could adversely affect our business, financial condition and results of operations.

Our results of operations could be adversely affected by general conditions in the global economy, the global financial markets, and adverse geopolitical and macroeconomic developments. U.S. and global market and economic conditions have been, and continue to be, volatile due to many factors, including tariffs and trade tensions, supply chain challenges, ongoing military conflicts, related sanctions, changes in U.S.-China relations, elevated inflation rates and the responses by central banking authorities to control such inflation, among others. General business and economic conditions that could affect our business, financial condition or results of operations include fluctuations in economic growth, debt and equity capital markets, bank failures, liquidity of the global financial markets, the availability and cost of credit, investor and consumer confidence, and the strength of the economies in which we, our manufacturers and our suppliers operate.

In addition, a severe or prolonged global economic downturn could result in a variety of risks to our business. For example, inflation rates, particularly in the United States, have been elevated compared to recent historical levels, and continued high rates of inflation may result, directly or indirectly, in increases in our operating costs (including our labor costs) and limits on our ability to access credit or otherwise raise capital on acceptable terms, if at all. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

In response to the invasion of Ukraine by Russia, the United States, United Kingdom and EU, along with others, imposed significant new sanctions and export controls against Russia, Russian banks and certain Russian individuals and may implement additional sanctions or take further punitive actions in the future. The full economic and social impact of the sanctions imposed on Russia (as well as possible future punitive measures that may be implemented), as well as the counter-measures imposed by Russia, in addition to the ongoing military conflict between Ukraine and Russia, which could conceivably expand into the surrounding region, remains uncertain; however, both the conflict and related sanctions have resulted and could continue to result in disruptions to trade, commerce, pricing stability, credit availability, supply chain continuity and reduced access to liquidity in both Europe and globally, and has introduced significant uncertainty into global markets. As a result, our business and results of operations, including conduct of any global clinical trials with sites in eastern Europe and western Asia, may be adversely affected by the ongoing conflict between

Ukraine and Russia and related sanctions, particularly to the extent it escalates to involve additional countries, further economic sanctions or wider military conflict.

Tensions between the United States and China have increased over the past few years as a result of disputes in areas including trade policy, intellectual property, cybersecurity and data privacy, as well as due to geopolitical conflicts such as the war between Ukraine and Russia. We conduct manufacturing and clinical development activities in China. Any unfavorable government policies on cross-border relations or international trade, changes to law, executive orders, tariffs, treaties or trade agreements, or deterioration in U.S.-China relations or international trade may adversely affect the import or export of our drug candidates and materials required for manufacturing or otherwise delay our product development activities, which could in turn have a material adverse effect on our business, financial condition and results of operations.

Our success is highly dependent on our ability to attract and retain highly skilled executive officers, employees and key consultants.

To succeed, we must recruit, retain, manage and motivate qualified clinical, scientific, technical and management personnel, and we face significant competition for experienced 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, including certain key consultants.

Furthermore, although we have employment offer letters with each of our executive officers, each of them may terminate their employment with us at any time. We do not maintain "key person" insurance for all of our executives or employees. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our operating results. In particular, the loss of one or more of our executive officers could be detrimental to us if we cannot recruit suitable replacements in a timely manner. The competition for qualified personnel in the biotechnology field is intense and as a result, we may be unable to continue to attract and retain qualified personnel necessary for the future success of our business. We could in the future have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts.

Many of the other biotechnology companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better prospects for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can continue to commercialize our lead product and develop and commercialize our product candidates will be limited and the potential for successfully growing our business will be harmed.

International trade policies, including tariffs, sanctions and trade barriers may adversely affect our business, financial condition, results of operations and growth prospects.

The current international trade and regulatory environment is subject to significant ongoing uncertainty. The U.S. government has recently announced substantial new tariffs affecting a wide range of products and jurisdictions and has indicated an intention to continue developing new trade policies, including with respect to the pharmaceutical industry. In response, certain foreign governments have announced or implemented retaliatory tariffs and other protectionist measures. These developments have created a dynamic and unpredictable trade landscape, which is adversely impacting, and may continue to adversely impact, our business.

Current or future tariffs may result in increased research and development expenses, including with respect to increased costs associated with active pharmaceutical ingredients, raw materials, laboratory equipment and research materials and components. In addition, such tariffs may increase our supply chain complexity and could also potentially disrupt our existing supply chain. Trade restrictions affecting the import of materials necessary for clinical trials could result in delays to our development timelines. Increased development costs and extended development timelines could place us at a competitive disadvantage compared to companies operating in regions with more favorable trade relationships and could reduce investor confidence, negatively impacting our ability to secure additional financing on favorable terms or at all. In addition, as we continue to commercialize our lead product and advance toward commercialization of our product candidates, tariffs and trade restrictions could hinder our ability to establish cost-effective production capabilities, negatively impacting our growth prospects.

Trade disputes, tariffs, restrictions and other political tensions between the U.S. and other countries may also exacerbate unfavorable macroeconomic conditions including inflationary pressures, foreign exchange volatility, financial market instability, and economic recessions or downturns. The ultimate impact of current or future tariffs and trade restrictions remains uncertain and could materially and adversely affect our business, financial condition, and prospects. While we actively monitor these risks, any prolonged economic downturn, escalation in trade tensions, or deterioration in international perception of U.S.-based companies could materially and adversely affect our business, results of operations and financial condition. In addition, trade developments have and may continue to heighten the risks related to the other risk factors described elsewhere in this Quarterly Report on Form 10-Q.

If we are unable to establish and maintain sales or marketing capabilities or enter into agreements with third parties to sell or market our lead product or product candidates, we may not be able to successfully sell or market our lead product or product candidates, if approved.

In order to successfully commercialize our lead product and commercialize any product candidates, if approved, we must build and maintain marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services for each of the territories in which we may have approval to sell or market our lead product or product candidates, if approved. We may not be successful in accomplishing these required tasks.

Establishing and maintaining an internal sales or marketing team with technical expertise and supporting distribution capabilities to continue to commercialize our lead product and commercialize our product candidates, if approved, will be expensive and time-consuming, and will require significant attention of our executive officers to manage. Any failure or delay in the development or maintenance of our internal sales, marketing and distribution capabilities could adversely impact the successful commercialization of our lead product or product candidates, if approved, if we do not have arrangements in place with third parties to provide such services on our behalf. Alternatively, if we choose to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems, we will be required to negotiate and enter into arrangements with such third parties relating to the proposed collaboration. If we are unable to enter into such arrangements, when needed, on acceptable terms or at all, we may not be able to successfully commercialize our lead product or any product candidate that may receive regulatory approval, or any such commercialization may experience delays or limitations. If we are unable to successfully commercialize our lead product or approved product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

In order to successfully implement our plans and strategies, we will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of June 30, 2026, we had 361 full-time employees, including 152 employees engaged in research and development. In order to successfully implement our development and commercialization plans and strategies, and as we continue to operate as a public company, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical, FDA and other comparable foreign regulatory authorities' review processes for our lead product and product candidates, while complying with any contractual obligations to contractors and other third parties we may have; and
- improving our operational, financial and management controls, reporting systems and procedures.

In addition, we are conducting multiple clinical trials of atacicept. Given the small size of our organization, we may encounter difficulties managing multiple clinical trials at the same time, which could negatively affect our ability to manage growth of our organization. Our future financial performance and our ability to successfully commercialize our lead product and develop and commercialize, if approved, our product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including key aspects of clinical development and manufacturing. We cannot assure you that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by third-party service providers is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval of our product candidates or otherwise advance our business. We cannot assure you that we will be able to manage our existing third-party service providers or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and/or engaging additional third-party service providers, we may not be able to successfully implement the tasks necessary to further commercialize our lead product or develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

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

Our headquarters is located in Brisbane, California, in a region which in the past has experienced severe earthquakes and fires. If earthquakes, fires, other natural disasters, terrorism or similar unforeseen events beyond our control prevent us from using all or a

significant portion of our office facilities, it may be difficult or, in certain cases, impossible for us to continue our business for a period of time. We do not have a comprehensive internal disaster recovery or business continuity plan in place and any third-party service provider plans are limited in nature. We may incur substantial expenses as a result of the absence or limited nature of our plans, which could have a material adverse effect on our business. Furthermore, parties integral to our supply chain are operating from single sites, increasing their vulnerability to natural disasters or other sudden, unforeseen and severe adverse events. If such an event were to affect our supply chain, it could have an adverse effect on our development plans and ability to conduct our clinical trials, and future commercialization plans.

Comprehensive tax reform legislation could adversely affect our business and financial condition.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the Inflation Reduction Act of 2022 includes provisions that will affect the U.S. federal income taxation of corporations, including imposing a minimum tax on the book income of certain large corporations and an excise tax on certain corporate stock repurchases that would be imposed on the corporation repurchasing such stock. Future guidance from the Internal Revenue Service and other tax authorities with respect to new or existing tax legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation. In addition, it is uncertain if and to what extent various states will conform to such legislation or any newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses under tax legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense. We continue to examine the impact tax legislation may have on our business. We urge investors to consult with their legal and tax advisers regarding the implications of past and potential future changes in U.S. tax laws on an investment in our common stock.

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

We have incurred losses during our history, we expect to continue to incur significant losses for the foreseeable future, and we may never achieve profitability. As of December 31, 2025, we had federal and state net operating loss (NOL) carryforwards of $389.9 million and $42.3 million, respectively, of which $10.2 million of federal NOL carryforwards and $37.0 million of state NOL carryforwards will begin expiring in the years 2032 and 2036, respectively, if not utilized. We also have $379.6 million of federal NOL carryforwards as of December 31, 2025 that do not expire. Our NOL carryforwards are subject to review and possible adjustment by the U.S. and state tax authorities. NOLs generated in tax years ending on or prior to December 31, 2017 are only permitted to be carried forward for 20 taxable years under applicable U.S. federal tax law. Federal NOLs generated in tax years ending after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal NOLs is limited to 80% of current year taxable income. At the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. For example, California recently enacted legislation that, with certain exceptions, suspends the ability to use California net operating losses to offset California income and limits the ability to use California business tax credits to offset California taxes, for taxable years beginning after 2023 and before 2027. It is generally uncertain if and to what extent various states will conform to federal tax laws.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change" (generally defined as a cumulative change in our ownership by "5-percent shareholders" that exceeds 50 percentage points over a rolling three-year period), the corporation's ability to use its pre-change NOLs and certain other pre-change tax attributes to offset its post-change income and taxes may be limited. Similar rules may apply under state tax laws. We may have experienced such ownership changes in the past, and we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which are outside our control. We have not conducted any studies to determine annual limitations, if any, that could result from such changes in the ownership. Our ability to utilize those NOLs could be limited by an "ownership change" as described above and consequently, we may not be able to utilize a material portion of our NOLs and certain other tax attributes, which could have an adverse effect on our cash flows and results of operations.

A variety of risks associated with marketing our lead product or any future product candidate we may develop internationally could significantly harm our business, financial condition, results of operations and prospects.

Although our lead product, TRUTAKNA, received accelerated approval from the FDA for treatment of IgAN, we plan to seek regulatory approval for our lead product, and product candidates we may develop, outside of the United States and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- differing regulatory requirements and reimbursement regimes in foreign countries;
- 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;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the FCPA or 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 United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism.

These and other risks associated with our international operations may significantly harm our business, financial condition, results of operations and prospects.

Risks related to our intellectual property

Our success depends on our ability to protect our intellectual property and our proprietary technologies.

Our commercial success depends in part on our and our current or future licensors', licensees' or collaborators' ability to obtain and maintain proprietary or intellectual property protection in the United States and other countries for our lead product and product candidates and technologies related to their various uses. We generally seek to protect our proprietary position by, among other things, filing patent applications in the United States and abroad related to our proprietary technologies, and their manufacture and uses that are important to our business, as well as inventions and improvements that are important to the development and implementation of our business. Our owned and in-licensed patents and patent applications in both the United States and certain foreign jurisdictions relate to our lead product and product candidates. There can be no assurance that the claims of our owned or in-licensed patents, or any patent application that issues as a patent, will exclude others from making, using or selling our lead product, product candidates, or any future product candidates or products that are substantially similar to our lead product, product candidates, or any future product candidates. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary and intellectual property position. We may seek to protect our proprietary position by acquiring or in-licensing additional relevant issued patents or pending applications from third parties. If we or our potential licensors, licensees or collaborators are unable to obtain or maintain patent protection with respect to our lead product or product candidates, proprietary technologies and their uses, our business, financial condition, results of operations and prospects could be significantly harmed.

Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology. There can be no assurance that our owned or in-licensed patent applications or our current or future licensors', licensees' or collaborators' patent applications will result in additional patents being issued or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents issued will not be infringed, designed around or invalidated by third parties.

Moreover, in the future, some of our owned or in-licensed patents and patent applications may be co-owned with third parties. If we are unable to obtain exclusive licenses to any such co-owners' interest in such patents or patent applications, then 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 may need the cooperation of any such co-owners in order to enforce such patents against third parties, and such cooperation may not be provided to us.

Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. Thus, the degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. These uncertainties and/or limitations in our ability to properly protect the intellectual property rights relating to our lead product or product candidates could significantly harm our business, financial condition, results of operations and prospects.

We cannot be certain that the claims in our U.S. pending patent applications and corresponding international applications will be considered patentable by the United States Patent and Trademark Office (USPTO) courts in the United States or by the patent offices

and courts in foreign countries, nor can we be certain that the claims in our issued patent(s) will not be found invalid or unenforceable if challenged.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our lead product or product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- patent applications must be filed in advance of certain events (e.g., third-party filings, certain sales or offers for sale, or other activities that might be legally deemed to be public disclosures) and we might not be aware of such events or otherwise might not succeed in filing applications before they occur;
- 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, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- patent applications may not result in any patents being issued;
- patents may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates.

The patent prosecution process is also expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection, for example, if patentable aspects are publicly disclosed, by us or a third party, such as by public use, sale or offer for sale, or publication.

In addition, although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Further, although we require our employees, commercial contractors, and certain consultants and investigators to enter into invention assignment agreements that grant us ownership of any discoveries or inventions made by them while in our employ, we cannot guarantee that we have entered into such agreements with each party, we cannot provide any assurances that all such agreements have been duly executed, and any of these parties may breach such agreements and claim ownership in intellectual property that we believe is owned or in-licensed by us. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our owned or any licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

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. Should any of the above events occur, it could significantly harm our business, financial condition, results of operations and prospects.

If we breach our license agreement with Ares, an affiliate of Merck, related to atacicept, the license agreement with Novartis related to MAU868, or the license agreement with Stanford related to VT-109, we could lose the ability to continue the development and commercialization of atacicept, MAU868, or VT-109, respectively.

We are dependent on patents, know-how and proprietary technology licensed or sublicensed to us from Ares, Novartis, and Stanford. Our commercial success depends upon our ability to develop, manufacture, market and sell our lead product and product candidates and use our and our licensor's proprietary technologies without infringing the proprietary rights of third parties. Ares, Novartis, or Stanford may have the right to terminate the applicable license agreement in full in the event we materially breach or default in the performance of any of the obligations under the applicable license agreement. A termination of any of our existing license agreements could result in the loss of significant rights and could harm our ability to continue to commercialize our lead product and commercialize our product candidates. Additionally, certain patents, know-how and proprietary technology of third parties, including certain composition of matter patents, are sublicensed to us and in the event the applicable license agreement

terminates, expires or is in dispute, it could result in the loss of significant rights and could harm our ability to continue to commercialize our lead product and commercialize our product candidates.

Disputes may also arise between us and Ares, an affiliate of Merck, Novartis, Stanford, or any future potential licensors, regarding intellectual property subject to a license agreement, including:

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

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

In addition, we acquired worldwide, exclusive rights to atacicept pursuant to the Ares Agreement, and worldwide, exclusive rights to develop, manufacture and commercialize MAU868 pursuant to the asset purchase agreement (Amplyx Agreement) with Amplyx Pharmaceuticals, Inc. (Amplyx), a wholly owned subsidiary of Pfizer, Inc., pursuant to which we acquired Amplyx's right, title and interest in the license agreement between Amplyx and Novartis related to MAU868. We also entered into an exclusive license agreement with Stanford for rights to VT-109. The Ares Agreement, Novartis License, and Stanford Agreement are complex, and certain provisions may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property, or increase what we believe to be our financial or other obligations under such agreement, either of which could have an adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangement on commercially acceptable terms, we may be unable to successfully commercialize our lead product or develop and commercialize the affected product candidates, which could have an adverse effect on our business, financial conditions, results of operations, and prospects.

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

We may be required to make significant payments under our license agreements related to our lead product and product candidates.

As consideration for the license under the Ares Agreement, we paid Ares $25.0 million in 2020 upon delivery and initiation of the transfer of specified information and materials and $15.0 million in January 2026 upon achievement of the BLA filing. Upon accelerated approval of TRUTAKNA by the FDA in July 2026, we became obligated to pay $20.0 million to Ares. We are required to pay Ares additional aggregate milestone payments, including $10.0 million due upon the first filing of an approval application in the EU, and up to $131.5 million upon the achievement of regulatory filing and approval milestones for other geographic regions and indications, and aggregate milestone payments of up to $515.0 million upon the achievement of specified worldwide aggregate net sales milestones, beginning with $15.0 million if net sales reach $250.0 million and $50.0 million if net sales reach $500.0 million. Commencing on the first commercial sale of licensed products, we are obligated to pay tiered royalties of low double-digit to mid-teen percentages on annual net sales of the products covered by the license. In the event we sublicense our rights under the Ares Agreement, we are obligated to pay Ares a percentage ranging from the mid-single-digit to the low double-digits of specified sublicensing income received.

Under the Amplyx Agreement, we are obligated to make certain milestone payments to Amplyx in an aggregate amount of up to $7.0 million based on the achievement of certain regulatory milestones. Further, we are required to pay Amplyx low single digit percentage royalties on net sales of MAU868 on a country-by-country and product-by-product basis. In addition, pursuant to the Novartis License, we are obligated to make certain milestone payments to Novartis in an aggregate amount of up to $62.0 million based on the achievement of certain clinical development, regulatory and sales milestones. Further, we are required to pay Novartis mid-to high-single digit percentage royalties based on net sales of MAU868 on a country-by-country and product-by-product basis.

Under the Stanford Agreement, we are obligated to make certain milestone payments to Stanford based on the achievement of certain development, regulatory, and commercial milestones. Further, we are required to pay Stanford royalties based on net sales of

VT-109 worldwide. In the event we sublicense our rights under the Stanford Agreement, we are obligated to pay Stanford a percentage of specified sublicensing income received.

If milestone or other non-royalty obligations become due, we may not have sufficient funds available to meet our obligations, which will adversely affect our business operations and financial condition.

If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical product candidates would be adversely affected.

The patent positions of biotechnology companies generally are highly uncertain, involve complex legal and factual questions for which important legal principles remain unsolved and have been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our lead product or product candidates, or which effectively prevent others from commercializing competitive technologies and product candidates. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, many countries restrict the patentability of methods of treatment of the human body.

Moreover, the coverage claimed in a patent application can be significantly reduced before a patent is issued, and its scope can be reinterpreted after issuance. Legal standards relating to valid and enforceable claim scope are unsettled in the United States and elsewhere and disputes challenging or re-defining scope are common in the biopharmaceutical industry. Even if patent applications we own or in-license currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we own or in-license may be challenged or circumvented by third parties or may be narrowed or invalidated as a result of challenges by third parties. Consequently, we do not know whether our lead product or product candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner which could significantly harm our business, financial condition, results of operations and prospects.

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

The process by which patent applications are examined and considered for issuance as patents involves consideration by the relevant patent office of "prior art" relative to the invented technology. Different countries have different rules about what information or events can be considered "prior art," and different requirements regarding when a patent application must be filed relative to any particular piece of potential prior art. Moreover, legal decisions can re-interpret or change whether particular information or events are considered to be "prior art." Still further, in the United States, patent applicants are required to notify the USPTO of any material "prior art" of which they are aware for the patent examiner to consider in addition to independent searches that the patent examiner is required to do. Also, in the United States and certain other jurisdictions, third parties are entitled to submit prior art to patent offices for consideration during examination.

We may not be aware of certain relevant prior art, may fail to identify or timely cite certain prior art, or may not be able to convince a patent examiner that our patent(s) should issue in light of the art. Also, we cannot be certain that all relevant art will be or was identified during examination of a patent application so that, even if a patent issues, it may be susceptible to challenge that it is not valid over art that was not considered during its examination.

We may be subject to a third-party pre-issuance submission of prior art to the USPTO or other jurisdictions, or become involved in post-grant challenges such as opposition, derivation, revocation, reexamination, post-grant review (PGR) and inter partes review (IPR), or other similar proceedings, or in litigation, challenging our patent rights, including by challenging the validity or the claim of priority of our patents. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize our lead product or product candidates and compete directly with us, without payment to us. Such challenges may result in loss of patent rights, loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our lead product or product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, including art of which we were unaware, and art which was not raised during prosecution of any of our patents or patent applications. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our technology or platform, or any product candidates that we may develop. Such a loss of patent protection would significantly impact our business, financial condition, results of operations and prospects. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop, or commercialize our lead product or current or future product candidates or could embolden competitors to launch

products or take other steps that could disadvantage us in the marketplace or draw us into additional expensive and time consuming disputes. Should any of these events occur, it could significantly harm our business, financial condition, results of operations and prospects.

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

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- we may not be able to detect infringement of our issued patents;
- others may be able to develop products that are similar to our lead product or product candidates, but that are not covered by the claims of the patents that we may in-license in the future or own;
- our competitors may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use and sell our lead product or product candidates;
- we, or our current or future collaborators or license partners, might not have been the first to make the inventions covered by the issued patents or patent applications that we may in-license in the future or own;
- we, or our current or future collaborators or license partners, might be found not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that the pending patent applications we may in-license in the future or own will not lead to issued patents;
- it is possible that there are prior public disclosures that could invalidate our patents, or parts of our patents, for which we are not aware;
- issued patents that we hold rights to may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- issued patents may not have sufficient term or geographic scope to provide meaningful protection;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may have an adverse effect on our business; and
- we may choose not to file a patent in order to maintain certain trade secrets, and a third party may subsequently file a patent covering such intellectual property.

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

Our commercial success depends significantly on our ability to operate without infringing, misappropriating or otherwise violating the patents and other proprietary rights of third parties. Claims by third parties that we infringe, misappropriate or otherwise violate their proprietary rights may result in liability for damages or prevent or delay our developmental and commercialization efforts.

Our commercial success depends in part on avoiding infringement, misappropriation or other violations of the patents and proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe, misappropriate or otherwise violate patents or other intellectual property rights owned or controlled by third parties. A finding by a court or administrative body that we infringe the claims of issued patents owned by third parties could preclude us from successfully commercializing our lead product or product candidates.

Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our lead product or product candidates, or impair our competitive position. There is a substantial amount of litigation adversarial activity, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology industry, including patent infringement lawsuits, and proceedings, such as oppositions, reexaminations, IPR proceedings, PGR proceedings, and other third party submissions, before the USPTO and/or corresponding foreign patent offices. In addition, many companies in intellectual property-dependent industries, including the biotechnology industry, have employed

intellectual property litigation as a means to gain an advantage over their competitors. Numerous third-party U.S. and foreign issued patents and pending patent applications may exist in the fields in which we are commercializing our lead product and developing our product candidates. There may be third-party patents or patent applications with claims to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our lead product or product candidates.

It is possible that one or more organizations will hold patent rights to which we will need a license. If those organizations refuse to grant us a license to such patent rights on reasonable terms, we may be unable to develop, manufacture, market, sell and commercialize products or services or perform research and development or other activities covered by these patents. In the event that any of these patents were to issue and be asserted against us, we believe that we would have defenses against any such assertion, including that such patents are not valid. However, if such defenses to such assertion were unsuccessful, we could be liable for damages, which could be significant and include treble damages and attorneys' fees if we are found to willfully infringe such patents. We could also be required to obtain a license to such patents, which may not be available on commercially reasonable terms or at all. If we are unable to obtain such a license, we could be precluded from commercializing any product or product candidates that were ultimately held to infringe such patents.

As the biotechnology industry expands and more patents are issued, the risk increases that our lead product or product candidates may be subject to claims of infringement of the patent rights of third parties. Because patent applications are maintained as confidential for a certain period of time, until the relevant application is published, we may be unaware of third-party patents that may be infringed by commercialization of our lead product or product candidates, and we cannot be certain that we were the first to file a patent application related to a product, product candidate or technology. Moreover, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our lead product or product candidates may infringe. In addition, identification of third-party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. There is also no assurance that there is not prior art of which we are aware, but which we do not believe is relevant to our business, which may, nonetheless, ultimately be found to limit our ability to make, use, sell, offer for sale or import our lead product or product candidates that may be approved in the future, or impair our competitive position. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Still further, we cannot rely on our experience that third parties have not so far alleged that we infringe their patent rights, as provisions of U.S. patent laws provide a safe harbor from patent infringement for therapeutic products under clinical development.

Any claims of patent infringement, misappropriation or other violations asserted by third parties would be time consuming and could:

- result in costly litigation that may cause negative publicity;
- divert the time and attention of our technical personnel and management;
- cause development delays;
- prevent us from successfully commercializing our lead product or product candidates;
- require us to develop non-infringing technology, which may not be possible on a cost-effective basis;
- subject us to significant liability to third parties; or
- require us to enter into royalty or licensing agreements, which may not be available on commercially reasonable terms, or at all, or which might be non-exclusive, which could result in our competitors gaining access to the same technology.

Any patent-related legal action against us claiming damages or seeking to enjoin commercial activities relating to our lead product or product candidates, or processes could subject us to significant liability for damages, including treble damages if we were determined to willfully infringe, and require us to obtain a license to manufacture or market our lead product or product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. Moreover, even if we or a future strategic partner were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. In addition, we cannot be certain that we could redesign our processes for our lead product or product candidates to avoid infringement, if necessary.

An adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from successfully commercializing our lead product or developing our product candidates, which could significantly harm our business, financial condition and operating results. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing our lead product or product candidates, if approved.

Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have an adverse effect on our ability to raise additional funds or otherwise significantly harm our business, financial condition, results of operations and prospects.

We may not be successful in obtaining or maintaining necessary rights from third parties that we identify as necessary for future product candidates we may develop through acquisitions and in-licenses.

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

While we may have in-licensed patents that cover our product candidates, it is possible that third parties may have blocking patents that prevent us from marketing, manufacturing or commercializing our patented products and practicing our in-licensed patented technology.

We may be unsuccessful in acquiring or in-licensing compositions, methods of use, processes, or other intellectual property rights from third parties that we identify as necessary for practicing inventions claimed by our patents, including the manufacture, sale and use of our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could significantly harm our business, financial condition, results of operations and prospects.

We may be involved in lawsuits to protect or enforce our patents, which could be expensive, time consuming and unsuccessful. Further, our issued patents could be found invalid or unenforceable if challenged in court.

Competitors or other third parties may infringe, misappropriate or otherwise violate our intellectual property rights. To prevent infringement or unauthorized use, we may be required to file infringement or other intellectual property claims, which can be expensive and time-consuming. In addition, in a patent infringement proceeding, a court may decide that a patent we may in-license in the future or own is not valid, is unenforceable, and/or is not infringed, or may refuse to stop the other party from using the technology at issue on the grounds that our owned or in-licensed patents do not cover the technology in question. If we or any of our potential future collaborators were to initiate legal proceedings against a third party to enforce a patent directed at our lead product or any of our product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable in whole or in part. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description, non-enablement, or obviousness-type double patenting. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution.

If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we may lose at least part, and perhaps all, of the patent protection on such product or product candidate. 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 our lead product or current or future product candidates. Such a loss of patent protection would significantly harm our business, financial condition, results of operations and prospects.

We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Our business could be harmed if in litigation the prevailing party does not offer us a license on commercially reasonable terms.

Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other legal proceedings relating to our intellectual property rights, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings.

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

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

During the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our existing products, programs or intellectual property could be diminished. Accordingly, the market price of shares of our common stock may decline. Such announcements could also harm our reputation or the market for our future products, which could significantly harm our business, financial condition, results of operations and prospects.

Derivation proceedings may be necessary to determine inventorship, and an unfavorable outcome may require us to cease using the related technology or to attempt to license rights from the prevailing party.

Derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine inventorship with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of derivation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with such proceedings could have an adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development or manufacturing partnerships that would help us bring our product candidates to market. Should any of these events occur, it could significantly harm our business, financial condition, results of operations and prospects.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our patents.

As is the case with other biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology industry involve a high degree of technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time consuming and inherently uncertain. Our ability to obtain patents is highly uncertain because, to date, some legal principles remain unresolved, and there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the United States. Furthermore, the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific, and factual issues. Changes in either patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection.

Further, the United States has enacted and implemented wide-ranging patent reform legislation and the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the U.S. federal courts, the USPTO, or similar authorities in foreign jurisdictions, 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 patent and the patents we might obtain or license in the future. For example, recent decisions raise questions regarding the award of patent term adjustment (PTA) for patents in families where related patents have issued without PTA. Thus, it cannot be said with certainty how PTA will or will not be viewed in the future and whether patent expiration dates may be impacted. An inability to obtain, enforce, and defend patents covering our proprietary technologies (including those for our lead product or product candidates) would adversely affect our business prospects and financial condition.

Similarly, changes in patent laws and regulations in other countries or jurisdictions, changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we may obtain in the future. Further, 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 United States and Europe. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. For example, if the issuance in a given country of a patent covering an invention is not followed by the issuance in other countries of patents covering the same invention, or if any judicial interpretation of the validity, enforceability or scope of the claims or the written description or enablement, in a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in another country, our ability to protect our intellectual property in those countries may be limited. Changes in either patent laws or in

interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection. For example, the complexity and uncertainty of European patent laws have also increased in recent years. In Europe, a new unitary patent system took effect on June 1, 2023, which will significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court (UPC). As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of any potential changes.

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

It is possible that we do not transfer or perfect ownership of all patents, patent applications or other intellectual property. This possibility includes the risk that we do not identify all inventors, or identify incorrect inventors, which may lead to claims disputing inventorship or ownership of our patents, patent applications or other intellectual property by former employees or other third parties. There is also a risk that we do not establish an unbroken chain of title from inventors to us. Errors in inventorship or ownership can sometimes also impact priority claims. If we were to lose ability to claim priority for certain patent filings, intervening art or other events may preclude us from issuing patents.

Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Such an outcome could significantly harm our business, financial condition, results of operations and prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and distraction to management and other employees.

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

Patents have a limited lifespan. Generally, issued patents are granted a term of 20 years from the earliest claimed non-provisional filing date. Various extensions may be available, but there can be no assurance that any such extensions will be obtained, and the life of a patent, and the protection it affords, is limited. In certain instances, patent term can be adjusted to recapture a portion of delay by the USPTO in examining the patent application (patent term adjustment) or extended to account for term effectively lost as a result of the FDA regulatory review period (patent term extension), or both. There is a risk that we may take action that detracts from any accrued patent term adjustment. Even if patents covering our lead product and product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Upon the expiration of our current patents, we may lose the right to exclude others from practicing these inventions. The expiration of these patents could also have a similar material adverse effect on our business, financial condition, prospects and results of operations.

Any of the foregoing could significantly harm our business, financial condition, results of operations and prospects.

Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time, and if we do not obtain protection under the Hatch-Waxman Amendments and similar non-United States legislation for extending the term of patents covering each of our product candidates, our business may be significantly harmed.

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. Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our United States patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, and similar legislation in the EU. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and 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 per approved drug product, and only those claims covering the approved drug product, a method for using it, or a method for manufacturing it may be extended. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our

patent rights for that product will be impacted and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced and could have a material adverse effect on our business.

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

Filing, prosecuting and defending patents in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States may be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we will not be able to prevent third parties from practicing our inventions in all countries outside the United States or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These infringing products may compete with our lead product or product candidates without any available recourse.

The laws of some other countries do not protect intellectual property rights to the same extent as the laws of the United States. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries. In addition, the legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to biopharmaceuticals. As a result, many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. Because the legal systems of many foreign countries do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceutical products, it could be difficult for us to stop the infringement, misappropriation or violation of our patents or our licensors' patents or marketing of competing products in violation of our proprietary rights. Proceedings to enforce our intellectual property and other proprietary 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 or the patents of our licensors at risk of being invalidated or interpreted narrowly, could put our patent applications or the patent applications of our licensors 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.

The ongoing conflict in Ukraine and related sanctions could significantly devalue our Russian and Eurasian patents. Recent Russian decrees may significantly limit our ability to enforce Russian patents. We cannot predict when or how this situation will change.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries 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 are 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, financial condition, results of operations and prospects may be significantly harmed.

In addition, recordation of licenses with respect to exclusively licensed patent rights outside of the United States is potentially costly and we might fail to record such rights timely. If we fail to timely record our patent rights, third parties may try to seek licenses from the patent owners, or we may not be able to recover full damages for patent infringement in jurisdictions where we have no such recordations, any of which could significantly harm our business, financial condition, results of operations and prospects.

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to the USPTO and various foreign patent offices at various points over the lifetime of our patents and/or patent applications. We have systems in place to remind us to pay these fees, and we rely on our outside patent annuity service to pay these fees when due. Additionally, the USPTO and various foreign patent offices require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, 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. If such an event were to occur, potential competitors might be able to enter the market with similar or identical products or technology, which could significantly harm our business, financial condition, results of operations and prospects.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business, financial condition, results of operations and prospects could be significantly harmed.

We intend to use registered or unregistered trademarks or trade names to brand and market ourselves and our products. Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business, financial condition, results of operations and prospects may be significantly harmed. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could significantly harm our business, financial condition, results of operations and prospects.

In addition, any proprietary name we propose to use with our current or future products in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

If we are unable to protect the confidentiality of our trade secrets, our business, financial condition, results of operations, prospects and competitive position would be significantly harmed.

In addition, we rely on the protection of our trade secrets, including unpatented know-how, technology and other proprietary information to maintain our competitive position. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions agreements with employees, consultants and advisors, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology or processes. Further, we cannot provide any assurances that all such agreements have been duly executed, and any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, or claim ownership in intellectual property that we believe is owned or in-licensed by us. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

Moreover, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced, and our competitive position would be harmed. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized. Any of the foregoing could significantly harm our business, financial condition, results of operations and prospects.

We may be subject to claims that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets.

We have entered into and may enter in the future into non-disclosure and confidentiality agreements to protect the proprietary positions of third parties, such as outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors, potential partners, lessees of shared multi-company property and other third parties. Many of our employees and consultants were previously employed at, may have previously provided or may be currently providing consulting services to, other biotechnology companies, including our competitors or potential competitors. Although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, collaborators and other third parties with whom we do business include provisions requiring such parties to assign rights in inventions to us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our future patents or patent applications. Defense of such matters, regardless of their merit, could involve substantial litigation expense and be a substantial diversion of employee resources from our business. We cannot predict whether we would

prevail in any such actions. Moreover, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from marketing or otherwise successfully commercializing our lead product or product candidates or technologies we may develop. Failure to defend against any such claim could subject us to significant liability for monetary damages or prevent or delay our developmental and commercialization efforts and cause us to lose valuable intellectual property rights or personnel, which could significantly harm our business, financial condition, results of operations and prospects. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

Parties making claims against us may be able to sustain the costs of complex intellectual property litigation more effectively than we can. 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. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have an adverse effect on our ability to raise additional funds or otherwise significantly harm our business, financial condition, results of operations and prospects.

Our rights to develop and successfully commercialize our technology, lead product, and product candidates may be subject, in part, to the terms and conditions of licenses granted to us by others.

We may enter into license agreements in the future with others to advance our research or commercialization of our lead product or product candidates. These and other licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products in the future. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in territories included in our licenses.

If we fail to comply with our obligations under any such license agreements, including obligations to make various milestone payments and royalty payments and other obligations, the licensor may have the right to terminate the license. If these agreements are terminated, we could lose intellectual property rights that are important to our business, be liable for any damages to such licensors or be prevented from developing and successfully commercializing our lead product or product candidates, and competitors could have the freedom to seek regulatory approval of, and to market, products identical to ours. Termination of these agreements or reduction or elimination of our rights under these agreements may also result in our being required to negotiate new or reinstated agreements with less favorable terms, cause us to lose our rights under these agreements, including our rights to important intellectual property or technology, or impede, delay or prohibit the further development or successful commercialization of our lead product or one or more product candidates that rely on such agreements. It is possible that we may be unable to obtain any additional licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to redesign our lead product or product candidates or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis.

In addition, subject to the terms of any such license agreements, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications covering the technology that we license from third parties. In such an event, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced and defended in a manner consistent with the best interests of our business, including the payment of all applicable fees for patents covering our lead product or product candidates. If our licensors fail to prosecute, maintain, enforce and defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our products that are subject of such licensed rights could be adversely affected. Further, we may not be able to prevent competitors from making, using and selling competing products. In addition, even where we have the right to control the prosecution of patents and patent applications we have licensed to and from third parties, we may still be adversely affected or prejudiced by the actions or inactions of our licensees, our licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution.

Our licensors may have relied on third-party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership 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 an adverse effect on our competitive position, business, financial condition, results of operations and prospects.

We may need to obtain additional licenses from existing licensors and others to advance our research or allow commercialization of our lead product or product candidates we develop. It is possible that we may be unable to obtain additional licenses at a reasonable cost or on reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to redesign our technology, lead product, product candidates, or the methods for manufacturing them 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 the affected product or product candidates, which could significantly harm our business, financial condition, results of operations and prospects significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current technology, manufacturing methods, lead product, product candidates, or future

methods or products resulting in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant. Should any of these events occur, it could significantly harm our business, financial condition, results of operations and prospects.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

Disputes may arise between us and our past, current or future licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patents and other rights to third parties;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- our right to transfer or assign the license;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

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

In spite of our best efforts, our licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize products and technology covered by these license agreements. If these in-licenses 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 identical to ours. This could significantly harm our competitive position, business, financial condition and prospects.

Intellectual property discovered through government funded programs may be subject to federal regulations such as "march-in" rights, certain reporting requirements 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.

We may develop, acquire, or license intellectual property rights that have been generated through the use of U.S. government funding or grants. Pursuant to the Bayh-Dole Act of 1980, the U.S. government has certain rights in inventions developed with government funding. These U.S. government rights include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right, under certain limited circumstances, to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (1) adequate steps have not been taken to commercialize the invention; (2) government action is necessary to meet public health or safety needs; or (3) government action is necessary to meet requirements for public use under federal regulations (also referred to as march-in rights). If the U.S. government exercised its march-in rights in our future intellectual property rights that are generated through the use of U.S. government funding or grants, we could be forced to license or sublicense intellectual property developed by us or that we license on terms unfavorable to us, and there can be no assurance that we would receive compensation from the U.S. government for the exercise of such rights. The U.S. government also has the right to take title to these inventions if the grant recipient fails to disclose the invention to the government or fails 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 to expend substantial resources. In addition, the U.S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for U.S. industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture

is not commercially feasible. This preference for U.S. industry may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. Any exercise by the government of any of the foregoing rights could harm our competitive position, business, financial condition, results of operations and prospects.

Risks related to our dependence on third parties

We rely, and expect to continue to rely, on third parties, including independent clinical investigators and CROs, to conduct certain aspects of our nonclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business, financial condition, results of operations and prospects could be significantly harmed.

We have relied upon and plan to continue to rely upon third parties, including independent clinical investigators and third-party CROs, to conduct certain aspects of our nonclinical studies and clinical trials and to monitor and manage data for our ongoing nonclinical and clinical programs. We rely on these parties for execution of our nonclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third-party contractors and CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for the conduct of clinical trials, as well as Good Laboratory Practices (GLPs), which include regulations and guidelines governing the conduct of certain nonclinical studies. Regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties or our CROs fail to comply with applicable GCPs, GLPs, or similar requirements, the data generated in our studies and clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials or nonclinical studies before approving our marketing applications, if ever. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials or nonclinical studies have complied with GCP or GLP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations or similar foreign requirements. Failure to comply and maintain adequate documentation with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be adversely affected if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Further, these investigators and CROs are not our employees and we will not be able to control, other than by contract, the amount of resources, including time, which they devote to our product candidates and clinical trials. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If independent investigators or CROs fail to devote sufficient resources to the development of our product candidates, or if CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed or precluded entirely, and our business, financial condition, results of operations and prospects could be significantly harmed.

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated. In addition, our CROs could fail to perform, we could terminate their agreements or they could go out of business. If our relationships with our CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding CROs involves substantial cost and requires management time and focus, and could delay development and commercialization of our product candidates. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can negatively impact our ability to meet our desired clinical development timelines. Additionally, CROs may lack the capacity to absorb higher workloads or take on additional capacity to support our needs. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays with CROs in the future or that these delays or challenges will not significantly harm our business, financial condition, results of operations and prospects.

Prior to obtaining the rights to MAU868 from Amplyx, third parties had been responsible for all development activities. Although we believe these historical development activities were conducted in accordance with applicable rules and regulations in material respects, we cannot assure you that we will not discover inaccuracies or noncompliance in prior development activities that have an adverse effect on the future development of MAU868. For example, a regulatory authority may choose to inspect an

investigational site and/or vendor such as a CRO for a MAU868 study that was previously conducted by Amplyx. Findings from such inspections could have an impact on the review of any future marketing applications by the FDA or foreign regulatory authorities.

In connection with our acquisition of MAU868, we have assumed the responsibility for ongoing clinical studies with MAU868, including related expenses and manufacturing and regulatory activities, which were previously managed and funded by Amplyx. This includes responsibility for the Phase 2 clinical trial of MAU868 for the treatment of reactivated BK virus infection in kidney transplant recipients previously conducted by Amplyx. Any adverse events or reactions experienced by subjects in the trial may be attributed to MAU868 and may limit our ability to obtain regulatory approval with labeling that we consider desirable, or at all.

We contract with third parties for the manufacture of our lead product and product candidates, and expect to continue to do so. This reliance on third parties increases the risk that we will not have sufficient quantities of our commercial product or product candidates necessary for their development, or obtain such quantities at an acceptable cost, which could delay, prevent or impair our commercialization or development efforts.

We do not currently have the infrastructure or internal capability to manufacture supplies of our lead product for commercialization or product candidates for use in development. We rely, and expect to continue to rely, on third-party manufacturers for the production of our lead product for commercialization and our product candidates for clinical trials under the guidance of members of our organization. Furthermore, raw materials for our lead product and product candidates are sourced, in some cases, from a single source supplier. If we were to experience an unexpected loss of supply of our lead product or product candidates for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing clinical trials.

We expect to continue to rely on third-party manufacturers for the commercial supply of our lead product and product candidates, if we obtain marketing approval. We may be unable to maintain or establish required agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the failure of the third party to manufacture our lead product or product candidates according to our schedule, or at all, including if our third-party contractors give greater priority to the supply of other products over our lead product or product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- the reduction or termination of production or deliveries by suppliers, or the raising of prices or renegotiation of terms;
- the termination or nonrenewal of arrangements or agreements by our third-party contractors at a time that is costly or inconvenient for us;
- the breach by the third-party contractors of our agreements with them;
- the failure of third-party contractors to comply with applicable regulatory requirements;
- the failure of the third party to manufacture our lead product or product candidates according to our specifications;
- the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;
- clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales;
- disruptions resulting from the effect of public health pandemics or epidemics; and
- the misappropriation of our proprietary information, including our trade secrets and know-how.

We have limited control over the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with cGMP regulations or similar foreign requirements for manufacturing both active drug substances and finished drug products. Third-party manufacturers may not be able to comply with cGMP regulations or similar foreign requirements. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, they will not be able to secure and/or maintain marketing approval for their manufacturing facilities. In addition, we have limited control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our lead product or product candidates, or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to successfully commercialize our lead product and develop our product candidates, if approved. We, or our contract manufacturers, any future collaborators and their contract manufacturers could be subject to periodic unannounced inspections by the FDA or other comparable foreign regulatory authorities, to monitor and ensure compliance with cGMP or similar foreign requirements. Despite our efforts to audit and verify regulatory

compliance, one or more of our third-party manufacturing vendors may be found on regulatory inspection by the FDA or other comparable foreign regulatory authorities to be noncompliant with cGMP regulations or similar foreign requirements. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including shutdown of the third-party vendor or invalidation of drug product lots or processes, fines, injunctions, civil penalties, delays, suspension, variation or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our lead product, product candidates or other drugs necessary for the successful commercialization of our lead product or development of our product candidates and significantly harm our business, financial condition, results of operations and prospects.

Furthermore, if the third-party providers of therapies or therapies in development used in combination with our product candidates are unable to produce sufficient quantities for clinical trials or for commercialization of our product candidates, or if the cost of combination therapies is prohibitive, our development and commercialization efforts would be impaired, which would significantly harm our business, financial condition, results of operations and prospects.

Our current and anticipated future dependence upon others for the manufacture of our lead product and product candidates or other drugs necessary for the successful commercialization of our lead product and development of our product candidates may adversely affect our future profit margins and our ability to successfully commercialize our lead product and any product candidates that receive marketing approval on a timely and competitive basis.

The manufacture of drugs is complex and our third-party manufacturers may encounter difficulties in production. If any of our third-party manufacturers encounter such difficulties, our ability to provide adequate supply of our product candidates for clinical trials or our lead product for patients could be delayed or prevented.

Manufacturing drugs, especially in large quantities, is complex and may require the use of innovative technologies. Each lot of an approved drug product must undergo thorough testing for identity, strength, quality, purity and potency. Manufacturing drugs requires facilities specifically designed for and validated for this purpose, and sophisticated quality assurance and quality control procedures are necessary. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures, product recalls or spoilage. When changes are made to the manufacturing process, we may be required to provide nonclinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes. If microbial, viral or other contaminations are discovered at the facilities of our manufacturer, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and significantly harm our business, financial condition, results of operations and prospects. The use of biologically derived ingredients can also lead to allegations of harm, including infections or allergic reactions, or closure of product facilities due to possible contamination. If our manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization as a result of these challenges, or otherwise, our development and commercialization efforts would be impaired, which would significantly harm our business, financial condition, results of operations and prospects.

If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

From time to time, we may evaluate various acquisition opportunities and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management’s attention from our existing programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and marketing approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions or pursue partnerships in the future, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities, and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

We may enter into collaborations with third parties for the development and commercialization of our lead product or product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of our lead product or product candidates.

In the future, we may partner with third-party collaborators for the development and commercialization of our lead product or product candidates. Our likely collaborators for any future collaboration arrangements would likely include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies.

We will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our lead product or product candidates. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements. Collaborations involving our lead product or product candidates could pose numerous risks to us, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations and may not perform their obligations as expected;
- collaborators may deemphasize or not pursue development or commercialization of our lead product or product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus, including as a result of a sale or disposition of a business unit or development function, or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our lead product or 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;
- a collaborator with marketing and distribution rights to multiple products may not commit sufficient resources to the marketing and distribution of our product relative to other products;
- collaborators may not properly obtain, maintain, defend or enforce our intellectual property rights or may use our proprietary information and intellectual property in such a way as to invite litigation or other intellectual property related proceedings that could jeopardize or invalidate our proprietary information and intellectual property or expose us to potential litigation or other intellectual property related proceedings;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our lead product or product candidates or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of our lead product or the applicable product or product candidates;
- collaboration agreements may not lead to development or commercialization of products or product candidates in the most efficient manner or at all; and
- if a collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our drug development or commercialization program could be delayed, diminished or terminated.

If we decide to establish collaborations in the future, but are not able to establish those collaborations on commercially reasonable terms, we may have to alter our development and commercialization plans.

Our drug development programs, the commercialization of our current or any future products or product candidates we may develop, and the successful commercialization of our lead product will require substantial additional cash to fund expenses. We may continue to seek to selectively form collaborations to expand our capabilities, potentially accelerate research and development activities and provide for commercialization activities by third parties. Any of these relationships 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.

If we seek collaborations in the future, we will face significant competition in seeking appropriate collaborators and the negotiation process is time-consuming and complex. 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 or comparable foreign regulatory authorities, the potential market for the subject product or product candidate, the costs and complexities of manufacturing and delivering such product or product candidate to patients, the potential of competing drugs, the existence of uncertainty with respect to our ownership of intellectual property and industry and market conditions generally. The potential collaborator may also consider alternative products, product candidates, or technologies for similar indications that may be available to collaborate on and whether such collaboration could be more attractive than the one with us for our product or product candidates. Further, we may not be successful in our efforts to establish a collaboration or other alternative arrangements for future product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view them as having the requisite potential to demonstrate safety and efficacy.

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. Even if we are successful in entering into a collaboration, the terms and conditions of that collaboration may restrict us from entering into future agreements on certain terms with potential collaborators.

If and when we seek to enter into additional collaborations, we may not be able to negotiate 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 a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

Risks related to ownership of our common stock

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

The trading price of our common stock has been, and is likely to be, highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. For example, the closing price of our common stock from January 1, 2025 to July 29, 2026, has ranged from a low of $18.86 to a high of $55.67. The stock market in general, and pharmaceutical and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies.

Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Quarterly Report on Form 10-Q, these factors include:

- the timing and results of nonclinical studies and clinical trials of our current or any future product candidates we may develop or those of our competitors;
- regulatory actions with respect to our product candidate or our competitors' products;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- the success of competitive products or announcements by potential competitors of their product development efforts;
- developments associated with our license with Ares, an affiliate of Merck, including any termination or other change in our relationship with Ares or Merck;
- developments associated with our license with Novartis, including any termination or other change in our relationship with Novartis or Amplyx;
- developments associated with our license with Stanford, including any termination or other change in our relationship with Stanford;
- actual or anticipated changes in our growth rate relative to our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;

- the results of our efforts to in-license or acquire additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- market conditions in the pharmaceutical and biotechnology sector;
- the public release of clinical trial data from companies perceived by investors to be comparable to us;
- changes in the structure of healthcare payment systems;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;
- sales of our securities by us, our insiders or our other stockholders; and
- general geopolitical, macroeconomic, industry and market conditions, including tariffs and trade tensions, supply chain challenges, ongoing military conflicts, related sanctions, changes in U.S.-China relations, elevated inflation rates and the responses by central banking authorities to control such inflation.

In addition, the trading prices for common stock of other biotechnology companies have been highly volatile as a result of factors unrelated to the specific company or its technology. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

The realization of any of the above risks or any of a broad range of other risks, including those described in this "Risk Factors" section, could have a dramatic and adverse impact on the market price of our common stock.

Our business could be negatively affected as a result of actions of activist stockholders, and such activism could impact the trading value of our securities.

Stockholders may, from time to time, engage in proxy solicitations or advance stockholder proposals, or otherwise attempt to effect changes and assert influence on our board of directors and management. Activist campaigns that contest or conflict with our strategic direction or seek changes in the composition of our board of directors could have an adverse effect on our operating results and financial condition. A proxy contest would require us to incur significant legal and advisory fees, proxy solicitation expenses and administrative and associated costs and require significant time and attention by our board of directors and management, diverting their attention from the pursuit of our business strategy. Any perceived uncertainties as to our future direction and control, our ability to execute on our strategy, or changes to the composition of our board of directors or senior management team arising from a proxy contest could lead to the perception of a change in the direction of our business or instability which may result in the loss of potential business opportunities, make it more difficult to pursue our strategic initiatives, or limit our ability to attract and retain qualified personnel and business partners, any of which could adversely affect our business and operating results. If individuals are ultimately elected to our board of directors with a specific agenda, it may adversely affect our ability to effectively implement our business strategy and create additional value for our stockholders. We may choose to initiate, or may become subject to, litigation as a result of the proxy contest or matters arising from the proxy contest, which would serve as a further distraction to our board of directors and management and would require us to incur significant additional costs. In addition, actions such as those described above could cause significant fluctuations in our stock price based upon temporary or speculative market perceptions or other factors that do not necessarily reflect the underlying fundamentals and prospects of our business.

If we experience material weaknesses in internal control over financial reporting in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. Section 404 of the Sarbanes-Oxley Act of 2002 (Section 404) requires that we evaluate and determine the effectiveness of our internal control over financial reporting and provide a management report on internal control over financial reporting on an annual basis. Our independent registered public accounting firm is required to attest to our management report on internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002. The process of compiling the system, process, and controls documentation necessary to perform the evaluation required under Section 404 is costly and challenging. We have incurred additional professional fees and other expenses and expended significant management efforts to comply with Section 404. In particular, these expenses and efforts increased in connection with the requirement to furnish an attestation report on internal control over financial reporting by our independent registered public accounting firm in our Annual Reports on Form 10-K for the years ended December 31, 2024 and 2025. We expect that these increased levels of expenses and efforts associated with Sarbanes-Oxley compliance will continue.

We have in the past and may in the future identify material weaknesses in our internal control over financial reporting. If we identify any such material weaknesses, if we are unable to comply with the requirements of Section 404 in a timely manner, if we are unable to assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be adversely affected, and we could become subject to investigations by the stock exchange on which our securities are listed, the SEC, or other regulatory authorities, which could require additional financial and management resources.

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

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

As of June 30, 2026, there were 71,955,885 shares of common stock outstanding.

Further, certain holders of our common stock have rights, subject to certain conditions, to require us to file registration statements covering the sale of their shares or to include their shares in registration statements that we may file for ourselves or our other stockholders. We also register all shares of common stock that we issue under our equity compensation plans. Such shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates.

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

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

We may seek additional capital through a variety of means, including through public or private equity, debt financings or other sources, including up-front payments and milestone payments from strategic collaborations. For example, since our initial public offering, we have completed a number of follow-on public offerings of our common stock. To the extent that we raise additional capital through the sale of equity or convertible debt or equity securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. Such financing may result in dilution to stockholders, imposition of debt covenants, increased fixed payment obligations or other restrictions that may affect our business. If we raise additional funds through up-front payments or milestone payments pursuant to strategic collaborations with third parties, we may have to relinquish valuable rights to our lead product or product candidates, or grant licenses on terms that are not favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

We do not currently intend to pay dividends on our common stock and, consequently, your ability to achieve a return on your investment will depend on appreciation of the value of our common stock.

We have never declared or paid any cash dividends on our equity securities. 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. In addition, the terms of the 2025 Loan Agreement restrict our ability to declare and pay dividends without the prior written consent of Oxford. Any return to stockholders will therefore be limited to any appreciation in the value of our common stock, which is not certain.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws and Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions also could 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 not all members of the board are elected at one time;
- 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 the board;
- 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;
- prohibit our stockholders from calling a special meeting of our stockholders;
- prohibit cumulative voting;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a stockholder rights plan, or so-called "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 66 2/3% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our amended and restated certificate of incorporations or amended and restated bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law (DGCL), which prohibits a person who owns 15% or more 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 15% or more of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States are the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware (or, if and only if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if and only if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) and any appellate court therefrom is the sole and exclusive forum for the following claims or causes of action under the Delaware statutory or common law:

- any derivative claim or cause of action brought on our behalf;
- any claim or cause of action for a breach of fiduciary duty owed by any of our current or former directors, officers, or other employees to us or our stockholders;
- any claim or cause of action against us or any of our current or former directors, officers or other employees arising out of or pursuant to any provision of the DGCL, our amended and restated certificate of incorporation, or our bylaws (as each may be amended from time to time);
- any claim or cause of action seeking to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws (as each may be amended from time to time, including any right, obligation, or remedy thereunder);
- any claim or cause of action as to which the DGCL confers jurisdiction to the Court of Chancery of the State of Delaware; and
- any claim or cause of action against us or any of our current or former directors, officers, or other employees governed by the internal-affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court's having personal jurisdiction over the indispensable parties named as defendants.

This choice of forum provision would not apply to claims or causes of action brought to enforce a duty or liability created by the Securities Act, the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction.

To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause or causes of action arising under the Securities Act, including all causes of action asserted against any defendant to such complaint. For the avoidance of doubt, this provision is

intended to benefit and may be enforced by us, our officers and directors, the underwriters to any offering giving rise to such complaint, and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying such offering. 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 amended and 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 a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find the exclusive forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business, financial condition, results of operations and prospects.

General risk factors

If our information technology systems, or those of any of our third-party partners (such as contract research organizations and clinical trial sites), or our data are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; additional costs; loss of revenue or profits; and other adverse consequences.

In the ordinary course of business, we and our third-party partners (such as contract research organizations and clinical trial sites) process confidential information, including intellectual property, proprietary business information, preclinical and clinical trial data and personal data (such as sensitive information) (collectively, Confidential Information).

As a result, we and our third-party partners are vulnerable to a variety of evolving threats that could cause security incidents. Cyberattacks, malicious internet-based activity, online and offline fraud and other similar activities threaten the confidentiality, integrity, and availability of our Confidential Information and information technology systems, and those of our third-party partners. These threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors that are becoming increasingly sophisticated in using techniques and tools – including artificial intelligence – that circumvent security controls, evade detection and remove forensic evidence.

Some actors, including without limitation nation-state and nation-state-supported actors, now engage and are expected to continue to engage in cyberattacks for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and our third-party partners (such as contract research organizations and clinical trial sites) may be vulnerable to a heightened risk of these attacks, including retaliatory cyberattacks that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our services.

We and our third-party partners are also subject to a variety of evolving threats, including but not limited to errors or malfeasance by personnel, malware (including as a result of advanced persistent threat intrusions), malicious code (such as viruses and worms), software vulnerabilities, hacking, denial or degradation of service attacks, misconfigurations, credential stuffing, social-engineering attacks (including deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), ransomware attacks, supply-chain attacks, software "bugs", server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, attacks enhanced or facilitated by AI, telecommunications and electrical failures, earthquakes, fires, floods and other similar threats. Any integration of AI in our or any third party's operations, products or services is expected to pose new or unknown cybersecurity risks and challenges.

In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, ability to provide our products or services, loss of Confidential Information and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

Remote work has increased risks to our information technology systems and Confidential Information, as more of our employees utilize network connections, computers, and devices outside our premises or network, including working at home, while in transit and in public locations. Additionally, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

In addition, our reliance upon third-party partners and technologies to operate critical business systems and to process Confidential Information could introduce new cybersecurity risks and vulnerabilities, including supply-chain attacks, and other threats to our business operations. We rely on third-party partners in a variety of contexts, including, without limitation, third-party providers of cloud-based infrastructure, encryption and authentication technology, employee email, content delivery to customers, and other functions. We also rely on third-party partners to provide other products, services, parts, or otherwise to operate our business. Our ability to monitor these third parties' cybersecurity practices is limited, and these third parties may not have adequate information security measures in place. Previously, we've been notified that certain third-party partners have experienced data breaches that may have involved our Confidential Information. If our third-party partners experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party partners fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps to detect, mitigate, and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of our third-party partners). We may not, however, detect and remediate all such vulnerabilities including on a timely basis. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

Any of the previously identified or similar threats could cause a security incident or other interruption from time to time that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our Confidential Information or our information technology systems, or those of the third-party partners. A security incident or other interruption could disrupt our ability (and that of our third-party partners (such as contract research organizations and clinical trial sites)) to provide our products or services. We may expend significant resources or modify our business activities (including our clinical trial activities) in an effort to protect against security incidents. Additionally, certain data privacy and security obligations may require us to implement and maintain specific security measures, industry-standard or reasonable security measures to protect our information technology systems and Confidential Information. If a significant system failure, accident or security breach were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss, corruption or unauthorized disclosure of our trade secrets, personal data or other proprietary or sensitive information or other similar disruptions. For example, the loss of clinical trial data from completed or ongoing clinical trials could result in delays in our development and regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

Applicable data privacy and security obligations may require us to notify relevant stakeholders, including affected individuals, customers, regulators and investors, of security incidents. Such disclosures are costly, and the disclosures or the failure to comply with such requirements could lead to adverse consequences. Security incidents, or perceived security incidents, may result in material adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing information (including personal data); substantial remediation costs; litigation (including class actions); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversion of management attention; interruptions in our operations (including availability of data); financial loss; and other similar harms.

There can also be no assurance that our cybersecurity risk management program and processes, including our policies, controls or procedures, will be fully implemented, complied with or effective in protecting our information technology systems and Confidential Information. Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be certain that our insurance coverage will be adequate or sufficient to protect us from or mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available to us on economically reasonable terms, or at all, or that such coverage will pay future claims.

In addition to experiencing a security incident, third parties may gather, collect, or infer Confidential Information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Additionally, our Confidential Information could be leaked, disclosed or revealed as a result of or in connection with our employees', personnel's or third-party partners' use of generative AI technologies.

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

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

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

Future changes in financial accounting standards or practices may cause adverse and unexpected revenue fluctuations and adversely affect our reported results of operations.

Future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our reported financial position or results of operations. Financial accounting standards in the United States are constantly under review and new pronouncements and varying interpretations of pronouncements have occurred with frequency in the past and are expected to occur again in the future. As a result, we may be required to make changes in our accounting policies. Those changes could affect our financial condition and results of operations or the way in which such financial condition and results of operations are reported. We intend to invest resources to comply with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from business activities to compliance activities.

The requirements of being a public company may strain our resources, result in more litigation and divert management's attention.

As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Stock Market LLC and other applicable securities rules and regulations. Complying with these rules and regulations has increased and will increase our legal and financial compliance costs, make some activities more difficult, time consuming or costly and increase demand on our systems and resources. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are required to disclose changes that have materially affected, or are likely to materially affect, our internal controls and procedures on a quarterly basis. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management's attention may be diverted from other business concerns, which could significantly harm our business, financial condition, results of operations and prospects. We may also need to hire additional employees or engage outside consultants to comply with these requirements, which will increase our costs and expenses.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are 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 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 our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business, financial condition, results of operations and prospects may be harmed.

These rules and regulations may make it more expensive for us to obtain director and officer liability insurance and, in the future, we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

By disclosing information in SEC filings required of a public company, our business and financial condition is more visible, which may result in threatened or actual litigation, including by competitors and other third parties. If those claims are successful, our business could be seriously harmed. Even if the claims do not result in litigation or are resolved in our favor, the time and resources needed to resolve them could divert our management's resources and seriously harm our business, financial condition, results of operations and prospects.

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our common stock may be volatile and, in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation and shareholder derivative actions. We may be the target of these types of litigation and claims in the future. These claims and litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business, financial condition, results of operations and prospects.

If securities or industry analysts do not publish research or reports, or if they publish adverse or misleading research or reports, regarding us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that securities or industry analysts publish about us, our business or our market. If few securities or industry analysts commence coverage of us, the stock price would be negatively impacted. If any of the analysts who cover us issue adverse or misleading research or reports regarding us, our business model, our intellectual property, our stock performance or our market, or if our operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

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

The terms of the 2025 Loan Agreement restrict our ability to declare and pay dividends without the prior written consent of Oxford.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

(a) None.

(b) None.

(c) The following table describes for the quarterly period covered by this report each trading arrangement for the purchase or sale of Company securities adopted, modified or terminated by our directors and officers that is either (1) a contract, instruction or written plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c), or a "Rule 10b5-1 trading arrangement," or (2) a "non-Rule 10b5-1 trading arrangement" (as defined in Item 408(c) of Regulation S-K):

				Type of Trading Arrangement				
Name	**Position**	**Action**	**Adoption/ Termination Date**	**Rule 10b5-1***	**Non-Rule 10b5-1****	**Total Shares of Class A Common Stock to be Sold*****	**Total Shares of Class A Common Stock to be Purchased**	**Expiration Date**
Joseph Young	Senior Vice President, Finance and Chief Accounting Officer	Adoption	April 7, 2026	X		Up to 19,800 shares	N/A	December 17, 2026
* Contract, instruction or written plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act.								
** "Non-Rule 10b5-1 trading arrangement" as defined in Item 408(c) of Regulation S-K under the Exchange Act.								
*** Represents the maximum number of shares that may be sold pursuant to the 10b5-1 trading arrangement. The number of shares to be sold is dependent on the satisfaction of certain conditions as set forth in the written plan.								

Item 6. Exhibits

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-40407), filed with the SEC on May 18, 2021).
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-40407), filed with the SEC on May 18, 2021).
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 amended, 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 amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1#	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2#	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File as its XBRL tags are embedded within the Inline XBRL document
101.SCH*	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104*	Cover Page formatted as Inline XBRL and contained in Exhibit 101

* Filed herewith.

The information in Exhibits 32.1 and 32.2 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (including this Quarterly Report on Form 10-Q), unless the Registrant specifically incorporates the foregoing information into those documents by reference.

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.

Vera Therapeutics, Inc.

Date: August 10, 2026

By: /s/ Marshall Fordyce
Marshall Fordyce, M.D.
Chief Executive Officer
(Principal Executive Officer)

Date: August 10, 2026

By: /s/ Sean Grant
Sean Grant
Chief Financial Officer
(Principal Financial Officer)

Exhibit 31.1

CERTIFICATIONS

I, Marshall Fordyce, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Vera 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: August 10, 2026

By: /s/ Marshall Fordyce

Marshall Fordyce, M.D.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, Sean Grant, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Vera 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: August 10, 2026

By: /s/ Sean Grant

Sean Grant
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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

In connection with the Quarterly Report of Vera Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

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

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

Date: August 10, 2026

By: /s/ Marshall Fordyce

Marshall Fordyce, M.D.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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

In connection with the Quarterly Report of Vera Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

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

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

Date: August 10, 2026

By: /s/ Sean Grant

Sean Grant
Chief Financial Officer
(Principal Financial Officer)