UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 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: 001-40708

CLIMB BIO, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**83-2273741**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
20 William Street **Suite 145** **Wellesley Hills, MA**	**02481**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (866)-857-2596

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	**CLYM**	**The Nasdaq Stock Market LLC (The Nasdaq Global Market)**

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 April 30, 2026, the registrant had 57,260,523 shares of common stock, $0.0001 par value per share, outstanding.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q (Quarterly Report) contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended (Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (Exchange Act), that involve substantial risk and uncertainties. All statements, other than statements of historical fact, contained in this Quarterly Report, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth, are forward-looking statements. The words "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "potential," "predict," "project," "should," "target," "will," "would," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

The forward-looking statements in this Quarterly Report include, among other things, statements about:

- the initiation, timing, progress and results of our research and development programs, nonclinical studies and clinical trials;
- the anticipated timing of the submission and clearance of investigational new drug applications (IND) and comparable foreign applications for budoprutug and CLYM116;
- our estimates regarding the potential patient populations for our product candidates;
- our estimates regarding expenses, future revenue, capital requirements, need for additional financing and the period over which we believe our cash, cash equivalents and marketable securities, including the proceeds from our private placement in April 2026, will be sufficient to fund our operating expenses and capital expenditure requirements;
- our plans to develop and, if approved, subsequently commercialize our product candidates;
- the timing of and our ability to submit applications for, and obtain and maintain regulatory approvals for our product candidates;
- our intellectual property position and our expectations regarding our ability to obtain, maintain and enforce intellectual property protection for our product candidates;
- our estimates regarding the size of the potential markets for our product candidates and our ability to serve those markets;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our competitive position and expectations regarding developments and projections relating to our competitors and any competing products that are or might become available;
- the impact of government laws and regulations;
- the benefits of, and our ability to satisfy our obligations under, our license agreements, including the technology transfer and exclusive license agreement (the Mabworks Agreement) with Beijing Mabworks Biotech Co., Ltd. (Mabworks);
- our ability to enter into future collaborations, strategic alliances, or option and license arrangements; and
- our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act (JOBS Act).

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in this Quarterly Report particularly in the "Risk Factor Summary" below and in Part II, Item 1A, "Risk Factors," that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

You should read this Quarterly Report and the documents that we reference herein and have filed or incorporated by reference hereto completely and with the understanding that our actual future results may be materially different from what we expect. The forward-looking statements contained in this Quarterly Report are made as of the date of this Quarterly Report, and we do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

Risk Factor Summary

Our business is subject to numerous risks and uncertainties, including those risks discussed in further detail below. These risks include, among others, the following:

- We have incurred significant losses since our inception and expect to continue incurring substantial losses for the foreseeable future.
- If we are unable to access capital when needed and on acceptable terms, we may be forced to delay, reduce, or discontinue our product candidate development programs, commercialization efforts, or other operations.
- We currently have no source of product revenue and may never become profitable.
- Our future success is dependent on the regulatory approval and commercialization of our product candidates, and if we are unable to successfully develop and commercialize our product candidates, or experience any delay in doing so, our business could be materially harmed.
- Preliminary, initial, or interim results from clinical trials that we announce, present, or publish from time to time may change as more data and information become available (or are updated based upon audit, validation and verification procedures of the data/information commonly performed for clinical trials) that could result in material changes in the final trial results.
- Nonclinical and clinical development involves a lengthy, complex, and expensive process, which is uncertain and may not predict final outcomes, and our product candidates may not demonstrate safety or efficacy in later-stage trials or satisfy regulatory requirements. Further, clinical development in immunology and autoimmune diseases presents inherent challenges, such as disease heterogeneity, variable clinical course, and evolving regulatory expectations for clinically meaningful endpoints, any of which may delay or impair our ability to obtain regulatory approval.
- If we encounter difficulties enrolling or retaining patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- We face significant competition in an environment of rapid technological change, and our competitors may develop or obtain regulatory approval for products before us or develop products that are safer, less expensive, or more effective than our product candidates, which could impair our commercial prospects.
- Our estimates of market opportunity and forecasts of market growth for our product candidates may prove to be inaccurate, and even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, or at all.
- We are, have been, and may in the future become, involved in litigation that could result in significant costs, divert the attention of management and harm our business.
- Enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval and commercialize our product candidates, if and when approved, and may affect the prices we may charge for such product candidates, if and when approved.
- Disruptions in our supply chain or manufacturing, including reliance on single-source suppliers and the complexities of biologics manufacturing, could delay, prevent, or impair our development or commercialization efforts.
- If we are unable to obtain, maintain, or enforce adequate intellectual property protection, our competitive position could be harmed, and we rely heavily on certain in-licensed patents and other intellectual property rights in connection with our development of our product candidates and may be required to acquire or license additional patents or other intellectual property rights to continue to develop and commercialize our product candidates.
- With respect to budoprutug, we own two pending U.S. provisional applications, nine pending U.S. nonprovisional patent applications, three pending Patent Cooperation Treaty international patent applications (each, a PCT application), and eight pending ex-U.S. patent applications, and we have also exclusively licensed four issued U.S. patents and at least 45 ex-U.S. patents or patent applications under our license agreement (the CRH Agreement) with Cancer Research Technology Limited (CRH). With respect to CLYM116, we have one exclusively in-licensed PCT application under the Mabworks Agreement and co-own three pending provisional patent applications with Mabworks. We can provide no assurance that any of our current or future patent applications will result in issued patents. If we are unable to obtain, maintain and protect sufficient patent and other intellectual property rights for our product candidates and technology, or if the scope of patent and other intellectual property rights obtained is not sufficiently broad, we may not be able to compete effectively in our market.

- If our information technology systems or data, or those of third parties upon which we rely, such as contract research organizations (CROs), are or were compromised or interrupted, we could experience adverse consequences resulting from such compromise or interruption, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse consequences.
- We may not be able to attract or retain key personnel necessary to execute our business strategy.
- The trading price of our common stock has been and may continue to be volatile, and purchasers of our common stock could incur substantial losses.
- We have identified material weaknesses in our internal control over financial reporting; if we are unable to remediate these material weaknesses, or if we identify additional material weaknesses in the future, or otherwise fail to maintain effective internal control over financial reporting, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business.

PART I - FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements (unaudited)

Climb Bio, Inc.
Condensed Consolidated Balance Sheets
(In thousands, except share and per share amounts)
(unaudited)

	March 31, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 8,356	$ 35,685
Short-term marketable securities	101,208	65,395
Prepaid expenses and other current assets	3,840	4,769
Total current assets	113,404	105,849
Long-term marketable securities	36,741	59,572
Operating lease right-of-use assets	447	505
Property and equipment, net	250	288
Other long-term assets	1,530	1,530
Total assets	$ 152,372	$ 167,744
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 860	$ 2,269
Accrued expenses and other current liabilities	2,948	4,459
Operating lease liabilities	263	256
Total current liabilities	4,071	6,984
Operating lease liabilities, net of current portion	216	285
Total liabilities	4,287	7,269
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Common stock, $0.0001 par value; 250,000,000 shares authorized; 47,768,543 and 47,766,338 shares issued and outstanding at March 31, 2026 and December 31, 2025, respectively	5	5
Additional paid-in capital	451,372	449,762
Accumulated other comprehensive income	157	435
Accumulated deficit	(303,449)	(289,727)
Total stockholders' equity	148,085	160,475
Total liabilities and stockholders' equity	$ 152,372	$ 167,744

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

Climb Bio, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)
(unaudited)

	Three Months Ended March 31,	
	2026	2025
Operating expenses:		
Research and development	$ 9,373	$ 17,327
General and administrative	5,838	5,691
Total operating expenses	15,211	23,018
Loss from operations	(15,211)	(23,018)
Other income (expense):		
Interest income	1,514	2,287
Foreign currency (loss)	(25)	(50)
Total other income, net	1,489	2,237
Net loss	$ (13,722)	$ (20,781)
Net loss per share, basic and diluted	$ (0.20)	$ (0.31)
Weighted-average common shares outstanding, basic and diluted	68,207,313	67,462,450
Comprehensive loss:		
Net loss	$ (13,722)	$ (20,781)
Other comprehensive income:		
Unrealized gain (loss) on marketable securities	(278)	263
Comprehensive loss	$ (14,000)	$ (20,518)

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

Climb Bio, Inc.
Condensed Consolidated Statements of Stockholders' Equity
(In thousands, except share amounts)
(unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2025	47,766,338	$ 5	$ 449,762	$ 435	$ (289,727)	$ 160,475
Vesting of restricted stock units	563	—	—	—	—	—
Issuance of common stock upon exercise of stock options	1,642	—	5	—	—	5
Stock-based compensation expense	—	—	1,605	—	—	1,605
Unrealized (loss) on marketable securities	—	—	—	(278)	—	(278)
Net loss	—	—	—	—	(13,722)	(13,722)
Balances at March 31, 2026	47,768,543	$ 5	$ 451,372	$ 157	$ (303,449)	$ 148,085

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2024	67,255,434	$ 7	$ 441,727	$ 23	$ (229,876)	$ 211,881
Vesting of restricted stock units	320,333	—	—	—	—	—
Stock-based compensation expense	—	—	2,022	—	—	2,022
Unrealized gain on marketable securities	—	—	—	263	—	263
Net loss	—	—	—	—	(20,781)	(20,781)
Balances at March 31, 2025	67,575,767	$ 7	$ 443,749	$ 286	$ (250,657)	$ 193,385

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

Climb Bio, Inc.
Condensed Consolidated Statements of Cash Flows
(In thousands)
(unaudited)

	Three Months Ended March 31,	
	2026	2025
Cash flows from operating activities:		
Net loss	$ (13,722)	$ (20,781)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	1,605	2,022
Non-cash operating lease expense	58	39
Accretion of discounts on marketable securities, net	(305)	(669)
Depreciation and amortization expense	38	—
Unrealized foreign currency transaction loss	21	24
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	929	1,893
Other long-term assets	—	(10)
Accounts payable	(1,409)	72
Accrued expenses and other current liabilities	(1,532)	2,035
Operating lease liabilities	(62)	(59)
Net cash used in operating activities	(14,379)	(15,434)
Cash flows from investing activities:		
Purchases of marketable securities	(44,855)	(58,751)
Proceeds from maturities of marketable securities	31,900	16,000
Net cash used in investing activities	(12,955)	(42,751)
Cash flows from financing activities:		
Proceeds from exercise of stock options	5	—
Net cash provided by financing activities	5	—
Effect of exchange rate changes on cash and cash equivalents	—	(24)
Net change in cash and cash equivalents	(27,329)	(58,209)
Cash and cash equivalents at beginning of period	35,685	87,229
Cash and cash equivalents at end of period	$ 8,356	$ 29,020
Supplemental disclosure of cash flow information:		
Cash paid for leases included in operating cash outflows	$ 73	$ 69

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

Climb Bio, Inc.
Notes to Condensed Consolidated Financial Statements
(unaudited)

1. Nature of Operations and Basis of Presentation

Organization

Climb Bio, Inc. (the Company), is a clinical-stage biotechnology company developing therapeutics for patients with immune-mediated diseases. The Company's pipeline includes budoprutug and CLYM116. Budoprutug is an anti-CD19 monoclonal antibody designed to treat a broad range of B-cell mediated diseases. The Company is currently developing budoprutug for the treatment of primary membranous nephropathy, immune thrombocytopenia, and systemic lupus erythematosus. CLYM116 is an anti-APRIL (A Proliferation-Inducing Ligand) monoclonal antibody currently being developed for the treatment of immunoglobulin A nephropathy. The Company was incorporated on October 18, 2018 in Delaware, and its corporate headquarters is in Massachusetts.

Risks and Uncertainties

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, protection of proprietary technology, dependence on key personnel, reliance on single-source suppliers and manufacturers, availability of raw materials, patentability of the Company's product candidates and processes and clinical efficacy and safety of the Company's product candidates, compliance with government regulations and the need to obtain additional financing to fund operations. Budoprutug, CLYM116, or any product candidate the Company may develop will require significant additional research and development efforts, including extensive nonclinical studies, clinical trials, and regulatory approval, prior to commercialization. These efforts will require significant amounts of additional capital, adequate personnel infrastructure and extensive compliance and reporting.

There can be no assurance that any future research and development will be successfully completed, that adequate protection for the Company's intellectual property will be obtained or maintained, that any product candidate developed will obtain necessary government regulatory approval or that any approved products will be commercially viable. Even if any future product development efforts are successful, it is uncertain when, if ever, the Company will generate revenue from product sales. The Company operates in an environment of rapid technological change and substantial competition from other pharmaceutical and biotechnology companies. In addition, the Company is dependent upon the services of its employees, consultants and other third parties.

Basis of Presentation and Principles of Consolidation

The accompanying unaudited interim condensed consolidated financial statements reflect the operations of the Company and its wholly owned subsidiaries. Intercompany transactions and balances have been eliminated in consolidation. The accompanying unaudited interim condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States (U.S. GAAP) and in accordance with the rules and regulations of the U.S. Securities and Exchange Commission (SEC) for Quarterly Reports on Form 10-Q. Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. GAAP as found in the Accounting Standards Codification (ASC) and Accounting Standards Update (ASU) of the Financial Accounting Standards Board (FASB).

The accompanying unaudited interim condensed consolidated financial statements as of March 31, 2026 and for the three months ended March 31, 2026 and 2025, are unaudited. The consolidated balance sheet as of December 31, 2025 was derived from the audited financial statements as of and for the year ended December 31, 2025, but does not include all disclosures required by U.S. GAAP. The unaudited interim condensed consolidated financial statements have been prepared on a basis consistent with the audited annual financial statements as of and for the year ended December 31, 2025, and, in the opinion of management, reflect all adjustments, consisting solely of normal recurring adjustments, necessary for the fair statement of the Company's financial position as of March 31, 2026, the condensed results of its operations for the three months ended March 31, 2026 and 2025, and its cash flows for the three months ended March 31, 2026 and 2025. The financial data and other information disclosed in these notes related to the three months ended March 31, 2026 and 2025 are also unaudited. The condensed results of operations for the three months ended March 31, 2026 are not necessarily indicative of the results to be expected for the full year ending December 31, 2026 or any other period. These unaudited interim condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements included in the Company's Annual Report on Form 10-K filed with the SEC on March 5, 2026 (Annual Report).

Liquidity

Since inception, the Company has experienced recurring losses from operations and generated negative cash flows from operations. The Company has an accumulated deficit of $303.4 million as of March 31, 2026 and expects to incur additional losses from operations in the future. In March 2025, the Company entered into an Equity Distribution Agreement (the Distribution Agreement) with Oppenheimer & Co. Inc., as agent (Oppenheimer), pursuant to which the Company may offer and sell shares of its common stock from time to time through Oppenheimer having an aggregate offering price of up to $22.4 million in an at the market offering. During the three months ended March 31, 2026, the Company did not issue and sell any shares of its common stock pursuant to the Distribution Agreement.

Cash, cash equivalents and marketable securities were $146.3 million as of March 31, 2026. Based on its current operating plan, the Company expects this balance will be sufficient to meet its projected operating requirements for at least the next twelve months from the filing date of these unaudited condensed consolidated financial statements. The Company is currently evaluating the impact of the recently completed private placement financing on its operating plan and expects to provide updated cash runway guidance at a later date. The Company anticipates that it will need to raise substantial financing in the future to fund its operations. The Company may finance future cash needs through the sale of equity, debt financings or other capital sources, which could include income from collaborations, strategic partnerships or other strategic arrangements. There are no assurances that the Company will be able to raise sufficient amounts of funding in the future on acceptable terms, or at all.

2. Summary of Significant Accounting Policies

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (JOBS Act). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued after the enactment of the JOBS Act until those standards apply to private companies. The Company has elected to avail itself of this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that it (i) is no longer an emerging growth company or (ii) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act. As a result, these unaudited condensed consolidated financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

There have been no material changes to the Company's significant accounting policies described in Note 2 to the consolidated financial statements included in the Annual Report.

Use of Estimates

The preparation of unaudited condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect reported amounts and disclosures. Accordingly, actual results could differ from those estimates. Key management estimates include those related to the accrual of research and development expenses and the valuation of stock-based awards. The Company evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors and adjusts those estimates and assumptions when facts and circumstances dictate.

Foreign Currency

The Company's reporting currency is the U.S. dollar. The functional currency of the Company and its subsidiaries is the U.S. dollar. Monetary assets and liabilities resulting from transactions denominated in currencies other than the functional currency are remeasured in the functional currency at exchange rates prevailing at the balance sheet date, and income items and expenses are translated into U.S. dollars at the average exchange rate in effect during the period. Exchange gains and losses resulting from remeasurement and foreign currency transactions are included in the determination of net loss.

Concentration of Credit Risk and Significant Suppliers and Manufacturers

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash, cash equivalents and marketable securities. The Company maintains its cash and cash equivalents at accredited financial institutions that may, at times, exceed federally insured limits. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships. The Company's investments in money market funds and marketable securities are held in segregated accounts at a third-party custodian. The Company has established guidelines relative to credit ratings and maturities intended to safeguard principal balances and maintain liquidity.

The Company is dependent on third-party suppliers and manufacturers for material used in its nonclinical and clinical development activities. In particular, the Company relies and expects to continue to rely on single-source suppliers and manufacturers to supply it with certain critical materials related to the Company's product candidates. The Company's development efforts could be adversely affected if a supplier or manufacturer is unable to successfully carry out its contractual obligations or meet expected deadlines. If a supplier or manufacturer needs to be replaced, the Company may not be able to complete its product development on its anticipated timelines and may incur additional expenses as a result.

Fair Value Measurements

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company's cash equivalents and marketable securities are carried at fair value, determined according to the fair value hierarchy (see Note 4). The carrying values of the Company's accounts payable and accrued expenses approximate their fair values due to the short-term nature of these liabilities.

Recently Issued Accounting Pronouncements Not Yet Adopted

In December 2023, the FASB issued ASU No. 2023-09 (ASU 2023-09), *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which requires, among other things, the following for public business entities: (i) enhanced disclosures of specific categories of reconciling items included in the rate reconciliation, as well as additional information for any of these items meeting certain qualitative and quantitative thresholds; (ii) disclosure of the nature, effect and underlying causes of each individual reconciling item disclosed in the rate reconciliation and the judgment used in categorizing them if not otherwise evident; and (iii) enhanced disclosures for income taxes paid, which includes federal, state, and foreign taxes, as well as for individual jurisdictions over a certain quantitative threshold. The amendments in ASU 2023-09 eliminate the requirement to disclose the nature and estimate of the range of the reasonably possible change in unrecognized tax benefits for the 12 months after the balance sheet date. The effective date of this update for non-public companies is for fiscal years beginning after December 15, 2025; early adoption is permitted. As the Company qualified for emerging growth company status when ASU 2023-09 was effective for public companies, the Company has elected to adopt this standard as of the effective date for a non-public company. The Company expects ASU 2023-09 to require additional disclosures in the notes to its consolidated financial statements.

In November 2024, the FASB issued ASU 2024-03 (ASU 2024-03), *Disaggregation of Income Statement Expenses*, which requires additional disclosures about specific types of expenses included in the expense captions presented on the face of the income statement, as well as disclosures about selling expenses. The provisions of ASU 2024-03 are effective for public business entities for fiscal years beginning after December 15, 2026, and interim periods beginning after December 15, 2027. Early adoption is permitted. The guidance is to be applied prospectively, with the option for retrospective application. The Company is currently evaluating the impact of ASU 2024-03 on its consolidated financial statements.

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its consolidated financial statements.

3. Marketable Securities

Marketable securities consisted of available-for-sale securities as follows (in thousands):

	As of March 31, 2026			
	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Short-term marketable securities:				
Corporate bonds	$ 43,835	$ 99	$ —	$ 43,934
U.S. Treasury securities	57,214	60	—	57,274
Total short-term marketable securities	$ 101,049	$ 159	$ —	$ 101,208
Long-term marketable securities:				
Corporate bonds	$ 21,137	$ 40	$ —	$ 21,177
U.S. Treasury securities	15,606	—	(42)	15,564
U.S. government agency debt securities	—	—	—	—
Total long-term marketable securities	$ 36,743	$ 40	$ (42)	$ 36,741

	As of December 31, 2025			
	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Short-term marketable securities:				
Corporate bonds	$ 31,874	$ 102	$ —	$ 31,976
U.S. Treasury securities	33,296	123	—	33,419
Total short-term marketable securities	$ 65,170	$ 225	$ —	$ 65,395
Long-term marketable securities:				
Corporate bonds	$ 50,341	$ 177	$ —	$ 50,518
U.S. Treasury securities	6,022	32	—	6,054
U.S. government agency debt securities	2,999	1	—	3,000
Total long-term marketable securities	$ 59,362	$ 210	$ —	$ 59,572

As of March 31, 2026, the Company's long-term marketable securities have contractual maturity dates between one and two years.

4. Fair Value Measurements

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

	Fair Value Measurements at March 31, 2026 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 7,998	$ —	$ —	$ 7,998
Marketable securities:				
U.S. Treasury securities	72,838	—	—	72,838
Corporate bonds	—	65,111	—	65,111
U.S. government agency debt securities	—	—	—	—
Total marketable securities	72,838	65,111	—	137,949
Total assets	$ 80,836	$ 65,111	$ —	$ 145,947

	Fair Value Measurements at December 31, 2025 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 35,320	$ —	$ —	$ 35,320
Marketable securities:				
U.S. Treasury securities	39,473	—	—	39,473
Corporate bonds	—	82,494	—	82,494
U.S. government agency debt securities	—	3,000	—	3,000
Total marketable securities	39,473	85,494	—	124,967
Total assets	$ 74,793	$ 85,494	$ —	$ 160,287

Cash equivalents and U.S. Treasury securities were valued by the Company based on quoted market prices for identical securities, which represent a Level 1 measurement within the fair value hierarchy. Corporate bonds and agency securities were valued by the Company using quoted prices in active markets for similar securities, which represent a Level 2 measurement within the fair value hierarchy. There were no transfers into or out of Level 3 for any of the periods presented.

5. Accrued Expenses and Other Current Liabilities

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

	March 31, 2026	December 31, 2025
Accrued external research and development expenses	$ 1,318	$ 1,816
Accrued payroll and related expenses	984	1,891
Accrued professional fees	533	693
Other accrued expenses and current liabilities	113	59
Total accrued expenses and other current liabilities	$ 2,948	$ 4,459

6. Commitments and Contingencies

Leases

There have been no material changes to the Company’s lease agreement during the three months ended March 31, 2026. For additional information on the Company's operating leases, see Note 7, Leases, of the consolidated financial statements in the Annual Report.

License Agreements (Budoprutug)

On June 27, 2024, the Company completed its acquisition (the Acquisition) of Tenet Medicines, Inc. (Tenet). As a result of the Acquisition, the following legacy Tenet agreements effectively became agreements of the Company.

Acelyrin Asset Purchase Agreement

On January 11, 2024, Tenet entered into an asset purchase agreement (the Asset Purchase Agreement) with Acelyrin, Inc. (Acelyrin) and WH2, LLC, which was subsequently transferred to the Company by operation of law upon the closing of the Acquisition, providing for the acquisition of certain assets of Acelyrin related to budoprutug, including certain assigned contracts. Under these assigned contracts, the Company received worldwide license (with the right to sublicense) rights to develop, manufacture, use and commercialize budoprutug for any non-oncology indication, and assumed certain liabilities of Acelyrin.

In addition, the Company inherited the rights and obligations, including financial obligations, under the CRH Agreement (as defined below) and the ProBioGen Agreement (as defined below).

In consideration for the license and other rights the Company received under the Asset Purchase Agreement with respect to Products (as such term is defined in the Asset Purchase Agreement), the Company is obligated to (i) make total payments of up to $157.5 million to Acelyrin upon the achievement of various development, regulatory and commercial milestones, (ii) pay royalties in the single-digit percentages, subject to specified reductions, to Acelyrin on worldwide net sales in a given calendar year, and (iii) make non-refundable and non-creditable payments to Acelyrin on sublicense income with rates ranging from the low single digit to mid teen percent depending on the stage of development of the most advanced Product at the time of such sublicense.

On December 31, 2025, the Company filed a complaint in Delaware Superior Court against Alumis Inc. and its wholly owned subsidiary, Acelyrin, relating to a dispute concerning potential milestone payments owed under the Asset Purchase Agreement as further described below under Legal Proceedings.

The Company records expense related to milestone payments when achievement of the milestone is assessed as probable. As of March 31, 2026, the Company has not recorded expense related to milestone payments under the Asset Purchase Agreement.

For additional information related to the Asset Purchase Agreement, please read Note 8, Commitments and Contingencies, to the Company's audited consolidated financial statements included in the Annual Report.

CRH Agreement

In connection with the Asset Purchase Agreement, in January 2024 Tenet was assigned a license agreement with Cancer Research Technology Limited (CRH) and, in connection with such assignment, Tenet entered into an amended and restated license agreement with CRH (the CRH Agreement) which was subsequently transferred to the Company by operation of law upon the closing of the Acquisition. The CRH Agreement granted the Company a worldwide exclusive license (other than specified patent rights and materials, which are licensed to the Company on a non-exclusive basis) to research, develop, test, manufacture or sell certain licensed products related to budoprutug, for all therapeutic uses except for oncology indications. The Company is permitted to grant a sublicense under these licenses with CRH's prior written consent.

The Company is obligated to pay CRH a mid-five figure digit fee on each anniversary of the effective date and up to an aggregate of £106.8 million ($141.2 million as of March 31, 2026) upon the achievement of specified development, regulatory, commercial and sales milestone events, including: (i) payments of up to mid-six figure digits in pounds sterling for certain development milestones, (ii) payments of up to low-eight figures in pounds sterling per indication (for up to three indications) for certain regulatory and commercial milestones and (iii) payments up to mid-eight figures in pounds sterling for certain sales milestones. The Company is also obligated to pay tiered royalties ranging from a rate in the mid-single digit to high-single digit percentage on net sales. The Company is also responsible for a sublicensing revenue payment ranging from a rate in the mid-single digit to mid-double digits for any sublicense revenue.

The Company records expense related to milestone payments when achievement of the milestone is assessed as probable. During the three months ended March 31, 2026 and 2025, the Company did not recognize any research and development expense related to the milestones.

For additional information related to the CRH Agreement, please read Note 8, Commitments and Contingencies, to the Company's audited consolidated financial statements included in the Annual Report.

ProBioGen Agreement

Under the Asset Purchase Agreement, Tenet was assigned a cell line development, manufacturing services and license agreement (the ProBioGen Agreement) originally entered into by ValenzaBio, Inc. and ProBioGen AG (ProBioGen) in February 2021, which was subsequently transferred to the Company by operation of law upon the closing of the Acquisition. The ProBioGen Agreement granted the Company a non-exclusive license to use cell lines in which ProBioGen's proprietary technology is applied, to research, develop, manufacture, use, sell, offer to sell, import or export budoprutug. This license includes a non-exclusive sublicense by ProBioGen of certain third-party patent rights, limited to the use of budoprutug.

The Company is obligated to (i) make payments of up to €10.0 million ($11.5 million as of March 31, 2026) upon the achievement of certain development, manufacturing and commercial milestones, including the start of a Phase 2 clinical trial for budoprutug, and (ii) make milestone payments of up to €7.0 million ($8.0 million as of March 31, 2026) upon the achievement of certain sales milestones. If the Company elects to contract ProBioGen to perform certain manufacturing services for budoprutug, the milestone payments would be reduced by €1.1 million ($1.2 million as of March 31, 2026).

The Company records expense related to milestone payments when achievement of the milestone is assessed as probable. During the three months ended March 31, 2026 and 2025, the Company did not recognize any research and development expense related to the milestones.

For additional information related to the ProBioGen Agreement, please read Note 8, Commitments and Contingencies, to the Company's audited consolidated financial statements included in the Annual Report.

License Agreement (CLYM116)

On January 8, 2025, the Company entered into the Mabworks Agreement pursuant to which Mabworks granted to the Company (i) an exclusive (even as to Mabworks and its affiliates), sublicensable right and license under certain patent rights and related know-how (the Licensed Intellectual Property) to develop, manufacture and commercialize Mabworks' proprietary antibodies associated with Mabworks' proprietary antibody program, CLYM116 and products containing CLYM116 (Licensed Products) outside of mainland China, Hong Kong, Macau, and Taiwan (Greater China), (ii) a non-exclusive, sublicensable right and license under the Licensed Intellectual Property to manufacture CLYM116 and Licensed Products in Greater China (the Licensed Territory) and (iii) a non-exclusive, sublicensable right and license under the Licensed Intellectual Property to develop CLYM116 and Licensed Products in Greater China in connection with certain global clinical studies (as described below).

Under the terms of the Mabworks Agreement, the Company paid to Mabworks a $9.0 million upfront payment, and the Company is obligated to pay a total of up to $30.0 million upon the achievement of certain development and regulatory milestones pertaining to the first indication for a Licensed Product, additional lower amounts upon the achievement of certain development and regulatory milestones pertaining to up to two additional indications for a Licensed Product and a total of up to $832.0 million upon the achievement of certain commercial milestones for all Licensed Products. In addition, the Company is obligated to pay Mabworks tiered royalties in the low-to mid-single-digit percentages on aggregate annual net sales of all Licensed Products in the Licensed Territory.

The Company recorded the upfront payment of $9.0 million as research and development expenses in the first quarter of 2025 in the unaudited condensed consolidated statements of operations and comprehensive loss. The Company records expense related to milestone payments when achievement of the milestone is assessed as probable. During the three months ended March 31, 2026, the Company did not record any research and development expense related to a milestone.

For additional information related to the Mabworks Agreement, please read Note 8, Commitments and Contingencies, to the Company's audited consolidated financial statements included in the Annual Report.

Legal Proceedings

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of its business activities. The Company records accruals for estimated losses when available information indicates a loss is probable and reasonably estimable. Significant judgment is required to determine both probability and the estimated amount. The Company expenses the costs related to its legal proceedings as they are incurred.

On December 31, 2025, the Company filed a complaint in Delaware Superior Court against Alumis Inc. and its wholly owned subsidiary, Acelyrin, relating to a dispute concerning potential milestone payments owed under the Asset Purchase Agreement seeking a declaratory judgment that the Company's budoprutug drug candidate is not a Product under the Asset Purchase Agreement, and that the Company does not owe a milestone payment sought by Alumis in connection with its development of budoprutug. This matter is currently pending. The Company is unable to predict the timeline for resolution or the outcome of this matter.

As of the date of these unaudited condensed consolidated financial statements, the Company is not party to any other material legal matters or claims.

Indemnification

In the ordinary course of business, the Company enters into agreements that may include indemnification provisions. Pursuant to such agreements, the Company may indemnify, hold harmless, and defend an indemnified party for losses suffered or incurred by the indemnified party. Some of the provisions will limit losses to those arising from third-party actions. In some cases, the indemnification will continue after the termination of the agreement. The maximum potential amount of future payments the Company could be required to make under these provisions is not determinable. In addition, the Company has entered into indemnification agreements with members of its board of directors and executive officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. To date, the Company has not incurred any material costs as a result of such indemnification provisions. The Company is not currently aware of any indemnification claims and has not accrued any liabilities related to such obligations in its unaudited condensed consolidated financial statements as of March 31, 2026.

7. Related Party Transactions

Equity

On December 11, 2025, the Company entered into an exchange agreement (the Exchange Agreement) with RA Capital Management, LP (RA Capital Management) and an entity affiliated with RA Capital Management (the Exchanging Holder), pursuant to which the Exchanging Holder exchanged an aggregate of 20,440,000 shares of the Company's common stock, beneficially owned by the Exchanging Holder for a pre-funded warrant to purchase the same number of shares of the Company's common stock (subject to adjustment in the event of stock splits, recapitalizations and other similar events affecting the Company's common stock), with an exercise price of $0.0001 per share. The pre-funded warrant is exercisable at any time and does not expire.

The Exchanging Holder is not entitled to exercise any portion of the pre-funded warrant if, upon giving effect or immediately prior to such exercise, such exercise would result in the aggregate number of shares of common stock beneficially owned by RA Capital Management, the Exchanging Holder, and their respective affiliates, collectively, to exceed 33.0% of the number of shares of common stock issued and outstanding immediately after giving effect to such exercise, as such percentage ownership is determined in accordance with the terms of the pre-funded warrant. The Exchanging Holder may increase or decrease such percentage to any other percentage not in excess of 33.0%; provided that any such increase will not be effective until the 61st day after notice from the Exchanging Holder is delivered to the Company. In addition, following the date of the Exchange Agreement, RA Capital Management may exchange additional shares of common stock beneficially owned by it or its affiliates for pre-funded warrants, subject to certain terms and conditions, including the Company's written consent.

The Company determined that the pre-funded warrant did not meet the classification of a liability under ASC 480, Distinguishing Liabilities from Equity. The Company concluded that the pre-funded warrant should be classified as equity based on an analysis performed under ASC 815-40, Contracts in an Entity's Own Equity. The Exchange Agreement did not have any cash impact, and the shares of common stock exchanged for the pre-funded warrant were retired.

8. Stock-Based Compensation

2019 and 2021 Equity Incentive Plans

The Company has outstanding awards under its 2019 Equity Incentive Plan (the 2019 Plan), but is no longer granting awards under this plan. The Company's 2021 Equity Incentive Plan (the 2021 Plan and, together with the 2019 Plan, the Plans) provides for the grant of incentive stock options, non-statutory stock options, restricted stock awards, restricted stock units (RSUs), stock appreciation rights and other stock-based awards to the Company's employees, officers, directors and consultants. Any shares that are returned under the 2019 Plan as a result of cancellation or forfeiture become available for grant under the 2021 Plan. Further, the number of shares of common stock reserved for issuance under the 2021 Plan automatically increases on January 1 of each year continuing through and including January 1, 2031, by 5% of the total number of shares of common stock outstanding on December 31 of the immediately preceding calendar year, or a lesser number of shares determined by the Company's board of directors. The number of shares reserved for issuance under the 2021 Plan was increased by 2,388,316 shares effective as of January 1, 2026 in accordance with the provisions of the 2021 Plan described above. As of March 31, 2026, 3,457,199 shares remained available for future grant under the 2021 Plan.

Under the terms of the 2021 Plan, options are granted at an exercise price no less than fair value of the Company's common stock on the grant date, except in certain cases related to significant corporate transactions. Options expire no later than ten years from the date of the grant.

2025 Inducement Plan

In March 2025, the Company's board of directors adopted the 2025 Inducement Plan (the Inducement Plan), pursuant to which the Company may grant nonstatutory stock options, stock appreciation rights, restricted stock, RSUs and other stock-based awards with respect to an aggregate of 1,250,000 shares of its common stock. Awards under the Inducement Plan may only be granted to new employees who were not previously an employee or director of the Company or are commencing employment with the Company following a bona fide period of non-employment, in either case, as an inducement material to the individual's entering into employment with the Company in accordance with the requirements of Nasdaq Stock Market Rule 5635(c)(4). On September 30, 2025, the Company's board of directors approved an amendment to the Inducement Plan to increase the number of shares of common stock authorized for issuance under the Inducement Plan by 750,000 shares. As of March 31, 2026, no shares remained available for issuance under the Inducement Plan.

Employee Stock Purchase Plan

The Company's 2021 Employee Stock Purchase Plan (the ESPP) allows employees, including executive officers, to contribute up to 15% of their earnings, subject to certain limitations, for the purchase of the Company's common stock at a price per share equal to the

lower of (a) 85% of the fair market value of a share of common stock on the first day of the offering period, or (b) 85% of the fair market value of a share of common stock on the last day of the offering period. The number of shares of common stock reserved for issuance under the ESPP automatically increases on January 1 of each calendar year through and including January 1, 2031, by the lesser of (1) 1% of the total number of shares of the Company's common stock outstanding on December 31 of the preceding calendar year or (2) a number of shares determined by the Company's board of directors. Shares subject to purchase rights granted under the ESPP that terminate without having been exercised in full will not reduce the number of shares available for issuance under the ESPP. The number of shares reserved for issuance under the ESPP was increased by 477,663 shares effective as of January 1, 2026 in accordance with the provisions of the ESPP described above. The first offering period under the ESPP began on December 16, 2025 and will end on June 15, 2026. As of March 31, 2026, no shares had been granted or purchased under the ESPP and 2,214,442 shares remained available for issuance under the ESPP.

Stock Option Valuation

The fair value of stock option grants is estimated on the date of grant using the Black Scholes option pricing model. Volatility is estimated based on the historical and implied volatilities of comparable publicly traded companies as the Company does not have sufficient history of trading in its common stock. The expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

The relevant data used to determine the fair value of the stock options during the three months ended March 31, 2026 and 2025 is as follows:

	Three Months Ended March 31,	
	2026	2025
Expected term (in years)	6.1	6.1
Expected volatility	98.9%	105.7%
Risk-free interest rate	3.8%	4.6%
Expected dividend yield	—	—

Stock Option Activity

Outstanding stock options consist of option grants with service-based vesting conditions, typically 25% on the first anniversary of the grant date with the remainder vesting monthly over the following three years. The activity for the stock options is as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2025	6,427,777	$ 2.81	9.05	$ 11,727
Options granted	2,208,040	4.15		
Options exercised	(1,642)	3.04		
Options forfeited	(152,530)	3.03		
Outstanding as of March 31, 2026	8,481,645	$ 3.15	9.10	$ 32,356
Vested and expected to vest as of March 31, 2026	8,481,645	$ 3.15	9.10	$ 32,356
Options exercisable as of March 31, 2026	1,327,862	$ 4.20	8.11	$ 4,033

The aggregate intrinsic value disclosed in the above table is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had strike prices lower than the fair value of the Company's common stock.

The weighted-average grant date fair value of stock options granted during the three months ended March 31, 2026 and 2025 was $3.33 and $1.50 per share, respectively.

Restricted Stock Units

The Company has outstanding RSUs with service-based vesting conditions and RSUs with performance-based vesting conditions. The

activity for RSUs is as follows:

	Shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2025	207,897	$ 7.50
Granted	441	5.67
Vested	(563)	2.81
Unvested at March 31, 2026	207,775	$ 7.51

Stock-Based Compensation

The following table sets forth stock-based compensation expense included in the Company's unaudited condensed consolidated statements of operations and comprehensive loss (in thousands):

	Three Months Ended March 31,	
	2026	2025
Research and development expenses	$ 572	$ 906
General and administrative expenses	1,033	1,116
Total stock-based compensation expense	$ 1,605	$ 2,022

As of March 31, 2026, there was $17.3 million of total unrecognized compensation cost related to unvested awards expected to vest, which is expected to be recognized over a weighted average period of 3.1 years.

9. Net Loss Per Share

The Company has generated a net loss in all periods presented, therefore the basic and diluted net loss per share are the same as the inclusion of the potentially dilutive securities would be anti-dilutive.

Basic and diluted net loss per share are computed using the weighted-average number of shares of common stock outstanding for the period. The Company issued a pre-funded warrant in December 2025 (see Note 7). The shares of common stock underlying the pre-funded warrant are included in the calculation of basic and diluted net loss per share because they are considered shares issuable for little or no consideration under ASC 260, Earnings Per Share. The following table shows the computation of basic and diluted net loss per share (in thousands, except share and per share data):

	Three Months Ended March 31,	
	2026	2025
Numerator:		
Net loss	$ (13,722)	$ (20,781)
Denominator:		
Weighted-average common shares outstanding, basic and diluted	47,767,313	67,462,450
Weighted-average common shares outstanding under the pre-funded warrant, basic and diluted	20,440,000	—
Weighted-average common shares outstanding, basic and diluted	68,207,313	67,462,450
Net loss per share, basic and diluted	$ (0.20)	$ (0.31)

The following table sets forth the outstanding potentially dilutive securities, presented as of period-end, that have been excluded in the calculation of diluted net loss per share for the periods presented because to do so would be anti-dilutive:

	March 31,	
	2026	2025
Stock options to purchase common stock	8,481,645	5,561,947
Unvested restricted stock awards and units	207,775	908,543
Shares of common stock issuable under Employee Stock Purchase Plan	20,731	—
Total potentially dilutive shares	8,710,151	6,470,490

10. Segments

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker (the CODM). The Company views its operations and manages its business as one operating and reportable segment, focused on developing therapeutics for patients with immune-mediated diseases. The Company's CODM is its chief executive officer.

Segment profit or loss is measured as net loss presented on the unaudited condensed consolidated statements of operations and comprehensive loss. For the purpose of evaluating segment performance and allocating resources, the CODM reviews the Company's financial information on a consolidated basis together with certain operating metrics and evaluates net loss against comparable prior periods and the Company's annual operating plan. The measure of segment assets is reported on the unaudited condensed consolidated balance sheets as total consolidated assets.

In addition to the significant expense categories included within net loss presented on the unaudited condensed consolidated statements of operations and comprehensive loss, the following table sets forth disaggregated research and development expenses (in thousands):

	Three Months Ended March 31,	
	2026	2025
Direct research and development expenses:		
Budoprutug	$ 5,363	$ 6,141
CLYM116[1]	1,193	9,120
Legacy programs[2]	22	299
Unallocated research and development expenses:		
Personnel-related (including stock-based compensation)	2,353	1,757
Other research and development expenses	442	10
Total research and development expenses	$ 9,373	$ 17,327

[1] Includes the upfront payment and the associated direct transaction costs incurred in connection with the Mabworks Agreement for the three months ended March 31, 2025.
[2] Includes direct expenses related to the Company's legacy product candidates ETX-123 and ETX-155.

11. Subsequent Events

On April 27, 2026, the Company entered into a securities purchase agreement (the Securities Purchase Agreement) with certain institutional accredited investors (the Investors), including an affiliate of RA Capital Management, pursuant to which the Company agreed to issue and sell to the Investors in a private placement an aggregate of 9,481,000 shares of the Company's common stock, par value $0.0001 per share (the Shares), at a price of $9.50 per Share and, to certain Investors in lieu of Shares, pre-funded warrants to purchase 2,106,000 shares of the Company's common stock (the Pre-Funded Warrants) at a price of $9.4999 per Pre-Funded Warrant (the 2026 Private Placement).

The 2026 Private Placement closed in April 2026, and the Company received aggregate gross proceeds from the 2026 Private Placement of approximately $110.0 million, before deducting placement agent fees and offering expenses. The Company has granted the Investors indemnification rights with respect to its representations, warranties, covenants and agreements under the Securities Purchase Agreement.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and related notes included in this Quarterly Report and the audited financial statements and notes thereto as of and for the year ended December 31, 2025 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on March 5, 2026. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve substantial risks and uncertainties. As a result of many factors, including those factors set forth in Part II, Item 1A. "Risk Factors" of this Quarterly Report, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. For further information regarding our forward-looking statements, see "Cautionary Note Regarding Forward-Looking Statements" in this Quarterly Report.

Unless the context requires otherwise, references in this Quarterly Report to "we," "us," and "our" refer to Climb Bio, Inc. and its wholly owned subsidiaries.

Overview

We are a clinical-stage biotechnology company committed to developing potential best-in-class therapeutics that address significant unmet need for patients living with immune-mediated diseases. We have built our pipeline by strategically acquiring or in-licensing product candidates that we believe have clear biological rationale, well-defined development pathways, and the potential to address multiple indications.

We are developing our product candidates for multiple immune-mediated diseases, as summarized in the pipeline figure below.

Budoprutug SC and CLYM116 Phase 1 trials conducted in healthy volunteers.
*Greater China defined as mainland China, Hong Kong, Macau, and Taiwan; Partner: Beijing Mabworks Biotech Co., Ltd.
APRIL = a proliferation-inducing ligand, IV = intravenous, mAbs = monoclonal antibodies, SC = subcutaneous

We acquired the rights to our product candidates through license and asset purchase agreements. We have worldwide rights to develop and commercialize budoprutug for all indications, except for oncology. We have rights to develop and commercialize CLYM116 for all indications worldwide outside of mainland China, Hong Kong, Macau, and Taiwan (Greater China).

Our lead product candidate, budoprutug, is a clinical-stage anti-CD19 monoclonal antibody (mAb) designed to deplete CD19-positive B cells. CD19 plays a mechanistic role across all stages of B-cell development, and emerging clinical evidence continues to support the importance of CD19 in immune-mediated diseases. By targeting CD19, budoprutug has the potential to provide rapid, profound, and durable reductions in B cells and pathogenic autoantibodies, which may allow for a disease-modifying therapeutic approach. We have focused our initial development strategy for budoprutug on primary membranous nephropathy (pMN), immune thrombocytopenia (ITP), and systemic lupus erythematosus (SLE), which we believe each offer a strong mechanistic rationale for CD19-directed therapy.

In March 2025, we received clearance from the FDA for a Phase 2, dose range finding clinical trial of budoprutug in pMN, known as PrisMN. We have initiated our Phase 2 clinical trial of budoprutug in pMN patients with persistent proteinuria despite optimized renin-angiotensin-aldosterone system (RAAS) inhibition in multiple countries and are actively enrolling patients. PrisMN, an open-label, dose-ranging Phase 2 clinical trial, is designed to further evaluate safety, pharmacokinetics (PK), pharmacodynamics (PD) (including B cells, anti-PLA2R (Phospholipase A2 Receptor) and total immunoglobulin), and preliminary efficacy, including complete and partial remission, and to identify a dose to carry forward into Phase 3. The FDA granted budoprutug orphan-drug designation for the treatment of pMN in January 2023 and FastTrack Designation for pMN in April 2026. We expect to have initial data, including B-cell and anti-PLA2R data from the low dose cohort (200 mg at 12-24 weeks) in the Phase 2 clinical trial in pMN in the fourth quarter of 2026.

Separately, in March 2025, we received clearance from the FDA for an open-label, dose-escalation Phase 1b/2a clinical trial of budoprutug in patients with ITP to evaluate safety, tolerability, PK, PD, and preliminary efficacy, including B cell depletion and platelet counts. We have also received regulatory clearance for this trial in multiple countries outside the United States, and we continue to activate sites and enroll and dose patients. Results from this trial are expected to provide a deeper understanding of budoprutug activity and dosing and will inform future development efforts in ITP and other immune-mediated diseases. We expect to have initial B-cell and platelet data from the low dose cohort (250 mg at 24 weeks) in the Phase 1b/2a clinical trial in ITP in June 2026, with additional data from the higher dose cohort[s] anticipated by the end of 2026.

In October 2024, we received FDA clearance for a Phase 1b clinical trial of budoprutug in moderate to severe SLE. We are actively enrolling patients in this global, open-label, dose-escalation Phase 1b trial. In this trial, a single dose of budoprutug will be administered in moderate to severe SLE patients to evaluate safety, tolerability, PK, PD, and preliminary efficacy, including B-cell depletion, autoantibody levels, and clinical activity. We expect to have initial B-cell data from the global Phase 1b clinical trial in SLE in the fourth quarter of 2026.

In December 2025, we received clearance of our IND to initiate a separate, parallel Phase 1b/2a clinical trial in SLE patients in China, which will complement our ongoing global Phase 1b clinical trial and also seek to enroll SLE patients who have lupus nephritis (LN). We expect to enroll the first patient in this study in the second quarter of 2026. The data from these trials in SLE are expected to provide insights into budoprutug activity and will also help to inform future development efforts for our program broadly.

The above described clinical trials of budoprutug in pMN, ITP and SLE utilize an intravenous (IV) formulation of budoprutug. In parallel, we are advancing a high-concentration subcutaneous (SC) formulation of budoprutug, which may offer a differentiated convenience profile and potential commercial advantage. In September 2025, we initiated a Phase 1 clinical trial of the SC formulation of budoprutug in healthy volunteers in Australia. We have completed dosing and announced topline data from this trial in May 2026. The SC formulation of budoprutug was generally well-tolerated and resulted in robust B-cell depletion, which was similar to the IV formulation at matched doses. These results support the continued development of the SC formulation, and we plan to initiate a multiple dose study in autoimmune disease patients to evaluate full B-cell depleting doses and optimal dosing regimen.

In addition to budoprutug, we are developing CLYM116, a next generation anti-APRIL (A PRoliferation-Inducing Ligand) mAb for the treatment of patients with immunoglobulin A nephropathy (IgAN) and other B-cell mediated diseases. CLYM116 is a highly potent, Fc-engineered antibody that prevents APRIL signaling by potently blocking the binding of APRIL to its receptors and promoting lysosomal APRIL degradation through a pH-dependent bind-and-release ‘sweeper’ mechanism. Through this unique binding profile and half-life extending Fc-engineering, CLYM116 has the potential to enable deep and durable inhibition of APRIL signaling and IgA production. In October 2025, we received clearance for our CTA in Australia to initiate a Phase 1 clinical trial of CLYM116 in healthy volunteers. We initiated the Phase 1 clinical trial in healthy volunteers in November 2025 and are actively enrolling subjects. We intend to present PK and PD modeling data from nonhuman primates to humans, as well as initial safety data from the ongoing Phase 1 study in healthy volunteers and anticipate having initial PK/PD data from this Phase 1 trial in mid-2026.

Separately, our partner, Mabworks, received clearance for their IND in December 2025 and initiated a Phase 1/2 clinical trial of CLYM116 in China designed to evaluate the safety, tolerability, PK, and PD in healthy volunteers and IgAN patients.

Since our inception, we have primarily funded our operations with proceeds from the sale and issuance of shares of our redeemable convertible preferred stock, our initial public offering (IPO), and the sale and issuance of shares in private placements of shares of our common stock and pre-funded warrants to certain institutional investors. We do not have any products approved for sale and have not generated any revenue from product sales since our inception. Our ability to generate product revenue will depend on the successful development, regulatory approval and eventual commercialization of one or more of our product candidates, if approved. We cannot assure you that we will ever be profitable or generate positive cash flow from operating activities. We expect to continue to incur operating losses for the foreseeable future and will need to raise substantial additional capital in the future. Until such time, if ever, as we can generate significant revenue from product sales, we may finance our operations through equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. Adequate funding may not be available when needed or on terms acceptable to us, or at all.

If we fail to obtain necessary capital when needed on acceptable terms, or at all, it could force us to delay, limit, reduce or terminate our product development programs, commercialization efforts or other operations. Insufficient liquidity may also require us to relinquish rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. Our ability to raise additional funds may be adversely impacted by the potential worsening of global economic conditions and the recent disruptions to, and volatility in, worldwide credit and financial markets, resulting from increased volatility in the trading prices for shares in the biopharmaceutical industry, or otherwise. Further, imposition of tariffs and other trade restrictions by the U.S., as well as reciprocal trade restrictions imposed by other countries, could adversely affect global economies, financial markets and the overall environment in which we do business, as further described in Part I, Item 1A, “Risk Factors” of this Annual Report on Form 10-K.

Cash, cash equivalents, and marketable securities were $146.3 million as of March 31, 2026. Based on its current operating plan, the Company expects this balance to fund operations into 2028, excluding the gross proceeds received from the April 2026 Private Placement (as defined below). The Company is currently evaluating the impact of the recently completed financing on its operating plan and expects to provide updated cash runway guidance at a later date. We have based our current estimate on assumptions that may prove to be wrong and that may change following our evaluation of our operating plan. We could use our available capital resources sooner than we currently anticipate, in which case we would be required to obtain additional financing, which may not be available to us on acceptable terms, or at all. See “—Liquidity and Capital Resources”.

2026 Private Placement

On April 27, 2026, we entered into a securities purchase agreement (the Securities Purchase Agreement) with certain institutional accredited investors (the Investors), including an affiliate of RA Capital Management L.P., pursuant to which we issued and sold to the Investors in a private placement an aggregate of 9,481,000 shares of our common stock at a price of $9.50 per share and, to certain Investors in lieu of shares, pre-funded warrants to purchase 2,106,000 shares of our common stock at a price of $9.4999 per pre-funded warrant (the 2026 Private Placement). The 2026 Private Placement closed on April 29, 2026. The Company received aggregate gross proceeds from the 2026 Private Placement of approximately $110.0 million, before deducting placement agent fees and offering expenses.

Components of Operating Results

Operating Expenses

Our operating expenses consist of research and development expenses and general and administrative expenses.

Research and Development

Research and development expenses consist of costs incurred for our research and development activities, including development of our product candidates, budoprutug and CLYM116, and our previous product candidates, ETX-123 and ETX-155, consisting primarily of the following:

- employee-related expenses, such as salaries, bonuses, benefits, stock-based compensation, and termination benefits, for employees engaged in research and development functions;
- expenses incurred in connection with the nonclinical and clinical development of our product candidates, including under agreements with CROs and consultants;
- the cost of third-party suppliers and manufacturers for material used in our development activities, including under agreements with contract development and manufacturing organizations (CDMOs);
- facilities and other expenses, which include direct and allocated expenses including rent; and
- payments made under third-party licensing agreements.

- We expense research and development costs to operations as incurred. Advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed.

Our direct research and development expenses are tracked on a program-by-program basis and consist primarily of external costs, such as fees paid to CDMOs, CROs, consultants and contractors, in connection with our nonclinical and clinical development activities. We do not allocate employee costs, costs associated with facility expenses, or other indirect costs, to specific programs because these costs are deployed across multiple product development programs and, as such, are not separately classified.

We expect our research and development expenses to increase substantially for the foreseeable future as we conduct our ongoing research and development activities. The process of conducting nonclinical studies, acquiring drug product supply, and conducting clinical trials necessary to obtain regulatory approval is costly and time consuming. We may never succeed in achieving marketing approval for budoprutug, CLYM116, or any product candidate we may develop.

The timelines and costs associated with research and development activities are uncertain and can vary significantly among product candidates and development programs due to the inherently unpredictable nature of nonclinical and clinical development. We anticipate that we will make determinations as to which indications to pursue in connection with our clinical development of budoprutug, CLYM116, or any product candidates we may develop and how much funding to direct to each such indication on an ongoing basis in response to nonclinical and clinical results, regulatory developments, and ongoing assessments as to each such indication's commercial potential. Our future research and development costs may vary significantly and differ materially from expectations, and a change in the outcome of variables with respect to the development of budoprutug, CLYM116, or any product candidates we may develop could significantly change the costs and timing associated with such development. See the section titled "Risk Factors—Risks Related to our Financial Position and Need for Additional Capital."

General and Administrative

Our general and administrative expenses consist primarily of personnel-related expenses such as salaries, bonuses, benefits, stock-based compensation, and termination benefits, for our personnel in executive, finance and accounting, legal, human resources, business development, information technology and other administrative functions. Other significant general and administrative expenses include legal fees relating to corporate matters and intellectual property, professional fees for accounting, audit, regulatory, tax and consulting services, insurance costs, as well as investor and public relations costs.

We expect that our general and administrative expenses will increase for the foreseeable future, including increases in headcount as we continue to support our growth strategy and, if any product candidates receive marketing approval, commercialization activities, as well as to support our operations generally.

Other Income (Expense)

Interest Income

Our interest income consists of interest earned on our cash, cash equivalents and marketable securities, including amortization of purchase premiums and accretion of discounts of marketable securities.

Foreign Currency Gain (Loss)

Our foreign currency gain (loss) consists of foreign exchange gains and losses resulting from remeasurement of foreign currency transactions to the U.S. Dollar.

Results of Operations

Comparison of the Three Months Ended March 31, 2026 and 2025

The following table sets forth our results of operations (in thousands):

	Three Months Ended March 31,		Change
	2026	2025	$
Operating expenses:			
Research and development	$ 9,373	$ 17,327	$ (7,954)
General and administrative	5,838	5,691	147
Total operating expenses	15,211	23,018	(7,807)
Loss from operations	(15,211)	(23,018)	7,807
Other income (expense):			
Interest income	1,514	2,287	(773)
Foreign currency (loss)	(25)	(50)	25
Total other income, net	1,489	2,237	(748)
Net loss	$ (13,722)	$ (20,781)	$ 7,059

Operating Expenses

Research and Development

The following table sets forth our research and development expenses (in thousands):

	Three Months Ended March 31,		Change
	2026	2025	$
Direct research and development expenses:			
Budoprutug	$ 5,363	$ 6,141	$ (778)
CLYM116	1,193	9,120	(7,927)
Legacy programs	22	299	(277)
Unallocated research and development expenses:			
Personnel-related (including stock-based compensation)	2,353	1,757	596
Other research and development expenses	442	10	432
Total research and development expenses	$ 9,373	$ 17,327	$ (7,954)

Research and development expenses decreased from $17.3 million for the three months ended March 31, 2025 to $9.4 million for the three months ended March 31, 2026. The decrease was due primarily to the $9.0 million upfront payment and associated transaction costs made during the three months ended March 31, 2025 in connection with the Mabworks Agreement and our license of CLYM116 with no similar payment made during the three months ended March 31, 2026. This decrease related to the CLYM116 program was offset by $1.1 million of nonclinical and clinical costs incurred during the three months ended March 31, 2026 for which there were no similar costs incurred during the three months ended March 31, 2025.

The decrease in spend of $0.8 million related to the budoprutug program was driven primarily by a decrease in nonclinical and chemistry, manufacturing and controls costs of $3.0 million offset by increased costs of $2.2 million as we advanced our clinical trials of budoprutug in pMN, ITP and SC formulation of budoprutug in healthy volunteers.

The decrease in legacy programs was primarily due to certain programs, ETX-123 and ETX-155, that are no longer being pursued.

Personnel-related expenses increased by $0.6 million due primarily to increased headcount, partially offset by a decrease in stock-based compensation expenses of $0.3 million. The increase in other research and development expenses of $0.4 million was primarily due to consulting and regulatory expenditures incurred for non-specific programs.

General and Administrative

General and administrative expenses increased by $0.1 million from $5.7 million for the three months ended March 31, 2025 to $5.8 million for the three months ended March 31, 2026. The increase was due primarily to higher personnel-related expenses of $0.3 million from increased headcount and higher consulting fees of $0.1 million, partially offset by a decrease in legal fees of $0.3 million. General and administrative expenses for the three months ended March 31, 2026 and 2025 included stock-based compensation expense of $1.0 million and $1.1 million, respectively.

Other Income (Expense)

Interest Income

Interest income decreased from $2.3 million for the three months ended March 31, 2025 to $1.5 million for the three months ended March 31, 2026, due primarily to lower invested balances during the three months ended March 31, 2026 as compared to the three months ended March 31, 2025.

Foreign Currency (Loss)

Foreign currency (loss) was not material in either of the three months ended March 31, 2026 or 2025.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have primarily funded our operations with proceeds from the sale and issuance of shares of our redeemable convertible preferred stock, our IPO, the sale and issuance of shares of our common stock and pre-funded warrants to purchase shares of our common stock in private placements including the 2026 Private Placement. We have not generated any revenue from product sales or otherwise. We have incurred net losses from operations since our inception and anticipate we will continue to incur net losses for the foreseeable future. As of March 31, 2026, we had cash, cash equivalents and marketable securities of $146.3 million.

In March 2025, we entered into an Equity Distribution Agreement (the Distribution Agreement) with Oppenheimer & Co. Inc., as agent (Oppenheimer), pursuant to which we may offer and sell shares of our common stock from time to time through Oppenheimer having an aggregate offering price of up to $22.4 million in an at the market offering. During the three months ended March 31, 2026, we did not issue and sell any shares of our common stock pursuant to the Distribution Agreement.

Cash Flows

The following table sets forth our cash flows (in thousands):

	Three Months Ended March 31,	
	2026	2025
Net cash used in operating activities	$ (14,379)	$ (15,434)
Net cash used in investing activities	(12,955)	(42,751)
Net cash provided by financing activities	5	—

Operating activities

For the three months ended March 31, 2026, net cash used in operating activities was $14.4 million, resulting from our net loss of $13.7 million and cash used by changes in our operating assets and liabilities of $2.1 million, partially offset by $1.4 million in non-cash charges. Cash used by changes in our operating assets and liabilities primarily consisted of a decrease in accounts payable and accrued expenses and other current liabilities of $1.4 million and $1.5 million, respectively, partially offset by an increase of prepaid expenses and other current assets of $0.9 million.

For the three months ended March 31, 2025, net cash used in operating activities was $15.4 million, resulting from our net loss of $20.8 million, partially offset by $1.5 million in non-cash charges and $3.9 million from cash provided by changes in our operating assets and liabilities. Cash provided by changes in our operating assets and liabilities primarily consisted of increases in prepaid expenses and other current assets and accrued expenses and other liabilities of $1.9 million and $2.0 million, respectively.

Investing activities

For the three months ended March 31, 2026, net cash used in investing activities was $13.0 million, consisting primarily of purchases of $44.9 million of marketable securities, partially offset by $31.9 million in proceeds received from maturities of marketable securities.

For the three months ended March 31, 2025, net cash used by investing activities was $42.8 million, consisting primarily of purchases of $58.8 million of marketable securities, partially offset by $16.0 million in proceeds received from maturities of marketable securities.

Financing activities

For the three months ended March 31, 2026, there was an immaterial amount of cash provided by financing activities due to the exercise of stock options.

For the three months ended March 31, 2025, there were no financing activities.

Funding Requirements

Cash, cash equivalents, and marketable securities were $146.3 million as of March 31, 2026. Based on our current operating plan, we expect this balance to fund operations into 2028, excluding the gross proceeds received from the April 2026 Private Placement. The Company is currently evaluating the impact of the recently completed financing on its operating plan and expects to provide updated cash runway guidance at a later date. We have based our current estimate on assumptions that may prove to be wrong and that may change following our evaluation of our operating plan. We could exhaust our available capital resources sooner than we expect. We anticipate that our expenses will increase for the foreseeable future as we continue to advance our current product candidates and any product candidates we may develop, expand our corporate infrastructure, and incur costs associated with potential commercialization.

We are subject to all of the risks typically related to the development of biopharmaceutical candidates, and we may encounter unforeseen expenses, difficulties, complications, delays, and other unknown factors that may adversely affect our business. Our future funding requirements will depend on many factors, including the following:

- the number and scope of development, nonclinical and clinical programs we decide to pursue, and the timing, cost and progress of activities related to such programs;
- the progress, costs and results of our clinical trials of budoprutug in pMN, ITP, and SLE, our Phase 1 clinical trial of the SC formulation of budoprutug, our Phase 1 clinical trial of CLYM116, and any future clinical trials of our product candidates;
- the costs of manufacturing our product candidates by third parties;
- the terms of any collaborations, license or research and development agreements we may enter into;
- the cost of regulatory requirements, regulatory submissions and timing of regulatory approvals;
- the costs involved in prosecuting and enforcing patent and other intellectual property claims;
- the potential delays in our development programs and clinical trial activities due to the effects of global events, including macroeconomic conditions and supply chain disruptions;
- the impact of inflationary pressures on salaries and wages, and costs of goods and transportation expenses, including the impact of tariffs and other trade restrictions;
- the cost of commercialization activities if any of our product candidates are approved for sale, including marketing, sales and distribution costs; and
- our efforts to enhance operational systems and hire personnel to support development of budoprutug, CLYM116, or any product candidates we may develop.

Furthermore, our operating plans may change, and we may need additional funds to meet operational needs and capital requirements for clinical trials and other research and development expenditures. Until such time, if ever, as we can generate substantial revenue from product sales, we may finance our operations through equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed or on favorable terms or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders.

Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends. If we raise funds through collaborations, or other similar arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or our product candidates or grant licenses on terms that may not be favorable to us and may reduce the value of our common stock. Our failure to raise capital or enter into such other arrangements when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts, or grant rights to develop and market budoprutug, CLYM116, or any product candidates we may develop even if we would otherwise prefer to develop and market such product candidates ourselves.

Contractual Commitments and Obligations

There have been no material changes to our cash requirements from those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2025.

Critical Accounting Policies and Estimates

This management's discussion and analysis of our financial condition and results of operations is based on our unaudited condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP). The preparation of our unaudited condensed consolidated financial statements in conformity with U.S. GAAP requires us to make estimates and assumptions that affect the amounts reported in the unaudited condensed consolidated financial statements and notes to the unaudited condensed consolidated financial statements. Some of those judgments can be subjective and complex, and therefore, actual results could differ materially from those estimates under different assumptions and conditions.

There have been no material changes to our critical accounting policies and estimates from those disclosed in our audited consolidated financial statements and notes thereto as of and for the year ended December 31, 2025 included in our Annual Report on Form 10-K.

Recently Issued Accounting Pronouncements Not Yet Adopted

See Note 2 to our unaudited condensed consolidated financial statements included in this Quarterly Report.

Emerging Growth Company Status

We are an emerging growth company, as defined in the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued after the enactment of the JOBS Act until those standards apply to private companies. Other exemptions and reduced reporting requirements under the JOBS Act for emerging growth companies include an exemption from the requirement to provide an auditor's report on internal controls over financial reporting pursuant to the Sarbanes-Oxley Act, an exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation, and less extensive disclosure about our executive compensation arrangements. We have elected to use the extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that (i) we are no longer an emerging growth company or (ii) we affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our consolidated financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates. We will cease to be an emerging growth company on December 31, 2026.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

As a smaller reporting company, we are not required to provide the information requested by this item pursuant to Item 305(e) of Regulation S-K.

Item 4. Controls and Procedures.

Disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our chief executive officer (our principal executive officer) and chief financial officer (our principal financial officer) or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Our management, under the supervision and with the participation of our chief executive officer and chief financial officer (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2026. Based on our evaluation, our chief executive officer and chief financial officer have concluded that our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) were not effective as of March 31, 2026 because of the material weaknesses in our internal control over financial reporting described below.

Notwithstanding the material weaknesses, management believes the unaudited condensed consolidated financial statements included in Part I of this Quarterly Report present fairly, in all material respects, our financial condition, results of operations and cash flows as of and for the periods presented in accordance with generally accepted accounting principles in the United States.

Material Weaknesses in Internal Control Over Financial Reporting

In connection with the preparation of our consolidated financial statements for the year ended December 31, 2020, we identified material weaknesses in our internal control over financial reporting, two of which remain unremediated as of March 31, 2026. A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the annual or interim consolidated financial statements will not be prevented or detected on a timely basis. The material weaknesses are as follows:

- We did not design or maintain an effective control environment. Specifically, we lacked a sufficient number of professionals with an appropriate level of accounting knowledge, training and experience to appropriately analyze, record and disclose accounting matters commensurate with accounting and reporting requirements. The lack of personnel contributed to the following material weakness.
- We did not design and maintain formal accounting policies, procedures and controls to achieve complete, accurate and timely financial accounting, reporting and disclosures, including segregation of duties and controls over the preparation and review of journal entries, account reconciliations and consolidation.

These material weaknesses did not result in a misstatement to the unaudited condensed consolidated financial statements. However, these material weaknesses could result in a misstatement of our account balances or disclosures that would result in a material misstatement of our annual or interim consolidated financial statements that would not be prevented or detected.

Remediation Efforts to Address Material Weaknesses

Management has concluded that the material weaknesses in internal control over financial reporting were due to the fact that we were a private company with limited resources when the material weaknesses were identified for the year ended December 31, 2020, and did not have the necessary business processes and related internal controls formally designed and implemented, coupled with the appropriate resources with the appropriate level of experience and technical expertise, to oversee our business processes and controls.

We have implemented measures designed to improve internal control over financial reporting to remediate the control deficiencies that led to our material weaknesses. The remediation measures we have taken include:

- Hired qualified personnel with appropriate expertise to perform specific functions and ensure adequate segregation of key duties and responsibilities;
- Designed and implemented improved policies, processes, and internal controls, including senior management review and audit committee oversight, to achieve complete, accurate and timely financial accounting, reporting and disclosures;
- Implemented and formalized policies, processes, and internal controls to identify and assess complex accounting transactions and other technical accounting and financial reporting matters; and
- Implemented financial systems to improve segregation of duties and controls and reliability of system generated data.

We believe we have made substantial progress toward achieving the effectiveness of our internal control over financial reporting and disclosure controls and procedures. The actions that have been taken are subject to continued review and testing by management as well as oversight by the audit committee of our board of directors. We will not be able to conclude whether the steps we have taken will fully remediate these material weaknesses in our internal control over financial reporting until we have completed our remediation efforts and subsequent evaluation of their effectiveness.

Changes in Internal Control over Financial Reporting

There have not been any changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter to which this Quarterly Report relates 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

Information with respect to legal proceedings is described in Note 6 "Commitments and Contingencies" in the Notes to the Unaudited Condensed Consolidated Financial Statements contained in Part I, Item I of this Quarterly Report, which is incorporated herein by reference.

Item 1A. Risk Factors.

RISK FACTORS

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

Risks Related to our Financial Position and Need for Additional Capital

We have incurred significant losses since our inception, expect to continue to incur substantial losses for the foreseeable future and may never achieve or sustain profitability.

We are a clinical-stage biotechnology company with a limited operating history. Our efforts are focused primarily on the treatment of unmet needs in immune-mediated diseases. We are initially developing our lead product candidate budoprutug in pMN, ITP and SLE. In addition, in January 2025, we expanded our pipeline of B-cell targeted therapeutics by entering into the Mabworks Agreement, pursuant to which Mabworks granted us licenses to develop, manufacture and commercialize CLYM116, an anti-APRIL monoclonal antibody, and products containing CLYM116.

To date, we have not received regulatory approvals for any of our product candidates or generated any revenue from product sales. We do not expect to generate revenue from product sales for the foreseeable future. Budoprutug and CLYM116 are both in early stages of research and development. As a result, we are not profitable, and we have incurred significant operating losses since inception and expect to continue to incur substantial losses, including expenses incurred to advance the development of budoprutug and CLYM116, conduct clinical trials, pursue regulatory approvals, maintain, expand, and protect our intellectual property portfolio, operate as a public company, potentially acquire or in-license other technologies, and build the capabilities necessary for potential commercialization of our product candidates, if approved. Our net loss was $13.7 million for the three months ended March 31, 2026 and $59.9 million for the year ended December 31, 2025. As of March 31, 2026, we had an accumulated deficit of $303.4 million. We may never achieve or sustain profitability.

If we are unable to access capital when needed, it could force us to delay, reduce or terminate our product candidate development programs, commercialization efforts, or other operations.

Conducting nonclinical studies and clinical trials, obtaining regulatory approvals, and preparing for potential commercialization are costly, time-consuming, and subject to significant uncertainty. Cash, cash equivalents, and marketable securities were $146.3 million as of March 31, 2026. Based on its current operating plan, the Company expects this balance to fund operations into 2028, excluding the gross proceeds received from the April 2026 private placement. The Company is currently evaluating the impact of the recently completed financing on its operating plan and expects to provide updated cash runway guidance at a later date. We have based our current estimate on assumptions that may prove to be wrong and that may change following our evaluation of our operating plan. We could exhaust our available capital resources sooner than we expect. In addition, our operating plan may change, and we may require additional capital sooner than anticipated. Our future need for additional funding depends on many factors, including:

- the number and scope of development, nonclinical and clinical programs we decide to pursue, and the timing, cost and progress of activities related to such programs;
- the progress, costs and results of our clinical trials of budoprutug in pMN, ITP, and SLE, our Phase 1 clinical trial of the SC formulation of budoprutug, our Phase 1 clinical trial of CLYM116, and any future clinical trials of our product candidates;

- the costs of manufacturing our product candidates by third parties;
- the terms of any collaborations, license or research and development agreements we may enter into;
- the cost of regulatory requirements, regulatory submissions and timing of regulatory approvals;
- the costs involved in prosecuting and enforcing patent and other intellectual property claims;
- the potential delays in our development programs and clinical trial activities due to the effects of global events, including macroeconomic conditions and supply chain disruptions;
- the impact of inflationary pressures on salaries and wages, and costs of goods and transportation expenses, including the impact of tariffs and other trade restrictions;
- the cost of commercialization activities if any of our product candidates are approved for sale, including marketing, sales and distribution costs; and
- our efforts to enhance operational systems and hire personnel to support the development of our product candidates.

We cannot be certain that additional funding will be available on acceptable terms, or at all. Our ability to raise additional capital may be adversely impacted by disruptions to, or continuing volatility in, the credit and financial markets in the U.S. and worldwide, including increased volatility in the trading prices for shares of public companies in the biopharmaceutical sector, actual and perceived changes in interest rates and inflation, macroeconomic uncertainties, or otherwise. We have no committed source of additional capital, and if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates or other research and development initiatives.

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

Until such time, if ever, as we can generate substantial revenues from product sales, we may need or may seek to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital through the sale of common stock, convertible securities or other equity securities, our stockholders' ownership interest may be diluted, and the terms of these securities could include liquidation or other preferences and anti-dilution protections that could adversely affect the rights of a common stockholder. In addition, debt financing, if available, may result in fixed payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures, creating liens, redeeming stock or declaring dividends, that could adversely impact our ability to conduct our business. Further, securing financing could require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect our management's ability to oversee the development of our product candidates. Additional capital may not be available to us, or even if it is, the cost of such capital may be high.

Further, we have issued, and may in the future issue additional, equity securities as consideration for business development transactions, which may also dilute our existing stockholders' ownership interests. For example, we issued additional shares of our common stock in connection with the Acquisition, and in the concurrent private placement (the Acquisition Private Placement) as well as shares of our common stock and pre-funded warrants to purchase shares of our common stock in the 2026 Private Placement.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market our product candidates that we would otherwise prefer to develop and market ourselves.

We currently have no source of product revenue and may never become profitable.

We have never commercialized a product or generated any revenues from commercial product sales, or otherwise, and we may never become profitable. Our ability to generate revenue from product sales or achieve profitability will depend upon our ability, alone or with any future collaborators, to successfully commercialize our product candidates or any products that we may develop, in-license or acquire in the future. Even if we are able to successfully achieve regulatory approval for our product candidates, we do not know when

our product candidates will generate revenue from product sales for us, if at all. Our ability to generate revenue also depends on a number of additional factors, including our or any current or future collaborators' ability to:

- complete and submit INDs to the FDA that allow commencement of clinical trials for our product candidates;
- complete development activities, including the necessary clinical trials;
- complete and submit biologics license applications (BLAs) to the FDA and obtain regulatory approval for indications for which there is a commercial market;
- complete and submit applications to, and obtain regulatory approval from, foreign regulatory authorities;
- set a commercially viable price for any products;
- establish and maintain supply and manufacturing relationships with third parties, and ensure adequate and legally compliant manufacturing of bulk drug substances and drug products to maintain that supply;
- develop a commercial organization capable of sales, marketing and distribution for any products for which we obtain marketing approval and intend to sell ourselves in the markets in which we choose to commercialize on our own;
- find suitable distribution partners to help us market, sell and distribute our approved products in other markets;
- obtain coverage and adequate reimbursement from third-party payors, including government and private payors;
- achieve market acceptance for any products;
- establish, maintain and protect our intellectual property rights; and
- attract, hire and retain qualified personnel.

In addition, because of the numerous risks and uncertainties associated with pharmaceutical product development, our product candidates may not advance through development or achieve the endpoints of applicable clinical trials. We are unable to predict the timing or amount of increased expenses, or when or if we will be able to achieve or maintain profitability. In addition, our expenses could increase beyond expectations if we decide or are required by the FDA or foreign regulatory authorities, to perform studies or trials in addition to those that we currently anticipate. Even if we can complete the development and regulatory process for our product candidates, we anticipate incurring significant costs associated with commercializing any such products. Even if we can generate revenue from the sale of any of our product candidates that may be approved, we may not become profitable.

We may be required to make significant payments in connection with our license agreements, which could strain our capital resources.

We may be required to make significant payments under our license and asset purchase agreements, including development, regulatory, commercial and sales-based milestone, and royalty payments. These obligations may be substantial and strain our capital resources, and we may not have sufficient funds when payments become due. If we fail to meet payment or diligence obligations, licensors may terminate the agreements, resulting in the loss of rights to budoprutug, CLYM116 or any other product candidate we may license.

As a result of our acquisition (the Acquisition) of Tenet Medicines, Inc. (Tenet), certain legacy Tenet agreements effectively became agreements of ours, including an asset purchase agreement (the Asset Purchase Agreement) with Acelyrin, Inc. (Acelyrin), the CRH Agreement, and a cell line development, manufacturing services and license agreement with ProBioGen AG. In addition, in January 2025, we entered into the Mabworks Agreement, pursuant to which we obtained licenses to develop, manufacture and commercialize CLYM116, and products containing CLYM116, in certain territories.

We may be obligated to make significant future payments under these agreements, including obligations to pay certain contingent development, commercial, sales and regulatory milestones and royalties, as well as other obligations, as applicable. Certain of these agreements set forth specific development, regulatory and commercial events, the occurrence of which would result in related payments that we would be obligated to make. These potential obligations represent significant cash amounts that we may ultimately be obligated to pay. We cannot guarantee that we will have sufficient funds available to meet these obligations if and when these payments become due. The obligation to pay some or all of these milestone and royalty amounts may materially harm our development efforts, as well as our overall financial condition.

Risks Related to our Business and the Development of our Product Candidates

Our future success is dependent on the regulatory approval and commercialization of our product candidates, and if we are unable to successfully develop and commercialize our product candidates, or experience any delay in doing so, our business could be materially harmed.

Our future success depends on developing our product candidates, obtaining regulatory approval and successfully commercializing our product candidates. Delays or failures in clinical development, regulatory review, or commercialization could prevent or delay us from generating revenue or achieving profitability. Regulatory approval processes are lengthy, complex, and inherently uncertain, and regulatory expectations may evolve during development.

We do not have any product candidates that have gained regulatory approval, and we are substantially dependent on the success of budoprutug and CLYM116. As a result, our prospects, including our ability to finance our operations and generate revenue, are dependent on our ability to obtain regulatory approval for budoprutug and CLYM116, and, if approved, to successfully commercialize budoprutug and CLYM116. We cannot commercialize our product candidates or any product candidates we may develop in the U.S. without first obtaining regulatory approval for the product from the FDA; similarly, we cannot commercialize our product candidates or any product candidates we may develop outside of the U.S. without obtaining regulatory approval from comparable foreign regulatory authorities.

Under the Prescription Drug User Fee Act (PDUFA), the FDA's standard review process for a BLA is meant to take 10 months from the date a BLA is accepted for filing, but that process may take longer to complete, and FDA approval is never guaranteed. Before obtaining regulatory approvals for the commercial sale of our product candidates for a target indication, we must demonstrate with substantial evidence gathered in nonclinical and well-controlled clinical trials, and, with respect to approval in the U.S., to the satisfaction of the FDA, that the product candidate is potent, safe and pure for use for that target indication and that the manufacturing facilities, processes and controls are adequate. If our product candidates encounter undesirable safety signals, insufficient efficacy results, development delays, regulatory issues or other problems, our development plans and business would be significantly harmed.

For example, the FDA reviews an application to determine whether there is "substantial evidence" to support a finding of effectiveness for the proposed product for its intended use(s). The FDA has interpreted this evidentiary standard to generally require two adequate and well-controlled clinical trials to establish effectiveness of a new product. In February 2026, the Commissioner of FDA and the Director of Center for Biologics Evaluation and Research published an editorial in the New England Journal of Medicine in which they declared that, in most cases, the new default requirement for FDA approval of a new product will be one adequate and well-controlled pivotal clinical trial plus confirmatory evidence, rather than two pivotal clinical trials. In determining whether to rely on one trial, the FDA will focus on the single trial's quality, including magnitude of effect, appropriateness of control arms, endpoint selection, statistical power, blinding, handling of missing data, biological plausibility and alignment with intermediate biomarkers. The FDA has long had authority to approve new products on the basis of one trial plus confirmatory evidence and, in recent years, the agency has exercised that authority with respect to certain types of products. The FDA now takes the position that this will be the new official default standard for most product candidates. At this point, it is unclear how this new policy will be implemented by the FDA and how, if at all, it will affect our clinical development programs

Even if approved, our products may be subject to post-approval requirements, limitations on use, labeling changes, safety monitoring, or withdrawal or changes in law, guidance, or waiver from the FDA. A deferral of the requirement to conduct pediatric studies may be granted for several reasons, including a finding that the product or therapeutic candidate is ready for approval for use in adults before pediatric trials are complete or that additional safety, potency and purity data need to be collected before the pediatric trials begin.

Additionally, pediatric studies may be required pursuant to the Pediatric Research Equity Act (PREA) or comparable foreign requirements. The law requires the FDA to send a PREA Non-Compliance letter to sponsors who have failed to submit their pediatric assessments required under PREA, have failed to seek or obtain a deferral or deferral extension or have failed to request approval for a required pediatric formulation. It further requires the FDA to publicly post the PREA Non-Compliance letter and sponsor's response. For any of our product candidates for which we seek regulatory approval in the U.S. or the European Union (EU), we cannot guarantee that we will be able to obtain a waiver or alternatively complete any required studies and other requirements in a timely manner, or at all, which could result in an issuance and publication of a PREA Non-Compliance letter and associated reputational harm, our product candidate being considered misbranded and, subject to relevant enforcement action, invalidation of the marketing application, and financial penalties.

The applicable legislation in the EU also requires sponsors to either conduct clinical trials in a pediatric population in accordance with a Pediatric Investigation Plan approved by the Pediatric Committee of the European Medicines Agency (EMA) or to obtain a waiver or deferral from the conduct of these studies by this Committee. For any product candidates for which we seek regulatory approval in the U.S. or the EU, we cannot guarantee that we will be able to obtain a waiver or alternatively complete any required studies and

other requirements in a timely manner, or at all, which could result in associated reputational harm and subject us to enforcement action.

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

Obtaining regulatory approval for marketing of our product candidates in one country does not ensure we will be able to obtain regulatory approval in other countries, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in other countries.

Even if our product candidates were to successfully obtain approval from the FDA and comparable foreign regulatory authorities, any approval might contain significant limitations related to use restrictions for specified age groups, gender or subpopulation of target indication, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements, obligations, or review timelines. If we are unable to obtain regulatory approval for one or more jurisdictions, or an approval contains significant limitations, we may not be able to obtain sufficient funding or generate sufficient revenue to continue the development of budoprutug, CLYM116 or any product candidate that we may discover, in-license, develop or acquire. Also, any regulatory approval of our product candidates, once obtained, may be withdrawn.

Furthermore, even if we obtain regulatory approval for any of our product candidates, such product's commercial success will depend on a number of factors, including the following:

- development of a commercial organization or establishment of a commercial collaboration with a commercial infrastructure;
- establishment of commercially viable pricing and adequate reimbursement from third-party and government payors;
- the ability of our third-party manufacturers to manufacture quantities of such product in commercially sufficient processes and at a scale sufficient to meet anticipated demand and enable us to reduce our cost of manufacturing;
- our success in educating physicians and patients about the benefits, administration and use of such products;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing treatments;
- the effectiveness of our own or our potential strategic collaborators' marketing, sales and distribution strategy and operations;
- acceptance of such product as potent, safe and pure by patients and the medical community; and
- a continued acceptable safety profile of such product following approval.

Many of these factors are beyond our control. If we, or our potential commercialization collaborators, are unable to successfully commercialize our product candidates, we may not be able to earn sufficient revenue to continue our business.

Even if our product candidates receive regulatory approval, they may still face future development and regulatory difficulties.

Even if we obtain regulatory approval for any of our product candidates, it would be subject to ongoing requirements by the FDA and comparable foreign regulatory authorities governing the manufacture, quality control, further development, labeling, packaging, storage, distribution, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-market information. The safety profile of any product will continue to be closely monitored by the FDA and comparable foreign regulatory authorities after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of such product candidate, they may require labeling changes or establishment of a Risk Evaluation and Mitigation Strategy (REMS) or similar strategy, impose significant restrictions on a product's indicated uses or marketing, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance.

In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practice (cGMP) requirements and other regulations. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates or the manufacturing facilities for such product candidates, fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters;
- impose restrictions on the marketing or manufacturing of such product candidate;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require us or any future collaborator to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific remediation actions and penalties for noncompliance;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates, if approved, and generate revenue. The FDA strictly regulates the advertising and promotion of drug products, and drug products may only be marketed or promoted for their FDA approved uses, consistent with the product's approved labeling. Violations may lead to civil, criminal and administrative sanctions by the FDA or other enforcement authorities.

Advertising and promotion of any product candidate that obtains approval in the U.S. will be heavily scrutinized by the FDA, the Department of Justice, the Office of Inspector General of the U.S. Department of Health and Human Services (HHS), state attorneys general, members of Congress and the public. For example, there has been increased scrutiny by the current government administration on advertising practices, and recently, the FDA issued a generic "notice letter" to a substantial number of companies directing such companies to "remove any noncompliant advertising and bring all promotional communications into compliance."

Additionally, advertising and promotion of any product candidate that obtains approval outside of the U.S. will be heavily scrutinized by relevant foreign regulatory authorities.

Existing government regulations may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval 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 or be subject to fines or enhanced government oversight and reporting obligations, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

Our ability to develop and market new product candidates may also be impacted by litigation challenging the FDA's approval of another company's drug product. In April 2023, the U.S. District Court for the Northern District of Texas invalidated the approval by the FDA of mifepristone, a drug product which was originally approved in 2000 and whose distribution is governed by various measures adopted under a REMS. The Court of Appeals for the Fifth Circuit declined to order the removal of mifepristone from the market but did hold that plaintiffs were likely to prevail in their claim that changes allowing for expanded access of mifepristone, which the FDA authorized in 2016 and 2021, were arbitrary and capricious. In June 2024, the U.S. Supreme Court reversed that decision after unanimously finding that the plaintiffs (anti-abortion doctors and organizations) did not have standing to bring this legal action against the FDA. On October 11, 2024, the Attorneys General of three states filed an amended complaint in the district court in Texas challenging the FDA's actions. On January 16, 2025, the district court in Texas agreed to allow these states to file an amended complaint and continue to pursue this challenge. Thereafter, on September 30, 2025, the district court declined to dismiss the case and, instead, transferred it to federal district court in the Eastern District of Missouri. Depending on the outcome of this litigation, our ability to develop new product candidates and to maintain approval of any product candidates, if and when approved, could be delayed, undermined or subject to protracted litigation.

Preliminary, initial, or interim results from clinical trials that we announce, present, or publish from time to time may change as more data and information become available (or are updated based upon audit, validation and verification procedures of the data/information commonly performed for clinical trials) that could result in material changes in the final trial results.

From time to time, we may announce, present or publish preliminary, initial, or interim data or other information from our clinical trials, such as the preliminary data we announced from the Phase 1b clinical trial of budoprutug for the treatment of pMN. Any such data and other results from our clinical trials may materially change as more patient data and information become available. Such data and information may also undergo significant change following subsequent auditing, validation and verification procedures that are commonly conducted in clinical trials. Thus, any preliminary, initial, or interim data or other information may not be predictive of final results from the clinical trial and should be viewed with caution until the final data are available. We may also arrive at different conclusions, or other determinations that may qualify such results, once we have received and fully evaluated the additional data.

Differences between preliminary, initial or interim results and final results could lead to significantly different interpretations or conclusions of the trial outcomes. Further, others, including regulatory authorities and collaboration or regional partners, 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 product candidates, the approvability or commercialization of our product candidates, and our business, in general. In addition, the information we choose to publicly disclose regarding a particular clinical trial is based on what is typically extensive information, and investors may not agree with what we determine is material or otherwise appropriate information to publicly disclose.

If the preliminary, initial or interim 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 reputation, business, results of operations, financial condition and prospects.

Nonclinical and clinical development involves a lengthy, complex and expensive process with an uncertain outcome. The outcome of nonclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA or comparable foreign regulatory authorities. Further, clinical development in immunology and autoimmune diseases presents inherent challenges, which may delay or impair our ability to demonstrate clinical benefit and obtain regulatory approval for our product candidates.

To obtain the requisite regulatory approvals to commercialize our product candidates, we must demonstrate through extensive nonclinical studies and clinical trials that such product candidates are potent, safe and pure in humans to the satisfaction of the FDA. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain.

A product candidate can fail at any stage of testing, even after observing promising signs of activity in earlier nonclinical studies or clinical trials, as demonstrated by the failure of our legacy program, ETX-810, which failed to achieve statistically significant separation from placebo on the primary endpoint in either of our Phase 2a clinical trials in diabetic peripheral neuropathic pain or lumbosacral radicular pain. The results of nonclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Initial success in clinical trials may not be indicative of results obtained when such trials are completed. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through nonclinical studies and initial clinical trials.

Further, clinical development in immunology and autoimmune diseases, including pMN, ITP, SLE, and IgAN, presents inherent challenges, such as heterogeneous disease courses, variable endpoints, competition to enroll patients in trials, background therapy effects, and long-duration studies, which may delay or impair our ability to demonstrate clinical benefit and obtain regulatory approval for our product candidates. Regulators may require additional studies, protocol modifications, or changes to endpoints, and guidance from regulators can evolve, which could affect our development plans and timing. Manufacturing scale-up, assay validation, and process comparability for biologics can also delay trials or approvals. Any delays could increase our costs, shorten any effective exclusivity periods we may obtain for a product candidate, and enable competitors to reach the market earlier than us, reducing commercial viability for our product candidates.

A number of companies in the biotechnology industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or emergence of unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence clinical trials are never approved and there can be no assurance that any of our future clinical trials will ultimately be successful or support further nonclinical or clinical development of our product candidates. Our success is dependent on the progress and outcomes of our development efforts, including our Phase 2 clinical trial of budoprutug for pMN, our Phase 1b/2a clinical trial of budoprutug for ITP, our Phase 1b clinical trial of budoprutug for SLE, our Phase 1 clinical trial of the SC formulation of budoprutug

in healthy volunteers, and our Phase 1 clinical trial of CLYM116. In addition, the commencement and rate of completion of nonclinical studies and clinical trials may be delayed by many factors, including:

- inability to generate sufficient nonclinical or other in vivo or in vitro data to support the initiation of clinical trials;
- nonclinical studies or clinical trials may show a product candidate to be less effective than expected (e.g., a clinical trial could fail to meet its primary endpoint(s)) or have unacceptable side effects or toxicities;
- failure to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful;
- delays in reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- delays in identifying, recruiting and training suitable clinical investigators;
- differences in trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials;
- delays in reaching a consensus with regulatory authorities on trial design and any nonclinical studies required in support of our product candidates and the potential for a delay in site initiations;
- delays in recruiting suitable patients to participate in our clinical trials;
- delays in manufacturing, testing, releasing, validating or importing/exporting sufficient stable quantities of our product candidates we may develop for use in nonclinical studies or clinical trials or the inability to do any of the foregoing;
- insufficient or inadequate supply or quality of our product candidates or other materials necessary for use in nonclinical studies or clinical trials, or delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for such studies or trials;
- imposition of a temporary or permanent clinical hold by regulatory authorities;
- developments on trials conducted by competitors for related technology that raise FDA or foreign regulatory authority concerns about risk to patients of the technology broadly, or if the FDA or a foreign regulatory authority finds that the investigational protocol or plan is clearly deficient to meet its stated objectives;
- delays in recruiting, screening and enrolling patients and delays caused by patients withdrawing from clinical trials or failing to return for post-treatment follow-up;
- difficulty collaborating with patient groups and investigators;
- failure by our CROs, other third parties or us to adhere to clinical trial protocols;
- failure to perform in accordance with the FDA's or any other regulatory authority's good clinical practices (GCP) or applicable regulatory guidelines in other countries;
- occurrence of adverse events associated with any of our product candidates that are viewed to outweigh such product candidate's potential benefits, or occurrence of adverse events in trial of the same class of agents conducted by other companies;
- the cost of nonclinical studies and clinical trials of our product candidates being greater than we anticipate;
- clinical trials of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon development of such product candidate;
- imposition of a clinical hold by regulatory authorities as a result of a serious adverse event, or after an inspection of trial sites or manufacturing facilities or otherwise;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- transfer of manufacturing processes to larger-scale facilities operated by a third-party CDMO and delays or failure by our CDMOs or us to make any necessary changes to such manufacturing process; and
- third parties being unwilling or unable to satisfy their contractual obligations to us.

Any inability to successfully initiate or complete nonclinical studies or clinical trials could result in additional costs to us or impair our ability to generate revenue from product sales. Clinical trial delays could also shorten any periods during which our products have patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may seriously harm our business. In addition, changes in marketing approval

policies during the development period, changes in or the enactment or promulgation of additional statutes, regulations or guidance or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application.

For example, in December 2022, with the passage of the Food and Drug Omnibus Reform Act (FDORA), Congress required sponsors to develop and submit a diversity action plan (DAP) for each Phase 3 clinical trial or any other "pivotal study" of a new drug or biological product. These plans are meant to encourage the enrollment of more diverse patient populations in late-stage clinical trials of FDA-regulated products. In June 2024, as mandated by FDORA, the FDA issued draft guidance outlining the general requirements for DAPs. On January 27, 2025, in response to an Executive Order issued by President Trump on January 21, 2025, on Diversity, Equity and Inclusion programs, the FDA removed the draft DAP guidance from its website. Thereafter, following litigation, the FDA restored the draft DAP guidance to the FDA website but stated that "information on this page may be modified and/or removed in the future subject to the terms of the court's order and implemented consistent with applicable law." In light of these ongoing actions, there is considerable uncertainty surrounding the draft DAP guidance and how the FDA will consider DAPs in connection with its review of clinical studies.

If we seek to conduct clinical trials in foreign countries or pursue marketing approvals in foreign jurisdictions, we must comply with numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process varies among countries and jurisdictions and may include all of the risks associated with FDA approval described above and risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ jurisdiction-to-jurisdiction from that required to obtain FDA approval. Approval by foreign regulatory authorities does not ensure approval by the FDA and, similarly, approval by the FDA does not ensure approval by regulatory authorities outside the U.S. Successful completion of clinical trials is a prerequisite to submitting a marketing application to foreign regulatory authorities or the FDA for each product candidate and, consequently, the ultimate approval and commercial marketing of any product candidate.

We may experience negative or inconclusive results, or regulators may be unwilling to accept nonclinical or clinical data obtained in foreign jurisdictions, which may result in our deciding, or our being required by regulators, to conduct additional clinical studies or trials or abandon some or all of our product development programs, which could harm our business.

In addition, the FDA and other regulatory authorities' policies with respect to clinical trials may change and additional government regulations may be enacted. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted, and our product development costs may increase if we experience delays in testing or marketing approvals. In addition, if we make manufacturing or other changes to our product candidates, we may need to conduct additional studies to bridge such new formulations to earlier versions. We do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. We may also decide to change the design or protocol of one or more of our clinical trials, which could result in delays.

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

Certain adverse events and undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or pause clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities. If undesirable side effects do occur in our future clinical trials they could cause delay or even discontinuance of further development of our product candidates, which would impair our ability to generate revenue and would have a material adverse effect on our business, results of operations, financial condition and cash flows and prospects.

As a result of undesirable side effects or further safety issues that we may experience in our clinical trials in the future, we may not receive approval to market our product candidates, which could prevent us from ever generating revenue or achieving profitability. Results of our trials could reveal an unacceptably high severity and prevalence of side effects.

In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of, or deny approval of, our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Safety signals within APRIL/CD19 classes, including with respect to any products that may compete with our product candidates, could affect regulatory approval, labeling, or market uptake, if approved. Any of these occurrences may have a material adverse effect on our business, results of operations, financial condition and cash flows and prospects.

Additionally, if any of our product candidates receive marketing approval, and we, or others, later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result, including:

- we may be forced to suspend marketing of such product;
- regulatory authorities may withdraw their approvals of such product;
- regulatory authorities may require additional warnings on the label that could diminish the usage or otherwise limit the commercial success of such product;
- the FDA or other regulatory bodies may issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings about such product;
- the FDA may require the establishment or modification of a REMS or a comparable foreign regulatory authority may require the establishment or modification of a similar strategy that may, for instance, restrict distribution of our products and impose burdensome implementation requirements on us;
- we may be required to change the way the product is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to subjects or patients;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved.

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

We may not be able to continue our ongoing clinical trials or initiate new clinical trials on a timely basis or at all if we are unable to recruit and enroll a sufficient number of eligible patients to participate in these trials through completion of such trials as required by the FDA or other comparable foreign regulatory authorities. Patient enrollment is a significant factor in the timing of clinical trials. Our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate. There may be limited patient pools from which to draw for clinical trials.

The eligibility criteria of our clinical trials will further limit the pool of available study participants as we will require that patients have specific characteristics that we can measure or to assure their disease is either severe enough or not too advanced to include them in a study. Patient enrollment for our clinical trials may be affected by other factors, including:

- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to trial sites;
- the design of the trial;
- the availability and efficacy of approved drugs for the disease under investigation, including the potential availability of drug candidates currently in development;
- perceived risks and benefits of the product candidate under study;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials and clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications that we are investigating;
- clinicians' willingness to screen their patients for biomarkers to indicate which patients may be eligible for enrollment in our clinical trials;
- our ability to obtain and maintain patient consents;
- patient referral practices of physicians;

- the ability to monitor patients adequately during and after treatment; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

In addition, our clinical trials may compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition would reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site.

Our inability to enroll enough patients for our clinical trials would result in significant delays or might require us to abandon one or more clinical trials. Delays in patient enrollment may result in increased costs, affect the timing or outcome of our clinical trials, product candidate development and approval process and jeopardize our ability to seek and obtain the regulatory approval required to commence product sales and generate revenue, which could prevent completion of these trials, adversely affect our ability to advance the development of our product candidates, cause the value of our company to decline and limit our ability to obtain additional financing if needed. Furthermore, even if we can enroll enough patients for our clinical trials, we may have difficulty maintaining participation in our clinical trials through the treatment and any follow-up periods.

We are also required to register certain clinical trials and post the results of completed clinical trials on a government-sponsored database, such as www.ClinicalTrials.gov in the U.S., within certain time frames. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

We could be subject to product liability lawsuits based on the use of our product candidates in clinical testing or, if obtained, following any such product's marketing approval and commercialization. Product liability lawsuits brought against us or any of our future collaborators could divert our resources and attention, require us to cease clinical testing, cause us to incur substantial liabilities or limit commercialization of our product candidates.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of biotechnology products. Currently, we have no products that have been approved for commercial sale; however, the use of our product candidates by us and any collaborators in clinical trials may expose us to liability claims. We will face an even greater risk if a product candidate is approved by regulatory authorities and introduced commercially.

Product liability claims may be brought against us or our partners if any product candidate we develop allegedly causes injury or is found to be otherwise unsuitable for human use during product testing, manufacturing, marketing or sale. Any such product liability claim may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties.

Claims could also be asserted under state consumer protection acts. Such claims could be made by participants enrolled in our clinical trials, patients, health care providers, biotechnology companies, our collaborators or others using, administering or selling any of our future approved products. If we cannot successfully defend ourselves against any such claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates, if approved. Even successful defense would require significant financial and management resources.

Regardless of the merits or eventual outcome, product liability claims may result in:

- decreased demand for any of our future approved products;
- injury to our reputation;
- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- significant litigation costs;
- substantial monetary awards to, or costly settlements with, patients or other claimants;
- product recalls or a change in the indications for which any approved drug products may be used;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and

- the inability to commercialize our product candidates.

Although the clinical trial process is designed to identify and assess potential side effects, clinical development does not always fully characterize the safety and efficacy profile of a new medicine, and it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If any of our product candidates were to cause adverse side effects during clinical trials or after approval, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use such product candidate. If any of our product candidates are approved for commercial sale, we will be highly dependent upon consumer perceptions of us and the safety and quality of such product. We could be adversely affected if we are subject to negative publicity associated with illness or other adverse effects resulting from physicians' or patients' use or misuse of any approved products or any similar products distributed by other companies.

Although we maintain product liability insurance coverage, including clinical trial liability, this insurance may not fully cover potential liabilities that we may incur. The cost of any product liability litigation or other proceeding, even if resolved in our favor, could be substantial. We will need to increase our insurance coverage if we commercialize any product that receives regulatory approval. In addition, insurance coverage is becoming increasingly expensive. If we are unable to maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims, it could prevent or inhibit the development and commercial production and sale of our product candidates, which could harm our business.

We face significant competition in an environment of rapid technological change, and there is a possibility that our competitors may achieve regulatory approval before us or develop therapies that are safer, less expensive or more advanced or effective than us, which may harm our financial condition and our ability to successfully market or commercialize our product candidates.

The development and commercialization of new drug products is highly competitive. Moreover, the immunology and inflammation field is characterized by rapidly changing technologies, significant competition, and a strong emphasis on intellectual property. We will face competition with respect to our product candidates from major pharmaceutical companies, specialty pharmaceutical companies, and biotechnology companies. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for development, manufacturing, and commercialization.

There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the disease indications for which we are developing budoprutug or CLYM116. Some of these competitive products and therapies are based on scientific approaches that are similar to our approach, and others are based on entirely different approaches.

The competitive landscape for budoprutug includes multiple companies developing biologics and other modalities targeting CD19 for immune-mediated diseases. We are aware of several companies developing naked monoclonal antibodies, including Amgen Inc., which has an approved treatment, UPLIZNA (inebilizumab), for neuromyelitis optica spectrum disorder, immunoglobulin G4-related disease (IgG4-RD), and generalized myasthenia gravis (gMG), and IASO Biotherapeutics, Inc. (RD129/IASO782) in Phase 1 development for autoimmune disease. AbbVie Inc. is developing a CD19-targeting glucocorticoid receptor modulator antibody-drug conjugate (ABBV-319). Companies developing bispecific T-cell engagers or CD19 bifunctional monoclonal antibodies include but are not limited to, Cullinan Therapeutics, Inc. (CLN-978), Zenas BioPharma, Inc. (obexelimab), L. Hoffmann-La Roche Ltd. (RG6382) and Merck & Co., Inc. (CN201). Companies developing CD19 chimeric antigen receptor T-cell (CAR-T) and chimeric antigen receptor-natural killer (CAR-NK) therapies include but are not limited to Novartis AG (YTB323), Bristol Myers Squibb Company (BMS-986353), Cabaletta Bio, Inc. (CABA-201), Kyverna Therapeutics, Inc.(mivocabtagene autoleucel) and Nkarta, Inc. (NKX019).

The competitive landscape for CLYM116 includes, but is not limited to, companies developing biologics targeting APRIL or BAFF/APRIL for IgAN, such as Otsuka Pharmaceutical Co., Ltd, which has an approved treatment for IgAN, VOYXACT (sibeprenlimab), Novartis AG (zigakibart), Jade Biosciences, Inc. (JADE-101), Vertex Pharmaceuticals Incorporated (povetacicept) and Vera Therapeutics, Inc, which has submitted a BLA for FDA approval of atacicept for the treatment of IgAN. In addition, companies targeting CD38, such as Biogen Inc. (felzartamab) and Takeda Pharmaceutical Company Limited (mezagitamab), companies developing degraders for IgAN such as Biohaven, Ltd. (BHV-1400), and companies developing IgA sweeper antibodies such as argenx (ARGX-121) are also potential competitors for CLYM116.

Many of our current or potential competitors, either alone or with their collaboration partners, may have significantly greater financial resources and expertise in research and development, manufacturing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products. Mergers and acquisitions in the pharmaceutical, biotechnology, and gene therapy industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These

competitors also compete with us in recruiting and retaining qualified scientific and management consultants and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize product candidates that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than budoprutug or CLYM116, or that would render budoprutug or CLYM116 obsolete or non-competitive. Our competitors also may obtain FDA or other regulatory approval for their product candidates more rapidly than we may obtain approval for budoprutug and CLYM116, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, technologies developed by our competitors may render budoprutug or CLYM116 uneconomical or obsolete, and we may not be successful in marketing budoprutug or CLYM116 against competitors.

In addition, as a result of the expiration or successful challenge of our patent rights, we could face more litigation with respect to the validity or scope of patents relating to our competitors' products. The availability of our competitors' products could limit the demand, and the price we are able to charge, for budoprutug or CLYM116.

If we successfully obtain approval for budoprutug or CLYM116, we believe that the key competitive factors that will affect the success of these candidates will be efficacy, safety, tolerability, convenience, price and the availability of reimbursement from government and other third-party payors relative to such competing products. Our commercial opportunity could be reduced or eliminated if our competitors have products that are superior in one or more of these categories.

Drug development is highly uncertain, and if we are unable to successfully develop and commercialize our product candidates, or experience significant delays in doing so, our business may be harmed.

Drug development is a highly uncertain undertaking and involves a substantial degree of risk. For example, previously we paused or discontinued the development of all of our legacy product candidates for the treatment of neuronal excitability disorders, including ETX-155 and ETX-123, which were still in drug discovery stages, and we may not ever obtain regulatory approval for our product candidates. In addition, as a company, we have no prior experience developing biological product candidates. As such, we may encounter delays or difficulties in our efforts to develop and commercialize budoprutug and CLYM116.

To date, we have not initiated or completed a pivotal clinical trial, obtained marketing approval for any product candidate, manufactured a commercial scale product or arranged for a third party to do so on our behalf, or conducted the sales and marketing activities necessary for successful product commercialization. Our short operating history as a company makes any assessment of our future success and viability subject to significant uncertainty.

We will encounter risks and difficulties frequently experienced by early-stage biotechnology companies in rapidly evolving fields, and we have not yet demonstrated an ability to successfully overcome such risks and difficulties. If we do not address these risks and difficulties successfully, our business may be harmed.

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

Our market opportunity estimates and growth forecasts are subject to significant uncertainty and are based on assumptions and estimates which may not prove to be accurate. We currently focus our research and product development on budoprutug for the treatment of pMN, ITP, and SLE and on CLYM116 for the treatment of IgAN. Our understanding of the patient populations with these diseases is based on estimates in published literature.

These estimates, and our estimates and forecasts relating to size and expected growth based on these estimates, may prove to be incorrect and new studies may reduce the estimated incidence or prevalence of these diseases.

The number of patients in the U.S. and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with budoprutug or CLYM116, or patients may become increasingly difficult to identify and access. Even if the patient populations meet our size estimates and growth forecasts, our business may not grow at similar rates, or at all. Our growth is subject to many factors, including our success in implementing our business strategy, which is subject to many risks and uncertainties.

Our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for our product candidates, the ability to obtain coverage and reimbursement, the ability to gain market share and whether we own the commercial rights for that territory. If the number of addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect or the treatment population is narrowed by competition,

physician choice or treatment guidelines, we may not generate significant revenue from sales of our product candidates, even if approved. Further, there are several factors that could contribute to making the actual number of patients who receive our product candidates less than the potentially addressable market. These include the lack of widespread availability of, and limited reimbursement for, new therapies in many underdeveloped markets.

We have no experience in sales, marketing and distribution and may have to enter into agreements with third parties to perform these functions, which could prevent us from successfully commercializing our product candidates.

We currently have no sales, marketing or distribution capabilities. To commercialize our product candidates, we must either develop our own sales, marketing and distribution capabilities or make arrangements with third parties to perform these services for us. If we decide to market or distribute our product candidates on our own, we will have to commit significant resources to developing a marketing and sales force and supporting distribution capabilities. If we decide to enter into arrangements with third parties for performance of these services, we may find that they are not available on terms acceptable to us, or at all. If we are not able to establish and maintain successful arrangements with third parties or build our own sales and marketing infrastructure, we may not be able to commercialize our product candidates, which would adversely affect our business, results of operations, financial condition and cash flows and prospects.

Disruptions at the FDA and other government agencies from funding cuts, personnel losses, regulatory reform, government shutdowns and other developments could hinder our ability to obtain guidance from the FDA regarding our clinical development program and develop and secure approval of our product candidates in a timely manner, which would negatively impact our business.

Disruptions at the FDA and other agencies, including workforce changes, budget constraints, regulatory reform, government shutdowns, or public health emergencies could delay inspections, guidance from the FDA, and application review, which could hinder our ability to secure approval of our product candidates in a timely manner. Even with the user-fee program established under the PDUFA, resource constraints could delay PDUFA dates, and changes in government policy or enforcement priorities may alter review practices and post-approval obligations with respect to the FDA or other comparable regulatory agencies.

The FDA and comparable regulatory agencies in foreign jurisdictions, such as the EMA and Committee for Medicinal Products for Human Use (CHMP), play an important role in the development of our product candidates by providing guidance on our clinical development programs and reviewing our regulatory submissions, including INDs, requests for special designations and marketing applications. If these oversight and review activities are disrupted, then correspondingly our ability to develop and secure timely approval of our product candidates could be impacted in a negative manner.

For example, the recent loss and retirement of FDA leadership and personnel could lead to disruptions and delays in FDA guidance, review and approval of our product candidates. In July 2025, the Trump Administration began to carry out layoffs at the FDA and, in November 2025, Congress agreed to provide full-year funding for the FDA through September 30, 2026, at a slight decrease compared to previous spending levels. There were several reports in 2025 of the FDA failing to meet its PDUFA goal dates for approval of a new drug application (NDA) or BLA due to heavy workload and limited resources.

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

In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. Over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions and could impact our ability to access the public markets and obtain necessary capital in order to continue our operations.

At the same time, disruptions at the FDA and other government agencies may result from public health events similar to the COVID-19 pandemic. For example, during the pandemic, a number of companies announced receipt of Complete Response Letters due to the FDA's inability to complete required inspections for their applications. In the event of a similar public health emergency in the future, the FDA may not be able to continue its current pace and review timelines could be extended. Regulatory authorities outside the U.S. facing similar circumstances may adopt similar restrictions or other policy measures in response to a similar public health emergency and may also experience delays in their regulatory activities.

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

Risks Related to Legal and Regulatory Compliance

Enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval and commercialize our product candidates, if and when approved, and may affect the prices we may charge for such product candidates, if and when approved.

The U.S. and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product for which we obtain marketing approval.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively, the Affordable Care Act (ACA), was enacted, which includes measures that have significantly changed the way health care is financed by both governmental and private insurers. There have been executive, judicial and congressional challenges to certain aspects of the ACA. For example, on June 17, 2021, the U.S. Supreme Court dismissed a judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, in August 2011, the Budget Control Act of 2011 was signed into law, which, among other things, included aggregate reductions to Medicare payments to providers of, on average, 2% per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments including the Infrastructure Investment and Jobs Act and the Consolidated Appropriations Act of 2023, will stay in effect until 2032 unless Congress takes additional action.

Recently, there has been increasing legislative and enforcement interest in the U.S. with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. presidential executive orders, congressional inquiries and legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs.

On August 16, 2022, the Inflation Reduction Act (IRA) was signed into law by President Biden. The new legislation has implications for Medicare Part D, which is a program available to individuals who are entitled to Medicare Part A or enrolled in Medicare Part B to give them the option of paying a monthly premium for outpatient prescription drug coverage.

Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (that began in 2025). The IRA permits the Secretary of the HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years.

Specifically, with respect to price negotiations, Congress authorized Medicare to negotiate lower prices for certain costly single-source drug and biologic products that do not have competing generics or biosimilars and are reimbursed under Medicare Part B and Part D. The Centers for Medicare & Medicaid Services (CMS) may negotiate prices for ten high-cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Part D drugs in 2027, 15 Part B or Part D drugs in 2028, and 20 Part B or Part D drugs in 2029 and beyond. This provision applies to drug products that have been approved for at least nine years and biologics that have been licensed for 13 years. Drugs and biologics that have been approved for a single rare disease or condition were originally categorically excluded from price negotiation. With passage of the One Big Beautiful Bill Act on July 3, 2025, which was signed into law on July 4, 2025, Congress extended this exemption to drugs and biologics with multiple orphan drug designations.

Since CMS may establish a maximum price for these products in price negotiations, we would be fully at risk of government action if any of our product candidates are the subject of Medicare price negotiations. Given this risk, these provisions of the IRA may also further heighten the risk that we would not be able to achieve the expected return on any product candidate, if approved, or the full value of our patents protecting any such approved drug products if prices are set after any such approved products have been on the market for nine years.

The first cycle of negotiations for the Medicare Drug Price Negotiation Program commenced in the summer of 2023 and the prices of the ten drugs that were the subject of these negotiations became effective January 1, 2026. The second cycle of negotiations with participating drug companies occurred during 2025, and any negotiated prices for this second set of drugs will be effective starting January 1, 2027.

Further, the legislation subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering a price that is not equal to or less than the negotiated "maximum fair price" under the law or for taking price increases that exceed inflation. In addition to the drug price negotiation program, the IRA established inflation rebate programs under Medicare Part B and Part D. These programs require manufacturers to pay rebates to Medicare if they raise their prices for certain Part B and Part D drugs faster than the rate of inflation. On December 9, 2024, with issuance of its 2025 Physician Fee Schedule final regulation, CMS finalized its rules governing the IRA inflation rebate programs. The new law also caps Medicare out-of-pocket drug costs at an estimated $2,000 a year.

On June 6, 2023, Merck & Co. filed a lawsuit against the HHS and CMS asserting that, among other things, the IRA's Drug Price Negotiation Program for Medicare constitutes an uncompensated taking in violation of the Fifth Amendment of the Constitution. Subsequently, a number of other parties with similar constitutional claims against the HHS and CMS. Every court that has thus far considered substantive challenges to the Medicare drug price negotiation program has ruled against the pharmaceutical industry, dismissing both constitutional and statutory arguments. For example, on May 8, 2025, the U.S. Court of Appeals for the Third Circuit rejected AstraZeneca L.P.'s challenge to the Medicare price negotiation program, finding that the program did not violate the company's due process rights under the Constitution since there is no protected property interest in selling goods to Medicare beneficiaries at a price higher than what the government is willing to pay in reimbursement.

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

In addition, the Trump Administration has taken a number of actions to reduce the costs of pharmaceutical products. For example, on April 15, 2025, President Trump issued an Executive Order which directs HHS to take steps to reduce the prices of pharmaceutical products. Such measures include streamlining the state drug importation program and modifying provisions of the 340B program. Further, on May 12, 2025, President Trump issued an additional Executive Order calling on pharmaceutical manufacturers to voluntarily reduce the prices of medicines in the U.S. The Order provides that if such actions do not lower the costs of pharmaceuticals, the Secretary of HHS would pursue other actions, including proposing a rulemaking that imposes most-favored-nation (MFN) pricing in the U.S. Thereafter, on July 31, 2025, the President issued letters to 17 pharmaceutical companies reiterating the requirements of the May 12, 2025, Executive Order and demanding that such companies extend MFN pricing to Medicaid patients, guarantee MFN pricing for newly-launched drug products, return increased revenues abroad to American patients and provide for direct purchasing at MFN pricing. Since that time, virtually all of these pharmaceutical companies have entered into agreements with the administration to provide for lower prices on certain pharmaceuticals. On February 5, 2026, President Trump launched TrumpRx.gov, a website that directs individuals to pharmaceutical manufacturer websites that are offering price discounts based on the Trump Administration's pricing agreements with pharmaceutical manufacturers.

Separately, on December 23, 2025, CMS, through its Center for Medicare and Medicaid Innovation, proposed two five-year pilot programs to implement a "reference pricing" regime for drugs paid for under Medicare for 25% of covered beneficiaries. The programs are referred to as the Global Benchmark for Efficient Drug Pricing (GLOBE) Model for Medicare Part B drugs, and the Guarding U.S. Medicare Against Rising Drug Costs for Medicare Part D drugs. Under the proposed pilot programs, a manufacturer would owe rebates to Medicare if prices for their drugs exceeded the prices paid by other economically comparable reference countries, defined in the proposed regulations as Organisation for Economic Co-operation and Development countries with a gross domestic product (GDP) of $400 billion and a per capita GDP that is at least 60% of the U.S. per capita GDP (an initial list of 19 reference countries is included in the proposed rule). These pilot programs are proposed to go into effect beginning October 1, 2026.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare organizations and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs.

These measures could reduce the ultimate demand for our product candidates, if and when approved, and any other products we may develop, or put pressure on our product pricing.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

This may be especially true with respect to products approved pursuant to the accelerated approval pathway. State Medicaid programs and other payers are developing strategies and implementing significant coverage barriers, or refusing to cover these products outright, arguing that accelerated approval drugs have insufficient or limited evidence despite meeting the FDA's standards for accelerated approval. In the EU, similar political, economic and regulatory developments may affect our ability to profitably commercialize our product candidates, if and when approved, and any other products we may develop.

In markets outside of the U.S. and the EU, reimbursement and healthcare payment systems vary significantly by country and many countries have instituted price ceilings on specific products and therapies. In many countries, including those of the EU, the pricing of prescription pharmaceuticals is subject to governmental control and access. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product.

To obtain reimbursement or pricing approval in some countries, we or our collaborators may be required to conduct a clinical trial that compares the cost-effectiveness of our product to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels, our business could be materially harmed.

We expect that the healthcare reform measures that have been adopted and may be adopted in the future may result in more rigorous coverage criteria and additional downward pressure on the price that we receive for any approved product and could seriously harm our future revenues. 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 revenue, attain profitability or commercialize our products.

Our business operations and current and future relationships with investigators, health care professionals, consultants, third-party payors and customers will be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Healthcare providers and others play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Although we do not currently have any products on the market, our operations may be, directly or indirectly through our prescribers, customers and third-party payors, subject to various U.S. federal and state healthcare laws and regulations.

These laws may impact, among other things, our current business operations, including our clinical research activities and proposed sales, marketing and education programs and constrain the business of financial arrangements and relationships with healthcare providers and other parties through which we may market, sell and distribute our products for which we obtain marketing approval. In addition, we may be subject to additional healthcare, statutory and regulatory requirements and enforcement by foreign regulatory authorities in jurisdictions in which we conduct our business. The laws that may affect our ability to operate include:

- the U.S. federal Anti-Kickback Statute, which makes it illegal for any person or entity, including a prescription drug manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration, including any kickback, bribe, or rebate, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual, or the purchase, lease, order, arrangement, or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. 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;
- the U.S. federal civil and criminal false claims laws, including the False Claims Act (FCA), which can be enforced through "qui tam" or "whistleblower" actions, and civil monetary penalty law, which impose criminal and civil penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other federal health care programs that are false, fictitious or fraudulent; knowingly making, using, or causing to be made or used, a false record or statement material to a false, fictitious or fraudulent claim or an obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing or concealing such an obligation to pay money to the federal government. In addition, a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim under the FCA;

- the U.S. federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false fictitious or fraudulent statement or entry in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA fraud provisions without actual knowledge of the statute or specific intent to violate it;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH) and their implementing regulations, also imposes obligations, including mandatory contractual terms, on "covered entities," including certain healthcare providers, health plans, healthcare clearinghouses, and their respective "business associates" that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity as well as their covered subcontractors, with respect to safeguarding the privacy, security and transmission of individually identifiable health information, as well as analogous state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts;
- the U.S. federal Physician Payments Sunshine Act and its implementing regulations, which require certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the CMS, an agency within the HHS under the Open Payments Program, information related to direct or indirect payments and other transfers of value made 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;
- U.S. federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- analogous U.S. state laws and regulations, including state anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and other relevant compliance guidance promulgated by the federal government that otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities; and state and local laws requiring the registration of pharmaceutical sales representatives; and
- European and other foreign law equivalents of each of the laws, including reporting requirements detailing interactions with and payments to healthcare providers.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs.

It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance 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 the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from U.S. government funded healthcare programs, such as Medicare and Medicaid, or similar programs in other countries or jurisdictions, disgorgement, imprisonment, contractual damages, reputational harm, diminished profits, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and the delay, reduction, termination or restructuring of our operations. Further, defending against any such actions can be costly and 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.

If any of the physicians or other providers or entities with whom we expect to do business is found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any of the above occur, it could adversely affect our ability to operate our business and our results of operations.

Actual or alleged non-compliance by us could result in investigations, significant civil or criminal penalties, exclusion of our company from government programs, reputational harm, and operational restrictions. Non-compliance could adversely affect our ability to operate our business and our results of operations.

We are subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, 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 claims, and mass arbitration demands; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences.

We process personal data and other sensitive data, including health data we collect about participants in connection with our clinical trials, proprietary and confidential business data, trade secrets, intellectual property, and sensitive third-party data. Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts, and other obligations that govern the processing of personal data by us and on our behalf.

In the U.S., federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, and consumer protection laws. These privacy laws include, without limitation, the following laws and regulations:

- Section 5 of the Federal Trade Commission Act, HIPAA, as amended by the HITECH (which imposes specific requirements relating to the privacy, security and transmission of individually identifiable health information for covered entities and their business associates); and
- The California Consumer Privacy Act of 2018 (CCPA) applies to personal information of consumers, business representatives, and employees, and requires businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights. In addition, the California Privacy Rights Act (CPRA) amended the CCPA and expanded the CCPA's requirements, including by adding a new right for individuals to correct their personal information and establishing a new regulatory agency to implement and enforce the law.

In addition to California, many other states have passed comprehensive privacy laws similar to the CCPA and CPRA. These laws are either in effect or will go into effect sometime before the end of 2026. Like the CCPA and CPRA, these laws create obligations related to the processing of personal information, as well as special obligations for the processing of "sensitive" data (which includes health data in some cases). Some of the provisions of these laws may apply to our business activities. We expect other states will be considering similar laws in the future, and Congress has also been debating passing a federal privacy law. These laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products.

Outside the U.S., an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the EU's General Data Protection Regulation and the equivalent law in the U.K. (together the GDPR) impose strict requirements for processing the personal data of individuals, including sensitive data that we may process such as health data.

We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. For example, certain privacy laws, such as the GDPR and the CCPA, require our customers to impose specific contractual restrictions on their service providers. We publish privacy policies, marketing materials and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences. Our obligations related to data privacy and security are quickly changing in an increasingly stringent fashion, creating some uncertainty as to the effective future legal framework. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or in conflict among jurisdictions. Preparation for and compliance with these obligations requires us to devote significant resources. These obligations may necessitate changes to our information technologies, systems, and practices and to those of any third parties that process personal data on our behalf. Although we try to comply with all applicable data privacy and security obligations, we may at times fail (or be perceived as having failed). Despite our efforts, our personnel or third parties upon whom we rely may fail to comply with such obligations, which could negatively impact our business operations and compliance posture. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the third-party providers (such as research institutions) who share this information with us, may contractually limit our ability to use and disclose the information.

If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with 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-related claims, and mass arbitration demands; additional reporting requirements and oversight; bans on processing personal data; and orders to destroy or not use personal data.

Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations, including our clinical trials; inability to process personal data 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 revision or restructuring of our operations.

We have sought and received Fast Track designation for budoprutug and may in the future seek additional designations for our product candidates, including Breakthrough Therapy, Fast Track and Priority Review designations in the U.S., and PRIority MEdicines (PRIME) Designation in the EU, but we might not receive such designations, and even if we do, such designations may not lead to a faster development or regulatory review or approval process.

We have received and may in the future seek certain designations for our product candidates that could expedite review and approval by the FDA. A Breakthrough Therapy product is defined as a product that is intended, alone or in combination with one or more other products, to treat a serious condition, and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development.

For products that have been designated as Breakthrough Therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens.

The FDA may also designate a product for Fast Track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For Fast Track review products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a Fast Track product's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a Fast Track review product may be effective.

We have received Fast Track designation for budoprutug for the treatment of pMN and may seek Fast Track designation for budoprutug in other indications or for other of our product candidates, but such designation may not lead to a faster development or regulatory review and approval process or increase the likelihood that such product candidate will receive regulatory approval.

We may also seek a Priority Review designation for our product candidates. If the FDA determines that a product candidate offers major advances in treatment or provides a treatment where no adequate therapy exists, the FDA may designate the product candidate for priority review. A Priority Review designation means that the goal is for the FDA to review an application for marketing approval in six months, rather than the standard review period of 10 months. On June 17, 2025, the FDA announced the creation of a new voucher program to expedite the development and approval of new drug products. Vouchers issued under the new program, which is known as the Commissioner's National Priority Voucher (CNPV) Program, may reportedly be redeemed by sponsors to shorten the review time of an NDA from approximately 10 to 12 months to one to two months. The FDA has indicated that the CNPV Program will convene experts from the FDA's offices for a team-based review rather than using the standard review system of a drug application being sent to numerous FDA offices. Clinical information will be reviewed by a multidisciplinary team of physicians and scientists who will pre-review the submitted information and convene for a one-day meeting. As of April 1, 2026, the FDA has issued 18 vouchers and approved 5 products under this program.

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

In the EU, we may seek PRIME designation for our product candidates. The PRIME program focuses on product candidates that target conditions for which there exists no satisfactory method of treatment in the EU, or even if such a method exists, the product candidate may offer a major therapeutic advantage over existing treatments. To be accepted for PRIME designation, a product candidate must meet the eligibility criteria in respect of its major public health interest and therapeutic innovation based on

information that is capable of substantiating the claims. The benefits of a PRIME designation include the appointment of a rapporteur of the CHMP to provide continued support and help to build knowledge ahead of a marketing authorization application, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review, meaning reduction in the review time for an opinion on approvability to be issued earlier in the application process. PRIME designation enables an applicant to request parallel EMA scientific advice and health technology assessment advice to facilitate timely market access. Even if we receive PRIME designation for our product candidates, the designation may not result in a materially faster development process, review or approval compared to conventional EMA procedures. Further, obtaining PRIME designation does not assure or increase the likelihood of EMA's grant of a marketing authorization.

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

We may pursue accelerated approval (U.S.) or conditional authorization (EU) of our product candidates based on surrogate endpoints or limited datasets, but regulators can require pre-approval readiness (e.g., confirmatory trials underway), extensive post-approval commitments, labeling controls, and can withdraw approvals if benefit is not verified or safety/efficacy concerns arise. Accelerated/conditional pathways do not guarantee faster overall timelines or ultimate full approval. A product may be eligible for accelerated approval if it treats a serious or life-threatening condition, generally provides a meaningful advantage over available therapies, and demonstrates an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA or other applicable regulatory agency makes the determination regarding whether a surrogate endpoint is reasonably likely to predict long-term clinical benefit. Prior to seeking such accelerated approval, we will seek feedback from the FDA and otherwise evaluate our ability to seek and receive such accelerated approval.

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

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

The FDA may withdraw approval of a product candidate approved under the accelerated approval pathway if, for example, the trial required to verify the predicted clinical benefit of our product candidate fails to verify such benefit or does not demonstrate sufficient clinical benefit to justify the risks associated with the drug. The FDA may also withdraw approval if other evidence demonstrates that our product candidate is not shown to be safe or effective under the conditions of use, we fail to conduct any required post approval trial of our product candidate with due diligence or we disseminate false or misleading promotional materials relating to our product candidate.

A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidates, or withdrawal of a product candidate, would result in a longer time period for commercialization of such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

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

FDA may also use such procedures to withdraw an accelerated approval if a sponsor fails to conduct any required post-approval study of the product with due diligence. The new procedures include the provision of due notice and an explanation for a proposed withdrawal, and opportunities for a meeting with the FDA and a written appeal, among other things. We will need to fully comply with these and other requirements in connection with the development and approval of any of our product candidates that qualify for accelerated approval.

More recently, in March 2023, the FDA issued draft guidance that outlines its current thinking and approach to accelerated approval. The FDA indicated that the accelerated approval pathway is commonly used for approval of oncology drugs due to the serious and life-threatening nature of cancer. Although single-arm trials have been commonly used to support accelerated approval, a randomized controlled trial is the preferred approach as it provides a more robust efficacy and safety assessment and allows for direct comparisons to an available therapy. To that end, the FDA outlined considerations for designing, conducting, and analyzing data for trials intended to support accelerated approvals of oncology therapeutics. Subsequently, in December 2024 and January 2025, the FDA issued additional draft guidances relating to accelerated approval. These guidances describe FDA's latest thinking on what it means to conduct a confirmatory trial with due diligence and how the agency plans to interpret whether such a study needs to be underway at the time of approval. While these guidances are currently only in draft form and will ultimately not be legally binding even when finalized, we will need to observe the FDA's guidance closely if we seek accelerated approval for any of our product candidates. Accordingly, even if we do receive accelerated approval, we may not experience a faster development or regulatory review or approval process, and receiving accelerated approval does not provide assurance of ultimate full FDA approval.

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

We have received orphan drug designation for budoprutug for the treatment of pMN, but we may be unable to realize the benefits associated with orphan drug designation, including market exclusivity.

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 in the U.S., or a patient population greater than 200,000 in the U.S. when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the U.S. will be recovered from sales in the U.S. for that drug or biologic. In order to obtain orphan drug designation, the request must be made before submitting a BLA.

In the U.S., orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval of that particular product for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a BLA, to market the same biologic (meaning, a product with the same principal molecular structural features) for the same indication for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. As a result, even if budoprutug receives orphan exclusivity, the FDA can still approve other biologics that do not have the same principal molecular structural features for use in treating the same indication or disease or the same biologic for a different indication or disease during the exclusivity period. Furthermore, the FDA can waive orphan exclusivity if we are unable to manufacture a sufficient supply of budoprutug or if a subsequent sponsor demonstrates clinical superiority over budoprutug.

The FDA granted orphan drug designation to budoprutug for the treatment of pMN. We may seek orphan drug designation for budoprutug in other specific orphan indications in which there is a medically plausible basis for the use of budoprutug and we may also seek orphan drug designation for CLYM116 or any future product candidates. We may never receive such designations. In addition, even with orphan drug designation, exclusive marketing rights in the U.S. may be limited if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of our product candidates to meet the needs of patients with the rare disease or condition, or if a subsequent sponsor demonstrates clinical superiority over our product candidates, if approved.

The FDA and Congress may further reevaluate and revise the Orphan Drug Act and its regulations and policies. For example, in September 2021, the Court of Appeals for the 11th Circuit held that, for the purpose of determining the scope of orphan drug exclusivity, the term "same disease or condition" means the designated "rare disease or condition" and not the "indication or use" for which the product is approved. Subsequently, in another case, a federal district court in Washington, D.C. followed the reasoning of the 11th Circuit decision and that decision was appealed to the U.S. Court of Appeals for the D.C. Circuit. On February 3, 2026, the Consolidated Appropriations Act of 2026 was enacted into law. It overruled these court decisions and codified the FDA's longstanding interpretation of the scope of orphan drug exclusivity to apply to "the same drug for the same approved use or indication within such designated rare disease or condition." This change, which applies retroactively, expressly authorizes the FDA to approve multiple versions of the same orphan drug for different sub-indications and subpopulations, such as adult and pediatric patients or multiple variations of the same disease that are caused by different genetic variants.

We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future or whether Congress will take legislative action, and it is uncertain how any changes might affect our business. Depending on what changes the FDA or Congress may make to orphan drug regulations and policies, our business could be adversely impacted.

If approved, our product candidates regulated as biologics may face competition from biosimilars approved through an abbreviated regulatory pathway.

If our product candidates regulated as biologics are approved, they may face biosimilar competition, which could reduce our pricing power with respect to such product candidate and market share. Future legislative or regulatory changes in the U.S. or EU could shorten data exclusivity periods and affect our commercial prospects. Substitution dynamics, payer policies, and evolving guidance from the FDA or EMA could introduce uncertainty that may increase competitive pressure and compress net pricing.

The Biologics Price Competition and Innovation Act of 2009 (BPCIA) created an abbreviated approval pathway for biologic products that are biosimilar to or interchangeable with an FDA-licensed reference biologic 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 regulatory exclusivity, another company may still market a competing version of the reference product if the FDA approves a BLA for the competing product containing the sponsor's own nonclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of the other company's product.

In December 2022, Congress clarified through the FDORA, that the FDA may approve multiple first interchangeable biosimilar biological products so long as the products are all approved on the same first day on which such a product is approved as interchangeable with the reference product and the exclusivity period may be shared amongst multiple first interchangeable products. More recently, in October 2023, the FDA issued its first interchangeable exclusivity determination under the BPCIA.

We believe that any of our product candidates, if approved as a biologic product under a BLA, should qualify for the 12-year period of exclusivity. Nonetheless, the approval of biosimilar products referencing our product candidates would have a material adverse impact on our business due to increased competition and pricing pressures. Moreover, there is a risk that any exclusivity we do receive could be shortened due to congressional action or otherwise, or that the FDA will not consider our products to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation.

The extent to which a biosimilar, once licensed, will be substituted for any of our product candidates in a way that is similar to traditional generic substitution for non-biologic products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. If competitors are able to obtain regulatory approval for biosimilars referencing any of our product candidates, such product may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences. The ultimate impact, implementation, and meaning of the BPCIA are subject to uncertainty, and any new regulations, guidance, policies or processes adopted by the FDA to implement the law could have a material adverse effect on the future commercial prospects for our product candidates.

For example, in October 2025, the FDA issued draft guidance which proposes to eliminate the need for sponsors of biosimilar products to conduct comparative human clinical efficacy studies, allowing them to rely instead on analytical testing to demonstrate product differences from a reference product. In March 2026, the FDA issued another draft guidance with additional recommendations that soften the requirements for licensure of biosimilars.

In addition, foreign regulatory authorities may change their approval policies and new regulations may be enacted relating to non-patent exclusivity. For example, the European Commission launched a review of EU pharmaceutical legislation in November 2020. On December 11, 2025, the European Parliament and Council reached a provisional political agreement on the legislation, which is expected to be adopted by mid-2026. Key changes include updating regulatory data exclusivity to a new system with 8 years data exclusivity and a reduced market exclusivity period to 1 year, which can be extended if specific conditions are fulfilled. These provisions are expected to be adopted in the second quarter of 2026 and to take effect in mid-2028. If the legislation is finalized in line with the provisional political agreement, it will have a profound impact on the pharmaceutical industry in the EU.

We conduct clinical trials at sites outside the U.S. The FDA may not accept data from trials conducted in such locations, and the conduct of trials outside the U.S. could subject us to additional delays and expense.

We conduct clinical trials with trial sites that are located outside the U.S. The acceptance by the FDA or other regulatory authorities of trial data from clinical trials conducted outside their jurisdiction may be subject to certain conditions or may not be accepted at all. Trials outside the U.S. also present operational risks, including complying with local regulations, foreign exchange rate risk, potentially more limited IP protection, and geopolitical risks that can add cost and delay to conducting clinical trials. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the U.S., the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means.

In addition, even where the foreign trial data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for marketing approval unless the trial is well-designed and well-conducted in accordance with GCP requirements and the FDA is able to validate the data from the trial through an onsite inspection if deemed necessary.

Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the U.S. or the applicable jurisdiction.

If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in our product candidates not receiving approval for commercialization in the applicable jurisdiction. Conducting clinical trials outside the U.S. will also expose us to additional risks, including risks associated with:

- additional foreign regulatory requirements;
- foreign exchange fluctuations;
- compliance with foreign manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research;
- diminished protection of intellectual property in some countries; and
- interruptions or delays in our trials resulting from geopolitical events, such as war or terrorism.

Our failure to obtain regulatory approval in foreign jurisdictions would prevent us from marketing our product candidates outside the U.S.

If we succeed in developing our product candidates, we intend to market them in foreign jurisdictions in addition to the U.S. In order to market and sell products in other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing.

The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the U.S. generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the U.S., we must secure product pricing and reimbursement approvals before regulatory authorities will approve the product for sale in that country. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our product candidates in certain countries.

Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries and regulatory approval in one country does not ensure approval in any other country, while a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. If we fail to obtain approval of any of our product candidates by regulatory authorities in another country, we will be unable to commercialize any such product in that country, and the commercial prospects of that product candidate and our business prospects could decline. In addition, failure to obtain regulatory approval in one country or region could adversely affect future regulatory approvals in other countries.

Further, in many countries outside the U.S., a product candidate must also be approved for reimbursement before it can be sold in that country. In some cases, the price that we intend to charge for our products, if approved, is also subject to approval. Obtaining non-U.S. regulatory approvals and compliance with non-U.S. regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of any of our product candidates.

In addition, if we fail to obtain the non-U.S. approvals required to market any of our product candidates outside the U.S. or if we fail to comply with applicable non-U.S. regulatory requirements, our target markets will be reduced and our ability to realize the full market potential of such product candidate will be harmed and our business, financial condition, results of operations and prospects may be adversely affected.

Additionally, we could face heightened risks with respect to obtaining marketing authorization in the U.K. as a result of the withdrawal of the U.K. from the EU, commonly referred to as Brexit. As of January 1, 2025, the Medicines and Healthcare Products Regulatory Agency (MHRA), is responsible for approving all medicinal products destined for the U.K. market (i.e., Great Britain and Northern Ireland), and the EMA will no longer have any role in approving medicinal products destined for Northern Ireland. The MHRA relies on the Human Medicines Regulations 2012 (SI 2012/1916), as amended (HMR) as the basis for regulating medicines. The HMR has incorporated into domestic law the body of EU law instruments governing medicinal products that pre-existed prior to Brexit. On April 28, 2025, the U.K. Parliament adopted amendments to improve and strengthen the U.K.'s clinical trials regulatory regime, which will take effect on April 28, 2026. These changes were needed since the current U.K. requirements are based upon the now-repealed EU Clinical Trials Directive (2001/20/EC), which has been replaced by the European Clinical Trials Regulation (EU) No 536/2014 (CTR). Since the U.K. left the EU prior to the date on which the EU CTR took effect, the U.K. legal framework did not benefit from the same revisions as occurred at EU level.

As of January 1, 2024, a new international recognition procedure (IRP) applies which intends to facilitate approval of pharmaceutical products in the U.K. The IRP is open to applicants that have already received an authorization for the same product from one of the MHRA's specified Reference Regulators (RRs). The RRs notably include the EMA and regulators in the European Economic Area member states for approvals in the EU centralized procedure and mutual recognition procedure as well as the FDA (for product approvals granted in the U.S.). The RR assessment must have undergone a full and standalone review, and RR assessments based on reliance or recognition cannot be used to support an IRP application. A CHMP positive opinion or an Mutual Recognition/Decentralised Reliance Procedure positive end of procedure outcome is an RR authorization for the purposes of IRP.

Risks Related to our Dependence on Third Parties

We rely, and expect to continue to rely, on third parties to conduct, supervise, and monitor our nonclinical studies and clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.

We rely, and expect to continue to rely, on third-party CROs to conduct, supervise, and monitor our future nonclinical studies and clinical trials for our product candidates, and we do not currently plan to independently conduct nonclinical studies or future clinical trials of any other potential product candidates. While we have agreements governing their activities, we have limited influence over their actual performance and control only certain aspects of their activities. The failure of these third parties to successfully carry out their contractual duties or meet expected deadlines could substantially harm our business because we may not obtain marketing approval for or commercialize our product candidates in a timely manner or at all. Moreover, these agreements might terminate for various reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, product development activities may be delayed and such delays may harm our business.

Delays, errors, or non-performance from our CROs, CDMOs, and other third parties could delay the development, regulatory review, or commercialization of our product candidates. Our reliance on third parties for development activities will reduce our control over these activities. Nevertheless, we are responsible for ensuring that each of our studies and clinical trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on CROs does not relieve us of our regulatory responsibilities. Moreover, the FDA and comparable foreign regulatory authorities require us to comply with GCPs for conducting, monitoring, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial participants are protected. As a clinical trial sponsor, we will also have regulatory

requirements that directly apply to us. Regulatory authorities enforce these requirements through periodic inspections of trial sponsors, clinical investigators, and trial sites. If we or any of our CROs fail to comply with applicable GCPs, we or our CROs may be subject to enforcement or other legal actions, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials.

In addition, if and when we have an approved product, we will be required to report certain financial interests of our third-party investigators if these relationships exceed certain financial thresholds or meet other criteria. The FDA and comparable foreign regulatory authorities may question the integrity of the data from those clinical trials conducted by investigators who previously served or currently serve as scientific advisors or consultants to us from time to time and receive cash compensation in connection with such services or otherwise receive compensation from us that could be deemed to impact study outcome, proprietary interests in a product candidate, certain company equity interests or significant payments of other sorts.

We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with product candidates that were produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. We also are required to register certain clinical trials and post the results of certain completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified time frames. Failure to do so can result in enforcement actions and adverse publicity.

Our CROs may also have relationships with other entities, some of which may be our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to any of our development programs.

If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct any of our nonclinical studies or clinical trials in accordance with regulatory requirements or our stated protocols, 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 or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates, and we will not be able to, or may be delayed in our efforts to, successfully commercialize such product candidate, or we or they may be subject to regulatory enforcement actions. As a result, our results of operations and the commercial prospects for such product candidate would be harmed, our costs could increase and our ability to generate revenue could be delayed. To the extent we are unable to successfully identify and manage the performance of third-party service providers in the future, our business may be harmed.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays could occur, which could compromise our ability to meet our desired development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not harm our business.

We contract with third parties, including single-source manufacturers, for the manufacture of materials and expect to continue to do so for the development and, if approved, commercialization of our product candidates. This reliance on third parties increases the risk that we will not have sufficient quantities of such materials or that such supply will not be available to us at an acceptable cost or timelines, which could delay, prevent, or impair our development or commercialization efforts.

We do not have any manufacturing facilities. We contract with third parties, including single-source manufacturers, for the manufacture of materials for our product candidates, and we expect to continue to rely on such third parties for the manufacture of clinical and commercial supply of our product candidates. Reliance on these third parties introduces risks such as loss of control over quality and timing, regulatory compliance, supply interruptions, and potential misappropriation of proprietary information. If a third-party manufacturer fails to meet our requirements or terminates the relationship, we may not be able to secure an alternative in a timely or cost-effective manner, which could delay or prevent the development or commercialization of our product candidates.

We may be unable to establish future agreements or maintain existing agreements with third-party manufacturers or to do so on acceptable terms for one or more of our material needs. Even if we are able to establish and maintain agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the possible failure of the third party to manufacture our product candidates according to our schedule, or at all, including if the third party gives greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how;
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us; and
- reliance on the third party for regulatory compliance, quality assurance, safety, and pharmacovigilance and related reporting.

Any performance failure on the part of our existing or future manufacturers could delay any potential clinical development or marketing approval of our product candidates. We do not currently have arrangements in place for redundant supply for bulk drug substances.

If any one of our current contract manufacturers cannot perform as agreed, we may be required to replace that manufacturer, or we may be forced to manufacture the materials ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different third-party manufacturer, which we may not be able to do on reasonable terms, if at all. In either scenario, our clinical trial supply could be delayed significantly as we establish alternative supply sources. These materials must meet stringent regulatory standards, making it difficult to quickly qualify alternative sources.

In some cases, the technical skills required to manufacture our product candidates may be unique or proprietary to the original third-party manufacturer and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all.

In addition, if we are required to change third-party manufacturers for any reason, we will be required to verify that the new third-party manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidates according to the specifications previously submitted to the FDA or another regulatory authority.

The delays associated with the verification of a new third-party manufacturer could negatively affect our ability to develop or commercialize our drug product candidates in a timely manner or within budget.

Furthermore, a third-party manufacturer may possess technology related to the manufacture of our product candidates that such third-party manufacturer owns independently. This would increase our reliance on such third-party manufacturer or require us to obtain a license from such third-party manufacturer in order to have another third-party manufacturer our product candidates.

In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between its prior clinical supply used in its clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials.

Our current and anticipated future dependence upon others for the manufacture of our product candidates may adversely affect our future expenses and our ability to commercialize our product candidates, if we receive marketing approval, on a timely and competitive basis. Our reliance on single-source manufacturers also exposes us to pricing volatility and limits our ability to mitigate supply chain risks. If we are unable to secure adequate supply of materials to meet our operational needs, our ability to advance our pipeline, meet contractual obligations, or generate revenue could be materially and adversely affected.

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

We and any contract manufacturers and suppliers we engage are subject to numerous federal, state, and local environmental, health, and safety laws, regulations, and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment, and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous

materials into the ground, air, and water; and workplace health and safety. Under certain environmental laws, we could be held responsible for costs relating to any contamination at third-party facilities. We also could incur significant costs associated with civil or criminal fines and penalties. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research and product development efforts.

We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty, and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination.

Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended, which could have a material adverse effect on our business, results of operations, financial condition, and prospects.

In addition, we may incur substantial costs in order to comply with current or future environmental, health, and safety laws, regulations, and permitting requirements. These current or future laws, regulations, and permitting requirements may impair our development, or production efforts. Failure to comply with these laws, regulations, and permitting requirements also may result in substantial fines, penalties, or other sanctions or business disruption, which could have a material adverse effect on our business, results of operations, financial condition, and prospects.

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

We may not have access to the raw materials and other components necessary for the manufacturing of our product candidates.

We are dependent on third parties, including single-source suppliers, for the supply of various materials that are necessary to produce our product candidates for our clinical trials. Even with supply agreements, it is possible that the supply may be reduced or interrupted at any time. In such case, we may not be able to find other suppliers of acceptable materials in appropriate quantities at an acceptable cost. If we lose key suppliers or the supply of materials is diminished or discontinued, we may not be able to continue to develop, manufacture and market our product candidates in a timely and competitive manner. In addition, these materials are subject to stringent manufacturing processes and rigorous testing. Delays in the completion and validation of facilities and manufacturing processes of these materials could adversely affect our ability to complete trials and commercialize our products in a cost-effective and timely manner. Any disruption in the supply of these raw materials and other components due to quality issues, regulatory enforcement actions, manufacturing delays, geopolitical instability, or financial difficulties of the third parties could significantly delay our development efforts. In some cases, we may not be able to obtain suitable alternatives on commercially reasonable terms, or at all, without incurring substantial time and cost to validate new suppliers and obtain necessary regulatory approvals. If we encounter difficulties in the supply of these materials, or if we are not able to maintain our supply agreements or establish new supply agreements in the future or incur increased production costs as a result of any of the foregoing, our product development and business prospects could be significantly compromised.

If we are not able to establish future collaborations, we may have to alter some of our future development and commercialization plans.

Our product development programs and the potential commercialization of our product candidates will require substantial additional capital to fund expenses. We may decide to collaborate for the future development and potential commercialization of our product candidates. Furthermore, we may find that our programs require the use of proprietary rights held by third parties, and the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights. For example, in January 2025, we entered into the Mabworks Agreement, pursuant to which we obtained licenses to develop, manufacture and commercialize CLYM116, and products containing CLYM116, in certain territories.

We will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of any product candidates we may seek to develop with them. We cannot predict the success of any collaboration that we have entered into or will enter into.

We face significant competition in seeking appropriate collaborators, and many more established companies may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, financial 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. 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, EMA, the MHRA, or similar foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under future license agreements from entering into agreements on certain terms with potential collaborators. Collaborations are complex and time consuming to negotiate and document.

In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. We may not be able to negotiate further collaborations on a timely basis, on acceptable terms, or at all. Even if we are able to obtain a license to intellectual property of interest, we may not be able to secure exclusive rights, in which case others could use the same rights and compete with us. Collaboration partners may not prioritize our product candidates or otherwise not effectively pursue the development of such product candidates which may delay, reduce or terminate the development of such product candidate, reduce or delay its development program or delay its potential commercialization. Further, 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 delay, reduce or terminate the development of such 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. Doing so will likely harm our ability to execute our business plans. 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.

Changes in and uncertainty surrounding U.S. and international trade policies, particularly with respect to China, may adversely impact our business and operating results.

We are exposed to evolving U.S. and international trade policies, particularly those targeting China, which can directly impact our supply chain, costs, and ability to collaborate with Chinese partners. Recent and proposed U.S. legislation, including the BIOSECURE Act and Section 1260H of the National Defense Authorization Act, may restrict or prohibit federal funding for contracts with certain Chinese biotechnology companies and could limit our ability to work with key suppliers and collaborators such as Mabworks.

Our collaboration with Mabworks is central to our pipeline, and any restrictions, tariffs, or sanctions affecting Chinese biotech firms could require us to identify and qualify alternative suppliers or partners, which may not be feasible on a timely or cost-effective basis. In addition, tariffs on pharmaceutical products and ingredients imported from China, as well as potential retaliatory actions by the Chinese government, could increase our manufacturing costs, disrupt supply of raw materials, and delay development timelines.

The regulatory environment remains fluid, and future trade agreements, export controls, or sanctions could further impact our operations, costs, and competitive position. We may need to invest significant resources to adapt our supply chain, ensure compliance, and mitigate risks associated with geopolitical tensions and regulatory changes.

Some of our manufacturers and suppliers are located in China. Prior to the recent imposing of tariffs on China, trade tensions and conflicts between the U.S. and China had been escalating in recent years and, as such, we are exposed to the possibility of product supply disruption and increased costs and expenses in the event of changes to the laws, rules, regulations and policies of the governments of the U.S. or China, or due to geopolitical unrest and unstable economic conditions. Certain Chinese biotechnology companies may become subject to trade restrictions, sanctions, other regulatory requirements or proposed legislation by the U.S. government, which could restrict or even prohibit our ability to work with such entities, thereby potentially disrupting their supply of material to us.

For example, in February 2024, U.S. lawmakers called for investigations into and the imposition of possible economic sanctions against Chinese biotechnology companies WuXi AppTec and WuXi Biologics (together, Wuxi) over alleged ties to the Chinese military. Subsequently, in December 2025, as part of the Fiscal Year 2026 National Defense Authorization Act, President Trump signed into law the BIOSECURE Act. Under the BIOSECURE Act, U.S. government agencies cannot (1) buy or obtain biotechnology equipment or services provided by biotechnology companies of concern (BCCs), (2) enter into, extend, or renew a contract with any entity using biotechnology equipment or services provided by a BCC to perform a government contract, or (3) expend, loan or grant funds for biotechnology equipment or services provided by a BCC, whether directly or through a loan or grant recipient. The BIOSECURE Act does not name specific companies as BCCs but treats any company on the Department of Defense 1260H list of "Chinese military companies" as a BCC. On December 18, 2025, the Chairs of multiple Senate and House committees, including the

House Select Committee on China, sent a letter to the Department of Defense recommending that Wuxi be added to the 1260H list, which would make it a BCC. The 1260H list was updated by the Department of Defense in January 2024 and January 2025. On February 13, 2026, the Department published an updated list, which included WuXi AppTec, but then abruptly withdrew the list. The implications of this action remain unclear.

We currently rely on certain foreign or foreign-owned third-party vendors, including WuXi and its affiliates, to manufacture certain materials used in the development of our product candidates or to provide services in connection with such development activities. In addition, we rely on Mabworks, a Chinese corporation, pursuant to the Mabworks Agreement, to conduct nonclinical studies of CLYM116 and to provide clinical supply of CLYM116 for these studies. If these bills become law, or similar laws are passed, they would have the potential to severely restrict the ability of companies to contract with certain Chinese BCCs without losing the ability to contract with, or otherwise received funding from, the U.S. government. Such disruptions could have adverse effects on the development of our product candidates and our business operations.

Any unfavorable government policies on international trade, such as export controls, capital controls or tariffs, may increase the cost of manufacturing our product candidates and platform materials, affect the demand for our product candidates (if and once approved), the competitive position of our product candidates, and import or export of raw materials and finished product candidates used in our nonclinical studies and clinical trials, particularly with respect to any product candidates and materials that we import from China. On September 25, 2025, via a post on Truth Social, President Trump announced that, beginning October 1, 2025, all branded or patented drugs imported in the U.S. would face a 100% tariff. At the same time, President Trump indicated that these tariffs could be avoided by building pharmaceutical manufacturing facilities in the U.S. Thereafter, President Trump delayed the October 1st effective date of the tariffs on branded or patented pharmaceutical products announcing that the Trump Administration had now "begun preparing" tariffs on manufacturers that do not build in the U.S. or enter into a most-favored-nation drug pricing agreement with the Trump Administration. As a result of changes in tariffs that have been announced or implemented, and the underlying uncertainty currently surrounding international trade, we could experience a negative impact to our costs of materials and production processes, and supply chain disruptions and delays as a result of any new tariff policies or trade restrictions. We cannot yet predict the effect of the recently imposed U.S. tariffs on imports, or the extent to which other countries, in particular, China, will impose and maintain quotas, duties, tariffs, taxes or other similar restrictions upon imports or exports in the future, nor can we predict future trade policy or the terms of any renegotiated trade agreements and their impact on our business.

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

On April 2, 2026, President Trump issued a Proclamation invoking Section 232 of the Trade Expansion Act of 1962 to impose tariffs on imports of patented pharmaceuticals, biologics, and associated ingredients into the United States (the Proclamation). The Proclamation affects pharmaceutical manufacturers, importers, and supply chain participants. Specifically, beginning July 31, 2026, a 100% tariff will apply to pharmaceutical articles that are subject to a valid, unexpired U.S. patent and are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) or are listed in the FDA's Lists of Licensed Biological Products (Purple Book). The 100% tariff also applies to active pharmaceutical ingredients and key starting materials for such articles. Certain categories of products are exempt from these tariffs, including generic pharmaceuticals and biosimilars; U.S.-origin pharmaceutical products, active pharmaceutical ingredients and key starting materials; products classified in certain 10-digit tariff codes, listed in Annex IV of the Proclamation; drugs and associated ingredients for all approved indications that are designated as orphan pursuant to the Orphan Drug Act; drugs for certain specific uses, including nuclear medicines; plasma-derived therapies; fertility treatments; cell and gene therapies; antibody drug conjugates; medical countermeasures related to chemical, biological, radiological, and nuclear threats; animal health; and other specialty pharmaceutical products to be later identified by the Secretary of Commerce; and goods that qualify as "prototypes to be used exclusively for development, testing, product evaluation, or quality control purposes," may be excluded from the additional tariffs.

Risks Related to Intellectual Property

We rely heavily on certain in-licensed patents and other intellectual property rights in connection with our development of our product candidates and may be required to acquire or license additional patents or other intellectual property rights to continue to develop and commercialize our product candidates.

We rely heavily on patents, know-how and other intellectual property licensed from others. We are party to license agreements with each of CRH and Mabworks pursuant to each of which we are granted rights to intellectual property that are important to budoprutug and CLYM116, respectively.

Additionally, we may need to acquire or license intellectual property rights from additional third parties in the future in order to continue to develop or commercialize our product candidates. Any future license agreements where we in-license intellectual property may impose on us various development, regulatory or commercial diligence obligations, payment of milestones and royalties, and other obligations.

If we are unable to obtain, maintain, or enforce sufficient patent and other intellectual property rights, or if those rights are limited in scope, we may not be able to compete effectively or to develop, manufacture, or commercialize our product candidates. Licenses and collaborations may include diligence, milestone, royalty, field-of-use, or territorial restrictions; failure to comply can lead to termination and loss of rights. Complex license terms and disputes (scope, sublicensing, ownership, payments) can impact our freedom to operate, timelines, and costs.

If we fail to comply with any of the obligations under such license agreements, including payment terms and diligence terms, the licensors may have the right to terminate these agreements, in which case we may lose important intellectual property rights and we may not be able to develop, manufacture, market or sell our product candidates or may face other penalties under such agreements or be subject to litigation for breach of these agreements. In addition, such a termination could result in the licensor reacquiring the intellectual property rights and subsequently enabling a competitor to access the technology. Any such occurrence could materially adversely affect the value of any of our product candidates. Termination of license agreements or reduction or elimination of our rights under them may result in us having to negotiate a new or reinstated agreement, which may not be available on equally favorable terms, or at all, which may mean we are unable to develop or commercialize our product candidates.

For instance, these licenses may not provide exclusive rights to use the subject 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 our product candidates in the future, such as provisions under the license agreement with CRH prohibiting us from developing our product candidates for oncology indications, or provisions under the Mabworks Agreement prohibiting us from undertaking certain activities in Greater China. In that event, we may be required to expend significant time and resources to redesign our technology or the methods for manufacturing or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis.

Further, the agreements under which we currently license, and may license in the future, intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. Accordingly, material disputes may arise between us and our licensors, regarding intellectual property subject to such license agreement, including those relating to:

- the scope of rights, if any, granted under the license agreement and other interpretation-related issues;
- the scope and practice of any rights reserved by our licensors;
- whether a licensor had the right to grant the license agreement;
- whether third parties are entitled to compensation or equitable relief, such as an injunction, for our use of the intellectual property without their authorization;
- its right to sublicense patent and other rights to third parties under collaborative development relationships;
- whether we are complying with our obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates;
- our involvement in the prosecution of the licensed patents and our licensors' overall patent enforcement strategy;
- the allocation of ownership of inventions and know-how resulting from the creation or use of intellectual property by our licensors and by us and our partners, including jointly developed intellectual property; and
- the amounts of royalties, milestones or other payments due under the license agreement.

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, increase what we believe to be our financial or other obligations under the relevant agreement, or decrease the financial or other benefits it might otherwise receive under the relevant agreement. If material disputes over intellectual property that we have licensed prevent or impair our ability to maintain licensing arrangements on acceptable terms or are insufficient to provide us the necessary rights to use the intellectual property, we may be unable to successfully develop and commercialize our product candidates.

If we or any such licensors fail to adequately protect the relevant in-licensed intellectual property, our ability to commercialize our product candidates could suffer. Any material disputes with licensors or any termination of the licenses on which we depend would have a material adverse effect on our business, results of operations, financial condition and prospects.

With respect to budoprutug, we own two pending U.S. provisional applications, nine pending U.S. nonprovisional patent applications, three pending PCT applications and eight pending ex-U.S. patent applications, and we have also exclusively licensed four issued U.S. patents and at least 45 ex-U.S. patents or patent applications under our license agreement with CRH. With respect to CLYM116, we have one exclusively in-licensed PCT application under the Mabworks Agreement and co-own three pending U.S. provisional patent applications with Mabworks. We can provide no assurance that any of our current or future patent applications will result in issued patents for budoprutug or CLYM116. If we are unable to obtain, maintain and protect sufficient patent and other intellectual property rights for our product candidates and technology, or if the scope of patent and other intellectual property rights obtained is not sufficiently broad, we may not be able to compete effectively in our market.

Our success depends in significant part on our ability and the ability of our licensors, or future licensors, licensees or collaborators to obtain, maintain, enforce and defend patents and other intellectual property rights with respect to budoprutug, CLYM116, or any other product candidates we may develop and to operate our business without infringing, misappropriating or otherwise violating the intellectual property rights of others.

Our patent applications may not issue or may issue with limited scope, and issued patents can be challenged or circumvented, reducing our ability to prevent competitors from developing similar therapies. Oppositions, post-grant reviews, inter partes reviews, or litigation can narrow, invalidate, or render patents unenforceable, increasing costs and impacting collaborations and financing. Prosecution, maintenance, or enforcement errors, or lack of alignment with licensors, may compromise protection or priority.

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Furthermore, other parties may successfully challenge, invalidate or circumvent our issued patents so that our patent rights do not create an effective competitive barrier or revenue source.

A U.S. provisional patent application is not eligible to become an issued patent until, among other things, we file nonprovisional patent application within 12 months of filing of the provisional patent application. With regard to such U.S. provisional patent applications, if we do not timely file any nonprovisional patent applications, we may lose our priority dates with respect to our provisional patent applications and any patent protection on the inventions disclosed in our provisional patent applications. While we intend to timely file nonprovisional patent applications relating to our provisional patent applications, we cannot predict whether any such patent applications will result in the issuance of patents that provide us with any competitive advantage. If our licensors are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised.

If there are material defects in the form, preparation, prosecution, or enforcement of our or our licensors' patents or patent applications, such patents may be invalid and unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

The 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 U.S. and abroad.

We may be subject to a third-party pre-issuance submission of prior art to the United States Patent and Trademark Office (USPTO) or become involved in opposition, derivation, revocation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others, or other proceedings in the USPTO or applicable foreign offices that challenge priority of invention or other features of patentability.

An adverse determination in any such submission, proceeding or litigation could result in loss of exclusivity or freedom to operate, patent claims being narrowed, invalidated or held unenforceable, in whole or in part, limit the scope or duration of the patent protection of budoprutug, CLYM116 or any other product candidates, all of which could limit our ability to stop others from using or commercializing similar or identical product candidates or technology to compete directly with us, without payment to us, or result in our inability to manufacture or commercialize product candidates or approved products (if any) without infringing third-party patent rights. 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 budoprutug, CLYM116 or any other product candidates, or could have a material adverse effect on our ability to raise funds necessary to continue our research programs or clinical trials. 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.

We cannot be certain that the USPTO and courts in the U.S. or the patent offices and courts in foreign countries will consider the claims in our patents and applications covering budoprutug, CLYM116 and any other product candidates as patentable.

Method-of-use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products off-label. Although off-label prescriptions may infringe or contribute to the infringement of method-of-use patents, the practice is common and such infringement is difficult to prevent, including through legal action.

If we cannot obtain or lose patent protection for budoprutug, CLYM116 or any other product candidates, it could have a material adverse impact on our business. Additionally, as a licensee, we rely on third parties to file and prosecute patent applications and maintain patents and otherwise protect the licensed intellectual property under some of our license agreements. For example, under the license agreement with CRH, CRH is responsible for prosecuting and maintaining intellectual property protection for budoprutug in consultation with us. We have not had and do not have primary control over these activities for certain of our in-licensed patents or patent applications and other intellectual property rights. For example, we cannot be certain that such activities by CRH or other licensors will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights.

We have limited control over the manner in which CRH or our other licensors may initiate an infringement proceeding against a third-party infringer of such intellectual property rights, or defend certain intellectual property that may be licensed to us. It is possible that CRH or our other licensors infringement proceeding or defense activities may be less vigorous than if we conduct them ourselves. We cannot be certain that such activities by third parties have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights.

For example, under the Mabworks Agreement, Mabworks is responsible for prosecuting and maintaining intellectual property protection for CLYM116 in Greater China in consultation with us. We have not had and do not have primary control over these activities in Greater China for CLYM116.

We cannot be certain that such activities by Mabworks will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights in Greater China. Pursuant to the terms of the license agreements with some of our licensors, the licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents and even if we are permitted to pursue such enforcement or defense, we will require the cooperation of our licensors. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect its interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business.

If any of our licensors or any of our future licensors or future collaborators fail to appropriately prosecute and maintain patent protection for patents covering our product candidates, our ability to develop and commercialize our product candidates may be adversely affected and 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 prosecution of patent applications we have acquired or licensed from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensors and their counsel that took place prior to our

assuming control over patent prosecution. The patent prosecution process is expensive and time-consuming. We and our licensors, and any future licensors, licensees or collaborators, may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

It is also possible that we or our licensors will fail to identify patentable aspects of our research and development output in time to obtain patent protection or fail to file patent applications covering inventions made in the course of development and commercialization activities before a competitor or another third party files a patent application covering, or publishes information disclosing, a similar, independently-developed invention. Such competitor's or other third party's patent application may pose obstacles to our ability to obtain patent protection or limit the scope of the patent protection we may obtain.

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, collaborators, CROs, CDMOs, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after the initial filing date, or in some cases not at all. Therefore, we cannot be certain that we or our future licensors were the first to make the inventions claimed in our owned or any future licensed patents or pending patent applications, or were the first to file for patent protection of such inventions.

In addition, our technology acquired or licensed from various third parties, including our licensors, may be subject to retained rights. Our licensors often retain certain rights under their agreements with us, including the right to use the underlying technology for use in fields other than the fields licensed to us or for use in noncommercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology.

It is difficult to monitor whether our licensors limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to its licensed technology in the event of misuse by the licensor.

The patent position of biotechnology and pharmaceutical companies generally is uncertain, involves complex legal and factual questions and is the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors' patent rights are uncertain.

Our and our future licensors' pending, and future patent applications may not result in patents being issued that protect our technology or product candidates, in whole or in part, or which effectively exclude others from commercializing competitive technologies and product candidates. The patent examination process may require us or our future licensors to narrow the scope of the claims of our pending and future patent applications, and therefore, even if such patent applications 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.

Our and our licensors' patent applications cannot be enforced against third parties practicing the technology claimed in pending applications unless and until a patent issues from such applications, and then only to the extent the issued claims cover such technology. Any patents that we hold or license, or may in-license in the future may be challenged, narrowed, circumvented or invalidated by third parties. Consequently, we do not know whether budoprutug, CLYM116 or any other 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. Any of the foregoing could impair our competitive position and harm our business.

The patent protection we obtain for budoprutug, CLYM116 or any other product candidates and technologies may be challenged and rendered invalid or unenforceable.

Patent challenges, including oppositions, post-grant reviews, inter partes reviews, derivations, and litigation, can narrow, invalidate, or render our patents unenforceable, reducing exclusivity and enabling competitors to commercialize similar technologies. Adverse outcomes may limit our ability to prevent competition, shorten patent duration, or require costly and time-consuming legal proceedings.

Even if our owned or co-owned patent applications issue as patents, the issuance of any such patents is not conclusive as to their inventorship, scope, validity or enforceability, and such patents or patents we license from third parties, may be challenged, invalidated, narrowed or held to be unenforceable, including in the courts or patent offices in the U.S. and abroad, or circumvented.

We or our licensors may be subject to a third-party preissuance submission of prior art to the USPTO or equivalent foreign bodies, or become involved in opposition, derivation, revocation, re-examination, post-grant and inter partes review or interference proceedings challenging our or our licensors' patent rights or the patent rights of others.

An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our or our licensors' patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we may have to participate in interference or derivation proceedings declared by the USPTO to determine priority or ownership of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge priority of invention or other features of patentability. Such proceedings and any other patent challenges may result in loss of patent rights, loss of exclusivity, loss of priority or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products or limit the duration of the patent protection of our technology and product candidates. Such proceedings also may result in substantial costs and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Moreover, there could be public announcements of the results of hearings, motions or other developments related to any of the foregoing proceedings. If securities analysts or investors perceive those results to be negative, it could cause the price of shares of our common stock to decline. Any of the foregoing could harm our business.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Our reliance on third parties for development, manufacturing, and other services requires us to share trade secrets and confidential information, increasing the risk of misappropriation, inadvertent disclosure, or incorporation into others' technology. While we use confidentiality and related agreements, these may not provide adequate protection or remedies, and monitoring compliance is challenging. If competitors lawfully obtain or independently develop our trade secrets, or if unauthorized disclosure occurs, our competitive position could be impaired.

We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets. Despite these contractual agreements with third parties, sharing trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements.

Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may harm our business.

We may become involved in lawsuits to protect or enforce our patents, the patents of our licensors or other intellectual property, which could be expensive, time-consuming and unsuccessful, and issued patents covering our technology and product candidates could be found invalid or unenforceable if challenged.

Intellectual property litigation can be costly and time-consuming; adverse outcomes (invalidity, unenforceability, narrow claim construction) can limit our ability to prevent competition and harm our business. Litigation may also result in disclosure of confidential information and distract management, and enforcement can be especially challenging in some jurisdictions.

Competitors and other third parties may infringe, misappropriate or otherwise violate our owned, co-owned and licensed patents or other intellectual property. In addition, our owned, co-owned and licensed patents may become involved in inventorship or priority disputes. Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent is issued from such applications. To counter infringement or other unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents or that our patents are invalid or unenforceable.

In a patent infringement proceeding, a court may decide that an owned, co-owned or licensed patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our owned, co-owned and licensed patents do not cover the technology. An adverse result in any litigation proceeding could put one or more of our owned, co-owned or licensed patents at risk of being invalidated, held unenforceable or interpreted narrowly. We may find it impractical or undesirable to enforce our intellectual property against some third parties.

In patent litigation in the U.S., defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or insufficient written description. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution.

Third parties may also raise similar claims before the USPTO or an equivalent foreign body, even outside the context of litigation. Potential proceedings include re-examination, post-grant review, inter partes review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of, or amendment to our patents in such a way that they no longer cover our technology or any product candidates that we may develop.

The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution. If a defendant 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 the applicable product candidates or technology covered by the patent rendered invalid or unenforceable. Such a loss of patent protection would harm our business.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the ownership or priority of inventions 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. Such licenses may not be available on commercially reasonable terms, or at all, or may be non-exclusive.

If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture and commercialization of one or more of the product candidates we may develop. In addition, if we, our existing licensors or any future licensors are unsuccessful in any inventorship disputes to which we or they are subject, we may lose valuable intellectual property rights, such as exclusive ownership of, or the exclusive right to use, our owned, licensed or any future in-licensed patents. The loss of exclusivity or the narrowing of such patent claims could limit our ability to stop others from using or commercializing similar or identical technology and products. Any of the foregoing could harm our business. Even if we are successful in any of the foregoing disputes, it could result in substantial costs and be a distraction to management and other employees. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or proceeding.

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.

Most of our competitors are larger than we are and have substantially greater resources. They are, therefore, likely to be able to sustain the costs of complex patent litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing, misappropriating or otherwise violating our intellectual property. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims could result in substantial costs and diversion of management resources, which could harm our business. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to initiate anticipated clinical trials, continue our internal research programs or in-license needed technology or other product candidates. There could also be public announcements of the results of the hearing, motions or other interim proceedings or developments. If securities analysts or investors perceive those results to be negative, it could cause the price of shares of our common stock to decline. Any of the foregoing events could harm our business.

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

Legal protections for proprietary intellectual property vary in jurisdictions throughout the world. The enforcement of intellectual property rights can be difficult and costly, and some jurisdictions provide weaker protection than the U.S.

Competitors may use our technology in countries where we lack protection or where enforcement is limited and may export infringing products into protected markets. Efforts to enforce rights abroad can be expensive, time-consuming, and may not yield meaningful remedies, limiting our ability to secure a commercial advantage. Filing, prosecuting, maintaining, defending and enforcing patents and other intellectual property rights on budoprutug, CLYM116 or any other product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U.S. can be less extensive than those in the U.S. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal

and state laws in the U.S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from selling or importing products made using our inventions in and into the U.S. or other jurisdictions.

Competitors may use our technologies in jurisdictions where we have not obtained patent protection or other intellectual property rights to develop their own products and may export otherwise infringing, misappropriating or violating products to territories where we have patent or other intellectual property protection, but enforcement rights are not as strong as those in the U.S. These products may compete with budoprutug, CLYM116 or any other product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of some countries do not favor the enforcement of patents and other intellectual property rights, which could make it difficult for us to stop the infringement, misappropriation or other violation of our intellectual property rights generally. Proceedings to enforce our intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful.

Many countries, including EU countries, India, Japan and China, have compulsory licensing laws under which a patent owner may be compelled under specified circumstances to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In those countries, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. 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, which could harm our business.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent which might adversely affect our ability to develop and market our product candidates.

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending patent application in the U.S. and abroad that is relevant to or necessary for the commercialization of budoprutug, CLYM116 or any other product candidates in any jurisdiction. For example, freedom-to-operate analyses may miss relevant third-party rights or misinterpret scope or expiration, leading to infringement risk, redesigns, licensing costs, or delays. If we fail to identify or correctly interpret relevant patents, we may face costly litigation, delays, or be forced to obtain licenses on unfavorable terms, which could adversely affect the development and commercialization of our product candidates.

Patent applications in the U.S. and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering budoprutug, CLYM116 or any other product candidates could have been filed by third parties without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover budoprutug, CLYM116 or any other product candidates or their use.

Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market such product candidates. If we fail to identify and correctly interpret relevant patents or if we are unable to obtain licenses to relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, which may be significant, we may be temporarily or permanently prohibited from commercializing any of our product candidates that are held to be infringing.

We might, if possible, also be forced to redesign product candidates so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business and could harm our business.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from our licensors, otherwise experience disruption to our business relationships with our licensors, or we are unable to obtain licenses from other third parties on commercially reasonable terms or fail to comply with our obligations under such agreements, we could lose license rights that our important to our business and our business could be harmed.

We are a party to a number of license agreements under which we are granted rights to intellectual property that are important to our business, and we may enter into additional license agreements in the future for budoprutug, CLYM116 or any other product candidates.

Our existing license agreements impose on us, and we expect that any future license agreements where we in-license intellectual property will impose on us, various development, regulatory and commercial diligence obligations, payment of milestones and royalties and other obligations. If we fail to comply with our obligations under these agreements, or we are subject to bankruptcy-related proceedings, our licensors may have the right to terminate our licenses, in which case, we would not be able to market products covered by the licenses. Additionally, non-compliance with license terms (e.g., payment, diligence, reporting, or other obligations) can lead to termination or re-purchase of assets, loss of rights, or restrictions that delay development and commercialization of our product candidates.

We acquired our right to a number of licenses pursuant to the Asset Purchase Agreement, as well as from license agreements that Tenet entered into in connection with the Asset Purchase Agreement. Those license agreements impose on us various development, regulatory and commercial diligence obligations, payment of milestones and royalties and other obligations. To the extent a Product (as such term is defined in the Asset Purchased Agreement) exists under the Asset Purchase Agreement, Climb may also have diligence and payment obligations to Acelyrin, and Acelyrin may have certain related rights if we fail to comply with diligence obligations, including the right to re-purchase the Transferred Assets (as defined in the Asset Purchase Agreement), including our rights to the licenses subject to the Asset Purchase Agreement, in which case, we may not be able to market or develop such Product.

With respect to CLYM116, we have an existing license agreement with Mabworks, which imposes on us various development, regulatory and commercial diligence obligations, payment of milestones and royalties and other obligations. If we fail to comply with our obligations under the license agreement, Mabworks may have the right to terminate the license agreement, in which case, we may not be able to market or develop CLYM116.

Loss of licensed rights may require renegotiation on less favorable terms, or may enable competitors to access the technology, materially harming our business. We may need to obtain additional licenses from third parties to advance our research or commercialize budoprutug, CLYM116 or any other product candidates, and we cannot provide any assurances that third-party patents do not exist that might be enforced against budoprutug, CLYM116 or such other product candidates in the absence of such a license. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several 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 may fail to obtain any of these licenses on commercially 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 develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize budoprutug, CLYM116 or any other product candidates, which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and other forms of compensation. Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. Disputes may arise between us and our licensors regarding intellectual property subject to a license agreement, including:

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

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 not be able to successfully develop and commercialize our product candidates, which would have a material adverse effect on our business.

Moreover, some of our patents and patent applications in the future may be co-owned with third parties. If we are unable to obtain an exclusive license to any such co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, who could market competing products and technology. In addition, we may need the cooperation of any such co-owners to enforce such patents against third parties, and such cooperation may not be provided to us.

Patent terms may be inadequate to protect our competitive position on budoprutug, CLYM116 or any other product candidates for an adequate amount of time.

Patents have a limited lifespan. Even with possible extensions, patent protection may expire before or shortly after commercialization, enabling earlier competition and potentially reducing the amount of revenue we are able to generate from sale of any of our product candidates that receive approval. If we do not have sufficient patent life to protect our product candidates, our business and competitive position may be adversely affected. In the U.S., if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. nonprovisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering budoprutug, CLYM116 or any other product candidates are obtained, once the patent life has expired for a product candidate, we may be open to competition from competitive medications, including generic medications.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned, co-owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours.

In addition, we intend, or understand that our licensors intend, to pursue additional patent protection covering, when possible, compositions, methods of use, methods of manufacture, and dosing and formulations of budoprutug and CLYM116.

Any patent that may be issued from our nine owned pending U.S. nonprovisional patent applications, three owned pending PCT applications and six of our owned pending ex-U.S. patent applications relating to budoprutug is expected to expire in 2045, excluding any PTA that might be available following the grant of any such patent and any PTE that might be available following the grant of marketing authorizations.

With respect to budoprutug, the issued patents, or patents that may be issued from the pending patent applications that we exclusively in-license from CRH are expected to expire beginning in December 2026, excluding any PTA that might be available following the grant of any such patent and any PTE that might be available following the grant of marketing authorizations. In the case of one of the U.S. patents exclusively in-licensed from CRH, the patent term is adjusted by 1703 days and is expected to expire in August 2031. In each instance of the above, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to budoprutug.

Any patent that may be issued from our co-owned pending patent applications relating to CLYM116 is expected to expire in 2046, excluding any PTA that might be available following the grant of any such patent and any PTE that might be available following the grant of marketing authorizations.

With respect to CLYM116, the patents that may be issued from the pending patent application that we exclusively in-license from Mabworks are expected to expire in 2044, excluding any PTA that might be available following the grant of any such patent and any PTE that might be available following the grant of marketing authorizations. In each instance of the above, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to CLYM116.

Depending upon the timing, duration and conditions of any FDA marketing approval of budoprutug, CLYM116 or any other product candidates, one or more of our U.S. owned, co-owned or licensed patents may be eligible for limited PTE under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, and one or more of our foreign owned, co-owned or licensed patents may be eligible for PTE under similar legislation, for example, in the EU. In the U.S., the Hatch-Waxman Amendments permit a PTE 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. However, there are no assurances that the FDA or any comparable foreign regulatory authority or national patent office will grant such extensions, in whole or in part. For example, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, 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. Only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from approval, and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended.

If we are unable to obtain PTE or the term of any such extension is less than we request, the period during which we can enforce our patent rights for the applicable product candidate will be shortened, and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced.

Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and nonclinical data and launch their product earlier than might otherwise be the case, and our competitive position and business could be harmed.

Changes in patent law could diminish the value of our patents, thereby impairing our ability to protect our intellectual property for budoprutug, CLYM116 or any other product candidates.

Our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry is inherently uncertain, due in part to ongoing changes in the patent laws. Legal and policy changes can alter patentability, validity standards, and challenge mechanisms, affecting our ability to obtain, maintain, and enforce intellectual property protections. Court decisions, legislative reforms, and evolving international standards may narrow patent scope, increase uncertainty, and raise costs for intellectual property prosecution, enforcement, and defense. Depending on decisions by Congress, the federal courts, and the USPTO and equivalent institutions in other jurisdictions, the laws and regulations governing patents, and interpretation thereof, could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce existing or future patents.

For example, 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.

Therefore, there is increased uncertainty with regard to our ability to obtain patents in the future, as well as uncertainty with respect to the value of patents once obtained.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued and licensed patents. Assuming that other requirements for patentability are met, prior to March 2013, in the U.S., the first to invent the claimed invention was entitled to the patent, while outside the U.S., the first to file a patent application was entitled to the patent.

After March 2013, under the Leahy-Smith America Invents Act (Leahy-Smith Act) enacted in September 2011, the U.S. transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications are prosecuted and may also affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, inter partes review and derivation proceedings. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, particularly the first inventor-to-file provisions. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business.

However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued or licensed patents, all of which could harm our business.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated if we fail to comply with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on any patents and patent applications are required to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of a patent. In certain circumstances, we may rely on our licensors to pay these fees. The USPTO and various foreign patent agencies also require compliance with a number of procedural, documentary, fee payment and other similar requirements during the patent application and prosecution process.

Administrative errors or missed deadlines (by us or licensors) can lead to abandonment or loss of rights. Failure to pay fees, respond to official actions, or submit required documents can result in loss of patent protection in relevant jurisdictions. If we or our licensors, or any future licensors or collaborators, fail to maintain the patents and patent applications covering budoprutug, CLYM116 or any other product candidates, our competitors might be able to enter the market with similar or identical products or technology, which would harm our business.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could negatively impact the success of our business.

Our commercial success depends upon our ability and the ability of any of our collaborators to develop, manufacture, market and sell budoprutug, CLYM116 and any other product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and other proprietary rights of third parties.

There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. We may become party to, or be threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to budoprutug, CLYM116 or any other product candidates and technology, including re-examination, interference, post-grant review, inter partes review or derivation proceedings before the USPTO or an equivalent foreign body. Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we are developing our product candidates. In the event that any of these patents were asserted against us, we believe that we would have defenses against any such action, including that such patents are not valid or that we would be able to replace such technology with alternative, non-infringing technology.

However, if any such patents were to be asserted against us and our defenses to such assertion were unsuccessful and such alternative technology was not available or technologically or commercially practical, unless we obtain a license to such patents, 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, and we could be precluded from commercializing any product candidates that were ultimately held to infringe such patents. Any potential future legal proceedings relating to these patents could cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. If we are unsuccessful in our challenges to these patents and become subject to litigation or are unable to obtain a license on commercially reasonable terms with respect to these patents, it could harm our business.

Third parties may allege that we are infringing, misappropriating, or otherwise violating their intellectual property rights. Defending such claims can be costly, time-consuming, and distracting. If we are found to infringe, we may be required to obtain licenses (which may not be available on reasonable terms), pay damages, or cease development or commercialization of affected products.

We may also be required to indemnify collaborators or licensors, further increasing costs. Any of these outcomes could materially harm our business.

We may be subject to claims by third parties asserting that we or our employees have infringed upon, misappropriated or otherwise violated their intellectual property rights, or claiming ownership of what we regard as our own intellectual property.

Many of our employees were previously employed at other biotechnology or pharmaceutical companies. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's former employer.

Employee or consultant background intellectual property claims can lead to disputes, costs, delays, or loss of rights. We may face allegations that our personnel used or disclosed proprietary information from prior employers, or that we do not own inventions developed by our team. Litigation or disputes over intellectual property ownership can be costly, distract management, and may result in loss of rights or personnel. Litigation may be necessary to defend against these claims.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs, delay development of our product candidates and be a distraction to management. Any of the foregoing events would harm our business.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Intellectual property litigation can be expensive, time-consuming, and may divert management and technical personnel from core business activities. Even successful outcomes can result in significant costs and operational disruption. Public proceedings may also impact our reputation or stock price.

In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. 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. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources.

Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace, including compromising our ability to raise the funds necessary to initiate anticipated clinical trials, continue our research programs, license necessary technology from third parties or enter into development collaborations that would help us commercialize budoprutug, CLYM116 or any other product candidates, if approved. Any of the foregoing events would harm our business.

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

We rely on trade secrets and know-how to protect proprietary technology, especially where patent protection is unavailable or inappropriate. Trade secrets can be difficult to protect, and confidentiality agreements and security measures may be breached, and remedies may be inadequate. If our trade secrets are disclosed, misappropriated, or independently developed by competitors, our competitive position could be harmed.

Trade secrets and know-how can be difficult to protect. We seek to protect these trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, licensors, collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. We cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and 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 U.S. are less willing or unwilling to protect trade secrets.

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 our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be harmed.

As is common in the biotechnology industry, we engage the services of consultants to assist us in the development of our product candidates. Many of these consultants were previously employed at, or may have previously provided or may be currently providing consulting services to, other biotechnology companies including our competitors or potential competitors.

We may become subject to claims that we or our consultants inadvertently or otherwise used or disclosed trade secrets or other information proprietary to our consultants' former employers or their former or current clients. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team.

We may not be able to protect and enforce our trademarks and trade names or build name recognition in our markets of interest thereby harming our competitive position.

We intend to rely on both registered and common law rights for our trademarks. We plan to apply to register these trademarks with the USPTO and may in the future seek to register additional trademarks in the U.S. and other countries.

Trademark protection may be limited or unavailable in some jurisdictions, and third parties may oppose, cancel, or infringe our marks. Failure to secure or enforce trademarks can diminish brand value, create confusion, and harm our competitive position. Building name recognition in our markets of interest may be challenging, and litigation or administrative proceedings to protect trademarks can be costly and uncertain.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. Even robust intellectual property may not prevent all competition; alternative technologies, off-label use, safe-harbor R&D, and missed filings can erode intellectual property exclusivity.

Competitors may independently develop similar or alternative technologies, design around our patents, or benefit from aspects of our inventions that are not patentable or not protected. Intellectual property rights may not cover all threats, and the patents of others may adversely affect our business.

For example:

- others may be able to make products that are similar to any product candidates we may develop or utilize similar technology but that are not covered by the claims of the patents that we own, co-own or license now or own, co-own or license in the future;
- we, or our current or future licensors, might not have been the first to make the inventions covered by the issued patent or pending patent application that we own, co-own or license now or own, co-own or license in the future;
- we, or our current or future licensors, might 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 our pending owned, co-owned or licensed patent applications or those that we may own, co-own or license in the future will not lead to issued patents; issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in the U.S. under FDA-related safe harbor patent infringement exemptions or 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 harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could harm our business.

Risks Related to our Business Operations and Employee Matters

If our information technology systems or data, or those of third parties upon which we rely, such as CROs, are or were compromised or interrupted, we could experience adverse consequences resulting from such compromise or interruption, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse consequences.

In the ordinary course of our business, we may collect, store, use, transmit, disclose, or otherwise process proprietary, confidential, and sensitive data, including personal data (such as health-related data), intellectual property, and trade secrets using information technology networks and systems, including the Internet and artificial intelligence-based software.

Cyberattacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity and availability of our data and information technology systems, and those of the third parties upon which we rely. Such threats are prevalent and continue to increase and are becoming increasingly difficult to detect. These threats come from a variety of sources.

In addition to 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 now engage in attacks. Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we, and the third parties upon which we rely, may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and harm our business.

We and the third parties upon which we rely, such as CROs, may be subject to a variety of evolving threats, including but not limited to social-engineering attacks, including through the use of artificial intelligence and deep fakes, which may become increasingly more difficult to identify as fake, and phishing attacks, malicious code, such as viruses and worms, malware, including as a result of advanced persistent threat intrusions, denial-of-service attacks, such as credential stuffing, credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, geopolitical developments, earthquakes, fires, floods, and other similar threats. Ransomware attacks are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, loss of data 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. We also rely upon third-party service providers and technologies to operate critical business systems to process confidential information and personal data in a variety of contexts, including, without limitation, third-party providers of cloud-based infrastructure, encryption and authentication technology, employee email and other functions. Our ability to monitor these third parties' cybersecurity practices is limited, and these third parties may not have adequate information security measures in place. We may share or receive sensitive data with or from third parties, and if they experience a security incident or other interruption, we could experience adverse consequences.

Similarly, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third-party partners' supply chains have not been affected. While we may be entitled to damages if our third-party service providers 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.

Some of our personnel work from home, which poses increased risks to our information technology systems and data as they utilize network connections outside our premises. Future 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.

Any of the previously identified or similar threats could cause a security incident or other interruption. A security incident or other interruption could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our data or our information technology systems, or those of the third parties upon whom we rely. Additionally, sensitive data could be leaked, disclosed, or revealed as a result of or in connection with our employee's, personnel's, or vendor's use of generative artificial intelligence technologies. If such an event were to occur, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed, ongoing or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also harm our business.

We may expend significant resources or modify our business activities, including future clinical trial activities, to protect against security incidents. 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 data. 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 and remediate vulnerabilities, but we may be unable in the future to detect and remediate vulnerabilities because such threats and techniques change frequently, are often sophisticated in nature, and therefore may not be detected until after a security incident has occurred. These vulnerabilities therefore may pose material risks to our business. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities.

Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosures or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences.

These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and oversight; restrictions on processing data, including personal data; litigation, including class claims; indemnification obligations; negative publicity; reputational harm; monetary expenditures; interruptions in our operations, including availability of data; financial loss; and other similar harms.

Security incidents and attendant consequences may cause delays in the development of our product candidates and negatively impact our ability to grow and operate our business.

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 sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially 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 sensitive 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.

If we fail to attract and retain management and other key personnel, we may be unable to continue to successfully develop or commercialize our product candidates or otherwise implement our business plan.

Our ability to compete effectively in the pharmaceuticals industry depends on our ability to attract and retain highly qualified managerial, scientific, medical, legal, sales and marketing and other personnel. We are highly dependent on recruiting and retaining our management and scientific personnel. The loss of the services of any of these key personnel or the inability to recruit suitable replacements could impede or delay the successful development of our product candidates, completion of our clinical trials, and negatively impact our ability to implement our business plan. We also rely on the services of consultants and advisors who may have other commitments, which could limit their availability and impact our ability to execute our business strategy.

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

We are exposed to the risk that our employees, independent contractors, consultants, licensors, commercial collaborators, principal investigators, CROs and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or unauthorized activities that violate (1) the laws and regulations of the FDA, the EMA, the MHRA and other similar regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities, (2) manufacturing standards, (3) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the U.S. and abroad and (4) laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of individually identifiable information, including information obtained in the course of clinical trials, creating fraudulent data in our nonclinical studies or clinical trials or illegal misappropriation of product candidates, which could result in regulatory sanctions and harm our reputation.

We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred.

If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, including damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm and the delay, reduction, termination or restructuring of our operations.

Our international operations may expose us to business, regulatory, political, operational, financial, pricing and reimbursement risks associated with doing business outside of the U.S.

Operating internationally adds regulatory complexity, pricing and reimbursement variability, foreign exchange and logistics risks, and exposure to geopolitical and anti-corruption issues that can delay or limit market access. We may face different regulatory requirements, reduced intellectual property protection, trade restrictions, currency fluctuations, tax consequences, and challenges in staffing and managing foreign operations. Political instability, public health emergencies, and other disruptions can further impact our ability to operate and grow outside the U.S.

Our business strategy incorporates potential international expansion as we seek to conduct clinical trials, obtain regulatory approval for, and commercialize, our product candidates in patient populations outside the U.S. For example, we are actively conducting clinical trials in multiple countries outside of the U.S, including in Australia and Europe. If budoprutug, CLYM116 or any of our future product candidates are approved in international jurisdictions, we may hire sales representatives and conduct physician and patient association outreach activities outside of the U.S. Doing business internationally involves a number of risks, including but not limited to:

- multiple, conflicting and changing laws and regulations;
- failure by us to obtain and maintain regulatory approvals for the use of our products in various countries; rejection or qualification of foreign clinical trial data by the competent authorities of other countries;
- delays or interruptions in the supply of clinical trial materials resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- additional potentially relevant third-party patent and other intellectual property rights;
- complexities and difficulties in obtaining, maintaining, protecting and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- limits in our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our product candidates and exposure to foreign currency exchange rate fluctuations;
- currency exchange rate fluctuations and the resulting effect on our revenue and expenses and the cost and risk of entering into hedging transactions if we chose to do so in the future;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, including related public health guidance measures, boycotts, curtailment of trade and other business restrictions;
- certain expenses including, among others, expenses for travel and insurance; and
- regulatory and compliance risks that relate to anti-corruption compliance and record-keeping that may fall within the purview of the Foreign Corrupt Practices Act, its accounting provisions or its anti- bribery provisions or provisions of anti-corruption or anti-bribery laws in other countries.

Any of these factors could harm our future international expansion and operations and, consequently, our results of operations.

We may not be able to utilize a significant portion of our net operating loss carryforwards.

As of December 31, 2025, we had net operating loss (NOL) carryforwards of approximately $55.8 million for federal income tax purposes, $63.2 million for foreign income tax purposes and $9.5 million for state income tax purposes. The federal NOLs may be used to offset up to 80% of future taxable income each year while the state and foreign losses may be used to offset up to 100% of future taxable income. The federal and foreign NOL carryforwards can be carried forward indefinitely while the state NOL carryforwards will begin to expire in varying amounts in 2038. The NOL carryforwards subject to expiration could expire unused and be unavailable to offset future income tax liabilities.

We may not be able to utilize a significant portion of our NOL carryforwards or tax credits due to limitations under tax law, including Section 382 and 383 ownership change rules, and similar or corresponding provisions of foreign and state law, changes in tax law, or insufficient future taxable income. If we are unable to use these tax attributes, our future cash flows and financial condition could be adversely affected.

We have and may continue to seek to grow our business through acquisitions or investments in new or complementary businesses, products or technologies, through the licensing of products or technologies from third parties or through other strategic alliances, and the failure to manage acquisitions, investments, licenses or other strategic alliances, or the failure to integrate them with our existing business, could have a material adverse effect on our operating results, dilute our stockholders' ownership, increase our debt or cause us to incur significant expense.

Our success depends on our ability to continually enhance and broaden our product offerings in response to changing clinician and patients' needs, competitive technologies and market pressures. Accordingly, we have and may continue to consider opportunities to acquire, make investments in or license other technologies, products and businesses that may enhance our capabilities, complement our existing products and technologies or expand the breadth of our markets or customer base. For example, we entered into the Mabworks Agreement where we acquired licenses for the development, manufacture and commercialization of CLYM116 and products containing CLYM116 in certain territories.

Potential and completed acquisitions, strategic investments, licenses and other alliances, including our acquisition of Tenet and the Mabworks Agreement, involve numerous risks, including:

- difficulty assimilating or integrating acquired or licensed technologies, products, employees or business operations; issues maintaining uniform standards, procedures, controls and policies;
- unanticipated costs associated with acquisitions or strategic alliances, including the assumption of unknown or contingent liabilities and the incurrence of debt or future write-offs of intangible assets or goodwill;
- diversion of management's attention from our core business and disruption of ongoing operations;
- adverse effects on existing business relationships with suppliers, sales agents, health care facilities, surgeons and other health care providers;
- risks associated with entering new markets in which we have limited or no experience;
- potential losses related to investments in other companies;
- potential loss of key employees of acquired businesses; and
- increased legal and accounting compliance costs.

To finance any acquisitions, investments or strategic alliances, we may choose to issue shares of our common stock as consideration, which could dilute the ownership of our stockholders. For example, in June 2024 we issued 5,560,047 shares of our common stock as consideration in connection with the closing of the Acquisition, and we issued 31,238,282 shares of our common stock in connection with the closing of the Acquisition Private Placement, resulting in the issuance of a total of an additional 36,798,329 shares of our common stock. In addition, in April 2026, we issued 9,481,000 shares of our common stock and pre-funded warrants to purchase 2,106,000 shares of our common stock in connection with the closing of the 2026 Private Placement,

If the price of our common stock is low or volatile, we may be unable to consummate any acquisitions, investments or strategic alliances using our common stock as consideration. Additional funds may not be available on terms favorable to us, or at all.

Risks Related to our Common Stock

The trading price of our common stock has been and may continue to be volatile, and purchasers of our common stock could incur substantial losses.

Our stock price has been volatile. Through April 30, 2026, our stock price has fluctuated from a high trading price of $29.69 per share in August 2021 to a low trading price of $1.05 in April 2025. The stock market in general and the market for biotechnology companies in particular have also experienced extreme volatility that has often been unrelated to the operating performance of particular

companies. The market price for our common stock may continue to be volatile in the future and may be influenced by many factors, including:

- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- the commencement, enrollment or results of any clinical trials or nonclinical development activities we may conduct, or changes in the development status of our product candidates;
- adverse results from, delays in or termination of our clinical trials or those of our competitors;
- unanticipated serious safety concerns related to the use of any of our product candidates;
- adverse regulatory decisions, including results of regulatory interactions and review for any of our product candidates;
- lower than expected market acceptance of our product candidates following approval for commercialization;
- changes in financial estimates by us or by any securities analysts who might cover our stock;
- conditions or trends in our industry;
- changes in the market valuations of similar companies;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the pharmaceutical industry;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- announcements by us or our competitors of strategic transactions, significant acquisitions, strategic partnerships or divestitures;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- investors' general perception of our company and our business;
- actions by institutional or activist investors;
- changes to our business, including pipeline reprioritizations and restructurings;
- recruitment or departure of key personnel;
- overall performance of the equity markets;
- trading volume of our common stock;
- disputes or other developments relating to intellectual property rights, including patents, litigation matters and our ability to obtain, maintain, defend, protect and enforce patent and other intellectual property rights for our technologies;
- threats of or actual significant lawsuits, including patent or stockholder litigation;
- proposed changes to healthcare laws in the U.S. or foreign jurisdictions, or speculation regarding such changes;
- general political and economic conditions; and
- other events or factors, including the other factors described in this "Risk Factors" section, many of which are beyond our control.

In the past, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' stock, in particular following significant drops in stock price. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources from our business.

In addition, in the current volatile market for biotechnology stocks, in particular where shares are trading below cash balances, certain biotechnology investors have advocated for increases in short-term stockholder value through proposed corporate actions such as financial restructurings, special dividends, stock repurchases, mergers, other business combinations or sales of assets. Any such proposals directed at us could cause us to incur substantial costs and divert management's attention and resources from our business.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be our stockholders' sole source of gain.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. As a result, capital appreciation, if any, of our common stock will be our stockholders' sole source of gain for the foreseeable future.

We have broad discretion in the use of our cash, cash equivalents and marketable securities and may not use them effectively.

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

A significant portion of our common stock may be sold into the market, which could cause the market price of our common stock to drop significantly.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline significantly. Sales of substantial amounts of our common stock, or the perception that such sales could occur, could cause the market price of our common stock to decline and impair our ability to raise capital.

We have registered and intend to continue to register all shares of common stock that we may issue under our equity compensation plans. These shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates.

Additionally, the holders of approximately 38.0 million shares of our common stock and shares of our common stock issuable upon the exercise of pre-funded warrants, or their transferees, have rights, subject to some conditions, to require us to file one or more registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. If we were to register the resale of these shares, they could be freely sold in the public market without limitation. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

In connection with the Acquisition Private Placement, we entered into a registration rights agreement, pursuant to which we are required to register for resale the shares purchased in the Acquisition Private Placement and the consideration issued in the Acquisition. Pursuant to this agreement, in July 2024, we filed a registration statement covering the resale of the shares purchased by the purchasers in the Acquisition Private Placement and the consideration issued in connection with the Acquisition. In addition, in connection with the 2026 Private Placement, we entered into a registration rights agreement with the Investors, pursuant to which we agreed to register for resale the shares of our common stock and the shares of our common stock issuable upon exercise of the pre-funded warrants purchased in the 2026 Private Placement.

In addition, we agreed to use commercially reasonable efforts to cause such registration statement to become effective as soon as practicable after it was filed with the SEC and to keep such registration statement effective until the date the shares covered by the registration statement have been sold or can be resold without restriction under Rule 144 of the Securities Act.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of our company more difficult, limit attempts by our stockholders to replace or remove our current management and limit the market price 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 our company more difficult and may prevent attempts by stockholders to replace or remove current management. Such provisions may discourage proxy contests, delay or prevent mergers or acquisitions, and limit the ability of stockholders to influence corporate actions. Our amended and restated certificate of incorporation and amended and restated bylaws include provisions that:

- provide for a classified board of directors whose members serve staggered terms;
- authorize our board of directors to issue, without further action by the stockholders, shares of undesignated preferred stock with terms, rights and preferences determined by our board of directors that may be senior to our common stock;

- require that any action to be taken by our stockholders be effected at a duly called annual or special meeting and not by written consent;
- specify that special meetings of our stockholders can be called only by our board of directors, the chairperson of our board of directors or our chief executive officer;
- establish an advance notice procedure for stockholder proposals to be brought before an annual meeting, including proposed nominations of persons for election to our board of directors;
- prohibit cumulative voting in the election of directors;
- provide that our directors may be removed for cause only upon the vote of the holders of at least 66 2/3% of our outstanding shares of common stock;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum; and
- require the approval of our board of directors or the holders of at least 66 2/3% of our outstanding shares of common stock to amend our bylaws and certain provisions of our certificate of incorporation.

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, which is responsible for appointing the members of our management.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law (DGCL) which generally, subject to certain exceptions, prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any "interested" stockholder for a period of three years following the date on which the stockholder became an "interested" stockholder. Any delay or prevention of a change of control transaction or changes in our management could cause the market price of our common stock to decline.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law.

In addition, as permitted by Section 145 of the DGCL, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and officers provide that:

- We will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful.
- We may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law.
- We are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification.
- We will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification.
- The rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons.

We may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents. Claims for indemnification may reduce our available funds to satisfy third-party claims or to invest in our business.

Concentration of ownership of our common stock among our existing executive officers, directors and principal stockholders, including affiliates of RA Capital Management L.P., may limit or prevent new investors from influencing significant corporate decisions and also reduces the public float for our common stock, which could make our common stock less attractive to some investors or otherwise harm our stock price.

As of April 30, 2026, our executive officers, directors and current beneficial owners of 5% or more of our common stock, in the aggregate, beneficially own approximately 44.8% of our outstanding common stock, inclusive of affiliates of RA Capital Management, L.P., that own approximately 19.9% of our outstanding common stock, but they have the right to exercise pre-funded warrants at any time to purchase up to 33.0% of our common stock (as described below). These stockholders, acting together, are able to significantly influence all matters requiring stockholder approval, including the election of directors and any merger or other significant corporate transaction. The interests of this group of stockholders may not coincide with the interests of other stockholders.

In addition, as a result of this concentration of ownership, there is a limited number of shares of our common stock that are not held by officers, directors and principal stockholders (which is referred to as our public float), thereby adversely impacting the liquidity of our common stock and potentially depressing the price at which our stockholders' may be able to sell shares of common stock. This concentration may limit our stockholders' ability to influence corporate matters and could delay or prevent a change in control.

In December 2025, we entered into an exchange agreement (the Exchange Agreement) with RA Capital Management L.P., (RA Capital) and an entity affiliated with RA Capital (the Exchanging Holder) pursuant to which the Exchanging Holder exchanged an aggregate of 20,440,000 shares of our common stock beneficially owned by the Exchanging Holder for a pre-funded warrant to purchase the same number of shares of our common stock. The shares of our common stock exchanged by the Exchanging Holder were retired, and we had 47.7 million shares of common stock outstanding immediately after the transaction. The pre-funded warrant is exercisable at any time, however, the Exchanging Holder will not be entitled to exercise any portion of the pre-funded warrant if, upon giving effect or immediately prior to such exercise, such exercise would result in the aggregate number of shares of our common stock beneficially owned by RA Capital, the Exchanging Holder and their respective affiliates, collectively, to exceed 33.0% of the number of shares of our common stock issued and outstanding immediately after giving effect to such exercise, as such percentage ownership is determined in accordance with the terms of the pre-funded warrant. The Exchanging Holder may increase or decrease such percentage to any other percentage not in excess of 33.0%; provided that any such increase will not be effective until the 61st day after notice from the Exchanging Holder is delivered to us. In addition, in accordance with the terms of the Exchange Agreement, RA Capital and the Exchanging Holder have agreed to, and to cause each other account or fund managed by or affiliated with RA Capital to, vote all securities beneficially owned by them or their respective affiliates in excess of 33.0% of the total voting power of our outstanding capital stock, in proportion to and in accordance with the vote of all of our stockholders (excluding RA Capital and the Exchanging Holder and their respective affiliates). In addition, RA Capital purchased additional pre-funded warrants in the 2026 Private Placement, and the shares issuable upon the exercise of such pre-funded warrants will be subject to the Exchange Agreement.

We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses, or if we identify additional material weaknesses in the future or otherwise fail to maintain effective internal control over financial reporting, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business.

Prior to the completion of our IPO, we were a private company with limited accounting personnel to adequately execute our accounting processes and other supervisory resources with which to address our internal control over financial reporting. In connection with the preparation of our consolidated financial statements for the year ended December 31, 2020, we identified material weaknesses in our internal control over financial reporting, two of which remain unremediated as of March 31, 2026. The unremediated material weaknesses, and our remediation plan, are disclosed in Item 4, "Controls and Procedures," of this Quarterly Report.

We believe we have made substantial progress toward achieving the effectiveness of our internal control over financial reporting and disclosure controls and procedures. The actions that have been taken are subject to continued review and testing by management as well as oversight by the audit committee of our board of directors. We will not be able to conclude whether the steps we have taken will fully remediate these material weaknesses in our internal control over financial reporting until we have completed our remediation efforts and subsequent evaluation of their effectiveness.

If we are unable to remediate these weaknesses, or if additional weaknesses are identified, we may not be able to accurately or timely report our financial condition or results of operations, which could adversely affect our business and reputation. Failure to maintain effective internal controls could also result in regulatory investigations, actions, or negative impacts on our stock price.

If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (Exchange Act), the Sarbanes-Oxley Act, and the rules and regulations of the Nasdaq Stock Market. Section 302 of the Sarbanes-Oxley Act requires, among other things, that we report on the effectiveness of our disclosure controls and procedures in our quarterly and annual reports and Section 404 of the Sarbanes-Oxley Act requires that we perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting in our Form 10-K filings.

We cannot assure you that the measures we have taken to date, and are continuing to implement, or any measures we may take in the future, will be sufficient to identify or prevent future material weaknesses. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected. In addition, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting in our first annual report required to be filed with the SEC following the date we are no longer an emerging growth company or a smaller reporting company with less than $100 million in revenue.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our stock could decline and we could be subject to sanctions or investigations by the Nasdaq Stock Market, the SEC or other regulatory authorities. In addition, our common stock may not be able to remain listed on the Nasdaq Stock Market or any other securities exchange.

Our amended and restated certificate of incorporation designates the Court of Chancery of the State of Delaware and, to the extent enforceable, the federal district courts of the United States of America as the exclusive forums for substantially all disputes between us and our stockholders, which restricts our stockholders' ability to choose the judicial forum for disputes with us or our directors, officers, or employees.

Our amended and restated certificate of incorporation designates the Court of Chancery of the State of Delaware and, to the extent enforceable, the federal district courts of the United States of America as the exclusive forums for substantially all disputes between us and our stockholders. These provisions may restrict our stockholders' ability to choose the judicial forum for disputes with us or our directors, officers, or employees, and may discourage lawsuits or increase costs if a court finds such provisions unenforceable.

In addition, our amended and restated certificate of incorporation provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. These choice of forum provisions will not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction.

Such provisions are intended to benefit and may be enforced by us, our officers and directors, employees and agents, including the underwriters for any offering giving rise to such complaint and any other professional or entity who has prepared or certified any part of the document underlying the offering and may result in increased costs for stockholders to bring a claim.

We believe these provisions may benefit us by providing increased consistency in the application of Delaware law and federal securities laws by chancellors and judges, as applicable, particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. These choice of 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 with respect to such claims or make such lawsuits more costly for stockholders, although our stockholders will not be deemed to have waived our compliance with federal securities laws and the rules and regulations thereunder. 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, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions.

If a court were to find either choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions.

General Risk Factors

We are, have been, and may in the future become, involved in litigation that could result in significant costs, divert the attention of management and harm our business.

From time to time, we may be involved in litigation arising in the ordinary course of business or from specific events. These matters may relate to a wide range of issues, including contracts, intellectual property, employment matters, data protection and privacy, product liability, securities laws, stockholder allegations, or other business practices.

Even if we believe we have strong defenses, we may decide to settle claims for business or strategic reasons, particularly when the risks, costs, and burdens of litigation outweigh the potential benefits of continuing to defend a matter.

Litigation outcomes are unpredictable and the number and complexity of claims may increase as our business grows. Any current or future legal proceedings could materially adversely affect our business, financial condition, cash flows, and operating results.

If equity research analysts publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.

Our stock price and trading volume may be influenced by equity research analysts' reports published about us or our business, which we do not control. Unfavorable opinions or reports by an equity research analyst or downgrade by one or more equity research analysts could cause our stock price to decline.

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

Unfavorable global economic conditions, including volatility, inflation, recession, banking instability, military conflicts, sanctions, tariffs, and trade policy changes, could adversely affect our business, financial condition, stock price, and results of operations. These factors may impact our ability to raise capital, conduct clinical trials, and achieve operating goals.

The global credit and financial markets have experienced extreme volatility and disruptions, including as a result of actual or perceived changes in interest rates, inflation, and macroeconomic uncertainties, which has included severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, high inflation, uncertainty about economic stability, and increases in unemployment rates.

The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflicts or other geopolitical events. Sanctions, tariffs and general trade policy changes imposed by the U.S. and other countries may also continue to adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability.

There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. A severe or prolonged economic downturn could result in a variety of risks to our business, including a decrease in the demand for our product candidates and in our ability to raise additional capital when needed on acceptable terms, if at all. In addition, current inflationary trends in the global economy may impact salaries and wages, costs of goods and transportation expenses, among other things, and recent and potential future disruptions in access to bank deposits or lending commitments due to bank failures may create market and economic instability. We cannot anticipate all of the ways in which the foregoing, and the current economic climate and financial market conditions generally, could adversely impact our business.

We are an "emerging growth company" and a "smaller reporting company," and as a result of the reduced reporting requirements applicable to "emerging growth companies" and "smaller reporting companies," our common stock may be less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act. For as long as we continue to be an "emerging growth company," we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We may take advantage of these exemptions until we are no longer an "emerging growth company."

We will be an "emerging growth company" until December 31, 2026. We are also a "smaller reporting company," as defined in the Exchange Act. Even after we no longer qualify as an "emerging growth company," we may still qualify as a "smaller reporting company," which would allow us to continue to take advantage of many of the same exemptions from disclosure requirements. We

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

We may be unable to maintain adequate insurance coverage.

We presently have general liability, workers' compensation, directors' and officers', cybersecurity, and product liability insurance coverage. Although we believe we will be able to maintain such coverage for a reasonable cost and obtain any additional coverages that our business may require, no assurances can be made that we will be able to do so.

Changes in tax laws or regulations that are applied adversely to us may seriously harm our business.

Changes in tax laws or regulations, including the Organization for Economic Co-operation and Development Pillar Two rules and U.S. legislation such as the One Big Beautiful Bill Act or other tax related legislation, could adversely affect our business, financial performance, and tax treatment of future earnings. Existing tax laws may also be interpreted or applied adversely to us.

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

None.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Director and Officer Trading Arrangements

None of our directors or officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted or terminated a Rule 10b5-1 trading arrangement for the sale of our common stock that is intended to satisfy the affirmative defense conditions of the Exchange Act Rule 10b5-1(c) (Rule 10b5-1 Trading Plan) or adopted or terminated a non-Rule 10b5-1 trading arrangement (as defined in Item 408(c) of Regulation S-K) during the three months ended March 31, 2026.

Item 6. Exhibits.

Exhibit Number	Description of Exhibit	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
2.1	Agreement and Plan of Merger and Reorganization, dated as of April 10, 2024, by and among the Company, Tango Merger Sub, Inc., Tenet Medicines, Inc. and, solely in his capacity as the Company Equityholder Representative, Stephen Thomas.	8-K	001-40708	2.1	4/11/2024
3.1	Amended and Restated Certificate of Incorporation of the Registrant	10-Q	001-40708	3.1	11/12/2024
3.2	Amended and Restated Bylaws of the Registrant	8-K	001-40708	3.2	10/2/2024
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1+	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
32.2+	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File 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 certifications furnished in Exhibit 32.1 and 32.2 hereto are deemed to be furnished with this Quarterly Report and will not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it 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.

Climb Bio, Inc.

Date: May 7, 2026

By: /s/ Aoife Brennan

Aoife Brennan, M.B., Ch.B.
President and Chief Executive Officer
(*Principal Executive Officer*)

Date: May 7, 2026

By: /s/ Susan Altschuller

Susan Altschuller, Ph.D., MBA
Chief Financial Officer
(*Principal Financial Officer*)

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Aoife Brennan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Climb Bio, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: May 7, 2026

By: /s/ Aoife Brennan
Aoife Brennan, M.B., Ch.B.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Susan Altschuller, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Climb Bio, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: May 7, 2026

By: /s/ Susan Altschuller
Susan Altschuller, Ph.D., MBA
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 Climb Bio, Inc. (the "Company") on Form 10-Q for the period ending March 31, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: May 7, 2026

By: /s/ Aoife Brennan
Aoife Brennan, M.B., Ch.B.
President and Chief Executive Officer
(Principal Executive Officer)

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

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 Climb Bio, Inc. (the "Company") on Form 10-Q for the period ending March 31, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: May 7, 2026

By: /s/ Susan Altschuller
Susan Altschuller, Ph.D., MBA
Chief Financial Officer
(Principal Financial Officer)

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