UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2025

OR

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

Commission File Number 001-40708

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)**

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ NO ☒

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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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 June 30, 2025, the market value of voting stock held by non-affiliates of the registrant was $44.8 million. The calculation of the aggregate market value of voting and non-voting stock excludes certain shares of the registrant's common stock held by current executive officers, directors and stockholders that the registrant has concluded are affiliates of the registrant. Exclusion of such shares should not be construed to indicate that any such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the registrant or that such person is controlled by or under common control with the registrant.

As of February 27, 2026, the registrant had 47,767,980 shares of common stock, $0.0001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2026 Annual Meeting of Stockholders, which the registrant intends to file pursuant to Regulation 14A with the Securities and Exchange Commission not later than 120 days after the registrant's fiscal year ended December 31, 2025, are incorporated by reference into Part III of this Annual Report on Form 10-K.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that involve substantial risk and uncertainties. All statements, other than statements of historical fact, contained in this Annual Report on Form 10-K, 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 Annual Report on Form 10-K 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 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 Annual Report on Form 10-K particularly in the "Risk Factor Summary" below and in Part I, 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 Annual Report on Form 10-K 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 Annual Report on Form 10-K are made as of the date of this Annual Report on Form 10-K, 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, 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 six 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 six 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 Cancer Research Technology Limited (CRH). With respect to CLYM116, we have one exclusively in-licensed PCT application under the Mabworks Agreement and three co-owned 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. 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.

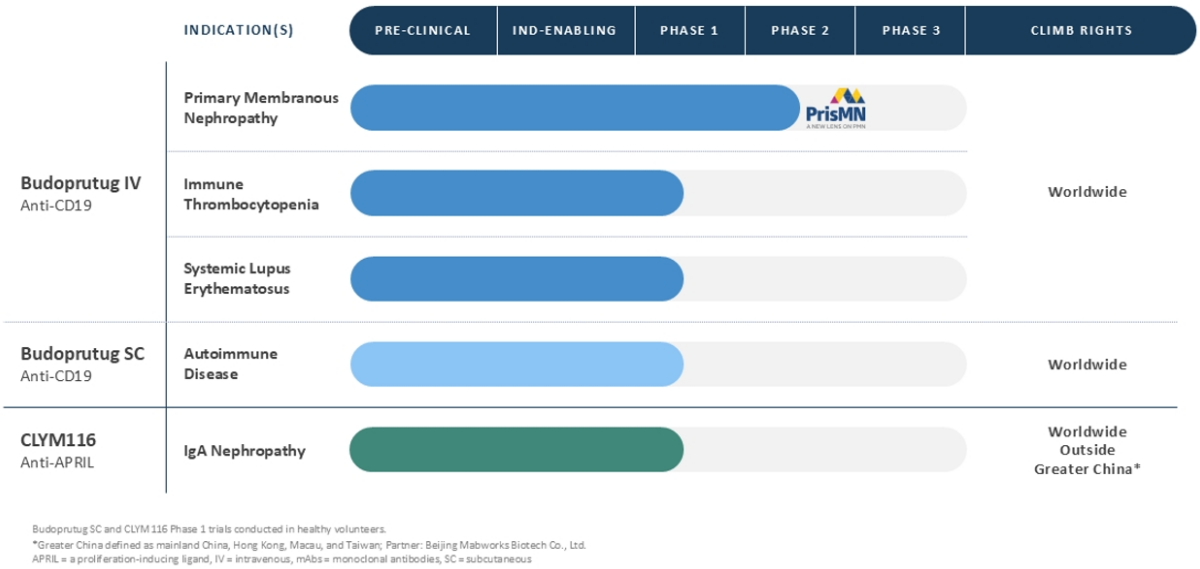
PART I

Item 1. Business.

Company 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.



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, which we refer to as Greater China.

Budoprutug

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 pMN, a rare, immune-mediated renal disease, autoantibodies acting against proteins in the glomerular basement membrane of the kidney drive proteinuria, nephrotic syndrome, and progressive loss of renal function. These autoantibodies are primarily secreted by plasmablasts that express CD19 but largely lack CD20, which help inform our rationale for targeting CD19-selective depletion. Early clinical data support this biological hypothesis and given the absence of approved therapies for pMN, we believe budoprutug may offer a meaningful and potentially durable treatment for patients.

ITP is a rare autoimmune disorder characterized by antibody-mediated platelet destruction, which results in bruising, bleeding episodes, hemorrhage, and fatigue. Current therapies, such as thrombopoietin receptor agonists (TPO-RAs) and rituximab, either do not address the underlying autoimmune driver or do not provide a durable response. By depleting CD19-expressing plasmablasts and some plasma cells, and their precursors, budoprutug may offer the potential for more sustained clinical responses or disease remission.

SLE is an additional development opportunity for budoprutug. SLE is a chronic, inflammatory autoimmune disorder characterized by the formation of autoantibodies and immune complexes that can lead to damage across multiple organs, including the skin, joints, and kidneys. CD19 is broadly expressed across multiple autoreactive B-cell subsets implicated in SLE pathogenesis, including naïve, memory, and plasmablast populations. Notably, recent third-party clinical data with CD19-directed modalities, including chimeric antigen receptor T-cell therapy (CAR-T), have demonstrated meaningful clinical activity and durable responses in patients with highly refractory SLE. Budoprutug may offer the potential for broad B-cell targeting with the safety and convenience of a mAb.

In March 2025, we received U.S. Food and Drug Administration (FDA) clearance for a Phase 2, dose range finding clinical trial of budoprutug in pMN, known as PrisMN. We dosed our first patient in the Phase 2 PrisMN clinical trial in November 2025 and are actively enrolling patients. Budoprutug was previously evaluated in a Phase 1b clinical trial in pMN, the results of which suggest that budoprutug may have the potential to induce remission of pMN in patients with moderate to severe disease. In that clinical trial, three out of five patients (60%) who received budoprutug and completed at least 48-weeks of follow-up achieved a complete remission of proteinuria, an important clinical endpoint in pMN. In addition, all five patients achieved complete peripheral B-cell depletion and, among the three patients with baseline anti-PLA2R (Phospholipase A2 Receptor) antibodies, serologic remission. Long-term follow-up data demonstrated durable reductions in proteinuria for up to three years after initial dosing in the four patients who received up to four doses of budoprutug. Additionally, three of these patients required no further immunosuppressive therapy. Notably, the FDA has granted budoprutug orphan-drug designation for the treatment of pMN.

Separately, in March 2025, we received FDA clearance for a Phase 1b/2a clinical trial of budoprutug in ITP. We are actively enrolling patients in the Phase 1b portion of this clinical trial to evaluate the safety, tolerability, pharmacokinetics (PK), pharmacodynamics (PD), and preliminary clinical efficacy, including B-cell depletion and platelet counts, of budoprutug in ITP.

In October 2024, we received FDA clearance for a Phase 1b clinical trial of budoprutug in 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.

In December 2025, we received clearance of our IND to initiate a separate, parallel Phase 1b 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).

Each of our clinical trials of budoprutug in pMN, ITP and SLE utilizes 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. We have generated nonclinical data using a proprietary SC formulation of budoprutug, which demonstrated high bioavailability, B-cell depletion, and favorable tolerability. 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 we anticipate sharing these data in the first half of 2026.

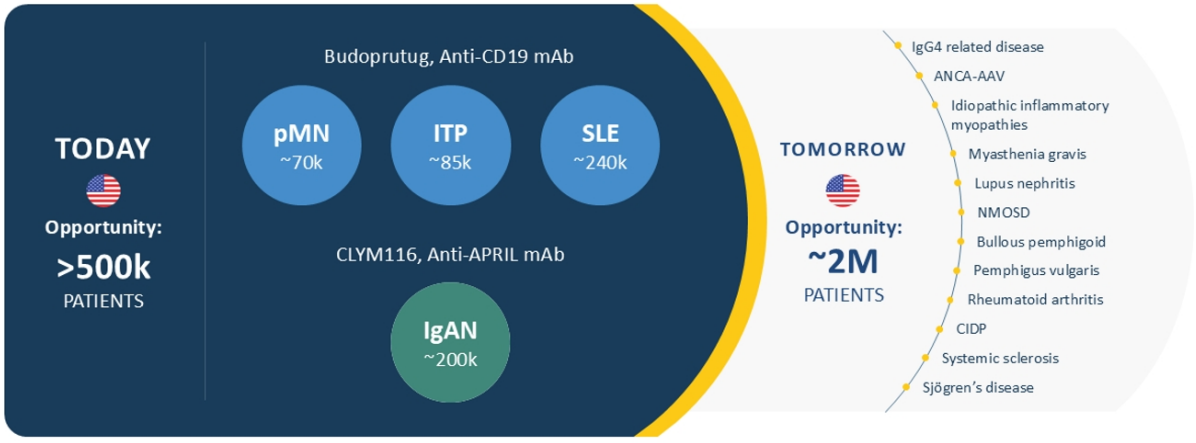
CLYM116

In addition to budoprutug, we are developing CLYM116, a next-generation anti-APRIL (A PRoliferation-Inducing Ligand) mAb for the treatment of IgA 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.

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.

Portfolio Approach

Budoprutug and CLYM116 represent a portfolio that we believe has the potential to address a broad spectrum of B-cell mediated diseases, including but not limited to the diseases identified in the image below. CD19 and APRIL are important and complementary targets in immune-mediated diseases, representing distinct leverage points along the B-cell lineage. We estimate that there are more than 500,000 patients in the U.S. across pMN, ITP, SLE, and IgAN, and approximately 2.0 million people in the U.S. living with immune-mediated diseases that budoprutug and CLYM116 have the potential to benefit. Given the prevalence of immune-mediated disease and the unmet need, we believe there is a meaningful market opportunity for differentiated therapies targeting immune-mediated diseases.



ANCA-AAV = antineutrophil cytoplasmic antibody-associated vasculitis, CIDP = Chronic inflammatory demyelinating polyradiculoneuropathy, IgAN = IgA Nephropathy, ITP = Immune Thrombocytopenia, NMOSD = Neuromyelitis optica spectrum disorder, pMN = Primary Membranous Nephropathy, SLE = Systemic Lupus Erythematosus, mAb = monoclonal Ab. Prevalence sources: B cell-mediated disease (internal research), IgAN (Tarpeyo CDER Integrated Review 2021, Filspari CDER Integrated Review 2022), ITP (internal research), pMN (internal research), SLE (Izmirly Arthritis Rheumatol 2021).

Our Strategy

Our strategy is to develop best-in-class treatments for patients with immune-mediated diseases, especially where we believe the mechanistic rationale is clear or clinically validated, patient populations are well-defined with high unmet need, development in multiple indications is feasible, and therapeutic differentiation can support meaningful value creation.

The key elements of our strategy include:

- **Advance budoprutug into late-stage development in pMN.** Based on encouraging Phase 1b data and the biologic rationale for CD19 in pMN, we are further evaluating budoprutug in a Phase 2 clinical trial in pMN. In November 2025, we achieved first-patient-in (FPI) in the PrisMN Phase 2 trial. The trial is designed to evaluate PD, including B cells, anti-PLA2R, and total immunoglobulin, and preliminary efficacy, including complete and partial remission, in pMN patients with persistent proteinuria despite optimized Renin-Angiotensin-Aldosterone System (RAAS) inhibition, and to identify a dose for Phase 3 clinical development.
- **Evaluate budoprutug in ITP and SLE**. Dosing is ongoing in our open-label, dose-escalation Phase 1b/2a clinical trial of budoprutug in previously treated patients with ITP. The trial is designed to evaluate safety, tolerability, PK, PD, and preliminary efficacy, including B-cell depletion and platelet counts. In addition, dosing is ongoing in our global, open-label, dose-escalation Phase 1b clinical trial of budoprutug in moderate to severe SLE patients. In this trial, we are administering a single dose of budoprutug to evaluate safety, tolerability, PK, PD, and preliminary efficacy, including B-cell depletion, autoantibody levels, and clinical activity. In December 2025, we received clearance of our IND to initiate a separate, parallel Phase 1b 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 LN.

- **Advance the SC formulation of budoprutug.** Given the chronic nature of many autoimmune diseases, we believe an SC formulation represents an important strategic and commercial differentiator. We are currently advancing a SC formulation of budoprutug, and nonclinical data of this formulation demonstrated high bioavailability and favorable tolerability at high concentration. In September 2025, we initiated a Phase 1 clinical trial of our SC formulation of budoprutug in healthy volunteers in Australia. We have completed dosing, and we anticipate sharing these data in the first half of 2026.
- **Expand budoprutug into additional B-cell mediated diseases.** Based on the breadth of CD19 biology and clinical precedent from anti-CD20 mAbs, we believe budoprutug may have pipeline-in-a-product potential across additional immune-mediated diseases. We expect data from our ongoing pMN, ITP, and SLE clinical trials, together with external data from CD20- and CD19-directed agents, to inform our future indication selection and development strategy in additional B-cell mediated diseases.
- **Accelerate development of CLYM116.** We believe CLYM116's differentiated 'sweeper' mechanism and potential for favorable PK and potent APRIL and IgA suppression position it for meaningful differentiation from other anti-APRIL and B-cell activating factor (BAFF)/APRIL programs. In preclinical studies, CLYM116 achieved deeper, more durable IgA reductions and demonstrated a longer half-life relative to a first-generation anti-APRIL antibody. In December 2025, we dosed the first subject in our Phase 1 clinical trial of CLYM116 in healthy volunteers, which is designed to evaluate safety, tolerability, PK, PD, including IgA reductions, and immunogenicity.
- **Explore opportunities to expand our pipeline through business development.** Business development is a core element of our corporate strategy, as demonstrated by our acquisition of Tenet Medicines, Inc. (Tenet) and the Mabworks Agreement. While focusing on the development of our existing product candidates, we plan to continue to evaluate external opportunities to expand our pipeline that are aligned with our strategy. We intend to prioritize opportunities that leverage our expertise in immune-mediated diseases and nephrology, supported by strong human biology and translational data, have well-defined development pathways, and have the potential for efficient, capital-disciplined development in clearly defined patient populations.

Immune-Mediated Disease Background

There are over one hundred known immune-mediated diseases, with a collective healthcare cost in the U.S. of over $100 billion each year. This places immune-mediated disease among the costliest categories of disease to diagnose and treat in the U.S. Immune-mediated diseases are complex conditions characterized by an immune system that mistakenly attacks the body's own cells and tissues, with clinical manifestations ranging from localized, organ-specific conditions like pMN and ITP, to systemic diseases such as SLE. A hallmark of many immune-mediated diseases is the presence of autoantibodies, produced by autoreactive B cells. In addition, B cells also contribute to disease pathogenesis through interactions with T cells and cytokine production.

In the early 2000s, anecdotal observations revealed that anti-CD20 B-cell depletion therapy, via treatment with rituximab, an anti-CD20 mAb, led to significant improvements in rheumatoid arthritis (RA) and other autoimmune conditions. This discovery transformed the understanding of autoimmune pathophysiology, highlighting the critical role of B cells and leading to rituximab's marketing authorization and inclusion in guidelines for treatment of multiple immune-mediated diseases.

Despite rituximab's success, limitations remain. For example, not all patients respond to treatment with rituximab, with certain B-cell subsets, such as tissue-resident B cells or CD20-low-expressing cells, often evading depletion. Further, rituximab does not directly deplete autoantibody-producing plasmablasts, delaying impact on circulating autoantibody levels. This has led to the development of newer therapeutic approaches aimed at achieving more rapid, deeper, and more sustained depletion of pathogenic B-lineage cells. Targeting B cells through the next generation of approaches and targets offers a promising strategy to mitigate the production of disease-causing autoantibodies and disrupt the cycle of autoimmunity. Recent advancements targeting B cells include effector-function-enhanced monoclonal antibodies, CAR T-cell treatments, and bispecific T-cell engagers (TCEs). In addition, therapies targeting various alternative B-cell surface antigens, as well as signaling cytokines, are being investigated. Among these, CD19 and APRIL have emerged as promising targets. We believe that CD19-directed B-cell depletion and APRIL-targeted modulation of IgA production represent complementary approaches with the potential to address a broad range of antibody-mediated diseases.

Budoprutug

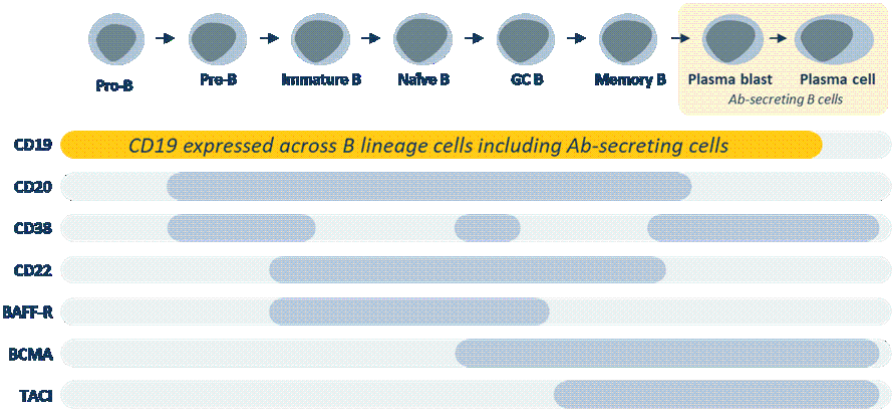
Our lead product candidate, budoprutug, is a highly potent anti-CD19 mAb with the potential to address a broad range of B-cell mediated diseases. We seek to position budoprutug as a potential best-in-class approach capable of delivering on efficacy, safety, and convenience.

Rationale for CD19 in Treating Immune-Mediated Diseases

Budoprutug is designed to target and deplete CD19-expressing B cells. We believe there is a significant advantage to targeting CD19 relative to other B-cell antigens for the treatment of immune-mediated diseases because of CD19's broad expression profile across many B-cell sub-types.

The CD19 antigen is found on pro-B cells and maintains surface expression throughout maturation to tissue-resident plasma cells. While CD19 expression tends to wane on bone marrow-resident plasma cells, we view this as an attractive benefit given those cells are a key component of humoral immune memory, which is responsible for actions such as conferring long-term protection post-vaccination and against infection. Most importantly, the ability to target both autoantibody-secreting cells and their progenitors provides a unique opportunity for rapid onset of action and durability of self-reactive B-cell depletion, which could potentially improve clinical benefit for patients with B-cell driven diseases.

The broad expression of CD19 across B lineage cells as compared to other B-cell targets is illustrated by the graphic below.



Notably, CD19-targeted therapies in development have demonstrated robust efficacy in controlled trials and case reports of patients with immune-mediated diseases. Meaningful clinical activity has been observed even in patients who have failed or relapsed on other B-cell targeted therapies, including agents targeting depletion through CD20, a finding that may reflect CD19's broader expression across the B-cell lineage and the ability to directly target plasmablasts and certain plasma cells. In this context, B-cell depletion with an anti-CD19 therapy can be viewed as acting upstream of other approaches to antibody-mediated diseases, including activation inhibitors and accelerators of antibody degradation, such as neonatal Fc receptor (FcRn)-targeted therapies. Additionally, a CD19-directed mAb, Uplinza (inebilizumab), has been approved by the FDA for the treatment of neuromyelitis optica spectrum disorder (NMOSD), immunoglobulin G4-related disease (IgG4-RD), and generalized myasthenia gravis (gMG), further supporting the clinical relevance of CD19 targeting in autoantibody-driven disease.

Rationale for a mAb-Based Approach to Targeting CD19

In the evolving landscape of B-cell targeted therapies, there are CD19-targeted approaches across multiple construct classes, including mAbs, CAR T-cell therapies, CAR-natural killer cell therapies, and TCEs. We believe a mAb-based approach to targeting CD19 is ideal for four key reasons:

- **Manufacturability**. mAbs traditionally have well-established manufacturing and supply chains, favorable cost-of-goods, and scalability. The ability to readily scale manufacturing and drug supply is critical to realizing the full potential of a product candidate.
- **Targeting**. mAbs generally have preferential targeting, and the core of their functionality is the ability to recognize and bind antigens with high specificity. One perceived limitation of the mAb-based approach to CD19-targeted B-cell depletion is that mAbs are unable to reach tissues, the desired site of action, and, even if they do, they lack the potency and functionality to deplete B cells within those tissues. However, in a transgenic mouse model, we observed dose dependent B-cell depletion in tissues (namely, bone marrow, lymph node and spleen) following budoprutug administration, supporting our view that mAbs can penetrate tissues and induce deep B-cell depletion. While patient-level data with anti-CD19 antibodies that directly demonstrate B-cell depletion at the tissue level are currently limited, there is clinical evidence from the widespread use of rituximab showing that

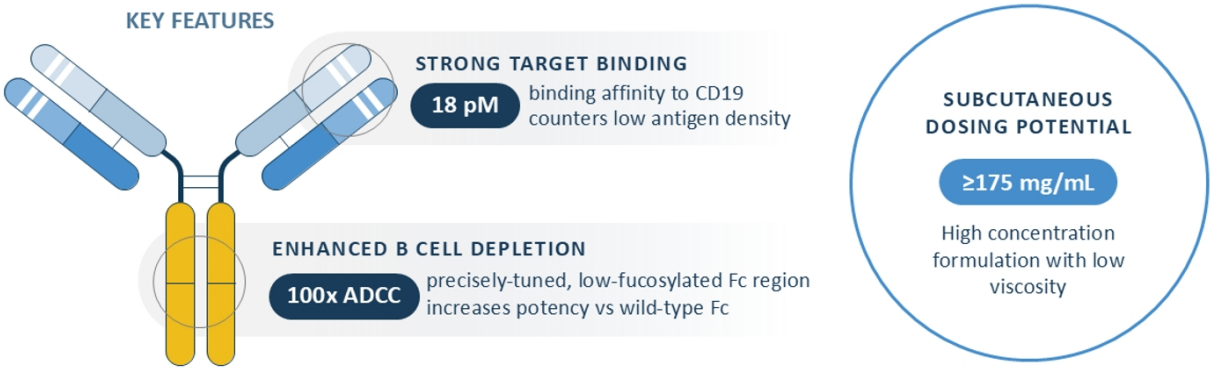
mAbs can induce dose-dependent reductions of target antigen-expressing B cells in tissues. More specifically, rituximab has been shown to deplete the CD20-positive B-cell populations resident within many different tissue types, including lymph node and spleen. These data suggest that CD19-targeted mAbs may be able to penetrate tissues and deplete antigen-expressing cells within those tissues.

- **Safety and Tolerability**. We believe the safety profile of mono-specific monoclonal antibodies compares favorably to other approaches to CD19 B-cell depletion. Specifically, TCEs and CAR T-cell therapies are projected to have higher risk for cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS). Both CRS and ICANS can be life-threatening and present poor equipoise for many patients with autoantibody driven diseases. Additionally, unlike with CAR T-cell therapies, there is no requirement for a lymphodepleting chemotherapy pretreatment regimen with mAbs. We also believe that the ability to titrate dose and redose over time provides additional flexibility to balance efficacy and tolerability in chronic autoimmune settings.
- **Patient-Tailoring and Access**. Targeting CD19 with a mAb presents the opportunity for optimized dosing and administration. Opportunity exists to formulate mAbs for both IV and SC administration. In addition, the potential for self-administration subcutaneously through autoinjectors or pens may offer optionality for development and facilitate patient-tailored treatment strategies. Such optionality in formulation and administration does not exist for cell-based approaches targeting CD19, which require in-hospital administration. In addition, mAb approaches provide dosing flexibility and can be administered in single or multiple doses as required to achieve the desired amount of drug delivery. Given physician familiarity with mAbs, we believe these therapies can be administered outside of tertiary referral centers in community hospitals that do not require special units, enabling broader patient access.

Our CD19 Approach: Budoprutug

Budoprutug, our lead product candidate, targets CD19, which is expressed across a wider repertoire of B-cell lineages than CD20, potentially enabling broader and more durable depletion of pathogenic B cells. While CD19-targeted CAR-T therapies have shown encouraging efficacy, both CAR T-cell and TCEs are associated with significant drawbacks, including high rates of CRS and ICANS. In addition, CAR T-cell therapies require lymphodepleting chemotherapy, which is associated with significant toxicities as well as an FDA-recognized risk of secondary malignancies. These therapies are also associated with a complex and costly manufacturing process and, for autologous cells, delay of treatment due to the time required for cell collection, modification, and re-infusion.

Budoprutug is a highly potent anti-CD19 mAb designed with a low-fucosylated Fc region, resulting in enhanced effector function and pronounced antibody dependent cellular cytotoxicity (ADCC). We believe there are several unique attributes of budoprutug that have the potential to differentiate it from other anti-CD19 treatment approaches for immune-mediated diseases. In the diagram below, we highlight budoprutug's key features, including its low picomolar activity, enhanced ADCC, and high concentration formulation. Taken together, we believe these key features of budoprutug create a compelling opportunity for broad utility across a number of immune-mediated diseases where unmet need remains high.

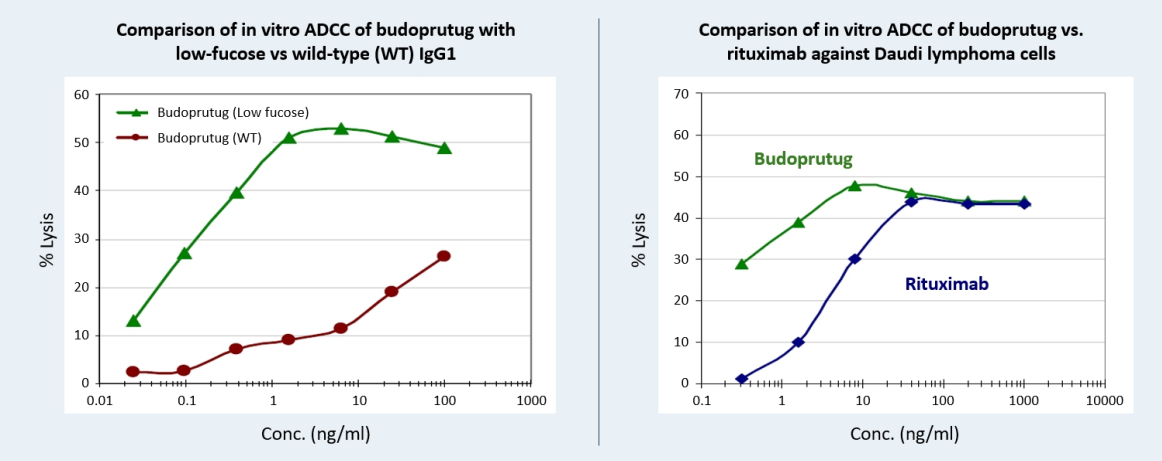


Picomolar Affinity

Budoprutug's high affinity for CD19 has the potential to overcome lower antigen density of CD19 on some B-cell sub-types, such as plasma cells, and enables direct targeting of those pathogenic B cells, which are upstream as a source of inflammation.

Functionally Enhanced ADCC

The glycoengineered, low-fucosylated Fc region of budoprutug increases affinity for Fc gamma receptors, thereby functionally enhancing ADCC. We believe that budoprutug's enhanced effector function coupled with potent antigen binding will drive deep and durable B-cell depletion. In the figure below, we show that budoprutug's glycoengineering demonstrated 100-fold improved potency relative to a budoprutug construct containing a wild type IgG1 backbone and that budoprutug demonstrated improved cell-killing potency against Daudi lymphoma cells relative to rituximab.



In an initial clinical trial of budoprutug in pMN, subjects receiving as low as 100 mg induction doses achieved undetectable levels of circulating B cells for at least 6 months. In patients with B-cell malignancies, repeated doses as high as 1,000 mg once weekly for four weeks were generally well-tolerated. These early data are encouraging, and we believe this feature of budoprutug will potentially lead to deep and durable depletion of both peripheral and tissue-resident B cells in patients with immune-mediated diseases, providing potentially significant opportunity for clinical benefit. We believe this profile, together with the convenience of a mAb-based approach, may offer an attractive balance of efficacy, safety, and practicality relative to other CD19-directed treatment modalities, including cell-based therapies.

High Concentration

We have been able to successfully formulate budoprutug to concentrations exceeding 175 milligrams per milliliter while maintaining low viscosity, creating an opportunity to pursue a SC dose form that potentially features a low volume injection. We believe there is an opportunity to optimize both the dosing regimen and dose form for specific patient populations, potentially enabling a patient-tailored approach to disease management.

Our Budoprutug Development Strategy

CD19 plays a mechanistic role across all stages of B-cell development, and emerging evidence from CD19-directed mAb, bispecific antibody, and CAR-T cell therapy studies demonstrates its importance in immune-mediated diseases. By targeting CD19-expressing cells, including plasmablasts and subsets of plasma cells, budoprutug has the potential to offer rapid, profound, and durable reductions in pathogenic autoantibodies, which may allow for a disease-modifying therapeutic approach. We have focused our initial development strategy for budoprutug on pMN, ITP, and SLE, which we believe each offer a strong mechanistic rationale for CD19-directed therapy.

Primary Membranous Nephropathy

Background on pMN

pMN is a rare immune-mediated disease characterized by proteinuria, nephrotic syndrome, and progressive loss of renal function. We estimate there are approximately 70,000 people in the U.S. with pMN. There are currently no therapies approved by the FDA for the treatment of pMN.

In pMN, B-lineage cells produce autoantibodies that target antigens present on glomerular podocytes, usually including antibodies to PLA2R. Immune complexes of antigen and autoantibody are deposited in the glomerular basement membrane where they mediate inflammation and injury to podocytes that eventually leads to proteinuria which, if left untreated, can lead to kidney failure. Clinically, pMN often presents with nephrotic syndrome, characterized by significant proteinuria, hypoalbuminemia, and edema. Diagnosis typically involves blood tests to measure cholesterol and protein levels, urine tests for proteinuria, glomerular filtration rate tests, and kidney biopsies to detect specific antibodies. The management of pMN is focused on achieving complete remission of proteinuria, as this has been definitively correlated to improved long term maintenance of renal function.

Without an approved treatment in the U.S., the standard of care in pMN includes supportive treatments to manage symptoms like hypertension and edema and, when necessary, immunosuppressive therapy, which may include corticosteroids, calcineurin inhibitors, or other agents. These treatments have undesirable side effects, including, among others, hypertension, neurotoxicity, metabolic abnormalities, a heightened risk of life-threatening bacterial, viral, and fungal infections, malignancies, hypoglycemia and gastrointestinal disturbances. Newer therapies, including rituximab, have been used with some success, however, the response to this treatment is delayed and the majority of treated patients do not achieve complete remission of the disease.

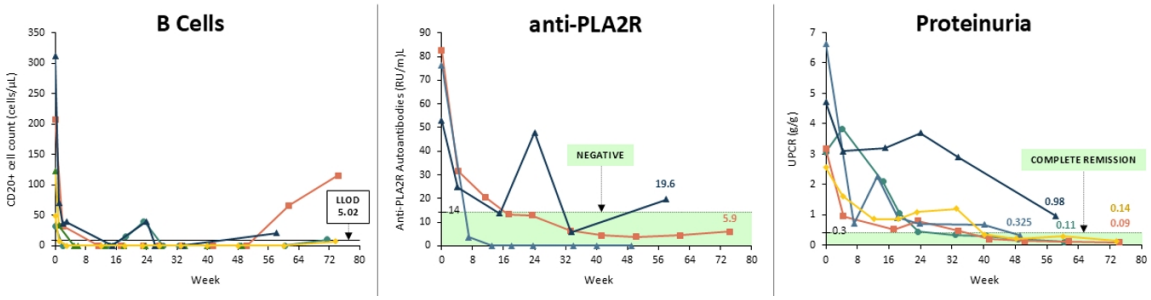
Disease flares following initial responses are common, and complications of treatment add to the overall disease burden. There remains an unmet medical need for more effective therapies for refractory cases and strategies to prevent long-term kidney damage and improve patient outcomes.

Budoprutug for pMN

pMN is caused by the destruction of podocytes mediated by autoantibodies to podocyte antigens, predominantly PLA2R autoantibodies. There is evidence that a majority of the autoantibody secretion come from plasmablasts, which are B-lineage cells that express CD19 but have largely lost CD20 expression. Given budoprutug's mechanism of targeting and depleting CD19-expressing cells from the pre-B-cells stage through the plasmablast stage, we believe that budoprutug administration may lead to a rapid decline in autoantibodies, permit healing of podocytes, and resolution of proteinuria.

A Phase 1b clinical trial of budoprutug demonstrated proof-of-concept for budoprutug in pMN. In this pilot study, budoprutug was administered in two IV infusions 14 days apart at Week 0 and Week 24. Three patients received 100 milligrams at each dose and two patients received 200 milligrams at each dose. Data from the five patients who received all four doses of budoprutug in the Phase 1b clinical trial is presented in the figure below.

- Three of five (60%) patients achieved complete remission of proteinuria at week 48 (right chart).
- Rapid and significant reductions in anti-PLA2R autoantibodies, a key driver of pMN, with serological remission occurred in the three patients that were PLA2R-positive at baseline (middle chart).
- Complete and sustained B-cell depletion was observed in all patients (5/5), with undetectable levels of B cells occurring after just two doses of study drug at doses as low as 100 mg (left chart).



Budoprutug was generally well-tolerated at doses up to 200 mg administered as two doses separated by 14 days, the highest dose tested in the study, with no reported drug-related serious adverse events. Among the eight patients who received at least one injection of budoprutug in the clinical trial, there were no deaths, there were three serious adverse events (grade 3 bacterial pneumonia, grade 4 rhabdomyolysis, and grade 3 chronic obstructive pulmonary disease), none of which were considered to be related to budoprutug by the investigator, and all of which resolved with treatment or observation. There were no discontinuations due to adverse events and there were no dose limiting toxicities observed. Four patients reported infections during the trial of which three were cases of COVID-19 and one was bacterial pneumonia.

Long-term follow-up data from the previously conducted Phase 1b trial demonstrated control of proteinuria for up to three years after initial dosing in four patients who received four doses of budoprutug. Additionally, in three of these four patients, no further immunosuppressive treatment was required.

We believe the Phase 1b data in pMN, together with the broader clinical experience with CD19-directed therapy in IgG4-mediated disease, support the potential of budoprutug to offer deep and durable remissions in pMN.

Clinical Development of Budoprutug for pMN

In March 2025, we received FDA clearance for a Phase 2 clinical trial, PrisMN, to further evaluate budoprutug in pMN. We have obtained regulatory clearances to open sites in Argentina, Brazil, Georgia, Taiwan, and Ukraine, and we continue to pursue regulatory clearance to open additional trial sites outside the U.S. The PrisMN trial is expected to enroll approximately 45 pMN patients who have persistent evidence of disease activity despite optimized RAAS inhibition. The trial is designed to evaluate safety, PD, including B cells, anti-PLA2R, and total immunoglobulin, and preliminary efficacy, including complete and partial remission, and to identify a dose for Phase 3 clinical development. In November 2025, we achieved FPI in the PrisMN study, and we anticipate reporting initial data from the first, low dose cohort, including B cells and anti-PLA2R, in the second half of 2026.

Immune Thrombocytopenia

Background on ITP

ITP is a rare autoimmune disorder characterized by autoantibody-mediated destruction of platelets, leading to low levels of circulating platelets and risk of bleeding. ITP is classified as acute (short term, remitting) or chronic (persistent). Acute cases are more common in children and chronic cases are more prevalent in adults. We estimate there are approximately 85,000 patients with chronic ITP in the U.S. Of these, there are approximately 24,000 adults with chronic ITP that is refractory to treatment.

In ITP, autoantibodies attach themselves to antigens on the surface of platelets, marking them for destruction in the spleen. Megakaryocytes in the bone marrow attempt to compensate by increasing platelet cell production but may themselves become targeted for destruction. Low platelet counts result in bruising or petechiae and purpura, hemorrhagic episodes or extensive bleeding, and chronic fatigue, which are all characteristic symptoms of ITP and commonly reported. Mortality is higher than is observed in aged-matched controls.

Current treatment recommendations of the American Society of Hematology exemplify the significant unmet need for ITP patients. Even if a patient is fortunate enough to stabilize on a first line therapy with corticosteroids or IV immunoglobulin, upwards of 80% relapse and move to second line treatments, which may include rituximab or TPO-RAs. Many of those necessitate a third line treatment with additional doses of rituximab and TPO-RAs, or a trial of fostamatinib or other immunosuppressive therapy. If unsuccessful, combination therapy or splenectomy are considered.

Budoprutug for ITP

Few current treatments target upstream disease pathogenesis. We believe the limitations of rituximab, including non-targeting of plasma cells, leaves opportunity for budoprutug in ITP. Because CD19 is expressed on antibody-producing plasmablasts and plasma cell subsets as well as their progenitors, we believe budoprutug has the potential to reduce production of pathogenic autoantibodies more durably than CD20-directed approaches.

Clinical Development of Budoprutug for ITP

In March 2025, we received FDA clearance to initiate a Phase 1b/2a open-label clinical trial in ITP to evaluate the safety, tolerability, PK, PD, and preliminary clinical activity of budoprutug. We have obtained regulatory clearances to open sites in Bulgaria, Greece, Serbia, Spain and Ukraine, and we are actively enrolling patients in these five countries. The trial consists of a dose-escalation and expansion design in previously treated patients with ITP, defined as a platelet count of less than 30,000/μL despite an adequate trial of at least one prior therapy. The Phase 1b dose-escalation portion of the trial includes three sequential cohorts of up to six patients each. Initial data from the Phase 1b portion of the trial, including B-cell depletion and platelet counts are anticipated in the second half of 2026.

Systemic Lupus Erythematosus

Background on SLE

SLE is a chronic, inflammatory autoimmune disorder characterized by the formation of autoantibodies and immune complexes that can lead to damage across multiple organs, including, but not limited to, the skin, joints, and kidneys. SLE has a prevalence of approximately 240,000 patients in the U.S., disproportionately affects women (9:1 female to male ratio) and has a higher prevalence among African American, Asian, African Caribbean and Hispanic individuals. Approximately one third of SLE patients in the U.S. will experience clinically significant renal involvement, most commonly manifesting as LN, a serious and potentially life-threatening complication driven by immune-complex deposition and inflammation within the kidney. LN is a major contributor to morbidity and long-term outcomes in SLE, with patients experiencing higher rates of hospitalization, accelerated organ damage, and progression to chronic kidney disease and end-stage renal failure.

The autoantibody targets and the mechanisms by which the antibodies that arise in SLE cause injury to vary across patients, which accounts for some of the differences in clinical presentation. Some antibodies that arise in SLE bind directly to cells that are then destroyed through phagocytosis or cytotoxicity, which is the case with thrombocytopenia and anemia in SLE. Some antibodies form immune complexes that deposit in blood vessels causing inflammation that injure tissue, as is the case with nephritis, synovitis, rash and vasculitis. Some antibodies bind mediators or receptors and very directly interfere with important functions, including antiphospholipid antibodies that trigger the clotting system causing strokes and miscarriages, or antibodies to elements in the nervous system that are thought cause fatigue, cognitive impairment, depression and even psychosis.

Current treatment of SLE aims to control symptoms, prevent flares, and minimize organ damage. Treatment typically begins with corticosteroids to rapidly reduce inflammation, then hydroxychloroquine to reduce the risk of another flare. When this is inadequate, or when patients cannot reduce steroids, treatments include broad spectrum oral immune suppressants, such as azathioprine or mycophenolate. Targeted inhibitors of the type I interferon receptor (anifrolumab) and of B-cell activating factor (belimumab) may also be utilized. However, despite these approaches, up to 20% of SLE patients progress to end stage renal failure, and the mortality from complications of these treatments, notably steroid therapy, is high in both renal and non-renal patients. In addition to preventing progression to renal failure, there is a need for therapeutic regimens that can reduce the use of steroids and their complications, address antiphospholipid syndrome, address fatigue and cognitive impairment and fetal risk, and prevent the accumulation of damage from repeated flares.

Budoprutug for SLE

We believe recent case reports and early clinical data from trials administering CD19 CAR T-cell therapies in SLE patients who were refractory to multiple lines of therapy are promising, with most patients achieving complete responses. While these data support the biological rationale for targeting CD19, several patients developed serious adverse events, including CRS and ICANS. In addition, the logistics and likely costly production of the CAR-T therapies could limit broad utility. This provides potential opportunity for a mAb approach to targeting CD19 such as budoprutug. We believe that a CD19-directed monoclonal antibody could capture many of the benefits of deep B-cell depletion, while offering a more predictable and potentially more manageable safety, logistics, and cost profile.

Clinical Development of Budoprutug for SLE

In October 2024, we received FDA clearance for our IND to evaluate budoprutug in a Phase 1b clinical trial in SLE. We have obtained regulatory clearances to open sites in Bulgaria, Georgia, Greece, Romania, Spain and Ukraine. We are currently enrolling patients in a global, open-label, dose-escalation Phase 1b trial, in which we will administer a single dose of budoprutug to patients with moderate to severe SLE to evaluate safety, tolerability, PK, PD, and preliminary efficacy, including augmented B cell and antibody analysis to assess whether budoprutug may have a long-term impact on autoreactive B memory cells as well as rapid depletion of antibody-producing plasmablasts. The trial includes four sequential cohorts of up to six patients each. We are initially dosing patients with a low dose of budoprutug to assess safety and tolerability prior to

advancing to a clinically relevant dose, and we expect the safety, PK, PD, and preliminary efficacy data generated from this trial to inform subsequent development in SLE and potentially other complex systemic autoimmune diseases. Initial data are anticipated in the second half of 2026.

In December 2025, we received clearance of our IND to initiate a separate, parallel Phase 1b 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 LN. We anticipate achieving FPI in the first half of 2026.

Subcutaneous Formulation

We are developing a SC formulation of budoprutug above 175 mg/ml while maintaining low viscosity, to help create an opportunity to pursue an SC dosing form that potentially features a low volume injection. We believe there is an opportunity to optimize both the dosing regimen and dose form for specific patient populations, potentially enabling a patient-tailored approach to disease management. An SC formulation could have advantages in many disease and patient settings where home-based dosing may be preferred. We have generated nonclinical data, including nonhuman primates (NHPs) data, supporting high bioavailability and favorable local tolerability of the SC formulation of budoprutug. 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 we anticipate sharing these data in the first half of 2026.

CLYM116

In January 2025, we entered into the Mabworks Agreement for rights to develop and commercialize CLYM116, an anti-APRIL mAb, in the territory outside of Greater China. We believe CLYM116 has the potential to deliver meaningful differentiation from first-generation APRIL and APRIL/BAFF inhibitors for patients with IgAN and other B-cell mediated diseases and represents a mechanistically complementary approach to our budoprutug program.

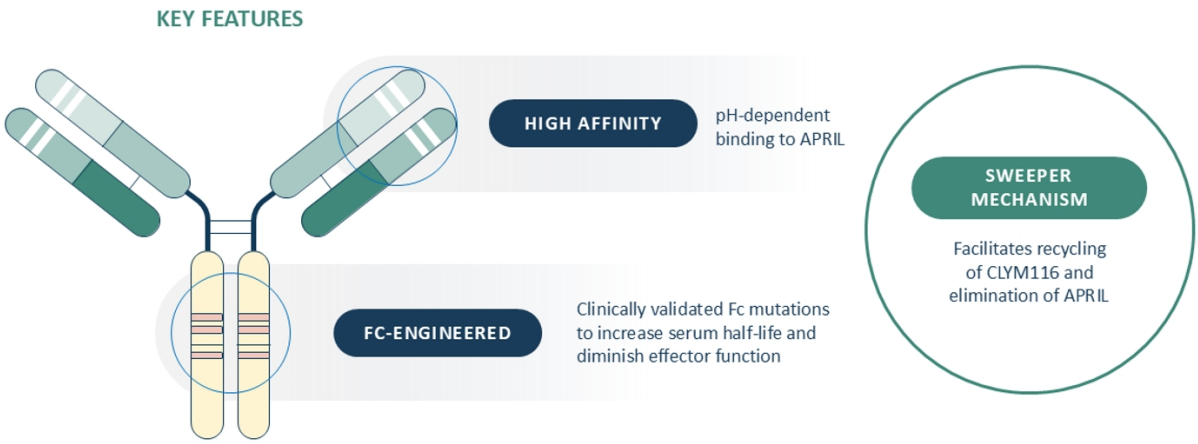
Rationale for APRIL in Treating Immune-Mediated Diseases

CLYM116 is engineered to prevent APRIL signaling through a differentiated, next-generation mechanism of action. APRIL was identified in a genome-wide association study as a susceptibility locus for IgAN, and has been implicated in several other autoimmune conditions, including SLE, RA, alopecia areata, MG, Sjogren's syndrome, and bullous pemphigoid. APRIL and its receptors play defined and non-redundant roles in the process of B-cell maturation and survival. Additionally, APRIL is involved in immunoglobulin class switching in B cells, thus contributing to the pathogenesis of diseases with aberrant Ig production. APRIL exerts its effects through binding to its two receptors: B-cell maturation antigen and transmembrane activator and CAML interactor. These two receptors also bind to a related ligand from the tumor necrosis factor family, called BAFF. While structurally related to BAFF, APRIL engages its receptors with distinct affinities and contributes to biologic functions not addressed by BAFF-directed agents.

While broad B-cell depletion with agents such as rituximab has been shown to be ineffective in IgAN, more targeted plasma cell modulation through APRIL or APRIL/BAFF inhibition has demonstrated clinically validated proteinuria reductions and the potential for disease-modifying benefit. There are currently two monoclonal antibodies targeting APRIL and three fusion proteins targeting both APRIL and BAFF under late-stage clinical investigation for IgAN. In November 2025, Otsuka Pharmaceutical Co., Ltd received accelerated approval from the FDA for sibreprenlimab, a mAb targeting APRIL, and Vera Therapeutics, Inc. submitted a BLA for FDA approval of atacicept, a mAb targeting APRIL/BAFF. In early clinical studies, these agents demonstrated reductions in free APRIL, serum immunoglobulin levels, proteinuria, and stabilization of the decline in kidney function, establishing proof-of-concept for APRIL signaling inhibition. However, available data indicate that current agents may provide incomplete suppression of APRIL biology, require frequent dosing, and may introduce BAFF-related immunosuppressive liabilities.

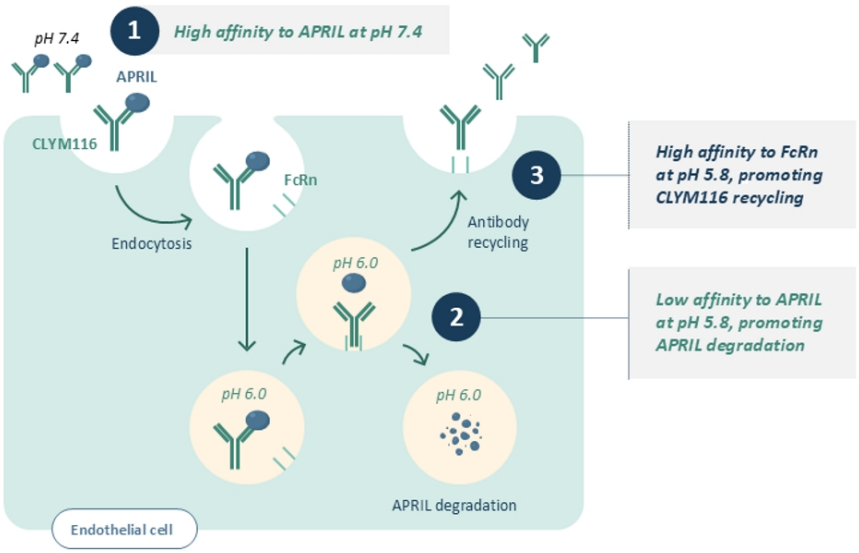
Our APRIL Approach: CLYM116

CLYM116 is designed to address key limitations observed with first-generation APRIL and APRIL/BAFF inhibitors. As illustrated in the graphic below, CLYM116 incorporates three core differentiating features: (1) a 'sweeper' mechanism of action that is designed to facilitate recycling of CLYM116 and the elimination of APRIL, (2) high-affinity, pH-dependent binding to APRIL, and (3) Fc engineering to extend serum half-life and minimize effector function. Collectively, these attributes support the potential for deeper and more durable APRIL and IgA suppression, a favorable tolerability profile without BAFF-related immunosuppression, and convenient SC administration with the potential for less frequent dosing. These characteristics may be particularly valuable in IgAN, a chronic disease affecting younger patients who require life-long therapy that minimizes treatment burden.



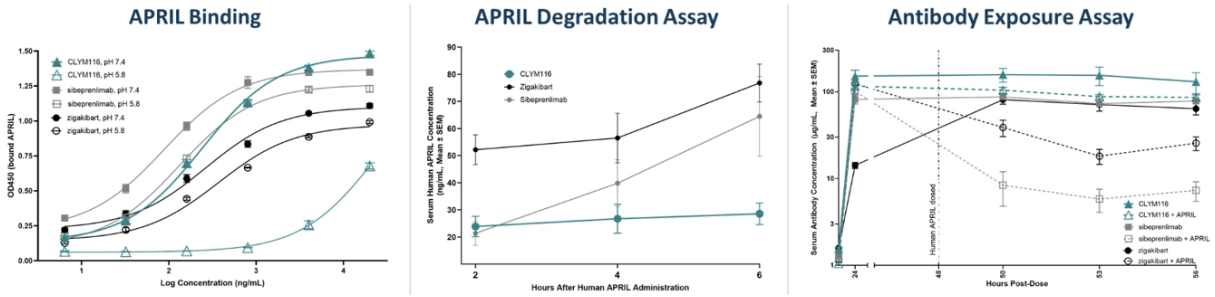
'Sweeper' mechanism

CLYM116 is the only known 'sweeper' anti-APRIL mAb in development. CLYM116's 'sweeper' mechanism of action employs a pH-dependent bind-and-release design coupled with Fc engineering to optimize APRIL elimination, antibody recycling, and long-duration pharmacology. As illustrated in the graphic below, (1) at physiologic pH (7.4), CLYM116 exhibits high-affinity binding to APRIL to promote efficient target engagement and potent blocking to APRIL, binding to its receptors; and (2) at endosomal pH (5.8), CLYM116 releases APRIL to promote APRIL degradation in the lysosome, while (3) maintaining high-affinity binding to FcRn to support efficient CLYM116 antibody recycling. This mechanism is intended to drive deep and durable suppression of APRIL signaling and downstream IgA production, providing the potential for improved activity and less frequent dosing vs. first generation anti-APRIL approaches or half-life extension alone.

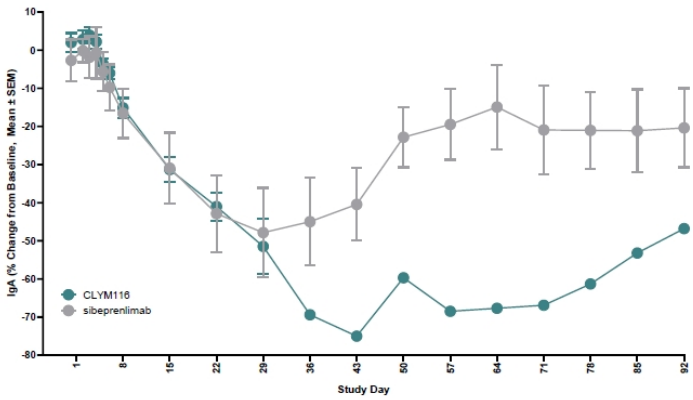


We believe early in vitro and in vivo data for CLYM116 support the mechanistic and pharmacologic profile described above. In preclinical studies, CLYM116 demonstrated pH-dependent binding, deep, and sustained clearance of APRIL, and enhanced antibody recycling, as compared to benchmark first-generation anti-APRIL mAbs, including sibeprenlimab (a third-party anti-APRIL mAb granted accelerated approval by the FDA for the treatment of IgAN) and zigakibart (a third-party anti-APRIL mAb in late-stage clinical trials). The left panel illustrates data from a pH-dependent enzyme-linked immunosorbent (ELISA) assay that demonstrated differential binding for CLYM116 at varying pH, whereas sibeprenlimab and zigakibart did not exhibit a comparable pH-dependent binding profile. In the APRIL degradation assay study depicted in the middle panel, wild-type C57BL/6 mice were administered either CLYM116, sibeprenlimab, or zigakibart (single dose, 10

mg/kg) and human APRIL (single dose, 15 mg/kg) 36 hours later. APRIL concentration was assessed every 2 hours thereafter. CLYM116 reduced circulating APRIL and demonstrated enhanced APRIL clearance kinetics as compared to sibeprenlimab and zigakibart. In the APRIL antibody exposure assay depicted in the right panel, humanized FcRn transgenic mice were administered either CLYM116, sibeprenlimab, or zigakibart (single dose, 10 mg/kg) and 48 hours later, administered either human APRIL (single dose, 15 mg/kg) or saline. Serum antibody concentration were measured over time. In the sibeprenlimab and zigakibart treated animals, antibody exposure decreased after the addition of APRIL compared to those injected with saline. In contrast, the exposure of CLYM116 continued to be maintained, even after the addition of APRIL, supporting the efficient recycling mechanism of CLYM116.

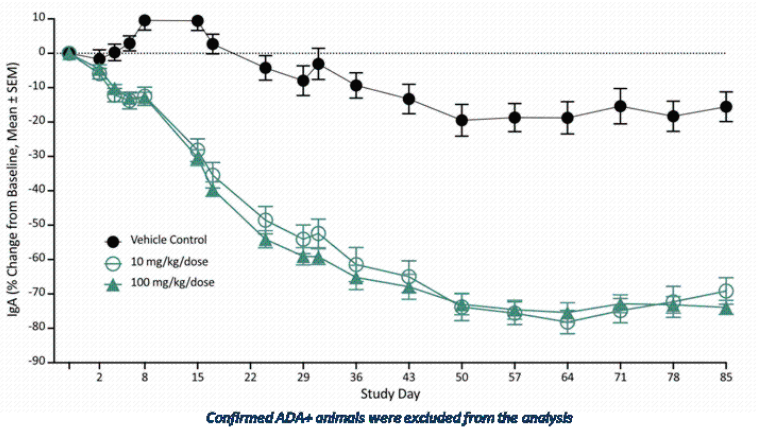


In subsequent head-to-head studies in NHPs, CLYM116 demonstrated approximately 85% bioavailability and an approximately 2-3 fold longer half-life compared to sibeprenlimab, supporting the potential for improved exposure and less frequent dosing in humans. Further, after a single SC administration of equivalent doses (6 mg/kg), CLYM116 demonstrated robust and durable free APRIL suppression and deeper and more prolonged IgA reduction compared to sibeprenlimab, as depicted in the figure below. CLYM116 demonstrated over 70% maximal reduction in IgA, with over 50% reduction in IgA maintained out to three months, supporting the potential for a differentiated activity profile relative to sibeprenlimab.



Confirmed ADA+ animals were excluded from the analysis

A 28-day repeat-dose toxicity study in NHPs showed a similar magnitude of IgA suppression. After three SC doses of CLYM116 on days 1, 15, and 29, an over 70% reduction of IgA was observed through the eight-week recovery period, as depicted in the figure below. In the subset of animals in the 100 mg/kg cohort that were observed through an extended six-month recovery period, sustained IgA suppression (over 70% from baseline) was observed through day 183. A favorable tolerability profile was observed in this study, as well as the prior NHP studies with no local tolerance issues identified on histopathology and no CLYM116 related toxicity findings.



Additionally, on a high performance liquid chromatography analysis, CLYM116 formed fewer high molecular weight complexes vs. sibeprenlimab, reflective of binding to distinct epitopes on APRIL. Notably, formation of high molecular weight complexes has been associated with potentially higher risk of immunogenicity in humans.

Our CLYM116 Development Strategy

Inhibition of APRIL signaling has potential application in the treatment of IgAN and other B-cell mediated diseases. CLYM116, with its unique anti-APRIL 'sweeper' mechanism, has the potential to demonstrate a differentiated, disease-modifying activity profile in IgAN.

IgA Nephropathy

Background on IgAN

IgAN, also known as Berger's disease, is an autoantibody-mediated disease caused by deposition of immune complexes containing IgA and IgG in the glomeruli. We estimate there are approximately 200,000 cases of IgAN in the U.S. with a higher prevalence in Europe and Asia. Diagnosis is made by kidney biopsy, and symptoms include hematuria, proteinuria, high blood pressure, and edema. If left untreated, 30% to 40% of patients will develop kidney failure within 10 years of diagnosis.

The standard of care for IgAN includes optimized supportive care, which focuses on controlling blood pressure, reducing proteinuria, and managing cardiovascular risk factors. This often involves the use of angiotensin-converting enzyme inhibitors (ACEi) or angiotensin receptor blockers (ARBs), along with lifestyle modifications such as a low-salt diet and smoking cessation. Despite these treatments, there is a need for more effective therapies to prevent disease progression, better biomarkers for early diagnosis and monitoring, and strategies to reduce the risk of kidney failure. Additionally, there is a need for personalized treatment approaches to address the variability in disease progression and response to therapy.

The KDIGO (Kidney Disease Improving Global Outcomes) Guideline for the treatment of IgAN was updated in September 2025, recommending important changes, including a more liberal kidney biopsy policy to enable earlier diagnosis and revised treatment goals, supporting stricter disease control. Additionally, KDIGO recommends initiation of treatment with therapies that prevent or reduce pathogenic IgA and immune complex formation along with therapies that manage the disease-induced nephron loss, which may result in the use of multiple treatment strategies simultaneously as treatment for IgAN continues to evolve.

In November 2025, sibeprenlimab (brand name VOYXACT) received FDA accelerated approval for adults with IgAN at risk for progression, marking a significant advancement as the first therapy targeting the APRIL pathway. Long-term kidney function data from the ongoing Phase 3 trial of sibeprenlimab is being generated to support full FDA approval. We believe that, while sibeprenlimab has demonstrated the validity of targeting the APRIL pathway for IgAN and represents an important step forward, a significant opportunity continues to exist for additional safe, effective treatment options with improved convenience.

Clinical Development of CLYM116 for IgAN

In October 2025, we received clearance for our CTA in Australia to initiate a Phase 1 single-ascending dose and multiple ascending dose clinical trial of CLYM116 in healthy volunteers. We achieved first-subject-in in December 2025 and are actively enrolling subjects to evaluate safety, tolerability, PK, PD (including IgA reductions) and immunogenicity. We anticipate reporting initial data from the Phase 1 study in mid-2026. Positive results from the Phase 1 trial would provide potential for advancement of CLYM116 into patients with IgAN.

In December 2025, our partner, Mabworks, received IND clearance to initiate a parallel Phase 1 clinical trial of CLYM116 (known as MIL116 in Greater China), in SLE patients in China, which is intended to complement our global Phase 1 trial and may support accelerated progression into later-stage clinical development, if warranted.

Legacy Programs

Previously, we focused on developing novel therapies for neuronal excitability disorders to address unmet needs in psychiatry, epilepsy, chronic pain, and other disorders of the peripheral and central nervous systems, and our lead program was ETX-123, a Kv7.2/3 potassium channel opener. In July 2023, we decided to pause further development of our Kv7 program, and we intend to seek a potential partner for this program.

License Agreements

Agreements Related to Budoprutug

On June 27, 2024, we completed our acquisition of Tenet, a private development stage biotechnology company. As a result of the acquisition, the following agreements effectively became our agreements.

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, providing for the acquisition of certain assets of Acelyrin related to budoprutug (the Transferred Assets), including certain assigned contracts.

Under these assigned contracts, we (i) received worldwide licenses (with the right to sublicense) to certain patents, know-how and other intellectual property rights to develop, manufacture, use and commercialize budoprutug for any non-oncology indication, and (ii) assumed certain liabilities of Acelyrin arising from (1) governmental authority action or notification relating to budoprutug, (2) contracts assigned to us pursuant to the Asset Purchase Agreement and (3) our ownership, lease or operation of the Transferred Assets. The Asset Purchase Agreement includes customary representations, warranties and covenants, as well as standard mutual indemnities, including those covering losses arising from any material breach of the Asset Purchase Agreement.

Under the Asset Purchase Agreement, we also acquired the rights and obligations, including financial obligations, under a license agreement with CRH, which Tenet subsequently amended and restated in the CRH Agreement (as defined below) and a cell line development, manufacturing services and license agreement with ProBioGen AG (ProBioGen).

Under the Asset Purchase Agreement, with respect to any "Product" (as such term is defined in the Asset Purchase Agreement), we are 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.

The royalty term continues for each Product on a country-by-country and Product-by-Product basis beginning on the first commercial sale of such Product and ending on the latest of (a) the date when such Product is no longer covered by a valid claim of a royalty-bearing patent (as such term is defined in the Asset Purchase Agreement) in such country, (b) the expiration of any regulatory exclusivity period for such Product in such country, and (c) the twelfth anniversary of the first commercial sale of such Product in such country.

We are obligated to use commercially reasonable efforts to commercialize at least one Product in the U.S., to the extent a Product exists under the Asset Purchase Agreement, and to achieve specified development, regulatory and commercial milestones for such Product set forth in the Asset Purchase Agreement.

To the extent a Product exists under the Asset Purchase Agreement, if Acelyrin asserts that we have failed to meet a specified diligence obligation under the Asset Purchase Agreement within specified time periods, and such failure is finally determined through a dispute resolution process, Acelyrin may elect, in lieu of a claim for damages, to repurchase the Transferred Assets at the then-fair market value of such Transferred Assets, as Acelyrin's sole and exclusive remedy for such breach.

If, within a specified period following the top line data readout from the first Phase 2 clinical trial of a Product, we receive a bona fide offer or proposal from a third party to sell, transfer or otherwise divest all or substantially all of the rights to the Transferred Assets or Products, or grant an exclusive license or exclusive sublicense to such third party to develop and commercialize Products under specified terms, then prior to entering into any discussions or negotiations with any third party in relation to such a transaction, we shall provide written notice to Acelyrin of such intent or receipt of proposal. Acelyrin shall have the right to negotiate with us the terms for a definitive agreement with respect to such sale, transfer or grant of the rights to Products for a specified period of time. If Acelyrin does not exercise its right to negotiate or the parties are unable to agree on the terms of a definitive agreement, we shall have the right to negotiate or enter into an agreement with a third party with respect to such transaction, subject to specified conditions.

We may not sell, assign or transfer all or substantially all of the rights to develop or commercialize a Product unless, as a condition to such sale, assignment or transfer, the purchaser, assignee or transferee (as applicable) assumes in writing all of our obligations as set forth in the Asset Purchase Agreement with respect to the applicable Products.

On December 31, 2025, we filed a complaint in Delaware Superior Court against Alumis Inc. and its wholly owned subsidiary, Acelyrin, relating to a dispute concerning the Asset Purchase Agreement seeking a declaratory judgment that budoprutug is not a Product under the Asset Purchase Agreement, and that we do not owe a milestone payment sought by Alumis in connection with our development of budoprutug. This matter is currently pending. We are unable to predict the timeline for resolution or the outcome of this matter. Irrespective of the outcome of this matter, our financial guidance includes the full potential milestone burden.

CRH Agreement

In connection with the Asset Purchase Agreement, in January 2024 Tenet was assigned a license agreement with CRH and, in connection with such assignment, Tenet entered into an amended and restated license agreement with CRH (the CRH Agreement). The CRH Agreement granted us a worldwide exclusive license (other than specified patent rights and materials, which are licensed to us on a non-exclusive basis) under certain know-how, patents and materials, or the licensed rights, to research, develop, test, manufacture or sell certain licensed products related to budoprutug, for all therapeutic uses except for oncology indications. We are permitted to grant a sublicense under these licenses with CRH's prior written consent.

CRH retains, on behalf of itself and the charitable company Cancer Research U.K., a worldwide, fully paid-up, perpetual and irrevocable right in the licensed rights and in certain intellectual property owned or controlled by us that is necessary to exploit the licensed products and used, conceived or generated in the course of exercising the license or exploiting any licensed product, or product-specific foreground intellectual property, for the purpose of non-commercial, non-clinical scientific research.

We are obligated to use commercially reasonable efforts to perform all activities set forth in a mutually agreed-upon development plan within the timelines set forth therein. We are also obligated to develop at least one licensed product in an autoimmune indication and to pursue worldwide regulatory authorization for licensed products. We must use commercially reasonable efforts to commercialize each licensed product throughout each of the specified major markets as soon as practicable following receipt of regulatory authorization for such product in such market.

Additionally, we must use commercially reasonable efforts to make the licensed product available through the United Kingdom (U.K.) and negotiate with relevant regulatory authorities to make each licensed product available through the National Health Service in England and Wales within a specified time of the licensed product being made available elsewhere in the territory. If we fail to meet one or more of these diligence obligations, and such failure is not remedied within the specified cure period, CRH shall have the right to terminate the CRH Agreement with respect to the relevant licensed product.

We are obligated to pay CRH a mid-five figure digit fee on each anniversary of the effective date. We are obligated pay up to an aggregate of £106.8 million ($143.6 million as of December 31, 2025) 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. We are also obligated to pay tiered royalties ranging from a rate in the mid-single digit to high-single digit percentage on net sales. The royalty term continues for each licensed product on a country-by-country basis beginning on the first commercial sale of such licensed product and ending on the latest of (a) the date when such licensed product is no longer covered by a valid claim of a licensed patent in such country, (b) the expiration of the exclusivity period for such licensed product in such country, and (c) the tenth anniversary of the first commercial sale of such licensed product in such country. We are 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 CRH Agreement shall remain in effect in each country in the territory until the expiry of our obligation to pay royalties in such country. Either party may terminate the CRH Agreement if the other party is in material breach that has not been remedied within the specified cure period or if the other party becomes insolvent.

CRH also has the right to terminate the CRH Agreement if we or one of our sublicensees or affiliates challenges a licensed patent, or if we are acquired by a tobacco company.

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 in February 2021.

The ProBioGen Agreement granted us a non-exclusive license under certain know-how, patents and materials, 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.

We are obligated to (i) make payments of up to €10.0 million ($11.7 million as of December 31, 2025) 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 ($8.2 million as of December 31, 2025) upon the achievement of certain sales milestones.

If we elect 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 December 31, 2025).

The ProBioGen Agreement will remain in effect until the services are completed for the service-related component and until the payment obligations expire in connection with the commercial license component. Both parties have the right to terminate the ProBioGen Agreement if the other party becomes insolvent, or materially breaches the ProBioGen Agreement and fails to remedy such default within the specified cure period.

Agreements Related to CLYM116

Mabworks Agreement

On January 8, 2025, we entered into the Mabworks Agreement with Mabworks, pursuant to which Mabworks granted to us: (1) 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 identified as MIL116 (the Licensed Compounds or CLYM116) and products containing the Licensed Compounds (Licensed Products) outside of Greater China (the Licensed Territory), (2) a non-exclusive, sublicensable right and license under the Licensed Intellectual Property to manufacture the Licensed Compounds and Licensed Products in Greater China and (3) a non-exclusive, sublicensable right and license under the Licensed Intellectual Property to develop the Licensed Compounds and Licensed Products in the Greater China in connection with certain global clinical studies (as described below).

Under the terms of the Mabworks Agreement, we paid to Mabworks a $9.0 million upfront payment, and we are 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, we are 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.

We are obligated to pay royalties on a Licensed Product-by-Licensed Product and country-by-country basis from the date of the first commercial sale in such country until the latest of: (i) the expiration of the last valid claim on the Licensed Intellectual Property covering the composition of matter of the Licensed Compound in such Licensed Product in such country; and (ii) ten years following the first commercial sale of such Licensed Product in such country (each, a Royalty Term). The royalty rate is subject to reduction on a Licensed Product-by-Licensed Product and country-by-country basis under certain circumstances. In the event that we grant sublicenses under the Licensed Intellectual Property, we will be obligated to pay Mabworks a percentage, in the mid-single-digits to low-double-digits, of certain consideration that we receive under such sublicenses.

We agreed to use commercially reasonable efforts to develop, obtain regulatory approval for and commercialize a Licensed Product in the U.S. We have also granted Mabworks a right of first refusal to develop and commercialize in Greater China any product we control that contains an antibody directed to tumor necrosis factor ligand superfamily member 13 (APRIL). Mabworks has agreed not to exploit in the Licensed Territory any product that is directed to APRIL during the term of the Mabworks Agreement. The Mabworks Agreement also contains a mechanism for the parties to collaborate on global clinical studies in the future, where we have a right to perform clinical studies in Greater China with Mabworks' approval in the event that Mabworks elects not to participate in such global clinical studies.

Unless earlier terminated, the Mabworks Agreement will expire on the expiration of the last to expire Royalty Term. Either party may terminate the Mabworks Agreement for the other party's material breach, following a customary notice and cure period, or insolvency. Additionally, we may terminate the Mabworks Agreement for any reason upon 60 days written notice to Mabworks.

Intellectual Property

We strive to protect the proprietary technology, inventions and improvements that are commercially important to our business, including seeking, maintaining, and defending patent rights, whether developed internally or licensed from third parties. We also rely on know-how relating to our proprietary technology, product candidates and continuing innovation to develop, strengthen and maintain our proprietary position. In addition, we plan to rely on data exclusivity, market exclusivity and patent term extensions or adjustments when available.

Our commercial success will depend in part on our ability to obtain and maintain patent and other proprietary protection for our technology, inventions and improvements; to defend and enforce our proprietary rights, including any patents that we may own or in-license in the future; and to operate without infringing the valid and enforceable patents and other proprietary rights of third parties. Intellectual property rights may not address all potential threats to our competitive advantage.

We intend, or understand that our licensors intend, to pursue patent protection covering, when possible, compositions, methods of use, methods of manufacture, dosing and formulations of budoprutug, CLYM116, and other intellectual property rights. We or our licensors also may pursue patent protection with respect to manufacturing and drug development processes and technologies. Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent agencies. We or our licensors may not be able to obtain patent protections for our compositions, methods of use, dosing and formulations, manufacturing and drug development processes and technologies throughout the world. Issued patents can provide protection for varying periods of time, depending upon the date of filing of the patent application, the date of patent issuance and the legal term of patents in the countries in which they are obtained.

In general, patents issued for applications filed in the U.S. can provide exclusionary rights for 20 years from the earliest nonprovisional application or PCT application filing date. In addition, in certain instances, the term of an issued U.S. patent that is directed to or claims an FDA-approved product can be extended to recapture a portion of the term effectively lost as a result of the FDA regulatory review period, which is called "patent term extension" (PTE). Further, the term of an issued U.S. patent may be adjusted if the issue of an original patent is delayed due to the failure of the U.S. Patent and Trademark Office (USPTO) to meet certain timelines during the prosecution of such patent, which is called "patent term adjustment" (PTA).

The restoration period for patents extended under PTE cannot be longer than five years and the total patent term, including the restoration period, must not exceed 14 years following FDA approval. The term of patents outside of the U.S. varies in accordance with the laws of the jurisdiction, but typically is also 20 years from its earliest filing date (as determined by the patent laws of that country) or PCT application filing date plus any extensions of term that may be available under national law. The actual protection afforded by a patent varies on a product-by-product basis, from country-to-country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions,

the availability of legal remedies in a particular country, and the validity and enforceability of the patent. Patent term may be inadequate to protect our competitive position on our products for an adequate amount of time.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. No consistent policy regarding the scope of claims allowable in patents in the field of biopharmaceuticals has emerged in the U.S. The relevant patent laws and their interpretation outside of the U.S. are also uncertain. Changes in either the patent laws or their interpretation in the U.S. and other countries may diminish our ability to protect our technology or product candidates and could affect the value of such intellectual property. In particular, our ability to stop third parties from making, using, selling, offering to sell or importing products that infringe our intellectual property will depend in part on our success in obtaining and enforcing patent claims that cover our technology, inventions, and improvements. We cannot guarantee that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications we or our licensors may file in the future, nor can we be sure that any patents that may be granted to us or our licensors in the future will be commercially useful in protecting our products, the methods of use, or the methods of manufacture of those products.

Moreover, even our issued patents do not guarantee us the right to practice our technology in relation to the commercialization of our products. Patent and other intellectual property rights in the pharmaceutical and biotechnology space are evolving and involve many risks and uncertainties. For example, third parties may have blocking patents that could be used to prevent us from commercializing our product candidates and practicing our proprietary technology, and our issued patents may be challenged, invalidated, deemed unenforceable or circumvented, which could limit our ability to stop competitors from marketing related products or could limit the term of patent protection that otherwise may exist for our product candidates.

In addition, the scope of the rights granted under any issued patents may not provide us with protection or competitive advantages against competitors with similar technology. Our competitors may independently develop similar technologies that are outside the scope of the rights granted under any issued patents. For these reasons, we may face competition with respect to budoprutug and CLYM116. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any particular product candidate can be commercialized, any patent directed to such product may expire or remain in force for only a short period following commercialization, thereby reducing the commercial advantage the patent provides.

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 product candidates we may develop and our technology and to operate our business without infringing, misappropriating or otherwise violating the intellectual property rights of others.

With respect to budoprutug, we own six pending U.S. provisional applications, nine pending U.S. nonprovisional patent applications, three pending PCT applications and six pending ex-U.S. patent applications. These applications relate to new uses of budoprutug, new formulations for budoprutug, and new methods of manufacturing budoprutug. With respect to manufacturing, at least four of these nine U.S. patent applications cover various aspects of a manufacturing process for budoprutug that we believe allows for more efficient and robust production of budoprutug. We co-own three pending U.S. provisional applications with Mabworks with respect to CLYM116, relating to new uses of CLYM116. We can provide no assurance that any of these current patent applications or future patent applications will result in issued patents or that any issued patents will provide us with any competitive advantage. Failure to obtain issued patents could have a material adverse effect on our ability to develop and commercialize budoprutug, CLYM116, or any product candidates we may develop. 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.

In-licensed Patents and Patent Applications

We exclusively in-license from CRH four issued U.S. patents and at least 45 ex-U.S. patents or patent applications under the CRH Agreement related to budoprutug. Each of the exclusively in-licensed patents and applications from CRH relate to budoprutug, including its composition-of-matter, uses, dosage forms, methods of making, or its derivatives and uses thereof.

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 the patent, and any PTE that might be available following the grant of marketing authorizations. For example, the term of one of the U.S. patents exclusively in-licensed from CRH is adjusted by 1703 days and is expected to expire in August 2031.

In addition to the budoprutug patents we in-license, we have filed additional patents providing protection that relate to new uses of budoprutug, new formulations for budoprutug, and new methods of manufacturing budoprutug. The patents that may be issued from these pending patent applications that we filed in 2025 are expected to expire in 2045, excluding any PTA that might be available following the grant of the patent and any PTE that might be available following the grant of marketing authorizations.

In January 2025, we exclusively in-licensed from Mabworks one PCT application. The application relates to CLYM116, including composition-of-matter, uses, and methods of making. The patents that may be issued from this 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 the patent and any PTE that might be available following the grant of marketing authorizations.

However, there can be no assurance that any of the pending patent applications will issue. Furthermore, there can be no assurance that we will benefit from any PTE or favorable adjustments to the term of any of the issued patents or patents that may issue from any pending patent applications in the future. The applicable authorities, including the FDA and the USPTO, may not agree with our assessment of whether such PTE should be granted or PTA is warranted, and if applicable, the extension or adjustment may be more limited than we request.

Trade Secrets and Other Protections

In addition to the protections afforded by patents and other regulatory protections, we may rely, in some circumstances, on trade secrets to protect our technology. Trade secrets may be useful to protect proprietary know-how that is not patentable or which we elect not to patent. Trade secrets may also be useful for processes or improvements for which patents are difficult to enforce. We also protect our products and proprietary technology through confidentiality agreements with employees, consultants, advisors, contractors and collaborators. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with a third party. These agreements may be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our commercial partners, collaborators, employees and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems.

Infringement of Third-Party Proprietary Rights

Our commercial success will depend in part on not infringing upon or otherwise violating the intellectual property and proprietary rights of third parties. If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue any future development and marketing of our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could also be forced, including by court order, to cease commercializing the infringing product or technology. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our products or force us to cease some of our business operations. For more information regarding these risks, see the section titled "Risk Factors—Risks Related to Intellectual Property."

Sales and Marketing

We have not yet defined our sales, marketing or product distribution strategy for budoprutug or CLYM116 because both programs are still in development. Our commercial strategy may include the use of strategic partners, distributors, a contract sales force, or establishing our own commercial sales force. We plan to further evaluate these alternatives as we approach potential approval for budoprutug and CLYM116.

Competition

The development and commercialization of new drug products is highly competitive. Moreover, the field of immune-mediated diseases is characterized by rapidly evolving science, significant competition, and a strong emphasis on intellectual property. We will face competition from major pharmaceutical companies, specialty pharmaceutical companies, and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for 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 the disease indications we are targeting with budoprutug or CLYM116. Some competitive products and therapies are based on similar scientific approaches, while 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 NMOSD, IgG4-RD, and 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 TCEs 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 CAR-T and chimeric antigen receptor-natural killer (CAR-NK) therapies include but are not limited to Novartis AG, Bristol Myers Squibb Company, Cabaletta Bio, Inc., Kyverna Therapeutics, Inc. and Nkarta, Inc.

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 and 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.

Manufacturing

We do not own or operate, and do not currently plan to establish any manufacturing facilities. We source all of our nonclinical and clinical supply through third-party contract development and manufacturing organizations (CDMOs).

For clinical supply, we utilize CDMOs who are obligated to comply with the FDA's current Good Manufacturing Practices (cGMPs) for the manufacture of drug substance and drug product. In connection with the development of our product candidates, we rely and expect to continue to rely on third parties for our manufacturing processes and for producing all clinical drug substance and drug product, and we anticipate continuing this model for commercial supply if our product candidates are approved. We have also used additional contract manufacturers for fill, finish, labeling, packaging, storage and distribution of investigational drug products, and we expect this outsourcing model to remain in place for commercial supplies of budoprutug, CLYM116, or any future product candidates. It is our intent to identify and qualify additional manufacturers to provide active pharmaceutical ingredients and fill-and-finish services prior to submission of a Biologics License Application (BLA) to the FDA for any product candidate.

The ProBioGen Agreement provides us with a non-exclusive license under certain know-how, patents and materials, to use cell lines incorporating ProBioGen's proprietary technology to research, develop, manufacture, use, sell, offer to sell, import or export budoprutug. In the first quarter of 2025, we completed a cell line switch from the original budoprutug manufacturing line to a new cell line and manufacturing process with approximately ten-fold higher productivity and better scalability. The characterization of material from both processes demonstrated comparability, and material from the new process has been cleared by regulatory authorities where we are conducting clinical trials for use in our ongoing and planned clinical trials.

We have filed multiple patent applications that protect our new manufacturing process using this new cell line. The patents that may be issued from these pending patent applications are expected to expire in 2045, excluding any applicable PTA. We can provide no assurance that any current or future patent applications will result in issued patents or that any issued patents will provide us with any competitive advantage.

Government Regulation

U.S. FDA Regulation Overview

The FDA and other regulatory authorities at federal, state, and local levels, as well as in foreign jurisdictions, including the European Union (EU), extensively regulate, among other things, the research, development, testing, manufacture, quality, safety, potency, purity, approval, labeling, packaging, storage, record keeping, advertising, promotion, sale, distribution, marketing, and post-marketing surveillance of pharmaceutical products such as the monoclonal antibodies that we are developing, budoprutug and CLYM116. We, along with third-party contractors, will be required to navigate the various nonclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of budoprutug and CLYM116. The regulatory requirements applicable to product development, approval and marketing require the expenditure of substantial time and financial resources. They also may be revised or reinterpreted by government agencies in ways that may have a significant impact on our business.

Licensure and Regulation of Biologics in the U.S.

In the U.S., the FDA regulates biologics under both the Federal Food, Drug and Cosmetic Act (FDCA) and the Public Health Services Act (PHSA) and their implementing regulations. A company, institution, or organization which takes responsibility for the initiation and management of a clinical development program for such products, and for their regulatory approval, is typically referred to as a sponsor. The failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject a sponsor to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve a pending BLA, withdrawal of an approval, imposition of a clinical hold, issuance of untitled or warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution, injunctions, debarment, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties.

The process required by the FDA before a biologic product may be marketed in the U.S. generally involves:

- completion of nonclinical studies, including laboratory evaluations, which must be conducted in accordance with the FDA's current good laboratory practice (GLPs);
- preparation of and submission to the FDA of an IND;

- approval by an institutional review board (IRB) or ethics committee for each clinical site before the trial may commence at that particular site;
- performance of adequate and well-controlled clinical trials, conducted under good clinical practice (GCP) requirements to establish the safety, purity and potency of the biologic for its intended indication;
- preparation of and submission to the FDA of a BLA that includes substantial evidence of potency, safety, and purity of the product from results of nonclinical testing and clinical trials;
- a determination by the FDA within 60 days of its receipt of a BLA that the application is sufficiently complete to file for review;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMPs and to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency, and of selected clinical investigation sites to assess compliance with GCPs;
- payment of application and program fees pursuant to the Prescription Drug User Fee Act (PDUFA);
- FDA approval of the BLA and licensure of the proposed product to permit commercial marketing of the product for particular indications for use in the U.S.; and
- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy (REMS), and any post-approval studies or other post-marketing commitments required by the FDA.

FDA Regulation of the Clinical Development Program

Prior to beginning a clinical trial in the U.S., we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational product to humans within a specific defined clinical study or studies. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes results of animal and in vitro studies assessing the toxicology, PK, pharmacology, and PD characteristics of the product candidate; chemistry, manufacturing, and controls (CMC) information; and any available human data or literature to support the use of the investigational product. An IND must be cleared before human clinical trials may begin in the U.S. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial, including any CMC issues. In such a case, the IND may be placed on clinical hold until the IND sponsor and the FDA resolve the outstanding concerns or questions. The FDA also may impose a partial clinical hold that would limit a trial, for example, to certain doses or for a certain length of time or to a certain number of subjects. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

With the passage of the FDA's Modernization Act 2.0 in December 2022, Congress eliminated provisions in both the FDCA and the PHSA that required animal testing in support of an NDA or BLA. While animal testing may still be conducted, the FDA was authorized to rely on alternative non-clinical tests, including cell-based assays, microphysiological systems, or bioprinted or computer models. In April 2025, the FDA released a roadmap to replace animal testing in nonclinical safety studies with scientifically validated new approach methodologies, such as organ-on-a-chip systems and computational modeling, which are referred to as in silica models, as well as advanced in vitro assays.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study.

Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. For new indications, a separate new IND may be required.

Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial, its informed consent form and other communications to study subjects before the clinical trial begins at that site. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB must monitor the study until completed, including any changes to the study plans while it is being conducted.

Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk, the clinical trial is not being conducted in accordance with the FDA's or IRB's requirements, if the investigational product has been associated with unexpected serious harm to subjects or that the trial is unlikely to meet its stated objectives.

Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data monitoring committee, which provides advice to the sponsor on whether or not a study should move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy.

Information about some clinical trials, including a description of the trial and trial results, must be submitted within specific timeframes to the National Institutes of Health for public dissemination on their ClinicalTrials.gov website. The failure to submit clinical trial information to clinicaltrials.gov is a prohibited act under the FDCA with violations subject to potential civil monetary penalties of up to $10,000 for each day the violation continues. Violations may also result in injunctions and criminal prosecution or disqualification from federal grants.

A development safety and update report detailing the results of the clinical trials must be submitted at least annually to the FDA. In addition, IND safety reports must be submitted to the FDA for any of the following: serious and unexpected suspected adverse reactions; findings from other trials or animal or in vitro testing that suggest a significant risk in humans exposed to the product; and any clinically important increase in the occurrence of a serious suspected adverse reaction over that listed in the protocol or investigator brochure.

Clinical Trials

Clinical trials are typically conducted in three sequential phases that may overlap or be combined.

- **Phase 1** trials evaluate safety, tolerability, PK, and sometimes PD endpoints in healthy volunteers or patients. Safety findings may limit dosing or progression.
- **Phase 2** trials assess preliminary efficacy, appropriate dosing, and additional safety data in a larger patient population. These trials help determine suitable dose regimens for Phase 3.
- **Phase 3** trials are adequate and well-controlled studies designed to confirm safety and efficacy for the intended indication. Successful completion of Phase 3 trials is typically required for full BLA approval.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These post-approval or post-marketing studies may be made a condition to approval of the BLA.

In December 2022, with the passage of Food and Drug Omnibus Reform Act of 2022 (FDORA), Congress began requiring 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 this DAP draft guidance from its website. Subsequently, in July 2025, pursuant to a court order, the FDA restored the draft DAP guidance to its website with a statement that "information on this page may be modified and/or removed in the future subject to the terms of the court's order and implemented consistent with applicable law."

In September 2025, the FDA issued final guidance with updated recommendations for GCPs aimed at modernizing the design and conduct of clinical trials. The updates are intended to help pave the way for more efficient clinical trials to facilitate the development of medical products. The final guidance is adopted from the International Council for Harmonisation's recently updated E6(R3) final guideline that was developed to enable the incorporation of rapidly developing technological and methodological innovations into the clinical trial enterprise. In addition, the FDA issued draft guidance outlining recommendations for the implementation of decentralized clinical trials.

In October 2025, the FDA issued final guidance that focuses on patient-focused drug development. The guidance outlines how stakeholders, such as patients, caregivers, researchers and medical product developers, can submit patient experience data in support of the development and approval of drug products. To that end, the guidance provides an overview of clinical outcome assessments (COAs) in clinical trials, and the role that COAs may play in evaluating the clinical benefit of a medical product.

Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate. In addition, the sponsor must develop and validate analytical methods for testing the identity, strength, quality and purity of the final product, or for biologics, the safety, purity and potency. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

In addition, under the Pediatric Research Equity Act (PREA), a BLA or supplement to a BLA must contain data to assess the safety, potency and purity of the investigational product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe, potent and pure. The FDA may grant deferrals for submission of data or full or partial waivers from the pediatric data requirements. A deferral may be granted for several reasons, including a finding that the investigational biologic is ready for approval for use in adults before pediatric trials are completed. The FDA is required to send a PREA Non-Compliance letter to sponsors who have failed to submit their pediatric assessments under PREA, have failed to seek or obtain a deferral or deferral extension or have failed to request approval for a required pediatric formulation.

Unless otherwise required by regulation, PREA does not apply to any investigational product for an indication for which orphan designation has been granted, although the FDA has taken steps to limit what it considers abuse of this statutory exemption in PREA by announcing that it does not intend to grant any additional orphan drug designations for rare pediatric subpopulations of what is otherwise a common disease. In May 2023, the FDA issued new draft guidance that further describes the pediatric study requirements under PREA. The FDA also maintains a list of diseases that are exempt from PREA requirements due to low prevalence of disease in the pediatric population.

In connection with our clinical development programs, we may conduct trials at sites outside the U.S. When a foreign clinical study is conducted under an IND, all IND requirements must be met unless waived. When a foreign clinical study is not conducted under an IND, the sponsor must ensure that the study complies with certain regulatory requirements of the FDA in order to use the study as support for an IND or application for marketing approval. Specifically, the studies must be conducted in accordance with GCP, including undergoing review and receiving approval by an independent ethics committee, and seeking and receiving informed consent from subjects. GCP requirements encompass both ethical and data integrity standards for clinical studies. The FDA's regulations are intended to help ensure the protection of human subjects enrolled in non-IND foreign clinical studies, as well as the quality and integrity of the resulting data. They further help ensure that non-IND foreign studies are conducted in a manner comparable to that required for IND studies.

BLA Submission, Review and Approval

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from pertinent nonclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's CMC and proposed labeling, among other things. The submission of a BLA requires payment of a substantial application user fee to FDA, unless a waiver or exemption applies.

Once the FDA receives an application, it has 60 days to review the BLA to determine if it is substantially complete to permit a substantive review, before it accepts the BLA for filing. If the FDA determines that a BLA does not satisfy this standard, the FDA will issue a Refuse to File (RTF) determination to the sponsor. The FDA may request additional information and studies, and the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. In October 2025, the FDA issued internal guidance clarifying that "materially incomplete or inadequately organized" applications that would not permit timely, efficient and complete review will be subject to RTFs. Once the submission is accepted for filing, the FDA begins an in-depth review of the BLA. Under the goals and policies agreed to by the FDA under the PDUFA, the FDA has 10 months from acceptance of filing in which to complete its initial review of a standard BLA and respond to the sponsor, and six months from acceptance of filing for a priority BLA. The FDA does not always meet its PDUFA goal dates. The review process and the PDUFA goal date may be extended by three months or longer if the FDA requests that the BLA sponsor provides additional information or clarification regarding information already provided in the submission before the PDUFA goal date.

The FDA seeks to meet these timelines for review of an application but its ability to do so may be affected by a variety of factors, including government budget and funding levels, the ability to hire and retain key personnel and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. For example, during the past decade, the U.S. government has shut down several times and certain regulatory agencies, including the FDA, have had to furlough critical employees and stop critical activities, including potentially the review of INDs and BLAs.

After the BLA is accepted for filing, the FDA reviews a BLA to determine, among other things, whether a product is safe, potent and pure, and whether the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued quality standards. The FDA may convene an advisory committee to provide clinical insight on application review questions.

Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information.

Moreover, the FDA will review a sponsor's financial relationship with the principal investigators who conducted the clinical trials in support of the BLA. Depending on the level of that compensation and any other financial interest a principal investigator may have in a sponsor, the sponsor may be required to report these relationships to the FDA. The FDA will then evaluate that financial relationship and determine whether it creates a conflict of interest or otherwise affects the interpretation of the trial or the integrity of the data generated at the principal investigator's clinical trial site. If so, the FDA may exclude data from the clinical trial site in connection with its determination of safety and efficacy of the investigational product.

Under the PHSA, the FDA may approve a BLA if it determines that the product is safe, pure and potent and the facility where the product will be manufactured meets standards designed to ensure that it continues to be safe, pure and potent. To reach this determination, the FDA must determine that the investigational product is effective and that its expected benefits outweigh its potential risks to patients. This "benefit-risk" assessment is informed by the extensive body of evidence about the product's safety, purity and potency in the BLA. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates a BLA and conducts any necessary inspections, the FDA may issue an approval letter or a Complete Response Letter (CRL). An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications.

A CRL, which indicates that the review cycle is complete, will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the CRL without first conducting required inspections, testing submitted product lots, or reviewing proposed labeling. In issuing the CRL, the FDA may recommend actions that the sponsor might take to place the BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information or require post-marketing testing and surveillance to monitor safety, potency or purity of a product. While CRLs were previously treated by the FDA as confidential and were only disclosed in action packages for approved products, the FDA announced in September 2025 that it will now release CRLs promptly after they are issued to sponsors.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a REMS, to ensure the benefits of the product outweigh its risks.

A REMS is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre-and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization and may limit further marketing of the product based on the results of these post-marketing studies.

Expedited Review Programs

The FDA is authorized to expedite the review of applications in several ways. While none of these expedited programs change the standards for approval, each may help expedite the development or approval process governing product candidates. A product is eligible for priority review if the FDA determines that it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or to provide a significant improvement in the treatment, diagnosis or prevention of a serious disease or condition compared to marketed products. For products containing new molecular entities, Priority Review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date (compared with ten months under standard review).

To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need by providing a therapy where none exists or a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. Fast track designation provides additional opportunities for frequent interactions with the FDA review team to expedite development and review of the product. The FDA may also review sections of the BLA for a fast track product on a rolling basis before the complete application is submitted, if the sponsor and FDA agree on a schedule for the submission of the application sections, and the sponsor pays any required user fees upon submission of the first section of the BLA. The review clock does not begin until the final section of the BLA is submitted. The FDA may decide to rescind the fast track designation if it determines that the qualifying criteria no longer apply.

In addition, a sponsor can request designation of a product candidate as a "breakthrough therapy." A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Products designated as breakthrough therapies are eligible for intensive guidance from the FDA on an efficient development program, organizational commitment to the development and review of the product including involvement of senior managers, and, like fast track products, are also eligible for rolling review of the BLA. Both fast track and breakthrough therapy products may also be eligible for accelerated approval and priority review if relevant criteria are met.

Accelerated Approval

Additionally, products studied for their safety, potency and purity in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit.

With the passage of 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."

In March 2023, the FDA issued draft guidance that outlines its current thinking and approach to accelerated approval. 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 assessment and allows for direct comparisons to an available therapy. Subsequently, in December 2024 and January 2025, the FDA issued additional draft guidances relating to accelerated approval. These guidances describe FDA's views on what it means to conduct a confirmatory trial with due diligence and how the agency plans to interpret whether such a study needs to be underway at the time of approval. While these guidances are currently only in draft form and will ultimately not be legally binding even when finalized, sponsors typically observe the FDA's guidance closely to ensure that their investigational products qualify for accelerated approval.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Furthermore, priority review, fast track designation, breakthrough therapy designation, and accelerated approval do not change the standards for approval and may not ultimately expedite the development or approval process.

Post-approval regulation

If regulatory approval for marketing of a product or new indication for an existing product is obtained, the sponsor will be required to comply with all regular post-approval regulatory requirements as well as any post-approval requirements that the FDA has imposed as part of the approval process. The sponsor will be required to report certain adverse reactions and production problems to the FDA, provide updated safety and efficacy information and comply with requirements concerning advertising and promotional labeling requirements. Manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMP regulations, which impose certain procedural and documentation requirements upon manufacturers. Accordingly, the sponsor and its third-party manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with cGMP regulations and other regulatory requirements.

A product may also be subject to official lot release, meaning that the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution.

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

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about a product;
- mandated modification of promotional materials and labeling and issuance of corrective information;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product recall, seizure or detention, or refusal to permit the import or export of products;

- injunctions or the imposition of civil or criminal penalties; and
- consent decrees, corporate integrity agreements, debarment, or exclusion from federal health care programs.

The FDA strictly regulates the marketing, labeling, advertising and promotion of prescription drug products placed on the market. This regulation includes, among other things, standards and regulations for direct-to-consumer advertising, communications regarding unapproved uses, industry-sponsored scientific and educational activities and promotional activities involving the Internet and social media. Promotional claims about a drug's safety or effectiveness are prohibited before the drug is approved.

After approval, a drug product generally may not be promoted for uses that are not approved by the FDA, as reflected in the product's prescribing information. In September 2021, the FDA published final regulations that describe the types of evidence that the agency will consider in determining the intended use of a drug or biologic.

It may be permissible, under very specific, narrow conditions, for a manufacturer to engage in nonpromotional, non-misleading communication regarding off-label information, such as distributing scientific or medical journal information. Moreover, with passage of the Pre-Approval Information Exchange Act in December 2022, sponsors of products that have not been approved may proactively communicate to payors certain information about products and product candidates in development to help expedite patient access upon product approval. Previously, such communications were permitted under FDA guidance but the new legislation explicitly provides protection to sponsors who convey certain information about products and product candidates in development to payors, including unapproved uses of approved products.

In addition, in January 2025, the FDA published final guidance outlining its policies governing the distribution of scientific information to healthcare providers about unapproved uses of approved products. The final guidance calls for such communications to be truthful, non-misleading and scientifically sound and to include all information necessary for healthcare providers to interpret the strengths and weaknesses and validity and utility of the information about the unapproved use of the approved product. If a company engages in such communications consistent with the guidance's recommendations, the FDA indicated that it will not treat such communications as evidence of unlawful promotion of a new intended use for the approved product.

If a company is found to have promoted off-label uses, it may become subject to adverse public relations and administrative and judicial enforcement by the FDA, the Department of Justice, or the Office of the Inspector General of the U.S. Department of Health and Human Services (HHS), as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes drug products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

Finally, if there are any modifications to the product, including changes in indications, labeling or manufacturing processes or facilities, the sponsor may be required to submit and obtain FDA approval of a new BLA or a BLA supplement, which may require the sponsor to develop additional data or conduct additional nonclinical studies and clinical trials. Securing FDA approval for new indications is similar to the process for approval of the original indication and requires, among other things, submitting data from adequate and well-controlled clinical trials to demonstrate the product's safety, purity and potency in the new indication.

Biosimilars and Reference Product Exclusivity

When a biological product is licensed for marketing by the FDA with approval of a BLA, the product may be entitled to certain types of market and data exclusivity barring the FDA from approving competing products for certain periods of time. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the ACA), was enacted in the U.S. and included the Biologics Price Competition and Innovation Act of 2009 (BPCIA). The BPCIA amended the PHSA to create an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with a FDA-licensed reference biological product. To date, the FDA has approved both biosimilar and interchangeable biosimilar products.

Under the BPCIA, a manufacturer may submit an application for licensure of a biologic product that is "biosimilar to" or "interchangeable with" a previously approved biological product or "reference product." In order for the FDA to approve a biosimilar product, it must find that there are no clinically meaningful differences between the reference product and proposed biosimilar product in terms of safety, purity, and potency. For the FDA to approve a biosimilar product as interchangeable with a reference product, the FDA must find that the biosimilar product can be expected to produce the same clinical results as the reference product, and (for products administered multiple times) that the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. 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 first day on which such a product is approved as interchangeable with the reference product.

A reference biologic is granted twelve years of exclusivity from the time of first licensure of the reference product. Approval of a 351(k) application may not be made effective until twelve years after the date of first licensure of the reference product, which under the statute excludes the date of licensure of supplements and certain other applications.

Additionally, a 351(k) application for a biosimilar or interchangeable biological product cannot be submitted for review until four years after the date on which the reference product was first licensed under Section 351(a) of the PHSA.

Even if a product is considered to be a reference product eligible for exclusivity, however, another company could market a competing version of that product if the FDA approves a full BLA for such 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 its product.

There have been recent government proposals to reduce the twelve-year reference product exclusivity period, but none has been enacted to date. At the same time, since passage of the BPCIA, many states have passed laws or amendments to laws, which address pharmacy practices involving biosimilar products. The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation, and impact of the BPCIA is subject to significant uncertainty. 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.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat rare diseases affecting fewer than 200,000 individuals in the U.S. Orphan designation must be requested before submitting a BLA. After the FDA grants orphan designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not convey any advantage in, or automatically shorten the duration of, the regulatory review or approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan exclusivity, which means that the FDA may not approve any other applications, including a full BLA, to market the same product 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. Orphan exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for clinical testing and waiver of BLA application fees, and seven years of market exclusivity upon approval. Orphan exclusivity applies only to the specific approved indication. It may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

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.

Pediatric Exclusivity

Pediatric exclusivity is another type of non-patent exclusivity in the U.S. and for biologics, if granted, provides for the attachment of an additional six months of regulatory exclusivity to the term of any existing regulatory exclusivity, including orphan exclusivity. This six-month exclusivity may be granted if a BLA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity that cover the product are extended by six months.

Patent Term Restoration and Extension

In the U.S., a patent claiming a new biologic product, its method of use or its method of manufacture may be eligible for a limited PTE under the Drug Price Competition and Patent Term Restoration Act of 1984, which permits a patent extension of up to five years for patent term lost during product development and FDA regulatory review. Assuming grant of the patent for which the extension is sought, the restoration period for a patent covering a product is typically one-half the time between the effective date of the IND clearing clinical studies and the submission date of the BLA, plus the time between the submission date of the BLA and the ultimate approval date. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date in the U.S. Only one patent applicable to an approved product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent for which extension is sought. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. The USPTO reviews and approves the application for any PTE in consultation with the FDA.

EU/Rest of World Regulation

In addition to regulations in the U.S., there are a variety of laws and regulations in other jurisdictions governing, among other things, clinical trials, commercial sales and distribution of medicinal products. Even if FDA approval of a particular product is obtained, a sponsor must still obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries and jurisdictions outside of the U.S., including the EU, have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials.

Clinical Trials in the EU

In the EU, clinical trials are governed by the Clinical Trials Regulation (EU) No 536/2014 (CTR), which entered into application on January 31, 2022 repealing and replacing the former Clinical Trials Directive 2001/20.

The CTR is intended to harmonize and streamline clinical trial authorizations, simplify adverse-event reporting procedures, improve the supervision of clinical trials and increase transparency. Specifically, the CTR, which is directly applicable in all member states of the EU (EU Member States), introduces a streamlined application procedure through a single-entry point, the "EU portal", the Clinical Trials Information System; a single set of documents to be prepared and submitted for the application; as well as simplified reporting procedures for clinical trial sponsors. A harmonized procedure for the assessment of applications for clinical trials has been introduced and is divided into two parts. Part I assessment is led by the competent authorities of a reference EU Member State selected by the trial sponsor and relates to clinical trial aspects that are considered to be scientifically harmonized across EU Member States. This assessment is then submitted to the competent authorities of all concerned EU Member States in which the trial is to be conducted for their review.

Part II is assessed separately by the competent authorities and Ethics Committees in each concerned EU Member State. Individual EU Member States retain the power to authorize the conduct of clinical trials on their territory.

Parties conducting certain clinical studies must, as in the U.S., post clinical trial information in the EU at the EudraCT website: https://eudract.ema.europa.eu.

In all cases, clinical trials must be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. Medicines used in clinical trials must be manufactured in accordance with the guidelines on cGMP and in a GMP licensed facility, which can be subject to GMP inspections.

The EU pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission's proposal for revision of several legislative instruments related to medicinal products was published in April 2023. The European Parliament requested several amendments in April 2024. 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 of data exclusivity and a reduced market exclusivity period to 1 year, which can be extended if specific conditions are fulfilled, adding launch/supply obligations, incentivizing antibiotic innovation with transferable vouchers, and streamlining approval procedures in the EU. If the legislation is finalized in line with the provisional political agreement it will have a profound impact on the pharmaceutical industry.

Brexit and the regulatory framework in the United Kingdom

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 (Great Britain and Northern Ireland), and the European Medicines Agency (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 the U.K.'s withdrawal from the EU. 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 CTR.

Following 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 EMA and regulators in the European Economic Area (EEA) member states for approvals in the EU centralized procedure and mutual recognition procedure as well as the FDA (for product approvals granted in the U.S.). The RR assessment must have undergone a full and standalone review. RR assessments based on reliance or recognition cannot be used to support an IRP application. A Committee for Medicinal Products for Human Use (CHMP) positive opinion or a Mutual Recognition Decentralised Procedure positive end of procedure outcome is an RR authorization for the purposes of IRP.

Other laws and regulations

Healthcare providers, including physicians and third-party payors in the U.S. and elsewhere will play a primary role in the recommendation and prescription of any drug products for which we obtain marketing approval. Our current and future arrangements with third-party payors, customers, healthcare providers, physicians and others, in connection with the clinical research, sales, marketing and promotion of products, once approved, and related activities, may expose a pharmaceutical manufacturer to broadly applicable fraud and abuse and other healthcare laws and regulations. In particular, the research of our product candidates, as well as the promotion, sales and marketing of healthcare items and services and certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business or financial arrangements. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include, but are not limited to:

- 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 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 laws, 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 for purposes of 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;
- 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 Centers for Medicare and Medicaid Services (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 healthcare professionals, (such as physician assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by the physicians and their immediate family members.
- 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.
- U.S. federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous U.S. state laws and regulations, including state anti-kickback and false claims and 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; 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.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Efforts to ensure that business arrangements comply with applicable healthcare laws involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting its rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, disgorgement, imprisonment, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, reporting obligations and oversight if we become subject to integrity and oversight agreements to resolve allegations of non-compliance, contractual damages, reputational harm, diminished profits and future earnings and curtailment of operations, any of which could adversely affect our ability to operate our business and the results of operations. In addition, commercialization of any drug product outside the U.S. will also likely be subject to foreign equivalents of the healthcare laws mentioned above, among other foreign laws. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business with are found to be not in compliance with applicable laws, they may be subject to similar penalties.

Data privacy and security laws

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 HITECH (which imposes specific requirements relating to the privacy, security and transmission of individually identifiable health information), and the California Consumer Privacy Act of 2018 (CCPA).

The 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. The CCPA provides for civil penalties of up to $7,500 per violation and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA increases compliance costs and potential liability with respect to other personal data we maintain about California residents. 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, at least 18 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. There are also states that are considering or have already passed comprehensive privacy laws during the 2023 legislative sessions that will go into effect in 2024 and beyond. There are also states that are specifically regulating health information that may affect our business. For example, Washington state recently passed a health privacy law that will regulate the collection and sharing of health information, and the law also has a private right of action, which further increases the relevant compliance risk. These laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products.

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

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 (EU GDPR) and the equivalent law in the U.K. (U.K. GDPR) and, together with EU GDPR, the GDPR, impose strict requirements for processing the personal data of individuals, including sensitive data that we may process such as health data. For example, under the GDPR, companies may face temporary or definitive bans on data processing and other corrective actions, as well as fines of up to 20 million euros under the EU GDPR, 17.5 million pounds sterling under the U.K. GDPR, or, in each case, 4% of annual global revenue, whichever is greater. Further, individuals may initiate litigation related to our processing of their personal data. Additionally, under various privacy laws and other obligations, we may be required to obtain certain consents to process personal data. Our inability or failure to do so could result in adverse consequences.

In the ordinary course of business, we may transfer personal data from Europe and other jurisdictions to the U.S. or other countries. The EEA, the U.K. and certain jurisdictions have enacted data localization laws and cross-border personal data transfer laws. In particular, the EEA and the U.K. have significantly restricted the transfer of personal data to the U.S. and other countries whose privacy laws it believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and U.K. to the U.S. in compliance with law, such as the EEA standard contractual clauses, the U.K. International Data Transfer Agreement and the EU-U.S. Data Privacy Framework (which allows for transfers for relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the U.S.

If there is no lawful manner for us to transfer personal data from the EEA, the U.K. or other jurisdictions to the U.S., or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business.

Additionally, companies that transfer personal data out of the EEA and U.K. to other jurisdictions, particularly to the U.S., are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the EU GDPR's cross-border data transfer limitations.

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.

Current and future healthcare reform legislation

The U.S. and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system. In March 2010 the 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 without specifically ruling on its constitutionality. Changes in presidential administrations have also resulted in shifts in policy priorities relating to ACA implementation and enforcement, contributing to continued uncertainty regarding the future of the law.

Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (IRA) into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025 and eliminates the Medicare Part D coverage gap beginning in 2025 through a newly established manufacturer discount program. It remains unclear how future legislative, regulatory, or administrative actions may affect the ACA or related coverage and payment provisions.

The IRA includes several provisions specifically affecting drug manufacturers. Among other things, the IRA:

- requires manufacturers of certain products to engage in price negotiations with Medicare beginning in 2026,
- imposes inflation-based rebates under Medicare Parts B and D, and
- replaces the Part D coverage gap discount program with a new manufacturer discount program beginning in 2025.

Under the IRA, CMS may negotiate prices for certain high-cost, single-source drugs and biologics reimbursed under Medicare Parts B and D. This provision applies to drug products that have been approved for at least 9 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.

CMS began the first negotiation cycle in 2023 and published negotiated prices for ten selected Part D drugs on August 15, 2024, which took effect on January 1, 2026. CMS announced fifteen additional drugs selected for negotiation on January 17,

2025, with negotiated prices for these drugs scheduled to take effect January 1, 2027. The agency has indicated its intent to continue implementing the program and pursue additional transparency measures.

The IRA subjects manufacturers to civil monetary penalties and potential excise taxes for noncompliance with negotiation or inflation-rebate requirements. The law also caps Medicare beneficiary annual out-of-pocket drug costs at approximately $4,000 in 2024 and $2,000 beginning in 2025. CMS finalized rules governing inflation rebate programs under Medicare Parts B and D in December 2024.

Several pharmaceutical manufacturers and industry groups, including Merck & Co., the U.S. Chamber of Commerce, Bristol Myers Squibb, PhRMA, and others, have filed lawsuits challenging the IRA's drug price negotiation provisions on constitutional and statutory grounds. HHS has generally won the substantive disputes in these cases or succeeded in getting claims dismissed for lack of standing. 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. Litigation involving these and other provisions of the IRA will continue with unpredictable and uncertain results.

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

The Trump Administration has also 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 Trump Administration to provide for lower prices on certain pharmaceuticals.

At the state level, individual states have enacted legislation intended to control pharmaceutical pricing, including pricing or reimbursement caps, transparency measures, restrictions on certain product access, and, in some cases, policies designed to encourage importation or bulk purchasing. Regional health systems and hospital networks are also increasingly using competitive bidding and formulary management to determine which products will be covered. Additional state or federal reform measures may further limit the amounts payors are willing to reimburse, reducing demand or increasing pricing pressure on our products if approved. This may be particularly true for products approved under the FDA's accelerated approval pathway; some state Medicaid programs and other payors have adopted significant coverage restrictions for such products, citing evidentiary concerns.

Accordingly, while it is unclear how the IRA and other such regulations and legislative actions will ultimately be implemented, we cannot predict with certainty what impact federal or state healthcare reforms will have on us. Such changes could impose new or more stringent regulatory requirements or result in reduced reimbursement for budoprutug or CLYM116, if approved, or any future products we may develop, any of which could adversely affect our business, results of operations, and financial condition.

In the EU, similar political, economic, and regulatory developments may affect our ability to profitably commercialize budoprutug or CLYM116, if approved. In addition to ongoing pricing and cost-containment pressures, legislative changes at the EU or Member State level may impose additional requirements or obstacles that increase operating costs. In many markets outside the U.S. and EU, reimbursement and healthcare payment systems vary significantly, and many countries have instituted price ceilings or other governmental controls. In such jurisdictions, pricing negotiations with governmental authorities may take considerable time after marketing approval is received. To obtain reimbursement or pricing approval in certain countries, we or our collaborators may be required to conduct cost-effectiveness or health technology assessment studies comparing our product to available therapies.

If reimbursement for our products is unavailable, limited, or set at a level insufficient to support commercial viability, our business could be materially harmed. We expect that future healthcare reform measures may result in more rigorous coverage standards and additional downward pressure on the prices we may receive for any approved products. Any reduction in reimbursement from government programs or private payors may adversely affect our future revenues and our ability to achieve or sustain profitability.

Foreign regulation

For other countries outside of the EU and the U.S., such as countries in Eastern Europe, Latin America or Asia, the requirements governing product development, the conduct of clinical trials, manufacturing, distribution, marketing approval, advertising and promotion, product licensing, pricing and reimbursement vary from country to country. Additionally, clinical trials must be conducted in accordance with GCP requirements and the applicable regulatory requirements and the ethical principles originating in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Additionally, to the extent that any of our product candidates, once approved, are sold in a foreign country, we may be subject to applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, corporate compliance obligations, and reporting of payments or other transfers of value to healthcare professionals.

Additional laws and regulations governing international operations

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

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

Various laws, regulations and executive orders also restrict the use and dissemination outside of the U.S., or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the U.S., it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the U.S., which could limit our growth potential and increase our development costs.

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

On February 10, 2025, President Trump issued an Executive Order directing the Attorney General to review the guidelines and policies governing FCPA investigations and enforcement actions. Per the Executive Order, this review will result in new Department of Justice FCPA guidelines intended to enhance American economic competitiveness and to safeguard national security interests. During the 180-day review period, any new FCPA investigations and enforcement actions are to be suspended absent authorization from the Attorney General, and all existing FCPA investigations and enforcement actions are required to be reviewed.

Coverage, pricing and reimbursement

Significant uncertainty exists as to the coverage, pricing and reimbursement status of any products that may receive regulatory approval. Successful commercialization of new drug products depends in part on the extent to which coverage and reimbursement will be available from government health administration authorities, private health insurers and other organizations. The availability of coverage and extent of reimbursement depend substantially, both domestically and abroad, on the extent to which the costs of drug products are paid for by third-party payors, such as government health care programs (*e.g.*, Medicare, Medicaid), health maintenance organizations, managed care providers, pharmacy benefit and similar healthcare management organizations, private health coverage insurers and other third-party payors. These third-party payors decide which medications they will pay for and establish reimbursement levels.

In the U.S., no uniform policy of coverage and reimbursement for drug products exists among third-party payors and coverage and reimbursement levels for drug products can differ significantly from payor to payor. Third-party payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. Factors payors consider in determining reimbursement include assessing whether the product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Moreover, the process for determining whether a payor will provide coverage for a product may be separate from the process for setting the reimbursement rate that the payor will pay for the product. One payor’s determination to provide coverage for a product does not assure that other payors will also provide coverage and reimbursement for the product. Third-party payors may also limit coverage to specific products on an approved list, or formulary, which might not include all FDA-approved products for a particular indication.

Increasing efforts by third-party payors in the U.S. and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. In order to secure coverage and reimbursement for any product that may be approved for sale, we may need to conduct expensive pharmacoeconomic studies to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA or comparable regulatory approvals. Additionally, we may also need to provide discounts to purchasers, private health plans or government healthcare programs. Our product candidates, if approved, may nonetheless not be considered medically necessary or cost-effective. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover the product after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products at a profit. We expect to experience pricing pressures from third-party payors in connection with the potential sale of any of our product candidates.

Outside of the U.S., the pricing of pharmaceutical products is subject to governmental control in many countries. For example, in the EU, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare a particular therapy's cost effectiveness to currently available therapies or so-called health technology assessments, to obtain reimbursement or pricing approval. Other countries may allow companies to fix their own prices for products but monitor and control product volumes and issue guidance to physicians to limit prescriptions. Efforts to control prices and utilization of pharmaceutical products will likely continue as countries attempt to manage healthcare expenditures. Historically, products launched in the EU do not follow U.S. price structures, and prices tend to be significantly lower.

Employees and Human Capital

As of December 31, 2025, we had 28 full-time employees, and one part-time employee, including a total of six employees with M.D., Ph.D. or equivalent degrees. Of these employees, 15 were engaged in research and development. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

We are committed to a work environment that is welcoming, inclusive and encouraging. To achieve our plans and goals, it is imperative that we attract and retain top talent. In order to do so, we aim to have a safe and encouraging workplace, with opportunities for our employees to grow and develop professionally, supported by strong compensation, benefits, and other incentives. In addition to competitive base salaries, we offer our employees discretionary cash-based performance bonuses and, in addition, may utilize our equity incentive plan to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards.

Corporate Information

We were incorporated under the laws of the state of Delaware in October 2018. Our principal mailing address is 20 William Street, Suite 145, Wellesley Hills, MA 02481. Our telephone number is (866) 857-2596. Our website is climbbio.com. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and all amendments to those reports are available free of charge on our website as soon as reasonably practicable after such material is electronically filed with, or furnished to, the Securities and Exchange Commission.

Item 1A. Risk Factors.

The following information sets forth risk factors that could cause our actual results to differ materially from those contained in forward-looking statements we have made in this Annual Report on Form 10-K 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 Annual Report on Form 10-K 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 mAb, 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 $59.9 million for the year ended December 31, 2025, and as of December 31, 2025, we had an accumulated deficit of $289.7 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. As of December 31, 2025, we had cash, cash equivalents and marketable securities of $160.7 million. Based on our current operating plan and assumptions, we believe our existing capital resources will be sufficient to fund our operations into 2028. We have based this estimate on assumptions that may prove to be wrong, and 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, as well as in the concurrent private placement of shares of our common stock to certain institutional investors (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 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 the Acquisition, certain legacy Tenet agreements effectively became agreements of ours, including the Asset Purchase Agreement, the CRH Agreement, and the ProBioGen Agreement. 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 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. Additionally, pediatric studies may be required pursuant to PREA or comparable foreign requirements.

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.

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.

The applicable legislation in the EU also requires sponsors to either conduct clinical trials in a pediatric population in accordance with a Pediatric Investigation Plan approved by the Pediatric Committee of the EMA or to obtain a waiver or deferral from the conduct of these studies by this Committee. For any 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.

For any of our 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 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.

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 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 cGMPs 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 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 GCPs 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 FDORA, Congress required sponsors to develop and submit a 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 NMOSD, IgG4-RD, and 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 CAR-T and CAR-NK therapies include but are not limited to Novartis AG, Bristol Myers Squibb Company, Cabaletta Bio, Inc., Kyverna Therapeutics, Inc. and Nkarta, Inc.

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 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 an 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 CRLs 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 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 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. 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. HHS has generally won the substantive disputes in these cases or succeeded in getting claims dismissed for lack of standing. 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 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.

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 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;
- 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 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 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 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 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 may seek certain 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 may 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 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. Vouchers under the CNPV Program will reportedly be given to companies aligned with U.S. national priorities.

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 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.

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 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 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 CTR (Regulation EU No 536/2014). 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 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 RRs. The RRs notably include the EMA and regulators in the EEA member states for approvals in the EU centralized procedure and mutual recognition procedure as well as the FDA (for product approvals granted in the 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.

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 six pending U.S. provisional applications, nine pending U.S. nonprovisional patent applications, three pending PCT applications and six 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 three co-owned 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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respect to CLYM116, we have one exclusively in-licensed PCT application under the Mabworks Agreement and three co-owned U.S. provisional patent applications with Mabworks. We can provide no assurance that any of these current patent applications or future patent applications will result in issued patents or that any issued patents will provide us with any competitive advantage. Failure to obtain issued patents could have a material adverse effect on our ability to develop and commercialize budoprutug, CLYM116 or any other product candidates we may develop.

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 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 owned pending 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 FCPA, 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 U.S. tax law, including Section 382 and 383 ownership change rules, 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 related Private Placement, resulting in the issuance of a total of an additional 36,798,329 shares of our common stock.

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 December 31, 2025, 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 an aggregate of 7.0 million shares of our common stock, 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 Private Placement related to the Acquisition, we entered into a registration rights agreement, pursuant to which we are required to register for resale the shares to be purchased in the 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 Private Placement and the consideration issued in connection with the Acquisition.

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.

Based upon our common stock outstanding as of December 31, 2025, our executive officers, directors and current beneficial owners of 5% or more of our common stock, in the aggregate, beneficially own approximately 36% of our outstanding common stock. In particular, affiliates of RA Capital Management, L.P., own approximately 24% of our outstanding common stock and, in addition, they have the right to exercise pre-funded warrants 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).

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 initial public offering (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 December 31, 2025. The unremediated material weaknesses, and our remediation plan, are disclosed in Item 9A, "Controls and Procedures," of this Annual Report on Form 10-K.

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 OECD 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 1B. Unresolved Staff Comments.

Not applicable.

Item 1C. Cybersecurity.

Risk Management and Strategy

We have implemented and maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical computer networks, third-party hosted services, communications systems, and our critical data, including intellectual property, confidential information that is proprietary, strategic or competitive in nature, and data related to nonclinical studies and clinical trials involving certain of our product candidates (Information Systems and Data).

We manage, identify and assess risks from cybersecurity threats by monitoring and evaluating our threat environment and risk profile using various methods including, for example: through the use of automated tools, including but not limited to tools for monitoring, remote wiping, threat detection, intrusion detection and prevention; conducting (through third parties) regular audits and threat assessments for internal and external threats; subscribing to reports and services that identify cybersecurity threats; analyzing reports of threats and actors; conducting vulnerability assessments to identify vulnerabilities; evaluating our and our industry's risk profile; and evaluating threats reported to us.

Depending on the environment, we implement and maintain various processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example: risk assessments, implementation of security standards and certifications, encryption of data in transit and at rest, network security controls, data segregation, access controls, systems monitoring, vendor risk management program, employee training and penetration testing.

As part of our cybersecurity risk management program, we maintain processes to assess and review the cybersecurity practices of third-party vendors and suppliers. Prior to engaging key third-party vendors and suppliers, we conduct a security assessment and, as appropriate, include security requirements in contracts.

We, like other companies in our industry, face cybersecurity risks in connection with our business. However, to date, risks from cybersecurity threats have not materially affected and are not reasonably likely to materially affect our business strategy, results of operations, and financial condition. For more information on our cybersecurity related risks, see "Risk Factors" under Part I, Item 1A of this Annual Report on Form 10-K.

Governance

Our board of directors considers cybersecurity risk management as part of its general oversight function. The audit committee of our board of directors is responsible for overseeing our cybersecurity risk management processes, including oversight and mitigation of risks from cybersecurity threats.

Our management team provides periodic updates to the audit committee regarding our cybersecurity program, including information about cyber risk management governance and status updates on various projects intended to enhance the overall cybersecurity posture of the Company. Our chief financial officer, with the assistance of third-party technical advisors, leads the operational oversight of company-wide cybersecurity strategy, policy, standards and processes and works across relevant departments to assess and help the Company and our employees to address cybersecurity risks. Our third-party technical advisors include consultants with over 20 years of experience in IT leadership as well as subject matter experts in cybersecurity that have extensive experience managing cybersecurity programs.

Item 2. Properties.

We lease approximately 5,728 square feet of office space for our company headquarters in Wellesley Hills, Massachusetts under a non-cancelable operating lease, as amended, that expires in December 2026, with an option to extend for an additional 12 months. We believe that our facility arrangement is sufficient for our current needs.

Item 3. Legal Proceedings.

Information with respect to legal proceedings is included in Note 8 of the Notes to Consolidated Financial Statements contained in Part II, Item 8 of this Annual Report on Form 10-K, which is incorporated herein by reference.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock has been listed on the Nasdaq Global Market under the symbol "ELYM" since August 10, 2021 and "CLYM" since October 2024. Prior to our IPO on August 10, 2021, there was no public market for our common stock.

Holders of Common Stock

As of February 27, 2026, there were 47,767,980 shares of our common stock issued and held by approximately 13 stockholders of record. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. We do not intend to pay cash dividends on our common stock for the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant.

Recent Sales of Unregistered Securities

During the fourth quarter of the year ended December 31, 2025, the Company did not sell any equity securities that were not registered under the Securities Act of 1933, as amended, and not previously reported on a Current Report on Form 8-K.

Issuer Purchases of Equity Securities

Not applicable.

Item 6. [Reserved]

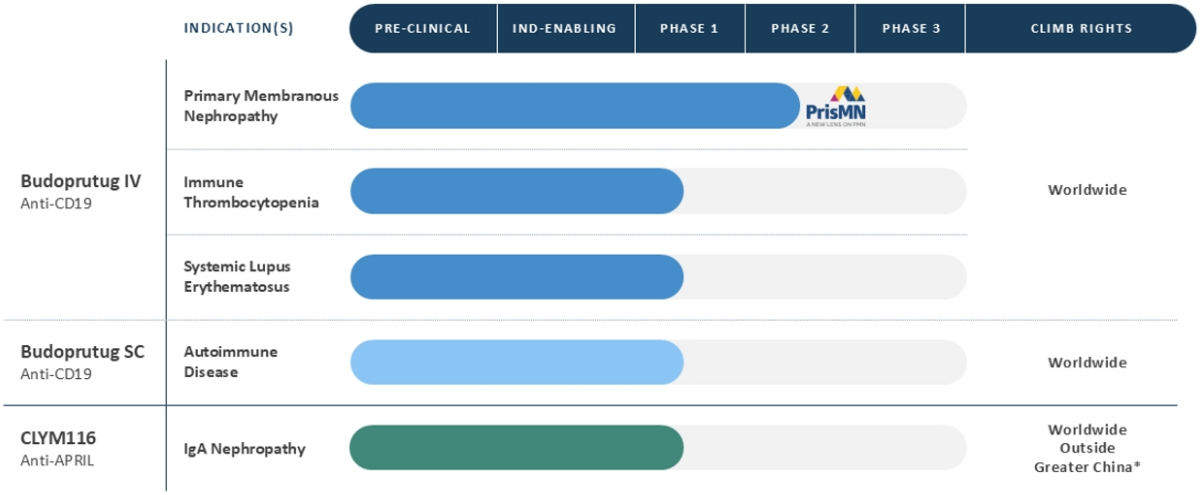
Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes included in "Item 8. Financial Statements and Supplementary Data." in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, 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 I, Item 1A. "Risk Factors" of this Annual Report on Form 10-K, 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 Annual Report on Form 10-K.

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 Greater China.

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, and the sale and issuance of shares in a Private Placement in connection with the Acquisition. 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.

Based on our current operating plan, we estimate that our cash, cash equivalents and marketable securities will be sufficient to fund our planned operations into 2028. We have based this estimate on assumptions that may prove to be wrong, and 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".

Components of Operating Results

Operating Expenses

Our operating expenses consist of (i) research and development expenses, (ii) acquired in-process research and development (IPR&D) expense, related party, and (iii) 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 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."

Acquired In-Process Research and Development, Related Party

Our acquired IPR&D expense consists of the fair value of consideration transferred in the Acquisition allocated to assets acquired that were in the research and development phase and determined to not have any alternative future use.

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 Loss

Our foreign currency loss consists of foreign exchange losses resulting from remeasurement of foreign currency transactions to the U.S. Dollar.

Results of Operations

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

	Year Ended December 31,		Change
	2025	2024	$
Operating expenses:			
Research and development	$ 46,713	$ 14,336	$ 32,377
Acquired in-process research and development, related party	—	51,659	(51,659)
General and administrative	21,170	16,025	5,145
Total operating expenses	67,883	82,020	(14,137)
Loss from operations	(67,883)	(82,020)	14,137
Other income (expense):			
Interest income	8,323	8,132	191
Foreign currency loss	(291)	(9)	(282)
Total other income, net	8,032	8,123	(91)
Net loss	$ (59,851)	$ (73,897)	$ 14,046

Comparison of the Years Ended December 31, 2025 and 2024

Operating Expenses

Research and Development

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

	Year Ended December 31,		Change
	2025	2024	$
Direct research and development expenses:			
Budoprutug	$ 25,045	$ 5,982	$ 19,063
CLYM116	11,964	—	11,964
Legacy programs	107	201	(94)
Unallocated research and development expenses:			
Personnel-related (including stock-based compensation)	8,232	7,990	242
Other research and development expenses	1,365	163	1,202
Total research and development expenses	$ 46,713	$ 14,336	$ 32,377

Research and development expenses increased from $14.3 million for the year ended December 31, 2024 to $46.7 million for the year ended December 31, 2025. The increase was due primarily to an increase of $19.1 million for our budoprutug program, which we acquired as part of the Acquisition on June 27, 2024. Costs incurred for our budoprutug program increased primarily due to costs related to the advancement of our clinical trials of budoprutug in pMN, ITP and SLE, and increased manufacturing costs, and milestone payments under our license agreements. Costs related to our CLYM116 program, which we licensed in January 2025, were $12.0 million, consisting of an upfront payment of $9.0 million under the Mabworks Agreement, milestone payments under our license agreements, and nonclinical, clinical, and manufacturing costs. Personnel-related expenses increased by $0.2 million due primarily to increased headcount and stock-based compensation expense, partially offset by a decrease due to prior year restructuring costs. Research and development expenses for the years ended December 31, 2025 and 2024 included stock-based compensation expense of $3.5 million and $3.0 million, respectively. Other research and development expenses increased by $1.2 million primarily due to an increase in consulting expenses to support our programs.

Acquired In-Process Research and Development, Related Party

Acquired IPR&D expense, related party was $51.7 million for the year ended December 31, 2024. This amount represents the recognition of IPR&D expense from the Acquisition completed on June 27, 2024.

General and Administrative

General and administrative expenses increased from $16.0 million for the year ended December 31, 2024 to $21.2 million for the year ended December 31, 2025. The increase was primarily due to an increase in personnel-related expenses of $3.3 million from increased headcount and stock-based compensation expense. General and administrative expenses for the years ended December 31, 2025 and 2024 included stock-based compensation expense of $4.6 million and $2.5 million, respectively. Legal expenses also increased by $1.0 million.

Other Income (Expense)

Interest Income

Interest income increased from $8.1 million for the year ended December 31, 2024 to $8.3 million for the year ended December 31, 2025 due to higher invested balances, partially offset by lower yields during 2025 as compared to 2024.

Foreign Currency Loss

Foreign currency loss for the year ended December 31, 2025 consisted of the remeasurement of transactions denominated in a foreign currency. Foreign currency loss was not material for the year ended December 31, 2024.

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, and the sale and issuance of shares of our common stock in the Private Placement in connection with the Acquisition. 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 December 31, 2025, we had cash, cash equivalents and marketable securities of $160.7 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 year ended December 31, 2025, 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):

	Year Ended December 31,	
	2025	2024
Net cash used in operating activities	$ (54,356)	$ (15,562)
Net cash provided by (used in) investing activities	2,833	(121,092)
Net cash provided by (used in) financing activities	(21)	130,729

Operating activities

For the year ended December 31, 2025, net cash used in operating activities was $54.4 million, resulting from our net loss of $59.9 million and cash used by changes in our operating assets and liabilities of $0.6 million, partially offset by $6.1 million in non-cash charges. Cash used by changes in our operating assets and liabilities primarily consisted of an increase in other long-term assets of $1.5 million and an increase in prepaid expenses and other current assets of $0.8 million, partially offset by an increase in accounts payable and accrued expenses and other current liabilities of $1.9 million.

For the year ended December 31, 2024, net cash used in operating activities was $15.6 million, resulting from our net loss of $73.9 million, partially offset by $56.6 million in non-cash charges, which consisted primarily of our IPR&D charge of $51.7 million, and cash provided by changes in our operating assets and liabilities of $1.7 million. Cash provided by changes in our operating assets and liabilities primarily consisted of a decrease in prepaid expenses and other current assets of $1.9 million.

Changes in prepaid expenses and other current assets, other assets, accounts payable, and accrued expenses and other current liabilities were generally due to the advancement of our research and development programs and the timing of vendor invoicing and payments.

Investing activities

For the year ended December 31, 2025, net cash provided by investing activities was $2.8 million consisting primarily of $111.1 million in proceeds received from maturities of marketable securities, partially offset by purchases of $108.1 million of marketable securities.

For the year ended December 31, 2024, net cash used by investing activities was $121.1 million, consisting primarily of purchases of $132.2 million of marketable securities, the issuance of a promissory loan of $5.0 million and cash paid of $4.6 million in connection with the Acquisition, partially offset by $20.8 million in proceeds received from maturities of marketable securities.

Financing activities

For the year ended December 31, 2025, net cash used by financing activities was less than $0.1 million, consisting of pre-funded warrant issuance costs, partially offset by $0.1 million in proceeds from exercises of stock options. On December 11, 2025, we entered into the Exchange Agreement, 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 common stock at an exercise price of $0.0001 per share. The exchange of common stock for the pre-funded warrant did not impact cash (See Note 6 to our consolidated financial statements included in this Annual Report on Form 10-K for a discussion of the Exchange Agreement).

For the year ended December 31, 2024, net cash provided by financing activities was $130.7 million, consisting of $119.7 million in proceeds received from the issuance of our common stock in the Private Placement in connection with the Acquisition and $11.0 million in proceeds from exercises of stock options.

Funding Requirements

We believe our existing cash, cash equivalents and marketable securities of $160.7 million as of December 31, 2025 will be sufficient to fund our operations into 2028. We have based this estimate on assumptions that may prove to be wrong, and 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

In the normal course of business, we enter into contracts with CROs, CDMOs, and other third parties for nonclinical studies and clinical trials, supply of materials and manufacturing services. These contracts do not contain material minimum purchase commitments and generally provide us with the option to cancel, reschedule and adjust our requirements based on our business needs, prior to the delivery of goods or performance of services. However, it is not possible to predict the maximum potential amount of future payments under these agreements due to the conditional nature of our obligations and the unique facts and circumstances involved in each agreement.

We have a lease agreement, as amended, for office space in Wellesley Hills, Massachusetts with remaining fixed payments of $0.3 million through December 2026, with an option to extend the lease through December 2027 for additional fixed payments of $0.3 million.

We have obligations under the Asset Purchase Agreement with Acelyrin with respect to Products (as defined in the Asset Purchase Agreement) and certain license agreements that may obligate us to make specified milestone and royalty payments. The payment obligations under these agreements are contingent upon future events, such as our achievement of specified development, regulatory and commercial milestones, or generating product sales. We are unable to estimate the timing or likelihood of achieving these milestones or generating future product sales. See Note 8 to our consolidated financial statements included in this Annual Report on Form 10-K for a discussion of these milestone and royalty obligations.

Critical Accounting Policies and Estimates

Our consolidated financial statements are prepared in accordance with GAAP. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue, costs and expenses, and the disclosure of contingent assets and liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events, and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 to our audited consolidated financial statements, appearing in Part II of Item 8 of this Annual Report on Form 10-K, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate certain research and development expenses. This process involves estimating the level of services performed and the associated cost incurred for services when we have not yet been invoiced or otherwise notified of actual costs, or when payments for such activities differ from the pattern of costs incurred. We make estimates of our accrued expenses or prepaid expenses as of each balance sheet date in our consolidated financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of certain estimates with the service providers. Examples of estimated accrued research and development expenses include those related to fees paid to:

- vendors in connection with nonclinical and clinical development activities, including CROs; and
- the cost of third-party suppliers and manufacturers for material used in our development activities, including CDMOs;

We base the expense recorded on our estimates of the services received and efforts expended pursuant to quotes and contracts with our vendors, CROs and CDMOs that conduct services and supply materials. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. In recording service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. Certain of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; while others require advance payments. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. We record these as prepaid expenses on our consolidated balance sheet. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates of such expenses and the amounts actually incurred.

Stock-Based Compensation

We measure our stock options with service-based vesting or performance-based vesting granted to employees, non-employee directors, consultants and independent advisors based on the estimated fair value on the date of grant using the Black-Scholes option-pricing model. We measure compensation expense for restricted common stock units based on the fair value on the date of grant using the market value of our common stock. Compensation expense for the awards is recognized over the requisite service period for employees and directors and as services are delivered for consultants and independent advisors, both of which are generally the vesting period of the respective award. We use the straight-line method to record the expense of awards with only service-based vesting conditions. We use the graded-vesting method to record the expense of awards with both service-based and performance-based vesting conditions, commencing once achievement of the performance condition becomes probable. The Black-Scholes option-pricing model uses as inputs assumptions we make for the volatility of our common stock, the expected term of our stock options, the risk-free interest rate for a period that approximates the expected term of our stock options and our expected dividend yield. We do not estimate and apply a forfeiture rate as we have elected to account for forfeitures of share-based awards as they occur.

Recently Issued Accounting Pronouncements Not Yet Adopted

See Note 2 to our audited consolidated financial statements, appearing in Part II of Item 8 of this Annual Report on Form 10-K.

Internal Controls 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 December 31, 2025. The material weaknesses, and our remediation plan, are disclosed in Part II of Item 9A of this Annual Report on Form 10-K.

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 presentation of only two years audited consolidated financial statements in a registration statement for an IPO, an exemption from the requirement to provide an auditor's report on internal controls over financial reporting pursuant to 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 7A. 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 8. Financial Statements and Supplementary Data.

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Climb Bio, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Climb Bio, Inc. and its subsidiaries (the "Company") as of December 31, 2025 and 2024, and the related consolidated statements of operations and comprehensive loss, of stockholders' equity and of cash flows for the years then ended, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP
Seattle, Washington
March 5, 2026

We have served as the Company's auditor since 2021.

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

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 35,685	$ 87,229
Short-term marketable securities	65,395	63,690
Prepaid expenses and other current assets	4,769	3,953
Total current assets	105,849	154,872
Long-term marketable securities	59,572	61,610
Operating lease right-of-use assets	505	490
Property and equipment, net	288	199
Other long-term assets	1,530	16
Total assets	$ 167,744	$ 217,187
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,269	$ 705
Accrued expenses and other current liabilities	4,459	4,069
Operating lease liabilities	256	157
Total current liabilities	6,984	4,931
Operating lease liabilities, net of current portion	285	375
Total liabilities	7,269	5,306
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Common stock, $0.0001 par value; 250,000,000 shares authorized; 47,766,338 and 67,255,434 shares issued and outstanding at December 31, 2025 and 2024, respectively	5	7
Additional paid-in capital	449,762	441,727
Accumulated other comprehensive income	435	23
Accumulated deficit	(289,727)	(229,876)
Total stockholders' equity	160,475	211,881
Total liabilities and stockholders' equity	$ 167,744	$ 217,187

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

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

	Year Ended December 31,	
	2025	2024
Operating expenses:		
Research and development	$ 46,713	$ 14,336
Acquired in-process research and development, related party	—	51,659
General and administrative	21,170	16,025
Total operating expenses	67,883	82,020
Loss from operations	(67,883)	(82,020)
Other income (expense):		
Interest income	8,323	8,132
Foreign currency loss	(291)	(9)
Total other income, net	8,032	8,123
Net loss	$ (59,851)	$ (73,897)
Net loss per share, basic and diluted	$ (0.88)	$ (1.53)
Weighted-average common shares outstanding, basic and diluted	67,812,145	48,163,301
Comprehensive loss:		
Net loss	$ (59,851)	$ (73,897)
Other comprehensive income:		
Unrealized gain on marketable securities	412	25
Comprehensive loss	$ (59,439)	$ (73,872)

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

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

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2023	27,626,435	$ 3	$ 263,577	$ (2)	$ (155,979)	$ 107,599
Vesting of restricted stock awards and units	154,599	—	—	—	—	—
Issuance of common stock upon exercise of stock options	2,676,071	—	10,979	—	—	10,979
Issuance of common stock in private placement, net of issuance cost of $250	31,238,282	3	119,747	—	—	119,750
Issuance of common stock for the acquisition of in-process research and development from a related party	5,560,047	1	41,867	—	—	41,868
Stock-based compensation expense	—	—	5,557	—	—	5,557
Unrealized gain on marketable securities	—	—	—	25	—	25
Net loss	—	—	—	—	(73,897)	(73,897)
Balances at December 31, 2024	67,255,434	7	441,727	23	(229,876)	211,881
Vesting of restricted stock units	929,563	—	—	—	—	—
Issuance of common stock upon exercise of stock options	21,341	—	65	—	—	65
Exchange of common stock for pre-funded warrant, net of issuance costs of $86	(20,440,000)	(2)	(84)	—	—	(86)
Stock-based compensation expense	—	—	8,054	—	—	8,054
Unrealized gain on marketable securities	—	—	—	412	—	412
Net loss	—	—	—	—	(59,851)	(59,851)
Balances at December 31, 2025	47,766,338	$ 5	$ 449,762	$ 435	$ (289,727)	$ 160,475

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

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

	Year Ended December 31,	
	2025	2024
Cash flows from operating activities:		
Net loss	$ (59,851)	$ (73,897)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	8,054	5,557
Non-cash operating lease expense	201	220
Accretion of discounts on marketable securities, net	(2,274)	(757)
Depreciation and amortization expense	97	—
In-process research and development, related party	—	51,659
Unrealized foreign currency transaction (gain) loss	18	(42)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(816)	1,942
Other long-term assets	(1,514)	(200)
Accounts payable	1,564	(963)
Accounts payable and accrued liabilities, related party	—	(177)
Accrued expenses and other current liabilities	372	1,445
Operating lease liabilities	(207)	(327)
Long-term liabilities	—	(22)
Net cash used in operating activities	(54,356)	(15,562)
Cash flows from investing activities:		
Purchases of property and equipment	(186)	—
Purchases of marketable securities	(108,078)	(132,197)
Maturities of marketable securities	111,097	20,750
Issuance of promissory loan in connection with asset acquisition	—	(5,000)
Cash paid in connection with asset acquisition, net of cash received	—	(4,645)
Net cash provided by (used in) investing activities	2,833	(121,092)
Cash flows from financing activities:		
Proceeds from exercise of stock options	65	10,979
Pre-funded warrant issuance costs	(86)	—
Proceeds from issuance of common stock in private placement, net of issuance costs	—	119,750
Net cash provided by (used in) financing activities	(21)	130,729
Effect of exchange rate changes on cash and cash equivalents	—	42
Net change in cash and cash equivalents	(51,544)	(5,883)
Cash and cash equivalents at beginning of period	87,229	93,112
Cash and cash equivalents at end of period	$ 35,685	$ 87,229
Supplemental disclosure of noncash investing and financing activities:		
Issuance of common stock in exchange for in-process research and development	$ —	$ 41,867
Settlement of promissory loan in connection with asset acquisition	$ —	$ 5,036

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

Note 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.

On June 27, 2024, the Company completed its acquisition of Tenet Medicines, Inc. (the Acquisition). In connection with the closing of the Acquisition, the Company issued and sold 31,238,282 shares of its common stock at a price of $3.84 per share in a private placement to several accredited institutional investors (the Private Placement). The Company received aggregate gross proceeds from the Private Placement of approximately $120.0 million, before deducting offering costs of $0.3 million (see Note 3). On January 8, 2025, the Company entered into a technology transfer and exclusive license agreement (the Mabworks Agreement) with Beijing Mabworks Biotech Co., Ltd. (Mabworks), for rights to develop and commercialize CLYM116 for all indications worldwide outside of mainland China, Hong Kong, Macau, and Taiwan (Greater China) (see Note 8).

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 consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States (U.S. GAAP). 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 consolidated financial statements reflect the operations of the Company and its wholly owned subsidiaries. Intercompany transactions and balances have been eliminated in consolidation.

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 $289.7 million as of December 31, 2025 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 year ended December 31, 2025, the Company did not issue and sell any shares of its common stock pursuant to the Distribution Agreement.

The Company believes its available cash, cash equivalents and marketable securities of $160.7 million as of December 31, 2025 will be sufficient to meet its projected operating requirements for at least the next twelve months from the filing date of these consolidated financial statements, and 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.

Note 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 consolidated financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

Use of Estimates

The preparation of 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.

Segment Information

The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. Significantly all of the Company’s tangible assets are held in the United States.

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.

Cash and Cash Equivalents

The Company considers all highly liquid investments with maturities of three months or less from the purchase date to be cash equivalents.

Marketable Securities

The Company classifies its marketable securities as available-for-sale. Marketable securities with remaining maturities of less than one year from the balance sheet date are classified as short-term marketable securities. Marketable securities with remaining maturities of greater than one year from the balance sheet date are classified as long-term marketable securities. The Company reports available-for-sale investments at fair value as of each balance sheet date and records unrealized gains or losses as a component of stockholders' equity in accumulated other comprehensive income (loss). Realized gains and losses of securities sold are determined on a specific identification basis and included in other income (expense) within the consolidated statements of operations and comprehensive loss.

When the fair value is below the amortized cost of a marketable security, the Company estimates the portion of the unrealized loss that relates to credit. The credit-related impairment amount is recorded in other income (expense) in the consolidated statements of operations and comprehensive loss. Credit losses are recognized through the use of an allowance for credit losses account in the consolidated balance sheet and subsequent improvements in expected credit losses are recorded as a reversal of an amount in the allowance account. If the Company intends to sell the security or it is more likely than not that the Company will be required to sell the security prior to recovery of its amortized cost basis, then the allowance for the credit loss, if any, is written-off and the excess of the amortized cost basis of the asset over its fair value is recognized in other income (expense) in the consolidated statements of operations and comprehensive loss. There were no credit losses recorded during the years ended December 31, 2025 and 2024.

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.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity that result from transactions and economic events other than those with stockholders. The Company's only element of other comprehensive income (loss) is unrealized gains and losses on available-for-sale marketable securities.

Asset Acquisitions

In determining whether an acquisition of assets and related liabilities should be accounted for as a business combination or asset acquisition, the Company first determines whether substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or a group of similar identifiable assets. If this is the case, the single identifiable asset or the group of similar assets is not deemed to be a business and the acquisition is accounted for as an asset acquisition. If this is not the case, the Company then further evaluates whether the acquisition includes, at a minimum, an input and a substantive process that together significantly contribute to the ability to create outputs. If so, the Company concludes that the acquisition is a business and accounts for it as a business combination.

The Company measures and recognizes asset acquisitions that are not deemed to be business combinations based on the cost to acquire the asset or group of assets, which includes transaction costs, allocated on a relative fair value basis. Goodwill is not recognized in asset acquisitions. In an asset acquisition, the cost allocated to acquire in-process research and development (IPR&D) with no alternative future use is charged to expense at the acquisition date.

Property and Equipment

Property and equipment are recorded at cost and depreciated using the straight-line method over the estimated useful life of each asset.

	Estimated Useful Life
Furniture and fixtures	5 years
Leasehold improvements	Shorter of remaining life of lease or useful life

When an item is sold or retired, the costs and related accumulated depreciation are eliminated, and the resulting gain or loss, if any, is credited or charged to operating loss in the consolidated statements of operations and comprehensive loss. Repairs and maintenance costs are expensed as incurred.

Leases

The Company accounts for leases under ASC Topic 842, Leases ("ASC 842"). In accordance with ASC 842, the Company accounts for a contract as a lease when it has the right to control the asset for a period of time while obtaining substantially all of the asset's economic benefits. The Company determines if an arrangement is a lease or contains an embedded lease at inception. For arrangements that meet the definition of a lease, the Company determines the initial classification and measurement of its right-of-use asset and lease liability at the lease commencement date and thereafter if modified. The lease term includes any renewal options that the Company is reasonably assured to exercise. The present value of lease payments is determined by using the interest rate implicit in the lease, if that rate is readily determinable; otherwise, the Company uses its estimated secured incremental borrowing rate for that lease term. The Company's policy is to not record leases with an original term of 12 months or less on its consolidated balance sheets and recognizes those lease payments in the income statement on a straight-line basis over the lease term. The Company's existing lease is for office space.

In addition to rent, leases may require the Company to pay additional costs, such as utilities, maintenance and other operating costs, which are generally referred to as non-lease components. The Company has elected to not separate lease and non-lease components. Only the fixed costs for lease components and their associated non-lease components are accounted for as a single lease component and recognized as part of a right-of-use asset and lease liability. Rent expense for operating leases is recognized on a straight-line basis over the reasonably assured lease term based on the total lease payments and is included in operating expense in the consolidated statements of operations and comprehensive loss.

Long-Lived Assets

Long-lived assets consist of property and equipment and right-of-use assets. The Company reviews the recoverability of its long-lived assets, including the related useful lives, whenever events or changes in circumstances indicate that the carrying amount of a long-lived asset might not be recoverable, based on undiscounted cash flows. If such assets are considered to be impaired, an impairment loss is recognized and is measured as the amount by which the carrying amount of the assets exceed their estimated fair value, which is measured based on the projected discounted future net cash flows arising from the assets.

Research and Development Expenses

Research and development expenses consist of costs incurred in performing research and development activities, including salaries and bonuses, stock-based compensation, employee benefits, termination benefits, facilities costs and depreciation, and external costs of vendors engaged to conduct research, nonclinical and clinical development activities as well as the cost of acquiring and licensing technology.

Upfront payments and milestone payments made for the licensing of technology are expensed as research and development over the period to which they relate. Costs for research and development activities are expensed in the period in which they are incurred. Payments for such activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the consolidated financial statements as prepaid expense or accrued research and development expense. Determining the prepaid and accrued balances at the end of any reporting period incorporate certain judgments and estimates by management that are based on information available to the Company including information provided by vendors regarding the progress to completion of specific tasks or costs incurred.

Patent costs

All patent-related costs incurred in connection with filing and prosecuting patent applications are recorded as general and administrative expenses as incurred.

Stock-Based Compensation

The Company measures its stock options with service-based vesting or performance-based vesting granted to employees, non-employee directors, consultants and independent advisors based on the estimated fair value on the date of grant using the Black-Scholes option-pricing model. The Company measures compensation expense for restricted common stock units based on the fair value on the date of grant using the market value of the Company's common stock. Compensation expense for the awards is recognized over the requisite service period for employees and directors and as services are delivered for consultants and independent advisors, both of which are generally the vesting period of the respective award. The Company uses the straight-line method to record the expense of awards with only service-based vesting conditions. The Company uses the graded-vesting method to record the expense of awards with both service-based and performance-based vesting conditions, commencing once achievement of the performance condition becomes probable. The Company accounts for forfeitures of share-based awards as they occur.

The Company classifies stock-based compensation expense in its consolidated statements of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

Income Taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements or in the Company's tax returns. Deferred tax assets and liabilities are determined on the basis of the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes.

The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to the provision for income taxes. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty in income taxes recognized in the consolidated financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the consolidated financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. Any resulting unrecognized tax benefits are recorded within the provision for income taxes.

Net Loss Per Share

Basic net loss per share attributable to common stockholders is computed by dividing net loss attributable to common stockholders by the weighted average number of common shares outstanding for the period. Diluted net loss per share attributable to common stockholders is computed by dividing net loss attributable to common stockholders by the weighted average number of common shares outstanding for the period, adjusted for potential dilutive common shares.

In periods in which the Company reported a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive.

The Company reported a net loss attributable to common stockholders for the years ended December 31, 2025 and 2024.

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. 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.

Note 3. Asset Acquisition and Private Placement with a Related Party

Background

The Company entered into (i) an Agreement and Plan of Merger and Reorganization, dated as of April 10, 2024 (the Acquisition Agreement), by and among the Company, Tango Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of the Company (Transitory Subsidiary), Tenet Medicines, Inc. (Tenet), a Delaware corporation, and, solely in his capacity as Tenet equityholder representative, Stephen Thomas, providing for the acquisition of Tenet by the Company through the merger of Transitory Subsidiary into Tenet, with Tenet surviving as a wholly owned subsidiary of the Company, (ii) a Securities Purchase Agreement, dated as of April 10, 2024 (the Securities Purchase Agreement), by and among the Company and several accredited institutional investors (the PIPE Investors) including funds affiliated with RA Capital Management, L.P. (RA Capital Management), pursuant to which the Company agreed to issue and sell to the PIPE Investors in the Private Placement an aggregate of 31,238,282 shares (the PIPE Shares) of the Company's common stock, and (iii) a registration rights agreement with the PIPE Investors, pursuant to which the Company agreed to register for resale the PIPE Shares.

On June 27, 2024, the Company completed its acquisition of Tenet in accordance with the terms of the Acquisition Agreement. Tenet was a private, development stage biotechnology company that was majority-owned by funds affiliated with RA Capital Management prior to the closing of the Acquisition. Immediately prior to the closing of the Acquisition and Private Placement, RA Capital Management beneficially owned approximately 43.9% of the Company's outstanding common stock. The Private Placement closed immediately following the closing of the Acquisition. The Company received aggregate gross proceeds from the Private Placement of approximately $120.0 million, before deducting offering costs of $0.3 million. The offering costs were recorded as a reduction of additional paid-in capital generated in connection with the Private Placement.

At the effective time of the Acquisition, by virtue of the Acquisition and without any action on the part of the holders of common stock of Tenet, (i) all issued and outstanding shares of the common stock of Tenet and (ii) all securities convertible into shares of common stock of Tenet were converted into the right to receive, in the aggregate, 5,560,047 shares of the Company's common stock.

Acquisition Accounting

The Company accounted for the Acquisition as an asset acquisition and accordingly, total consideration of $52.8 million, comprised of the fair value of common stock issued of $41.9 million, settlement of pre-existing loan of $5.0 million and transaction costs of $5.8 million, was allocated to the assets acquired and liabilities assumed on a relative fair value basis. The following table sets forth the allocation of the purchase consideration (in thousands):

Assets acquired		
In-process research and development	$	51,659
Cash and cash equivalents		1,204
Prepaid expenses and other current assets		1,861
Total assets acquired		54,724
Liabilities assumed		
Accounts payable		(1,603)
Accounts payable, related party		(101)
Accrued expenses and other current liabilities		(192)
Accrued expenses, related party		(76)
Total liabilities assumed		(1,972)
Net assets acquired	$	52,752

The value of the IPR&D was expensed in the consolidated statements of operations and comprehensive loss, as the IPR&D was determined to have no future alternative use.

Note 4. Marketable Securities and Fair Value Measurements

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

	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 December 31, 2024			
	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Short-term marketable securities:				
Corporate bonds	$ 33,519	$ 23	$ (5)	$ 33,537
U.S. Treasury securities	30,130	27	(4)	30,153
Total short-term marketable securities	$ 63,649	$ 50	$ (9)	$ 63,690
Long-term marketable securities:				
Corporate bonds	$ 33,982	$ 16	$ (43)	$ 33,955
U.S. Treasury securities	24,146	23	(15)	24,154
U.S. government agency debt securities	3,500	1	—	3,501
Total long-term marketable securities	$ 61,628	$ 40	$ (58)	$ 61,610

As of December 31, 2025, the Company's long-term marketable securities have contractual maturity dates between one and two years.

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 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

	Fair Value Measurements at December 31, 2024 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 85,612	$ —	$ —	$ 85,612
Marketable securities:				
U.S. Treasury securities	54,307	—	—	54,307
Corporate bonds	—	67,492	—	67,492
U.S. government agency debt securities	—	3,501	—	3,501
Total marketable securities	54,307	70,993	—	125,300
Total assets	$ 139,919	$ 70,993	$ —	$ 210,912

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.

Note 5. Accrued Expenses and Other Current Liabilities

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

	December 31,	
	2025	2024
Accrued payroll and related expenses	$ 1,891	$ 1,997
Accrued external research and development expenses	1,816	1,237
Accrued professional fees	693	746
Other accrued expenses and current liabilities	59	89
Total accrued expenses and other current liabilities	$ 4,459	$ 4,069

Note 6. Related Party Transactions

Equity

On December 11, 2025, the Company entered into an exchange agreement (the Exchange Agreement) with 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.

In June 2024, the Company issued shares to RA Capital Management and affiliates in connection with the Acquisition and Private Placement (see Note 3).

Service Agreements

As a result of the Acquisition, the following legacy Tenet agreements effectively became agreements of the Company.

Tenet was a party to a service agreement with Sera Services, Inc. (Sera Services), a wholly-owned subsidiary of Sera Medicines, LLC (Sera Medicines) to provide research and other services to the Company. Sera Medicines is an entity controlled by RA Capital Management, and Dr. Stephen Thomas, a current board member of the Company, owns a minority ownership in and is also a board member of Sera Medicines. No services were provided under the Sera Services Agreement for the year ended December 31, 2025 and, in March 2026, the Company terminated the agreement. The Company paid $0.1 million to Sera Services for services provided under the Sera Services Agreement for the year ended December 31, 2024.

Tenet was a party to a service agreement with Blackbird Clinical, Inc. (Blackbird), an entity controlled by RA Capital Management. Under the terms of the service agreement, Blackbird provided consulting services to Tenet in connection with its clinical trials. For the year ended December 31, 2024, the Company paid approximately $0.1 million to Blackbird under the Blackbird Service Agreement. In October 2024, the Company terminated the Blackbird Service Agreement.

Note 7. Leases

The Company leases office space under a non-cancelable operating lease in Wellesley, Massachusetts under a 24-month lease agreement that expires in December 2026. The lease contains rent escalation clauses and an option to extend the term of the lease for an additional 12-month period at a market rate determined according to the lease. At the lease's inception and as of December 31, 2025, the Company expects to exercise its option to extend the lease, and therefore the period covered by this option is included in the lease term.

In April 2025, the Company amended the lease to add space to the existing lease for additional fixed payments totaling $0.2 million through 2026 with an option to extend the lease through 2027 for additional fixed payments of $0.1 million. As the Company expects to exercise its option to extend the lease, the extension period is included in the lease term. Accordingly, the Company recorded an increase to operating lease right-of-use assets and operating lease liabilities of $0.2 million.

The Company previously leased office space in Bellevue, Washington, which expired in January 2025, and Cambridge, U.K., which expired in June 2024.

The components of lease expense were as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Operating lease cost	$ 250	$ 243
Short-term lease cost	—	—
Variable lease cost	9	86
	$ 259	$ 329

Supplemental disclosure of cash flow information related to leases was as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Cash paid for amounts included in the measurement of operating lease liabilities	$ 256	$ 350
Operating lease liabilities arising from obtaining right-of-use asset	$ 216	$ 510

The weighted-average remaining lease term and discount rate were as follows:

	Year Ended December 31,	
	2025	2024
Weighted-average remaining lease term - operating lease (in years)	2.0	2.9
Weighted-average discount rate - operating lease	8.5%	8.5%

As of December 31, 2025, the annual future minimum lease payments due under the Company's non-cancelable operating lease was as follows (in thousands):

Year ending December 31,	
2026	$ 293
2027	298
Total undiscounted lease payments	591
Less: imputed interest	(50)
Total operating lease liabilities	$ 541

Total operating lease liabilities in the table above are classified on the consolidated balance sheet as follows (in thousands):

Included in the consolidated balance sheet (in thousands):		
Current operating lease liability	$	256
Operating lease liability, net of current portion		285
Total operating lease liabilities	$	541

Note 8. Commitments and Contingencies

Operating Leases

The Company's commitments under its leases are described in Note 7.

License Agreements (Budoprutug)

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 (the Transferred Assets), including certain assigned contracts. Under these assigned contracts, the Company (i) received worldwide licenses (with the right to sublicense) to certain patents, know-how and other intellectual property rights to develop, manufacture, use and commercialize budoprutug for any non-oncology indication, and (ii) assumed certain liabilities of Acelyrin arising from (1) governmental authority action or notification relating to budoprutug, (2) contracts assigned to the Company pursuant to the Asset Purchase Agreement and (3) the Company's ownership, lease or operation of the Transferred Assets. The Asset Purchase Agreement includes customary representations, warranties and covenants, as well as standard mutual indemnities, including those covering losses arising from any material breach of the Asset Purchase Agreement.

Under the Asset Purchase Agreement, the Company also acquired the rights and obligations, including financial obligations, under a license agreement with Cancer Research Technology Limited (CRH), which Tenet subsequently amended and restated in the CRH Agreement (as defined below) and a cell line development, manufacturing services and license agreement with ProBioGen AG (ProBioGen).

Under the Asset Purchase Agreement with respect to any "Product" (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.

The royalty term continues for each Product on a country-by-country and Product-by-Product basis beginning on the first commercial sale of such Product and ending on the latest of (a) the date when such Product is no longer covered by a valid claim of a royalty-bearing patent (as such term is defined in the Asset Purchase Agreement) in such country, (b) the expiration of any regulatory exclusivity period for such Product in such country, and (c) the twelfth anniversary of the first commercial sale of such Product in such country.

The Company is obligated to use commercially reasonable efforts to commercialize at least one Product in the U.S., to the extent a Product exists under the Asset Purchase Agreement, and to achieve specified development, regulatory and commercial milestones for such Product set forth in the Asset Purchase Agreement.

To the extent a Product exists under the Asset Purchase Agreement, if Acelyrin asserts that the Company has failed to meet a specified diligence obligation under the Asset Purchase Agreement within specified time periods, and such failure is finally determined through a dispute resolution process, Acelyrin may elect, in lieu of a claim for damages, to repurchase the Transferred Assets at the then-fair market value of such Transferred Assets, as Acelyrin's sole and exclusive remedy for such breach.

If, within a specified period following the top line data readout from the first Phase 2 clinical trial of a Product, the Company receives a bona fide offer or proposal from a third party to sell, transfer or otherwise divest all or substantially all of the rights to the Transferred Assets or Products, or grant an exclusive license or exclusive sublicense to such third party to develop and commercialize Products under specified terms, then prior to entering into any discussions or negotiations with any third party in relation to such a transaction, the Company shall provide written notice to Acelyrin of such intent or receipt of proposal. Acelyrin shall have the right to negotiate with the Company the terms for a definitive agreement with respect to such sale, transfer or grant of the rights to Products for a specified period of time. If Acelyrin does not exercise its right to negotiate or the parties are unable to agree on the terms of a definitive agreement, the Company shall have the right to negotiate or enter into an agreement with a third party with respect to such transaction, subject to specified conditions.

The Company may not sell, assign or transfer all or substantially all of the rights to develop or commercialize a Product unless, as a condition to such sale, assignment or transfer, the purchaser, assignee or transferee (as applicable) assumes in writing all of our obligations as set forth in the Asset Purchase Agreement with respect to the applicable Products.

The Company records expense related to milestone payments when achievement of the milestone is assessed as probable. As of December 31, 2025, the Company has not recorded expense related to milestone payments under the Asset Purchase Agreement. 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 the Asset Purchase Agreement as further described below.

CRH Agreement

In connection with the Asset Purchase Agreement, in January 2024 Tenet was assigned a license agreement with 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) under certain know-how, patents and materials, or the licensed rights, 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. CRH retains, on behalf of itself and the charitable company Cancer Research U.K., a worldwide, fully paid-up, perpetual and irrevocable right in the licensed rights and in certain intellectual property owned or controlled by the Company that is necessary to exploit the licensed products and used, conceived or generated in the course of exercising the license or exploiting any licensed product, or product-specific foreground intellectual property, for the purpose of non-commercial, non-clinical scientific research.

The Company is obligated to use commercially reasonable efforts to perform all activities set forth in a mutually agreed-upon development plan within the timelines set forth therein. The Company is also obligated to develop at least one licensed product in an autoimmune indication and to pursue worldwide regulatory authorization for licensed products. The Company must use commercially reasonable efforts to commercialize each licensed product throughout each of the specified major markets as soon as practicable following receipt of regulatory authorization for such product in such market. Additionally, the Company must use commercially reasonable efforts to make the licensed product available through the U.K. and negotiate with relevant regulatory authorities to make each licensed product available through the National Health Service in England and Wales within a specified time of the licensed product being made available elsewhere in the territory. If the Company fails to meet one or more of these diligence obligations, and such failure is not remedied within the specified cure period, CRH shall have the right to terminate the CRH Agreement with respect to the relevant licensed product.

The Company is obligated to pay CRH a mid-five figure digit fee on each anniversary of the effective date. The Company is obligated to pay up to an aggregate of £106.8 million ($143.6 million as of December 31, 2025) 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 royalty term continues for each licensed product on a country-by-country basis beginning on the first commercial sale of such licensed product and ending on the latest of (a) the date when such licensed product is no longer covered by a valid claim of a licensed patent in such country, (b) the expiration of the exclusivity period for such licensed product in such country, and (c) the tenth anniversary of the first commercial sale of such licensed product in such country. 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 CRH Agreement shall remain in effect in each country in the territory until the expiry of our obligation to pay royalties in such country. Either party may terminate the CRH Agreement if the other party is in material breach that has not been remedied within the specified cure period or if the other party becomes insolvent. CRH also has the right to terminate the CRH Agreement if the Company or one of its sublicensees or affiliates challenges a licensed patent, or if the Company is acquired by a tobacco company.

The Company records expense related to milestone payments when achievement of the milestone is assessed as probable. During the year ended December 31, 2025, the Company recorded $1.0 million of research and development expense related to the milestones.

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 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 under certain know-how, patents and materials, 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 ($11.7 million as of December 31, 2025) 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 ($8.2 million as of December 31, 2025) 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 December 31, 2025).

The ProBioGen Agreement will remain in effect until the services are completed for the service-related component and until the payment obligations expire in connection with the commercial license component. Both parties have the right to terminate the ProBioGen Agreement if the other party becomes insolvent, or materially breaches the ProBioGen Agreement and fails to remedy such default within the specified cure period.

The Company records expense related to milestone payments when achievement of the milestone is assessed as probable. During the year ended December 31, 2025, the Company recorded $2.7 million of research and development expense related to the milestones.

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, identified as MIL116 (the Licensed Compounds or CLYM116) and products containing the Licensed Compounds (Licensed Products) outside of Greater China (the Licensed Territory), (ii) a non-exclusive, sublicensable right and license under the Licensed Intellectual Property to manufacture the Licensed Compounds and Licensed Products in Greater China and (iii) a non-exclusive, sublicensable right and license under the Licensed Intellectual Property to develop the Licensed Compounds and Licensed Products in the 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 is obligated to pay royalties on a Licensed Product-by-Licensed Product and country-by-country basis from the date of the first commercial sale in such country until the latest of: (i) the expiration of the last valid claim on the Licensed Intellectual Property covering the composition of matter of the Licensed Compound in such Licensed Product in such country; and (ii) ten years following the first commercial sale of such Licensed Product in such country (each, a Royalty Term). The royalty rate is subject to reduction on a Licensed Product-by-Licensed Product and country-by-country basis under certain circumstances. In the event that the Company grants sublicenses under the

Licensed Intellectual Property, the Company will be obligated to pay Mabworks a percentage, in the mid-single-digits to low-double-digits, of certain consideration received under such sublicenses.

The Company agreed to use commercially reasonable efforts to develop, obtain regulatory approval for and commercialize a Licensed Product in the U.S. The Company has also granted Mabworks a right of first refusal to develop and commercialize in Greater China any product the Company controls that contains an antibody directed to tumor necrosis factor ligand superfamily member 13 (APRIL). Mabworks has agreed not to exploit in the Licensed Territory any product that is directed to APRIL during the term of the Mabworks Agreement. The Mabworks Agreement also contains a mechanism for the parties to collaborate on global clinical studies in the future, where the Company has a right to perform clinical studies in Greater China with Mabworks' approval in the event that Mabworks elects not to participate in such global clinical studies. Unless earlier terminated, the Mabworks Agreement will expire on the expiration of the last to expire Royalty Term. Either party may terminate the Mabworks Agreement for the other party's material breach, following a customary notice and cure period, or insolvency. Additionally, the Company may terminate the Mabworks Agreement for any reason upon 60 days written notice to Mabworks.

The Company recorded the upfront payment of $9.0 million as research and development expenses in the first quarter of 2025 in the 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 year ended December 31, 2025, the Company recorded $1.0 million of research and development expense related to a milestone.

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 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 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 consolidated financial statements as of December 31, 2025.

Note 9. 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 authorized shares reserved for issuance under the 2021 Plan was increased by 3,362,771 shares effective as of January 1, 2025 in accordance with the provisions of the 2021 Plan described above. As of December 31, 2025, 3,124,834 shares remained available for future grant under the 2021 Plan. The number of shares reserved for issuance under the 2021 Plan was increased by 2,388,316 shares effective January 1, 2026.

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 awards, 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 December 31, 2025, 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 authorized shares reserved for issuance under the ESPP was increased by 672,554 shares effective as of January 1, 2025 in accordance with the provisions of the ESPP described above. The first offering period began on December 16, 2025 and will end on June 15, 2026. As of December 31, 2025, no shares had been granted or purchased under the ESPP and 1,736,779 shares remained available for issuance under the ESPP. The number of shares reserved for issuance under the ESPP was increased by 477,663 shares effective January 1, 2026.

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 option grants during the years ended December 31, 2025 and 2024 is as follows, presented on a weighted-average basis:

	Year Ended December 31,	
	2025	2024
Expected term (in years)	6.0	6.1
Expected volatility	103.6%	104.0%
Risk-free interest rate	4.3%	4.0%
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 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, 2024	2,817,751	$ 6.49	6.87	$ 19
Options granted	5,766,696	1.77		
Options exercised	(21,341)	3.04		
Options forfeited	(2,135,329)	4.85		
Outstanding as of December 31, 2025	6,427,777	$ 2.81	9.05	$ 11,727
Vested and expected to vest as of December 31, 2025	6,427,777	$ 2.81	9.05	$ 11,727
Options exercisable as of December 31, 2025	631,921	$ 6.24	8.00	$ 331

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 aggregate intrinsic value of options exercised during the years ended December 31, 2025 and 2024 was less than $0.1 million and $6.4 million, respectively.

The weighted-average grant date fair value of stock options granted during the years ended December 31, 2025 and 2024 was $1.45 and $5.56 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, 2024	1,228,876	$ 7.17
Granted	1,084	4.62
Vested	(929,563)	7.27
Forfeited	(92,500)	5.44
Unvested at December 31, 2025	207,897	$ 7.50

The total fair value of restricted stock vested during the years ended December 31, 2025 and 2024 was $1.5 million and $0.9 million, respectively

Stock-Based Compensation

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

	Year Ended December 31,	
	2025	2024
Research and development expenses	$ 3,503	$ 3,032
General and administrative expenses	4,551	2,525
Total stock-based compensation expense	$ 8,054	$ 5,557

Stock-based compensation expense for the year ended December 31, 2025 included $3.0 million related to performance-based RSUs that vested in the third quarter of 2025 upon achievement of the performance conditions. As of December 31, 2025, there was $11.7 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 2.9 years.

Note 10. Net Loss Per Share

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 6). 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):

	Year Ended December 31,	
	2025	2024
Numerator:		
Net loss	$ (59,851)	$ (73,897)
Denominator:		
Weighted-average common shares outstanding, basic and diluted	66,692,145	48,163,301
Weighted-average common shares outstanding under the pre-funded warrant, basic and diluted	1,120,000	—
Weighted-average common shares outstanding, basic and diluted	67,812,145	48,163,301
Net loss per share, basic and diluted	$ (0.88)	$ (1.53)

The following outstanding shares of potentially dilutive securities were excluded from the computation of diluted net loss per share for the periods presented because their effect would have been anti-dilutive:

	December 31,	
	2025	2024
Stock options to purchase common stock	6,427,777	2,817,751
Unvested restricted stock units	207,897	1,228,876
Shares of common stock issuable under the ESPP	23,944	—
Total potentially dilutive shares	6,659,618	4,046,627

Note 11. Income Taxes

The components of net loss before tax provision from income taxes are as follows (in thousands):

	Year Ended December 31,	
	2025	2024
United States	$ (59,579)	$ (67,137)
United Kingdom	(272)	(6,760)
Total	$ (59,851)	$ (73,897)

The following table presents a reconciliation of the Company's expected tax computed at the U.S. statutory federal income tax rate to the total provision for income taxes (in thousands):

	Year Ended December 31,	
	2025	2024
U.S. federal taxes at statutory rate	$ (12,569)	$ (15,518)
State taxes, net of federal benefit	—	1
Acquired in-process research and development, related party	—	7,698
Effect of cross-border transfers	1,303	—
Non-deductible officer compensation	293	575
Foreign rate differential	237	(211)
Stock-based compensation	83	588
Tax credits	(403)	(86)
Other expenses, net	(228)	(123)
Change in valuation allowance	11,284	7,076
Effective income tax rate	$ —	$ —

The significant components of the Company's deferred tax assets and liabilities are presented below (in thousands):

	December 31,	
	2025	2024
Deferred tax assets:		
Net operating losses	$ 28,202	$ 22,725
Intangible assets	4,447	1,946
Research and development expenses	3,824	2,388
Stock compensation expense, including 162m limitations	1,400	432
Research credits	1,104	702
Accrued compensation and benefits	332	303
Operating lease liabilities	113	121
Other expenses	37	13
Total deferred tax assets	39,459	28,630
Valuation allowance	(39,368)	(28,492)
Net deferred tax assets	91	138
Deferred tax liabilities:		
Operating lease, right-of-use asset	(106)	(112)
Other assets	15	(26)
Total deferred tax liabilities	(91)	(138)
Net deferred tax assets and liabilities	$ —	$ —

As of December 31, 2025, the Company had federal net operating loss carryforwards of $55.8 million, which may be available to offset future taxable income and do not expire but are limited in their usage to an annual deduction equal to 80% of annual taxable income. As of December 31, 2025, the Company had state net operating loss carryforwards of $9.5 million, which may be available to offset future taxable income and expire at various dates beginning in 2038. As of December 31, 2025, the Company also had U.S. federal and state research and development tax credit carryforwards of $1.0 million and $0.1 million, respectively, which may be available to offset future tax liabilities and expire at various dates beginning in 2039. As of December 31, 2025, the Company had foreign net operating loss carryforwards of $63.2 million, which may be available to offset future taxable income and do not expire.

Utilization of the U.S. federal and state net operating loss carryforwards and research and development tax credit carryforwards may be subject to a substantial annual limitation under Sections 382 and 383 of the Internal Revenue Code of 1986, and corresponding provisions of state law, due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income or tax liabilities. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain stockholders or public groups in the stock of a corporation by more than 50% over a three-year period. The Company has not conducted a study to assess whether a change of control has occurred or whether there have been multiple changes of control since inception due to the significant complexity and cost associated with such a study. If the Company has experienced a change of control, as defined by Section 382, at any time since inception, utilization of the net operating loss carryforwards or research and development tax credit carryforwards would be subject to an annual limitation under Section 382, which is determined by first multiplying the value of the Company's stock at the time of the ownership change by the applicable long-term tax-exempt rate, and then could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the net operating loss carryforwards or research and development tax credit carryforwards before utilization. Further, until a study is completed by the Company and any limitation is known, no amounts are being presented as an uncertain tax position.

As required by ASC 740, management of the Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets, which are comprised principally of net operating loss carryforwards. Management has determined that it is more likely than not that the Company will not recognize the benefits of its deferred tax assets and, as a result, a valuation allowance has been recorded.

The changes in the valuation allowance were as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Valuation allowance as of beginning of year	$ 28,492	$ 20,856
Net increases recorded to income tax provision	10,876	7,636
Valuation allowance as of end of year	$ 39,368	$ 28,492

The increase in the valuation allowance for deferred tax assets during the year ended December 31, 2025 related primarily to an increase in net operating losses. The increase in the valuation allowance for deferred tax assets during the year ended December 31, 2024 related primarily to increases in net operating losses and capitalized research and development costs.

The Company assesses the uncertainty in its income tax positions to determine whether a tax position of the Company is more likely than not to be sustained upon examination, including resolution of any related appeals of litigation processes, based on the technical merits of the position. For tax positions meeting the more-likely-than-not threshold, the tax amount recognized in the consolidated financial statements is reduced by the largest benefit that has a greater than fifty percent likelihood of being realized upon the ultimate settlement with the relevant taxing authority. No reserve for uncertain tax positions or related interest and penalties has been recorded at December 31, 2025 and 2024.

The Company is subject to taxation in the U.S. (federal and various states) and the U.K. Currently, no historical years are under examination. The Company's tax years starting in December 31, 2018 are open and subject to examination by the U.S. (federal and various states) and the U.K. taxing authorities due to the carryforward of utilized net operating losses and research and development credits.

Note 12. Defined Contribution Plans

The Company has a 401(k) defined contribution plan. Participation in the plan is available to substantially all U.S.-based employees. Company contributions are discretionary but the Company has an employer matching program pursuant to which the Company makes matching contributions of up to 4% of each participating employee's eligible compensation. For the years ended December 31, 2025 and 2024, total expense recognized from the 401(k) matching contributions was approximately $0.2 million and $0.1 million, respectively.

Prior to the Company's restructuring in 2024 (see Note 13), the Company had a workplace pension contribution scheme for U.K.-based employees. For the year ended December 31, 2024, the Company made contributions to the pension scheme of approximately $0.1 million.

Note 13. Restructuring Costs

In 2024, the Company shifted its focus from developing therapeutics for neuronal excitability disorders to immune-mediated diseases. In connection with this shift, the Company ceased its operations in the U.K. and separated from seven U.K. employees in 2024. The costs associated with this headcount reduction were fully recognized and all of the related payments were made by December 31, 2024. A summary of the restructuring costs recorded in the consolidated statements of operations and comprehensive loss for the year ended December 31, 2024 were as follows (in thousands):

	Year Ended December 31, 2024			
	ROU Asset Impairment	Severance and Benefit Costs	Stock-based Compensation	Total Restructuring Cost Recorded
Research and development expenses	$ —	$ 1,778	$ 944	$ 2,722
General and administrative expenses	—	475	161	636
Total restructuring costs	$ —	$ 2,253	$ 1,105	$ 3,358

Note 14. 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 in the 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 consolidated balance sheets as total consolidated assets.

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

	Year Ended December 31,	
	2025	2024
Direct research and development expenses:		
Budoprutug	$ 25,045	$ 5,982
CLYM116[1]	11,964	—
Legacy programs[2]	107	201
Unallocated research and development expenses:		
Personnel-related (including stock-based compensation)	8,232	7,990
Other research and development expenses	1,365	163
Total research and development expenses	$ 46,713	$ 14,336

[1] Includes the upfront payment and the associated direct transaction costs incurred in connection with the Mabworks Agreement for the year ended December 31, 2025.

[2] Includes direct expenses related to the Company's legacy product candidates ETX-123 and ETX-155.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

Not applicable.

Item 9A. Controls and Procedures.

Evaluation of Disclosure 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 the 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 December 31, 2025. 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 December 31, 2025 because of the material weaknesses in our internal control over financial reporting described below.

Notwithstanding the material weaknesses, management believes the consolidated financial statements as included in Item 8 of this Annual Report on Form 10-K present fairly, in all material respects, the Company's 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.

Management's Report on Internal Control Over Financial Reporting

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting. The Company's internal control over financial reporting is a process designed under the supervision of our executive chair and our chief accounting officer to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the Company's financial statements for external reporting purposes in accordance with generally accepted accounting principles.

As of December 31, 2025, management conducted an assessment of the effectiveness of the Company's internal control over financial reporting based on the framework established in "Internal Control—Integrated Framework" (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, management has determined that the Company's internal control over financial reporting was not effective as of December 31, 2025, because of the unremediated material weaknesses in our internal control over financial reporting described below.

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 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.

Management's report on internal control over financial reporting was not subject to attestation by the Company's independent registered public accounting firm pursuant to the rules of the SEC that permit the Company to provide only management's report.

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 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;
- Continued to design and implement 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;
- Continued to implement and formalize 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 ended December 31, 2025 that have materially affected, or are reasonably likely to materially affect our internal control over financial reporting.

Item 9B. Other Information.

Director and Officer Trading Arrangements

The adoption or termination of contracts, instructions or written plans for the purchase or sale of our securities by our Section 16 officers and directors for the three months ended December 31, 2025, each of which is intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act ("Rule 10b5-1 Plan"), were as follows:

Name (Title)	Action taken (Date of Action)	Type of Trading Arrangement	Nature of Trading Arrangement	Duration of Trading Arrangement	Aggregate Number of Securities
Stephen Thomas (Director)	Adoption (October 14, 2025)	Rule 10b5-1 trading arrangement	Sale	Until August 8, 2026, or, if earlier, upon the completed sale of the maximum shares	150,000

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Information required by this item and not set forth below will be set forth in the sections headed *Election of Directors* and *Executive Officers* contained in our definitive Proxy Statement to be filed with the Securities and Exchange Commission within 120 days after the conclusion of our fiscal year ended December 31, 2025 (the Proxy Statement) pursuant to General Instructions G(3) of Form 10-K and is incorporated herein by reference.

We have adopted a code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A current copy of our code of business conduct and ethics is available under the Corporate Governance section of our website at climbbio.com. If we make any substantive amendments to the code of business conduct and ethics or grant any waiver from a provision of the code of business conduct and ethics to any executive officer or director that are required to be disclosed pursuant to SEC rules, we will promptly disclose the nature of the amendment or waiver on our website or in a current report on Form 8-K.

Item 11. Executive Compensation.

The information required by this item will be set forth in our Proxy Statement in the sections headed *Executive and Director Compensation* and *Director Compensation* contained in our Proxy Statement and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Information required by this item will be set forth in the sections headed *Security Ownership of Certain Beneficial Owners and Management* and *Executive and Director Compensation* contained in our Proxy Statement and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Information required by this item will be set forth in the sections headed *Certain Related-Person Transactions* and *Information Regarding the Board of Directors and Corporate Governance* contained in our Proxy Statement and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

Information required by this item will be set forth in the sections headed *Ratification of Selection of Independent Registered Public Accounting Firm* contained in our Proxy Statement and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) Documents filed as part of this report

(1) Financial Statements. The following consolidated financial statements of Climb Bio, Inc., together with the report of PricewaterhouseCoopers LLP, an independent registered public accounting firm, required to be filed pursuant to Part II, Item 8 of this Annual Report on Form 10-K are included on the following pages:

	Page
Report of Independent Registered Public Accounting Firm (PCAOB ID 238)	112
Consolidated Balance Sheets	113
Consolidated Statements of Operations and Comprehensive Loss	114
Consolidated Statements of Stockholders' Equity	115
Consolidated Statements of Cash Flows	116
Notes to Consolidated Financial Statements	117

(2) Financial Statement Schedules. None.

(3) List of exhibits required by Item 601 of Regulation S-K. See part (b) below.

(b) Exhibits.

Exhibit Index

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	April 11, 2024
3.1	Amended and Restated Certificate of Incorporation of the Registrant as amended	10-Q	001-40708	3.1	November 12, 2024
3.2	Amended and Restated Bylaws of the Registrant	8-K	001-40708	3.2	October 2, 2024
4.1	Form of common stock certificate of the Registrant	10-K	001-40708	4.1	March 25, 2025
4.2	Amended and Restated Investors Rights Agreements, dated May 21, 2021, by and among the Registrant and the investors listed on Schedule A thereto	S-1	333-257980	10.1	August 2, 2021
4.3	Description of Securities	10-K	001-40708	4.3	March 25, 2025
4.4	Form of Pre-Funded Warrant	8-K	001-40708	4.1	December 11, 2025
10.1+	2021 Equity Incentive Plan	10-K	001-40708	10.1	March 25, 2025
10.2+	Forms of Option Agreement, Stock Option Grant Notice and Notice of Exercise under the 2021 Equity Incentive Plan	10-K	001-40708	10.2	March 25, 2025
10.3+	Forms of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement under the 2021 Equity Incentive Plan	10-K	001-40708	10.3	March 25, 2025
10.4+	2021 Employee Stock Purchase Plan	10-K	001-40708	10.4	March 25, 2025
10.5+	Form of Indemnification Agreement, by and between the Registrant and each of its directors and executive officers	S-1	333-257980	10.8	August 2, 2021
10.6	Registration Rights Agreement, dated April 10, 2024, by and among the Registrant and the persons party thereto	8-K	001-40708	10.5	April 11, 2024
10.7+	Offer Letter, dated June 12, 2024, between the Registrant and Aoife Brennan	8-K	001-40708	10.1	June 12,2024
10.8†	Asset Purchase Agreement, dated as of January 4, 2024, by and between Tenet Medicines, Inc., Acelyrin, Inc. and WH2, LLC	8-K	001-40708	10.1	June 27, 2024
10.9†	Amended and Restated License Agreement, dated as of January 11, 2024, by and between Tenet Medicines, Inc. and Cancer Research Technology Limited	8-K	001-40708	10.2	June 27, 2024
10.10†	Cell Line Development, Manufacturing Services and License Agreement, effective as	8-K	001-40708	10.3	June 27, 2024

	of February 9, 2021 by and between Valenza Bio, Inc. and ProBioGen, Inc.				
10.11+	Offer Letter, dated September 30, 2025 between the Registrant and Susan Altschuller, Ph.D, MBA	8-K	001-40708	10.1	October 1, 2025
10.12	Separation and Release of Claims Agreement, dated as of May 23, 2025, by and between the Registrant and Brett Kaplan, M.D.	8-K	001-40708	10.1	May 23, 2025
10.13+	Offer Letter, dated February 1, 2025 between the Registrant and Perrin Wilson	10-Q	001-40708	10.1	August 12, 2025
10.14+	Consulting Agreement, dated June 27, 2024, between the Registrant and Stephen Thomas	10-Q	001-40708	10.1	November 12, 2024
10.15+	Amendment to Consulting Agreement, dated November 1, 2024, between the Registrant and Stephen Thomas	10-Q	001-40708	10.2	November 12, 2024
10.16	Technology Transfer and Exclusive License Agreement, dated January 8, 2025, by and between the Registrant and Beijing Mabworks Biotech Co., Ltd.	10-K	001-40708	10.14	March 25, 2025
10.17	Equity Distribution Agreement, dated as of March 25, 2025, by and between the Registrant and Oppenheimer & Co. Inc.	8-K	001-40708	1.1	March 25, 2025
10.18	2025 Inducement Plan, as amended	10-Q	001-40708	10.1	November 6, 2025
10.19+	Form of Stock Option Grant Notice under the 2025 Inducement Plan	10-Q	001-40708	10.4	May 14, 2025
10.20+	Form of Restricted Stock Unit Award Grant Notice under the 2025 Inducement Plan	10-Q	001-40708	10.5	May 14, 2025
10.21+	Non-Employee Director Compensation Policy	10-Q	001-40708	10.6	May 14, 2025
10.22	Exchange Agreement, dated December 11, 2025, between the Registrant and the holders of the common stock listed on Schedule I attached thereto	8-K	001-40708	10.1	December 11, 2025
19.1	Insider Trading Policy	10-K	001-40708	19.1	March 25, 2025
21.1*	List of subsidiaries				
23.1*	Consent of Independent Registered Public Accounting Firm				
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				
97.1	Clawback Policy	10-K	001-40708	97.1	March 28, 2024
101.INS*	Inline XBRL Instance Document				
101.SCH*	Inline XBRL Taxonomy Extension Schema Document				
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF*	Inline XBRL Extension Definition Linkbase Document				
101.LAB*	Inline XBRL Taxonomy Label Linkbase Document				
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document				
104*	Cover Page Interactive Data File (embedded within inline XBRL document)				

* Filed herewith.
** The certifications furnished in Exhibit 32.1 and 32.2 hereto are deemed to be furnished with this Annual Report on Form 10-K 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.
+ Indicates management contract or compensatory plan.
† Portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

Climb Bio, Inc.

Date: March 5, 2026

By: /s/ Aoife Brennan

Aoife Brennan, M.B., Ch.B.
President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ Aoife Brennan **Aoife Brennan, M.B., Ch.B.**	President, Chief Executive Officer and Director *(Principal Executive Officer)*	March 5, 2026
/s/ Susan Altschuller **Susan Altschuller, Ph.D., MBA**	Chief Financial Officer *(Principal Financial Officer)*	March 5, 2026
/s/ Cindy J. Driscoll **Cindy J. Driscoll, MBA**	Senior Vice President, Finance *(Principal Accounting Officer)*	March 5, 2026
/s/ Douglas E. Williams **Douglas E. Williams, Ph.D.**	Director *(Chairman)*	March 5, 2026
/s/ Alexander Cumbo **Alexander Cumbo**	Director	March 5, 2026
/s/ Kimberlee C. Drapkin **Kimberlee C. Drapkin, CPA**	Director	March 5, 2026
/s/ Judith Dunn **Judith Dunn, Ph.D**	Director	March 5, 2026
/s/ Andrew Levin **Andrew Levin, M.D., Ph.D.**	Director	March 5, 2026
/s/ Stephen Thomas **Stephen Thomas, Ph.D.**	Director	March 5, 2026

Exhibit 21.1

List of Subsidiaries of Climb Bio, Inc.

Eliem Therapeutics (UK) Ltd. (England and Wales)

Climb Bio Operating Inc.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-286303, 333-278328, 333-270304, 333-263347 and 333-258771) and Form S-3 (Nos. 333-283166 and 333-280784) of Climb Bio, Inc. of our report dated March 5, 2026 relating to the financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
Seattle, Washington
March 5, 2026

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 Annual Report on Form 10-K 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: March 5, 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 Annual Report on Form 10-K 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: March 5, 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 Annual Report on Form 10-K of Climb Bio, Inc. (the "Company") for the period ended December 31, 2025, 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: March 5, 2026

By: /s/ Aoife Brennan

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

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

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 Annual Report on Form 10-K of Climb Bio, Inc. (the "Company") for the period ended December 31, 2025, 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: March 5, 2026

By: /s/ Susan Altschuller

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

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.