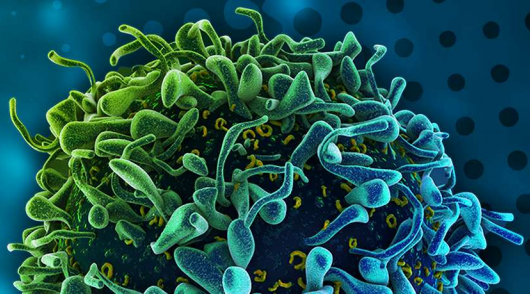

# Cullinan Therapeutics, Inc.
# 2025 Annual Report to Stockholders

# 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: 001-39856

# CULLINAN THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

| **Delaware** | **81-3879991** |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification No.) |
| **One Main Street<br>Suite 1350<br>Cambridge, MA** | **02142** |
| (Address of principal executive offices) | (Zip Code) |

**(617) 410-4650**

(Registrant's telephone number, including area code)

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 | CGEM | The Nasdaq Global Select 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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

| | | | |
|---|---|---|---|
| Large accelerated filer | ☐ | Accelerated filer | ☐ |
| Non-accelerated filer | ☒ | Smaller reporting company | ☒ |
| | | Emerging growth company | ☐ |

If an emerging growth company, indicate by check mark if the Registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the Registrant 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 ☒

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the Registrant as of June 30, 2025 was $442.2 million based on the closing price of the Registrant's shares of common stock on the Nasdaq Global Select Market on such date.

The number of shares of the Registrant's common stock outstanding as of February 23, 2026 was 60,526,128.

**DOCUMENTS INCORPORATED BY REFERENCE**

The Registrant intends to file a definitive proxy statement pursuant to Regulation 14A in connection with its 2026 Annual Meeting of Stockholders within 120 days of the end of the Registrant's fiscal year ended December 31, 2025. Portions of such proxy statement are incorporated by reference into Part II, Item 5 and Part III of this Annual Report on Form 10-K.

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## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that involve risks, uncertainties, and other factors that may cause actual results, levels of activity, performance, or achievements to be materially different from the information expressed or implied by these forward-looking statements. All statements, other than statements of historical facts, 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 and objectives of management, and expected market growth are forward-looking statements. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would", and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

Any forward-looking statements in this Annual Report on Form 10-K reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed in this Annual Report on Form 10-K and other filings with the Securities and Exchange Commission (the "SEC"), including the following:

- the commercial success, cost of development, and timing of the approval of our clinical-stage product candidates;
- the initiation, timing, progress, results, and cost of our research and development programs, and our current and future preclinical studies and clinical trials, including statements regarding the timing of initiation and completion of studies or clinical trials and related preparatory work, and the period during which the results of the trials will become available;
- our ability to submit, and obtain clearance of, any global regulatory filings, including new drug applications or investigational new drug applications, on our expected timelines, or at all;
- our ability to initiate, recruit, and enroll patients in and conduct our clinical trials at the pace that we project;
- our ability to obtain and maintain regulatory approval of our product candidates, and any related restrictions, limitations, or warnings in the label of any of our product candidates, if approved;
- the impacts of governmental legislation and regulations, including adverse effects from any potential future United States government shutdown;
- the effect of changes in global economic conditions, including uncertainties related to international trade policies, tariffs and supply chain dynamics, on our business and operations, including our expenses, supply chain, manufacturing processes, preclinical studies, and clinical trials;
- our ability to compete with companies currently marketing therapies or developing product candidates with targets or indications similar to our product candidates' targets or indications;
- our reliance on third parties to conduct our clinical trials and to manufacture drug substance and drug product for use in our clinical trials;
- the size and growth potential of the markets for any of our current and future product candidates, and our ability to serve those markets;
- our ability to identify and advance through clinical development any additional product candidates;
- the commercialization of our current and future product candidates, if approved, including our ability to successfully build a specialty sales force and commercial infrastructure to market our current and future product candidates;
- our ability to identify research priorities and apply a risk-mitigated strategy to efficiently discover and develop current and future product candidates;
- our ability to retain and recruit key personnel;
- our ability to obtain and maintain adequate intellectual property rights;
- our expectations regarding government and third-party payor coverage, pricing, and reimbursement;
- our estimates of our expenses, ongoing losses, capital requirements, the sufficiency of our current resources, and our needs for or ability to obtain additional financing;
- the milestone payments that we may receive from Taiho Pharmaceutical Co., Ltd.;

- potential investments in our pipeline and the potential for such product candidates;
- the potential benefits of strategic collaboration agreements, our ability to enter into additional strategic collaborations or arrangements, and our ability to attract collaborators with development, regulatory, and commercialization expertise; and
- developments and projections relating to our competitors or our industry.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and investors 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. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures, or investments we may make or collaborations or strategic partnerships we may enter into.

You should read this Annual Report on Form 10-K and the documents that we reference herein and have filed or incorporated by reference as exhibits hereto completely and with the understanding that our actual future results may be materially different from what we expect. 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 law.

This Annual Report on Form 10-K also contains estimates, projections, and other information concerning our industry, our business, and the markets for our product candidates. Information that is based on estimates, forecasts, projections, market research, or similar methodologies is inherently subject to uncertainties, and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. Unless otherwise expressly stated, we obtained this industry, business, market, and other data from our own internal estimates and research as well as from reports, research surveys, studies, and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data, and similar sources. While we are not aware of any misstatements regarding any third-party information presented in this Annual Report on Form 10-K, their estimates, in particular, as they relate to projections, involve numerous assumptions, are subject to risks and uncertainties and are subject to change based on various factors, including those discussed under the section titled “Risk Factors” and elsewhere in this Annual Report on Form 10-K.

**References to Cullinan in this Annual Report on Form 10-K**

Unless otherwise stated or the context indicates otherwise, all references herein to “Cullinan,” “Cullinan Therapeutics, Inc.,” “we,” “us,” “our,” “our company,” “the Company,” and similar references refer to Cullinan Therapeutics, Inc. and its consolidated subsidiaries, and “our board of directors” and “the Board” refer to the board of directors of Cullinan Therapeutics, Inc.

**Summary of the Material and Other Risks Associated with Our Business**

*Below is a summary of the principal factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, are summarized in "Risk Factors" and should be carefully considered, together with other information in this Annual Report on Form 10-K and our other filings with the Securities and Exchange Commission, before making an investment decision regarding our common stock.*

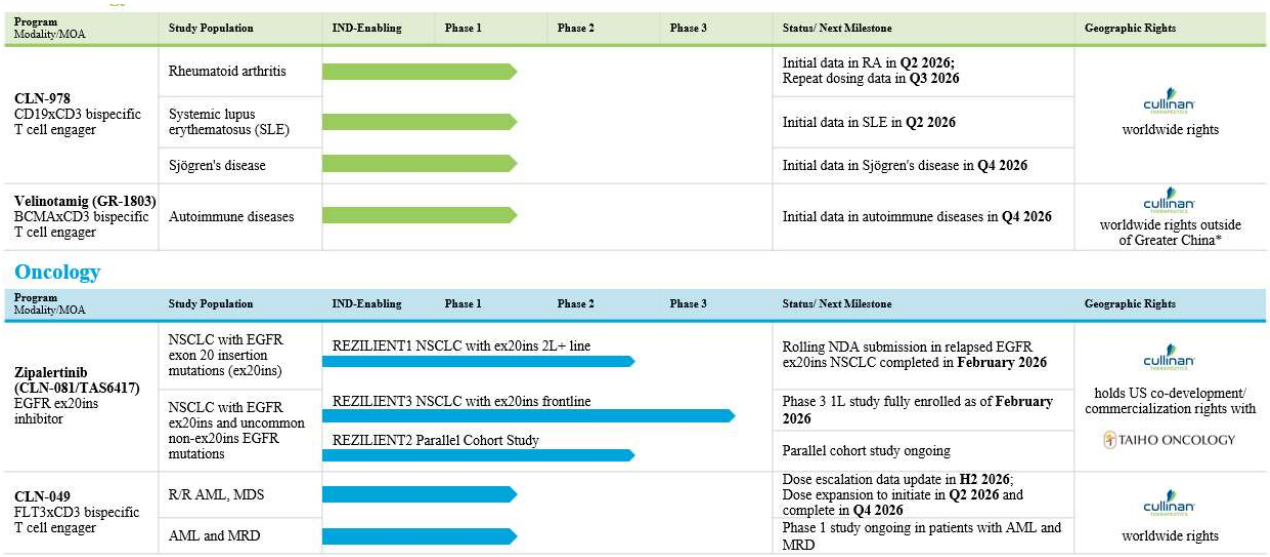
- We are early in our development efforts and are substantially dependent on our lead product candidates. If we are unable to advance these or any of our other current and future product candidates through clinical development, or to obtain regulatory approval and ultimately commercialize any such product candidates, either by ourselves or with or by third parties or if we experience significant delays in doing so, our business may be materially harmed.
- Difficulty in enrolling patients has delayed, and in the future could delay or prevent clinical trials of our product candidates and ultimately delay or prevent regulatory approval.
- Interim, "topline", and preliminary data from our clinical trials that we announce or publish may change as more patient data become available and are subject to confirmation, audit, and verification procedures that could result in material changes in the final data.
- Our product candidates may cause undesirable side effects or have other properties that delay or prevent their regulatory approval, limit their commercial potential, or result in significant negative consequences following any potential marketing approval.
- Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.
- We have incurred significant losses since inception, and we expect to incur losses over the next several years and may not be able to achieve or sustain revenues or profitability in the future.
- We will require substantial additional funding to develop and commercialize our current and future product candidates. If we are unable to raise capital when needed, we would be compelled to delay, reduce, or eliminate our product development programs or other operations.
- We may not be successful in our efforts to build a pipeline of product candidates with commercial value.
- Certain agreements provide our licensors, collaborators, or other shareholders in our development subsidiaries with rights that could delay or impact the potential sale of our development subsidiaries or could impact our ability to sell assets, or enter into strategic alliances, collaborations, or licensing arrangements with other third parties.
- Our reliance on a limited number of employees presents operational challenges that may adversely affect our business.
- We face substantial competition, which may result in others discovering, developing, or commercializing products before or more successfully than we do.
- If we are unable to obtain and maintain patent and other intellectual property protection for our current and future product candidates and technology, or if the scope of intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to commercialize any of our current or future product candidates or technology may be adversely affected.
- We currently rely and expect to continue to rely on the outsourcing of the majority of our development functions to third parties to conduct our preclinical 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 currently rely and expect to rely in the future on third parties to manufacture our product candidates. Our business could be harmed if the third-party manufacturers fail to provide us with sufficient quantities of our product candidates or fail to do so on acceptable timelines or at acceptable quality levels or prices.
- We are highly dependent on our key personnel. If we are not successful in retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

## PART I

### Item 1. Business.

### Overview

We are a biopharmaceutical company developing potential first- or best-in-class, high-impact therapies for autoimmune diseases and cancer. We pursue promising therapeutic targets while leveraging core expertise in T cell engagers, which are established in oncology and are now advancing into autoimmune diseases. With a clinical-stage pipeline built on a rigorous scientific approach and purposeful innovation, we are advancing our mission to deliver new standards of care for patients. Our current programs are summarized in the diagram and bullets below:




***Immunology***

- CLN-978 is a CD19xCD3 bispecific T cell engager that we are developing for autoimmune diseases. In the Phase 1 OUTRACE Program, CLN-978 is being evaluated in patients with systemic lupus erythematosus ("SLE"), rheumatoid arthritis ("RA"), and Sjögren's disease ("SjD"). The OUTRACE SLE Study is an ongoing global Phase 1 clinical trial in patients with moderate to severe SLE. The OUTRACE RA Study is a Phase 1 clinical trial in patients with active, difficult-to-treat RA, which is ongoing in Europe. We plan to share initial clinical data in SLE and RA in the second quarter of 2026 and repeat dosing data in RA in the third quarter of 2026. The OUTRACE SjD Study is an ongoing global Phase 1 clinical trial in patients with active, moderate to severe Sjögren's disease. We plan to share initial clinical data in Sjögren's disease in the fourth quarter of 2026.
- Velinotamig is a BCMAxCD3 bispecific T cell engager that we are developing for autoimmune diseases. Chongqing Genrix Biopharmaceutical Co., Ltd. ("Genrix"), from which we licensed velinotamig, is enrolling a Phase 1 clinical trial in China in patients with autoimmune diseases, initially in patients with SLE, followed by planned future expansion into other indications, and initial clinical data will be shared in the fourth quarter of 2026. We intend to use the data generated from this Phase 1 clinical trial to accelerate global clinical development. Following the completion of the Genrix Phase 1 clinical trial, we will conduct all further development of velinotamig in autoimmune diseases.

***Oncology***

- CLN-049 is a FLT3xCD3 bispecific T cell engager. CLN-049 is being evaluated in an ongoing Phase 1 clinical trial in patients with relapsed/refractory acute myeloid leukemia ("AML") or myelodysplastic syndrome ("MDS"). At the 2025 American Society for Hematology ("ASH") Annual Meeting, we shared monotherapy efficacy data from the ongoing dose escalation portion of the trial in a heavily pretreated all-comer population of patients with relapsed/refractory AML. We plan to share a clinical data update from the dose escalation portion of the trial in the second half of 2026. We also plan to begin enrolling dose expansion cohorts in the second quarter of 2026 and expect to complete enrollment in the fourth quarter of 2026 to determine the recommended Phase 2 dose for an expected single-arm pivotal registrational trial.

- Zipalertinib (CLN-081/TAS6417), on which we are collaborating with an affiliate of Taiho Pharmaceutical Co., Ltd. ("Taiho"), is an orally-available small-molecule, irreversible epidermal growth factor receptor ("EGFR") inhibitor that is designed to selectively target cells expressing EGFR exon 20 insertion mutations ("EGFR ex20ins") with relative sparing of cells expressing wild-type EGFR.
    - We are evaluating zipalertinib in the pivotal Phase 2b portion of the REZILIENT1 clinical trial in patients with EGFR ex20ins non-small cell lung cancer ("NSCLC") who progressed after prior systemic therapy. In February 2026, based on the primary efficacy data from REZILIENT1, Taiho completed a rolling submission of a new drug application ("NDA") seeking accelerated approval of zipalertinib for the treatment of patients with locally advanced or metastatic EGFR ex20ins NSCLC who have previously received platinum-based systemic chemotherapy.
    - Taiho is evaluating zipalertinib in a global Phase 3 clinical trial ("REZILIENT3") in combination with chemotherapy as a potential first-line treatment for locally advanced or metastatic EGFR ex20ins NSCLC adult patients. Taiho completed enrollment of the trial in February 2026 and expects to obtain top-line results by the end of 2026.
    - Taiho is also evaluating zipalertinib in a Phase 2 parallel cohort trial ("REZILIENT2"). Taiho shared emerging data from certain REZILIENT2 cohorts at the International Association for the Study of Lung Cancer ("IASLC") 2025 World Conference on Lung Cancer ("WCLC") and European Society for Medical Oncology ("ESMO") Congress 2025.

**Our Strategy**

Our strategy is to accelerate potential first- or best-in-class, high-impact therapies in autoimmune diseases and cancer. The key objectives we aim to achieve with our strategy are as follows:

- ***Explore the broad potential of CLN-978 in autoimmune diseases.*** Academic investigators and industry sponsors have published data across a variety of molecular targets and modalities highlighting the potential for a CD19xCD3 T cell engager to achieve sustained improvements in disease manifestations, including durable remission from symptoms in some cases, in multiple autoimmune disease indications, including SLE and RA. We believe that CLN-978 is highly-differentiated and has several potential advantages relative to other CD19-directed therapies currently in development, including monoclonal antibodies, chimeric antigen receptor T cell ("CAR T") therapies, as well as other T cell engagers, such as off-the-shelf subcutaneous administration and the ability to redirect T cells to lyse B cells expressing very low levels of CD19. We are therefore exploring the broad development of CLN-978 in autoimmune diseases.
- ***Advance CLN-049 for the treatment of a broad population of AML patients.*** The AML treatment paradigm is currently fragmented, and there are limited treatment options that are broadly applicable across AML subpopulations. Recent approvals are for small-molecule targeted therapies that address only smaller genetic and molecular subsets of AML. CLN-049 binds both mutated and wild-type FLT3, which is expressed on AML blasts in more than 80% of AML patients. Consequently, CLN-049 has the potential to address a broad population of AML patients without need for biomarker testing. We plan to advance CLN-049 into dose expansion in relapsed AML patients to determine a recommended Phase 2 dose for an expected single-arm pivotal registrational trial. We will also explore CLN-049 as a potential frontline treatment in combination with current standard-of-care treatment for patients with newly diagnosed AML.
- ***Unlock the near-term non-dilutive financial benefits of zipalertinib.*** In collaboration with Taiho, we are pursuing a broad, parallel development plan designed to exploit the potential of zipalertinib in multiple patient populations in the REZILIENT program. As zipalertinib is advanced closer to regulatory approvals and commercialization by Taiho, we move closer to potentially achieving certain non-dilutive financial benefits. Under an agreement with Taiho, we are eligible to receive $30.0 million and up to $100.0 million in payments from Taiho tied to United States ("U.S.") regulatory approvals in second-line and first-line EGFR ex20ins NSCLC, respectively. We are also eligible to receive 50% of any future pre-tax profits from potential U.S. sales of zipalertinib. We plan to use the potential proceeds from zipalertinib through our collaboration with Taiho to continue to advance the development of our priority programs, CLN-978 and CLN-049.

## Our Product Candidates

### CLN-978

#### *Overview*

CLN-978 is a half-life extended, humanized, single-chain bispecific T cell engager designed to simultaneously engage CD19 on B cells and CD3 on T cells, triggering redirected T cells to lyse B cells. CLN-978 contains two tandemly arranged single-chain variable fragments (“scFvs”) for CD19 and CD3 and a third domain in the form of a single-domain antibody (VHH) for binding to human serum albumin ("HSA") to prolong its serum half-life. CLN-978 demonstrated potency in both redirecting T cells to lyse low-CD19 expressing cells *in vitro* and activity in mice in B cell lymphoma models *in vivo*. In preclinical *in vivo* studies in non-human primates, treatment with CLN-978 at low doses led to profound B cell depletion in peripheral blood even after a single dose, and deep B cell depletion in lymphoid tissues was observed with multi-dose treatment. CLN-978 displayed similar induction of target B cell killing, T cell activation, and cytokine production in peripheral blood mononuclear cells derived from patients with SLE, RA or Sjögren’s as compared to healthy volunteers. We believe together these preclinical results support evaluation of CLN-978 for the treatment of B cell-mediated autoimmune diseases.

#### *Background for Targeting CD19 in Autoimmune Diseases*

B cells express the CD19 target and play a role in numerous autoimmune diseases which can affect multiple organ systems. Common to the pathophysiology of these disorders is the aberrant production of antibodies directed toward self-antigens, which are referred to as autoantibodies. Academic investigators and industry sponsors have published data across a variety of molecular targets and modalities demonstrating the potential for a CD19xCD3 T cell engager to achieve sustained improvements in disease manifestations, including durable remission from symptoms in some cases, in multiple treatment resistant autoimmune disease indications, including SLE and RA. These clinical data show that the profound depletion of B cells by CD19-directed therapy, followed by the re-emergence of a naïve B cell repertoire, effects a “reset” of the B cell compartment and a lasting elimination of autoreactive antibodies.

We believe broad B cell dysfunction is central to the pathogenesis of numerous autoimmune diseases, and we believe broadly and deeply depleting these cells by targeting CD19 appears to have the potential to effect an immune reset in these diseases.

We also believe that CLN-978 has several potential advantages relative to other CD19-directed therapies currently in development, including monoclonal antibodies, CAR T therapies, as well as other TCEs. Specifically, we believe CLN-978 demonstrates:

- potential for broader B cell lineage depletion due to its very high affinity binding to CD19;
- potential for a wider therapeutic index due to its approximately 10 times higher potency for B cell depletion relative to cytokine induction, as shown in preclinical studies;
- potential for more efficient deep tissue penetration due to the relatively small size of the CLN-978 molecule;
- potential for deeper tissue-level B cell depletion than attainable with monoclonal antibodies that work primarily through antibody-dependent cellular cytotoxicity ("ADCC");
- unlike most current generation autologous CAR T therapies, no need for lymphodepleting chemotherapy which is associated with significant toxicities and recognized risk of secondary malignancies; and
- off-the-shelf convenience without extended manufacturing lead times or limitation to certified treatment centers.

Based on the emerging clinical data supporting the efficacy for other CD19-directed therapies in multiple autoimmune diseases and our belief that CLN-978 has several potential advantages compared to other CD19-directed therapies in development, we are exploring the development of CLN-978 in a variety of autoimmune diseases and are committed to assessing its broad potential.

#### *Clinical Development*

*OUTRACE SLE*

In December 2024, we initiated a Phase 1 clinical trial in patients with active, moderate to severe SLE. The OUTRACE SLE Study is ongoing in the U.S., Europe and Australia. We plan to share initial clinical data from Part A, or the single target dose escalation portion of the trial, in the second quarter of 2026. The data will focus on safety and B cell depletion in peripheral blood, as well as other biomarker data, and preliminary clinical activity data.

*OUTRACE RA*

In April 2025, we initiated a Phase 1 clinical trial in patients with active, difficult-to-treat RA. The OUTRACE RA Study is ongoing in Europe. We plan to share initial clinical data from the single target dose escalation portion of the trial in the second quarter of 2026. The data will focus on safety and B cell depletion in peripheral blood and tissue, as well as other biomarker data, and preliminary clinical activity data. We plan to share initial repeat dosing data in the third quarter of 2026. The data will include B cell depletion in peripheral blood and tissue, as well as other biomarker data, and preliminary clinical activity data.

*OUTRACE SjD*

In June 2025, we initiated a Phase 1 clinical trial in patients with active, moderate to severe Sjögren's disease. The OUTRACE SjD Study is ongoing in the U.S. and Europe. We plan to share initial clinical data from Part A, or the single target dose escalation portion of the trial, in the fourth quarter of 2026. The data will focus on safety and B cell depletion in peripheral blood and tissue, as well as other biomarker data, and preliminary clinical activity data.

*Discontinued Clinical Development in B Cell Non-Hodgkin Lymphoma ("B-NHL")*

Three patients were treated in a Phase 1 dose escalation trial in patients with relapsed/refractory B-NHL. At the initial starting dose of 30 micrograms administered subcutaneously once weekly, two of the three patients experienced objective clinical benefit, including one patient who experienced a complete response. Grade 1 cytokine release syndrome (fever) occurred in two patients following the first dose of CLN-978 only, and no patients experienced immune effector cell-associated neurotoxicity syndrome. Other adverse events were mostly low-grade and/or mechanistically based (e.g., transient lymphopenia after the first dose only). Of the two patients with detectable B cells at baseline, both experienced rapid and deep B cell depletion after administration of CLN-978. These data support that CLN-978 can not only deplete peripheral blood B cells but also demonstrate clinical activity in a tissue resident disease at a dose with a favorable safety profile. Based on these broadly applicable initial clinical observations and emerging data for CD19-directed therapy in autoimmune diseases, development of CLN-978 in relapsed/refractory B-NHL was discontinued in early 2024, and CLN-978 development moved forward exclusively in autoimmune diseases.

**Velinotamig**

***Overview***

Velinotamig is a BCMAxCD3 bispecific T cell engager that we are developing for autoimmune diseases. In June 2025, we licensed from Genrix the exclusive rights to develop and commercialize velinotamig in all fields of use outside of mainland China, Hong Kong, Macau, and Taiwan (collectively referred to as "Greater China"). Velinotamig is designed to bind both BCMA and CD3 antigens, redirecting cytotoxic T cells to eliminate BCMA-expressing plasma cells. Its binding profile demonstrates a markedly higher affinity for BCMA, two orders of magnitude greater than for CD3, enabling the potential for efficient recruitment and activation of T cells while reducing the risk of non-specific T cell activation.

Genrix is evaluating velinotamig in China in a comprehensive clinical development program in patients with multiple myeloma. In November 2025, Genrix shared clinical data in a published ASH abstract in patients with relapsed/refractory multiple myeloma. In January 2026, Genrix announced acceptance and priority review by the National Medical Products Administration ("NMPA") in China for a Biologics License Application ("BLA") for velinotamig for the treatment of adult patients with relapsed or refractory multiple myeloma. We believe the efficacy profile of velinotamig in multiple myeloma, particularly results in patients with extramedullary disease, supports the potential of velinotamig in plasma cell-driven autoimmune diseases. We do not intend to develop velinotamig in multiple myeloma.

***Background for Targeting BCMA in Autoimmune Diseases***

BCMA is emerging as a promising therapeutic target in autoimmune diseases because it is broadly expressed on plasma cells, including long-lived plasma cells that may drive chronic autoantibody production central to the pathogenesis of certain autoimmune diseases. Depleting these cells by targeting BCMA could potentially improve outcomes in patients with certain autoimmune diseases. Academic investigators and industry sponsors have published data demonstrating that BCMA-targeted therapies can improve clinical manifestations in multiple autoimmune conditions.

***Clinical Development***

*Genrix Phase 1 Clinical Trial in Autoimmune Diseases*

Genrix is enrolling a Phase 1 clinical trial in China in patients with autoimmune diseases, initially in patients with SLE, followed by future planned expansion into other indications, and initial clinical data from the trial will be shared in the fourth quarter of 2026. We intend to use the data generated to accelerate global clinical development of the program. Following the completion of the Genrix Phase 1 clinical trial, we will conduct all further development of velinotamig in autoimmune diseases.

**CLN-049**

***Overview***

CLN-049 is a humanized bispecific T cell engager that we are developing for the treatment of AML and MDS. CLN-049 is comprised of two FLT3-binding domains, an Fc-silenced humanized IgG1 backbone, and CD3-binding scFvs fused to the C-terminus of the antibody's heavy chain. CLN-049 is designed to simultaneously bind to FLT3 on the extracellular domain of target leukemic cells and to CD3 on T cells, triggering the T cells to kill the target cancer cells. CLN-049 can bind to FLT3, which is expressed on AML blasts in more than 80% of AML patients, regardless of FLT3 mutational status. The FDA granted Fast Track designation to CLN-049 in December 2025 for the treatment of relapsed/refractory AML.

***Background on AML and FLT3***

FLT3 is a receptor tyrosine kinase and a proto-oncogene and is a well-validated target in AML. Studies using flow cytometry have shown that FLT3 is expressed on AML blasts in more than 80% of AML patients. Several kinase inhibitors targeting mutant FLT3 are approved for the treatment of relapsed/refractory AML; however their use is limited to the approximately 30% of the AML population that express mutant FLT3. By targeting the extracellular domain of FLT3, CLN-049 has the potential to address a broader population of AML patients. The American Cancer Society estimates that in 2026, there will be approximately 22,720 newly diagnosed patients with AML and approximately 11,500 deaths from AML in the U.S.

***Clinical Development***

*Phase 1 Clinical Trial in Relapsed/Refractory AML and MDS*

In December 2021, we initiated the ongoing Phase 1 clinical trial evaluating CLN-049 in relapsed/refractory AML patients and subsequently amended the eligible patient population to include refractory MDS patients. We completed the single ascending dose portion of the Phase 1 clinical trial testing IV administration of CLN-049 and initiated the multi-ascending dose portion of the clinical trial utilizing subcutaneous dosing in December 2022. Safety data from the single-ascending dose portion of the Phase 1 clinical trial was published at the 2023 European Hematology Association Congress. Following a review of data from the multi-ascending dose portion of the Phase 1 clinical trial of CLN-049, we reported that dose-limiting injection site reactions were observed during dose escalation with subcutaneous administration. Based on these findings we discontinued subcutaneous administration. However, based on observations of preliminary clinical activity, we elected to continue the multi-ascending dose portion with IV administration.

At the 2025 ASH Annual Meeting, we shared clinical data from the ongoing dose escalation portion of the Phase 1 clinical trial. As of an August 2025 data cutoff, among 32 patients treated at target doses greater than 6 micrograms/kilogram, CLN-049 demonstrated a complete response plus complete remission with partial hematological recovery ("CR+CRh") rate of 25%. And in 16 patients treated at the target dose of 12 micrograms/kilogram, CLN-049 demonstrated a CR+CRh rate of 31%. In 45 patients treated across all target doses, we observed a favorable safety profile, and at the highest target dose in regimens utilizing 2 step-up doses, we observed no grade 3 cytokine release syndrome and no dose-limiting adverse events. We plan to share a clinical data update from the dose escalation portion of the trial in the second half of 2026.

Based on the emerging efficacy and safety profile, we plan to initiate dose expansion cohorts in patients with relapsed/refractory AML and TP53 mutated AML in the second quarter of 2026. We expect to complete dose expansion enrollment by the fourth quarter of 2026 to determine the recommended Phase 2 dose for an expected single-arm pivotal registrational trial.

*Phase 1/2 Clinical Trial in Frontline AML*

In the fourth quarter of 2026, we plan to initiate a Phase 1/2 clinical trial evaluating CLN-049 as a potential frontline treatment in combination with current standard-of-care treatment for patients with newly diagnosed AML.

*Phase 1 Clinical Trial in AML and Measurable Residual Disease*

In December 2023, we initiated the ongoing Phase 1 clinical trial designed to evaluate the safety and preliminary efficacy of CLN-049 in patients with AML and measurable residual disease following induction therapy.

**Zipalertinib Collaboration with Taiho**

***Overview***

Zipalertinib is an orally bioavailable small molecule designed as a next generation, irreversible EGFR inhibitor with a novel pyrrolopyrimidine scaffold. Unique among the therapies in development that are targeting EGFR ex20ins, zipalertinib is designed to fit into the adenosine triphosphate-binding site of EGFR where it covalently modifies C797, thereby forming a durable drug-protein linkage that irreversibly inhibits the mutant receptor.

Pursuant to a co-development agreement, we are collaborating with a Taiho affiliate to develop zipalertinib for the treatment of a genetically defined subset of patients with NSCLC, and Taiho will commercialize zipalertinib. For the agreed-upon indication, we and Taiho share development costs equally, and each party will receive 50% of any future pre-tax profits from potential U.S. sales of zipalertinib. For any additional indications that Taiho chooses to develop independently, Taiho will bear all development costs until they have sufficient data to support a commercial purpose or submission of zipalertinib for such indication. At such time, 50% of Taiho's independent development costs, subject to certain adjustments, will be deducted from future pre-tax profits for potential U.S. sales of zipalertinib. Under a separate agreement, we also are eligible to receive up to $130.0 million from Taiho tied to EGFR ex20ins NSCLC U.S. regulatory milestones. The FDA granted Breakthrough Therapy designation to zipalertinib in 2022 for the treatment of patients with locally advanced or metastatic NSCLC harboring EGFR ex20ins who have previously received platinum-based systemic chemotherapy.

***Background on NSCLC and EGFR ex20ins mutations***

In the U.S., approximately 16% of NSCLC cases harbor EGFR mutations, with insertions at exon 20 accounting for 12% of those mutations. Patients with EGFR ex20ins have poorer outcomes than those with more common EGFR mutations, such as exon 19 deletions. There remains a significant unmet need for therapies targeting EGFR ex20ins in NSCLC that are safer and more effective.

***Clinical Development***

*Cullinan REZILIENT1: Phase 1/2a Module Results*

The Phase 1/2a portion of the REZILIENT1 clinical trial enrolled a total of 73 patients across 30, 45, 65, 100, and 150 milligram ("mg") twice-daily dose levels. The patient population was heavily pre-treated, with a median of two prior systemic therapies and 66% of patients having received two or more prior therapies at clinical trial entry (i.e., third line of therapy or greater). As of a May 9, 2022 data cutoff, among 39 patients treated at the recommended Phase 2 dose of 100 mg twice daily, 16 patients achieved a confirmed partial response, indicating a 41% confirmed overall objective response rate ("ORR"). At the 100 mg twice-daily dose, median progression free survival ("PFS") was 12 months.

*Cullinan REZILIENT1: Pivotal Phase 2b Clinical Trial*

In November 2022, we initiated the pivotal Phase 2b portion of the REZILIENT1 clinical trial of zipalertinib 100 mg twice daily in adult patients with locally advanced or metastatic EGFR ex20ins NSCLC who have previously received platinum-based systemic chemotherapy. The clinical trial is evaluating zipalertinib 100 mg twice daily in adult patients with locally advanced or metastatic EGFR ex20ins NSCLC who have previously received platinum-based systemic chemotherapy with or without amivantamab and other ex20ins targeted therapies.

In January 2025, we announced the Phase 2b portion of the REZILIENT1 trial met the primary endpoint of overall response rate in patients with locally advanced or metastatic EGFR ex20ins NSCLC who have previously received platinum-based systemic chemotherapy and shared the results at the 2025 American Society of Clinical Oncology ("ASCO") Annual Meeting. As of a December 2024 data cutoff, among 125 patients who received prior treatment with chemotherapy only, zipalertinib demonstrated a confirmed ORR of 40% and a median duration of response ("mDOR") of 8.8 months. At the IASLC 2025 WCLC, updated results were shared in patients who received prior treatment with chemotherapy and amivantamab with or without other ex20ins targeted therapies. As of a June 2025 data cutoff, among 84 patients, zipalertinib demonstrated an ORR of 27.4% and a mDOR of 8.5 months. And in 54 patients who received prior treatment with chemotherapy and amivantamab only, zipalertinib demonstrated a 31.5% ORR and a mDOR of 9.5 months. In the 2025 ASCO Annual Meeting and IASLC 2025 WCLC updates, zipalertinib demonstrated a manageable safety profile, consistent with previously reported data.

In February 2026, based on the primary efficacy data from the completed REZILIENT1 trial, Taiho completed the rolling submission of an NDA seeking accelerated approval of zipalertinib for the treatment of patients with locally advanced or metastatic EGFR ex20ins NSCLC who have previously received platinum-based systemic chemotherapy.

*Taiho REZILIENT3: Pivotal Phase 3 Clinical Trial*

In August 2023, Taiho initiated the ongoing global Phase 3 clinical trial testing zipalertinib plus standard-of-care chemotherapy versus standard-of-care chemotherapy alone as a potential first-line treatment for adult patients with locally advanced or metastatic EGFR ex20ins NSCLC. The clinical trial randomizes an estimated 272 patients to receive either the combination of the two treatments or standard-of-care chemotherapy alone. The primary endpoint is PFS. Taiho completed enrollment of the trial in February 2026 and expects to obtain top-line results by the end of 2026.

*Taiho REZILIENT2: Phase 2 Parallel Cohort Trial*

In August 2023, Taiho initiated the ongoing global Phase 2 parallel cohort clinical trial evaluating zipalertinib in NSCLC patients harboring ex20ins or uncommon non-ex20ins EGFR mutations. Emerging results from certain cohorts were shared at IASLC 2025 WCLC and ESMO Congress 2025. As of a March 2025 data cutoff, among 40 patients with NSCLC harboring uncommon non-ex20ins EGFR mutations, zipalertinib demonstrated a confirmed ORR of 30% and a mDOR of 7.75 months. As of a February 2025 data cutoff, among 16 evaluable patients with NSCLC harboring ex20ins or uncommon non-ex20ins EGFR mutations and central nervous system metastases, zipalertinib demonstrated a 31.3% intracranial ORR and 68.8% intracranial disease control rate, and the median intracranial duration of response was 8.1 months. In the IASLC 2025 WCLC and ESMO Congress 2025 updates, the safety profile of zipalertinib was consistent with previously reported data.

*Taiho Independent Clinical Development*

In November 2025, Taiho independently initiated an ongoing global Phase 3 clinical trial evaluating zipalertinib in an additional NSCLC indication.

**Preclinical Programs**

In addition to the product candidates described above, we are actively developing several preclinical programs in autoimmune diseases and oncology.

**Recently Discontinued Programs**

CLN-619 is a MICA/B monoclonal antibody that we were previously evaluating in Phase 1 clinical trials. In May 2025, following a review of the CLN-619 data from the disease-specific expansion cohorts for endometrial and cervical cancers, we announced discontinuation of further development of CLN-619 in patients with gynecological cancers as preliminary results did not meet our internal threshold for advancement. In November 2025, after a review of the emerging clinical data in patients with NSCLC and multiple myeloma, we discontinued further development of CLN-619.

CLN-617 is an interleukin-2 and interleukin-12 fusion protein that we were previously evaluating in a Phase 1 clinical trial. In November 2025, after a review of the emerging clinical data in patients with advanced solid tumors, we discontinued further development of CLN-617.

CLN-418 is a B7H4x4-1BB bispecific antibody that we licensed from Harbour BioMed US Inc. ("Harbour") and were previously evaluating in a Phase 1 clinical trial. In August 2024, following a review of the data from the Phase 1 clinical trial in solid tumors, we notified Harbour of our decision to terminate the license and collaboration agreement for CLN-418 (the "Harbour License Agreement"), effective November 2024. In connection with the termination of the Harbour License Agreement, we discontinued development of CLN-418 and returned development and commercial rights for CLN-418 to Harbour.

**Competition**

The biotechnology and pharmaceutical industries are characterized by the rapid evolution of technologies and understanding of disease etiology, intense competition, and a strong emphasis on intellectual property. We believe that our differentiated business model, approach, scientific capabilities, know-how, and experience provide us with competitive advantages. However, we face, and will continue to face, competition from companies focused on more traditional therapeutic modalities, such as small-molecule inhibitors. We expect substantial competition from multiple sources, including major pharmaceutical, specialty pharmaceutical, and existing or emerging biotechnology companies, academic research institutions, governmental agencies, and public and private research institutions worldwide.

Many of our competitors, either alone or through collaborations, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These companies also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites, and recruiting patients in clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. As a result, our competitors may discover, develop, license, or commercialize products before or more successfully than we do.

With respect to our CLN-978 program, we are aware of multiple companies with development-stage CD19 T cell engager programs for the treatment of autoimmune diseases, including but not limited to Amgen Inc., Roche Holdings AG, AstraZeneca plc, Merck & Co., Inc., Novartis AG, GSK plc., and Xencor, Inc. There are also companies with development stage CD19 monoclonal T cell engager programs for the treatment of autoimmune diseases, including but not limited to Zenas BioPharma, Inc., Eli Lilly and Company, and Climb Bio, Inc.

With respect to velinotamig, we are aware of multiple companies with development-stage BCMA T cell engager programs for the treatment of autoimmune diseases, including but not limited to Regeneron Pharmaceuticals, Inc., Candid Therapeutics, Inc., and Ouro Medicines, Inc.

With respect to CLN-978 and velinotamig there may also be competition from companies with marketed therapies or product candidates, leveraging other mechanisms of action, including but not limited to modalities such as cell therapies, immune cell engaging bispecifics, and monoclonal antibodies, which deplete or modulate B cells or other immune related pathways.

With respect to CLN-049, we are not aware of other FLT3xCD3 T cell engagers in clinical development. However, there are companies with targeted small-molecule therapies approved for the treatment of AML with FLT3 mutations, such as Astellas Pharma Inc., Daiichi Sankyo Co. Ltd., and Novartis AG. There are companies with development-stage FLT3 targeted small-molecule and monoclonal T cell engager programs, including but not limited to Aptose Biosciences Inc. and Veraxa Biotech GmbH. There are companies with development-stage FLT3 targeted cell therapy programs, including but not limited to Hemogenyx Pharmaceuticals plc and Senti Biosciences, Inc. There are also companies with development-stage programs for other AML related targets, leveraging other mechanisms of action such as T cell or immune engaging bispecifics or cell therapies for the treatment of AML, including but not limited to Amgen Inc., Aptevo Therapeutics, Inc., Johnson & Johnson, Gilead Sciences, Inc., Macrogenics, Sanofi S.A., and Molecular Partners AG.

With respect to zipalertinib, we are aware of other EGFR inhibitors that are approved or are in clinical development for the treatment of NSCLC patients harboring EGFR ex20ins. There are two companies with FDA approved therapies, including Johnson & Johnson and Dizal Pharmaceutical Co. Ltd. There are also companies with development-stage programs, including but not limited to Arrivent BioPharma, Inc. and Oric Pharmaceuticals, Inc.

**License and Collaboration Agreements**

***Adimab***

We have a collaboration agreement (the "Adimab Collaboration Agreement"), with Adimab, LLC ("Adimab"). Pursuant to the Adimab Collaboration Agreement, we selected a single-digit number of biological targets against which Adimab used its proprietary platform technology to discover and/or optimize antibodies, including antibody components that were used to generate CLN-978, based upon mutually agreed upon research plans. Under the Adimab Collaboration Agreement, we have the ability to select additional biological targets against which Adimab will provide additional antibody discovery and optimization services for delivery of binders with a specified range of binding affinities.

During the research term and evaluation term for a given research program with Adimab, we have a non-exclusive worldwide license under Adimab's technology to perform certain research activities and to evaluate the program antibodies to determine whether we want to exercise our option to obtain a royalty-free, fully paid, non-exclusive license under Adimab's background patent rights to exploit such antibodies sublicensable through multiple tiers (the "Adimab Option"). In the event we exercise the Adimab Option, we will pay an option fee for each target subject to certain adjustments.

Under the Adimab Collaboration Agreement, we paid a one-time, non-creditable, non-refundable technology access fee. We are also required to pay an annual access fee and research funding fees, which are creditable against the annual access fee, for Adimab's performance of its research obligations under the Adimab Collaboration Agreement. We are also obligated to make certain research delivery, clinical and sales milestone payments to Adimab in an aggregate amount of up to $15.8 million for each product, on a product-by-product basis, subject to certain reductions and discounts. As of December 31, 2025, we have incurred and paid a cumulative $0.5 million of milestone obligations for CLN-978 under the Adimab Collaboration Agreement.

Furthermore, we are obligated to pay certain royalty payments on a product-by-product basis at a low single-digit percentage of annual aggregate worldwide net sales. Such royalty obligations will expire on a country-by-country and product-by-product basis upon the later of (a) a certain low double-digit number of years after the first commercial sale of such product in such country and (b) the expiration of the last issued and not expired, permanently revoked, or invalid claim within a program patent covering such product as defined in the agreement.

We may terminate the Adimab Collaboration Agreement at any time, for any reason, upon a specified period of advance written notice. The term of the Adimab Collaboration Agreement expires upon the last research program's evaluation term in the event no Adimab Option is exercised or, in the event an Adimab Option is exercised, after the royalty term thereof expires at the later of a specified period or invalid patent coverage of the relevant product.

***Genrix***

In June 2025, we entered into a license agreement with Genrix (the "Genrix License Agreement"), pursuant to which Genrix granted us a global (excluding Greater China), exclusive license to develop and commercialize velinotamig, a BCMAxCD3 bispecific T cell engager, in all fields of use.

Under the terms of the Genrix License Agreement, we paid Genrix an upfront license fee of $20.0 million. Genrix will be eligible to receive up to $292.0 million in milestone payments based on the achievement of certain clinical and regulatory milestones. Genrix is also eligible to receive up to an additional $400.0 million in net sales-based milestones as well as tiered royalties ranging from mid-single digit to mid-teens, as a percentage of net sales of licensed products.

Unless earlier terminated, the Genrix License Agreement will continue in effect on a country-by-country basis until the expiration of our royalty obligations in such country. The Genrix License Agreement may be terminated by either party for a material breach by the other party, subject to notice and cure provisions, or in the event of the other party's insolvency. Additionally, subject to a notice period, we may terminate the Genrix License Agreement for convenience. In the Genrix License Agreement, each party made customary representations and warranties and agreed to customary covenants, including, without limitation, with respect to indemnification, for transactions of this type.

***DKFZ/Tübingen***

We are party to an exclusive license agreement (the "DKFZ/Tübingen License Agreement") for CLN-049 through our CLN-049 development subsidiary, Cullinan Florentine Corp. ("Cullinan Florentine"), with Deutsches Krebsforschungszentrum ("DKFZ"), Eberhard Karls University of Tübingen, Faculty of Medicine ("University of Tübingen"), and Universitätsmedizin Gesellschaft für Forschung und Entwicklung mbH, Tübingen ("UFE"). Pursuant to the DKFZ/Tübingen License Agreement, DKFZ and University of Tübingen, collectively referred to as the Licensor, granted Cullinan Florentine an exclusive (even as to Licensor, UFE and its and their affiliates), worldwide, milestone- and royalty-bearing, license under certain licensed patent rights, applications, technical information and know-how, with the right to grant sublicenses through multiple tiers to research, develop, commercialize or otherwise exploit licensed products, itself and through its affiliates and third parties, within the field. Cullinan Florentine has the sole right, but not the obligation, to prosecute and maintain all licensed patent rights worldwide, provided that Licensor may take over or continue such prosecution and maintenance if Cullinan Florentine elects to cease the prosecution or maintenance of a licensed patent right.

Under the DKFZ/Tübingen License Agreement, Cullinan Florentine is obligated to achieve certain regulatory and research and development performance benchmarks (collectively, the "Performance Benchmarks"), by certain specified dates (collectively, the "Performance Dates"). If a Performance Benchmark is not achievable by the applicable Performance Date, Cullinan Florentine may extend the Performance Date for any single Performance Benchmark by a mid-single digit amount of months by providing written notice to Licensor and paying a non-refundable, non-creditable extension fee per each such extension. Cullinan Florentine may extend the Performance Date for any single Performance Benchmark up to a low single digit amount of times, provided that Cullinan Florentine may only request an extension a mid-single digit amount of times. If Cullinan Florentine is unable to seek a further extension per the preceding sentence, then Cullinan Florentine may seek a further extension by providing written notice to Licensor and any such extension shall be subject to the prior written approval of the Licensor, such approval not to be unreasonably withheld or delayed. As of December 31, 2025, Cullinan Florentine is in compliance with the performance benchmark requirements of the DKFZ/Tübingen License Agreement.

Additionally, Cullinan Florentine shall pay certain non-refundable, non-creditable milestone payments to Licensor upon the occurrence of certain clinical and regulatory events by a licensed product, whether triggered by Cullinan Florentine, its affiliates or sublicensees. Each milestone payment is paid one time only up to an aggregate of $28.0 million. No milestone obligations have been incurred to date under the DKFZ/Tübingen License Agreement.

Furthermore, Cullinan Florentine is required to pay a running low to mid-single digit royalty percentage on net sales of each licensed product on a country-by-country and product-by-product basis during the royalty term, subject to certain offsets or reductions. The aggregate, worldwide royalties due to Licensor for net sales of any licensed product in a calendar year shall not be reduced to an amount less than low to mid-single digit percentages. Such royalty obligations will expire on a country-by-country and product-by-product basis upon the later of (a) the expiration of the last valid claim of a patent which covers a product in such country and (b) a low double-digit anniversary following the first commercial sale of a product in such country. Under certain conditions upon a first change in control, Cullinan Florentine shall pay a non-refundable, non-creditable mid-single digit percent of sale proceeds, provided, however, that such payment shall not be required following consummation of an initial public offering of Cullinan Florentine.

Either party may terminate the agreement upon a material breach by the other party or insolvency of the other party. Cullinan Florentine may terminate the DKFZ/Tübingen License Agreement for any or no reason after the first filing of an investigational new drug application ("IND") or clinical trial agreement, by providing prior written notice. Licensor may terminate the agreement by providing prior written notice, if we or any of our affiliates challenges the validity of certain patent rights. Unless earlier terminated, the DKFZ/Tübingen License Agreement continues on a perpetual basis.

***Taiho***

We have a co-development agreement with an affiliate of Taiho, pursuant to which we are collaborating to develop zipalertinib for the treatment of a genetically defined subset of patients with NSCLC, and Taiho will commercialize zipalertinib. For the agreed-upon indication, we and Taiho share development costs equally, and each party will receive 50% of any future pre-tax profits from potential U.S. sales of zipalertinib. For any additional indications that Taiho chooses to develop independently, Taiho will bear all development costs until they have sufficient data from such indication to support a commercial purpose or submission of zipalertinib for the additional indication. At such time, 50% of Taiho's independent development costs, subject to certain adjustments, will be deducted from future pre-tax profits for potential U.S. sales of zipalertinib. In November 2025, Taiho independently initiated an ongoing global Phase 3 clinical trial evaluating zipalertinib in an additional indication.

Under a separate agreement, we are also eligible to receive up to an additional $130.0 million from Taiho tied to EGFRex20ins NSCLC U.S. regulatory milestones. As of December 31, 2025, none of these milestones have been achieved.

***MIT***

We had an exclusive patent license agreement (the "MIT License Agreement") for the technology underlying CLN-617 with MIT through our development subsidiary, Cullinan Amber Corp. ("Cullinan Amber"). Under the terms of the MIT License Agreement, we have incurred and paid $0.7 million of milestone obligations through December 31, 2025. In November 2025, after a review of the emerging clinical data in patients with advanced solid tumors, we decided not to pursue further development of CLN-617. In connection with the decision not to pursue further development of CLN-617, we notified MIT of our decision to terminate the MIT License Agreement, effective February 2026 and returned the licensed patent rights for the technology underlying CLN-617 to MIT.

***Harbour***

We were party to the Harbour License Agreement with Harbour, pursuant to which Harbour granted to us an exclusive license for the development, manufacturing and commercialization of HBM7008 (CLN-418) in the U.S. In August 2024, following a review of the data from the Phase 1 clinical trial of CLN-418, the Company notified Harbour of its decision to terminate the Harbour License Agreement, effective November 2024. In connection with the termination of the Harbour License Agreement, the Company discontinued development of CLN-418 and returned development and commercial rights for CLN-418 to Harbour.

**Intellectual Property**

Our intellectual property is critical to our business, and we strive to protect it, including by obtaining, maintaining, defending, and enforcing patents and other intellectual property, in the U.S. and internationally, for our proprietary therapeutic molecules, technology, improvements, platforms, product candidates and components thereof, novel biological discoveries, new therapeutic approaches and potential indications, and other inventions that are important to our business. For our product candidates, generally we initially pursue patent protection covering compositions of matter, methods of use, and methods of production. Throughout the development of our product candidates, we will seek to identify additional means of obtaining patent protection that would potentially enhance commercial success, including improvement to pharmaceutical formulations, methods of use, and production.

As of February 13, 2026, our patent portfolio includes 18 patent families, including both patent applications we own, and patent applications exclusively in-licensed from external technology originators in a respective field. Specifically, we have exclusively in-licensed at least 48 granted patents and patent applications pending worldwide. Patents that may be issued from our pending patent applications, are expected to expire between 2034 and 2046, excluding any patent term adjustments or extensions, if applicable, that may be available. As to the patent term extension to restore patent term effectively lost following patent grant but during the FDA regulatory review process, the restoration period cannot be longer than five years, and the total patent term including the restoration period must not exceed 14 years following FDA approval.

We hold the worldwide intellectual property rights for CLN-978. Our portfolio related to our CLN-978 product candidate includes five patent families, directed to compositions, and methods of using such compositions therapeutically. The first two families of patent applications contain claims directed to CLN-978 compositions, which, if issued, are expected to expire in 2040, excluding any patent term adjustments or extensions, if applicable. Patent applications for both families have been filed in Australia, Canada, mainland China, the European Patent Office (the "EPO"), Hong Kong, Israel, Japan, and the U.S. The third family of patent applications contains claims directed to alternative formats of compositions related to CLN-978, which, if issued, are expected to expire in 2039. Patent applications have been filed for this family in Australia, Canada, mainland China, the EPO, Hong Kong, Israel, Japan, South Africa, and the U.S. There are two additional patent families claiming methods of use. These two families, if issued, are expected to expire in 2044, and the second is expected to expire in 2045, excluding any patent term adjustments or extensions, if applicable. Each of the patent families currently is comprised of a patent cooperation treaty (“PCT”) application. In September 2025, we were issued a composition of matter patent by the United States Patent and Trademark Office (the “USPTO”), which is expected to extend composition patent protection until at least 2042, excluding possible patent term extension.

We hold the worldwide, excluding Greater China, intellectual property rights for velinotamig. Our portfolio related to our velinotamig product candidate includes 4 patent families, directed to compositions and methods of using such compositions therapeutically. The first two patent families of patent applications contain claims directed to velinotamig compositions, which, if issued, are expected to expire between 2039 and 2045, excluding any patent term adjustments or extensions, if applicable. In December 2025, we were issued a composition of matter patent by the USPTO with an expiration date of 2042, excluding possible patent term extension. There are two additional patent families claiming methods of use. These two families, if issued, are expected to expire in 2046, excluding any patent term adjustments or extensions, if applicable.

We hold the worldwide intellectual property rights for CLN-049 through a development subsidiary that we had a 98% ownership interest in as of December 31, 2025. Our portfolio related to our CLN-049 product candidate includes two patent families, including one patent family, in-licensed from the University of Tübingen, directed to compositions and one patent family directed to the method of using such compositions therapeutically. The in-licensed family of patent applications contain claims directed to CLN-049 compositions, which, if issued, are expected to expire in 2039, excluding any patent term adjustments or extensions, if applicable. This patent family includes an issued U.S. patent which received patent term adjustment and is expected to expire in 2041. Patent applications have so far been filed for this family in Australia, Brazil, Canada, mainland China, the EPO, Hong Kong, India, Indonesia, Israel, Japan, South Korea, Malaysia, Mexico, New Zealand, the Philippines, Singapore, South Africa, Thailand, the U.S., and Vietnam. The additional patent family claims methods of use and, if issued, is expected to expire in 2046, excluding any patent term adjustments or extensions, if applicable.

We are collaborating on zipalertinib, for which Taiho holds the intellectual property rights, with an affiliate of Taiho. Zipalertinib is covered by a portfolio comprised of seven patent families that are in-licensed from Taiho. This portfolio includes a first family claiming specific EGFR-inhibiting compositions of matter which expires in 2034, excluding any patent term adjustments or extensions. This family includes granted patents or pending applications Australia, Brazil, Canada, mainland China, the EPO, India, Indonesia, Japan, South Korea, Malaysia, Mexico, Philippines, the Russian Federation, Singapore, Taiwan, Thailand, the U.S, and Vietnam. There are five additional families that are directed to methods of use in conditions comprising exon-20 insertion mutations, exon 18 mutations, and/or exon 21 mutations, as well as treatment regimens that are expected to expire between 2037 and 2046, excluding any patent term adjustments or extensions.

Individual patents extend for varying periods depending on the date of filing of the patent application or the date of patent issuance and the legal term of patents in the countries in which they are obtained. Generally, patents issued for regularly filed applications in the U.S. are granted a term of 20 years from the earliest effective non-provisional filing date. In addition, in certain instances, a patent term can be extended to recapture a portion of the U.S. Patent and Trademark Office (the "USPTO") review period in issuing the patent as well as a portion of the term effectively lost as a result of the FDA regulatory review period.

**Manufacturing**

We do not own or operate, nor do we currently have plans to establish, any manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for preclinical and clinical testing, as well as for commercial manufacture if any of our product candidates obtain marketing approval. We also rely, and expect to continue to rely, on third parties to package, label, store, and distribute our investigational product candidates and, if marketing approval is obtained, our commercial products. We believe this strategy allows us to maintain a more efficient infrastructure by eliminating the need for us to invest in our own manufacturing facilities, equipment, and personnel while also enabling us to focus our expertise and resources on the development of new product candidates.

We contract with contract manufacturing organizations ("CMOs") to receive materials manufactured for preclinical testing, as well as clinical supply material manufactured in compliance with current good manufacturing practice requirements ("cGMPs"). Because we rely on CMOs, we employ personnel with extensive technical, manufacturing, analytical, and quality experience to oversee work performed by those CMOs on our behalf. Our personnel have strong knowledge and understanding of the global regulations that govern manufacturing, documentation, quality assurance, and quality control of drug supply that are required to support our clinical development plans, and we conduct appropriate quality assurance oversight before and during clinical trials, in cooperation with our CMOs, to ensure compliance with the mutually agreed-upon process descriptions and cGMP regulations.

We utilize a global network of manufacturers for our programs in development, with vendors located in North America, Europe, and Asia. Certain nodes in the drug substance and drug product supply chains may rely on single source, third-party CMOs, which is typical for this stage of development and for companies of our profile. Any reduction or halt in supply of drug substance or drug product from these contract manufacturers, for any reason, could limit our ability to develop our product candidates until we either remedy the disruption or find a qualified replacement contract manufacturer, both of which may incur additional time and expense. However, in conjunction with our CMOs, we monitor and manage our supply chain network for potential changes and risks that could impact our global or regulatory manufacturing supply strategy. We have procured or have plans to procure sufficient drug substance to supply the planned initial clinical studies for our programs. At the appropriate time in development, we intend to put in place agreements under which our third-party contract manufacturers will generally provide us with necessary quantities of drug substance and drug product on a project-by-project basis, based on our projected development and commercial supply needs.

Our clinical product candidates, are manufactured from vials of master cell banks ("MCBs") derived from their respective production cell lines and are produced and tested in accordance with cGMPs and applicable regulations. We currently have one MCB for each of CLN-978 and CLN-049 and plan to establish an MCB for velinotamig, and we either already have in place or intend to produce GMP working cell banks ("WCBs") for each product candidate as needed later in development.

**Governmental Regulation**

The research, development, testing, manufacture, quality control, packaging, labeling, storage, record-keeping, distribution, import, export, promotion, advertising, marketing, sale, pricing, and reimbursement of drug and biologic products are extensively regulated by governmental authorities in the U.S. and other countries. The processes for obtaining regulatory approvals in the U.S. and foreign countries and jurisdictions, along with compliance of applicable statutes and regulations and other regulatory requirements, both pre-approval and post-approval, require the expenditure of substantial time and financial resources. The regulatory requirements applicable to drug and biological product development, approval, and marketing are subject to change, and regulations and administrative guidance often are revised or reinterpreted by the agencies in ways that may have a significant impact on our business.

***U.S. Food and Drug Administration Regulation***

The FDA and other U.S. regulatory authorities at federal, state, and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, safety, efficacy, import, export, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring, and post-approval reporting of drugs and biologics such as those we are developing. We, along with our vendors, collaboration partners, clinical research organizations ("CROs"), clinical trial investigators, and CMOs will be required to navigate the various preclinical, clinical, manufacturing, and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval of our product candidates. The process of obtaining regulatory approvals of drugs and ensuring subsequent compliance with appropriate U.S. federal, state, local, and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable regulatory requirements at any time during the product development process or post-approval may subject an applicant to delays in development or approval, as well as administrative and judicial sanctions.

In the U.S., the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act (as amended, the “FDCA"), and biologics under the FDCA and the Public Health Service Act (as amended, the "PHSA"), and their implementing regulations. Both drugs and biologics are also subject to other federal, state, and local statutes and regulations. We do not currently have any product candidates that have been approved by the FDA for marketing in the U.S.

Our product candidates must be approved for therapeutic indications by the FDA before they may be marketed in the U.S. For our biologic product candidates regulated under the FDCA and PHSA, such as CLN-978 and CLN-049, the FDA must approve a Biologics License Application ("BLA"). For our drug product candidates regulated under the FDCA, such as zipalertinib, the FDA must approve an NDA. The NDA and BLA approval processes are similar and generally involve the following:

- completion of extensive preclinical studies in accordance with applicable regulations, including studies conducted in accordance with good laboratory practice ("GLP") requirements;
- submission to the FDA of an IND which must become effective before clinical trials may begin and must be updated annually and when certain changes are made;
- approval by an institutional review board ("IRB") or independent ethics committee ("EC") at each clinical trial site before each clinical trial may be initiated;
- performance of adequate and well-controlled clinical trials in accordance with good clinical practice ("GCP") requirements and other clinical trial-related regulations to establish the safety and efficacy of the investigational product for each proposed indication;
- preparation and submission to the FDA of an NDA or BLA;
- payment of user fees for FDA review of the NDA or BLA, unless waived;
- a determination by the FDA within 60 days of its receipt of an NDA or BLA to file the application for review;
- satisfactory completion of one or more FDA pre-approval inspections of the manufacturing facility or facilities where the product will be produced to assess compliance with cGMPs to assure that the facilities, methods, and controls are adequate to ensure and preserve the drug or biological product’s identity, strength, quality and purity;
- satisfactory completion of any FDA audits of the clinical trial sites that generated the data in support of the NDA or BLA; and
- FDA review and approval of the NDA or BLA, including, where applicable, consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the drug or biologic in the U.S.

Before testing any drug or biologic in humans, the product candidate must undergo rigorous preclinical testing. Preclinical studies include *in vitro* and animal studies to assess preliminary safety and, in some cases, to establish the rationale for therapeutic use. The conduct of preclinical studies is subject to federal and state regulations and requirements, including GLP requirements for safety and toxicology studies. In the U.S., the results of the preclinical studies, together with manufacturing information and analytical data must be submitted to the FDA as part of an IND.

An IND is a request for authorization from the FDA to administer an investigational product to humans and must become effective before clinical trials may begin. 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, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. The IND will become effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions about the supportive data, or the study design, particularly regarding potential safety issues with conducting the clinical trial as described in the protocol. In this situation, the trials are placed on clinical hold, and the IND sponsor must resolve any outstanding FDA concerns before clinical trials can proceed.

Clinical trials involve the administration of the product candidate to healthy volunteers or patient participants under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCP requirements, which include the requirements that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters and criteria to be used in monitoring safety and evaluating effectiveness, including stopping rules that assure a clinical study will be stopped if certain adverse events should occur. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Furthermore, each clinical trial must be reviewed and approved by an IRB or EC, either centrally or at each institution at which the clinical trial will be conducted, to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable related to the anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed.

The FDA may, at any time during the initial 30-day IND review period or while clinical trials are ongoing under the IND, impose a partial or complete clinical hold based on concerns for patient safety and/or noncompliance with regulatory requirements. This order issued by the FDA would delay a proposed clinical study or cause suspension of an ongoing study until all outstanding concerns have been adequately addressed, and the FDA has notified us that investigations may proceed. Imposition of a clinical hold could cause significant delays or difficulties in completing planned clinical studies in a timely manner. In addition, the IRB or the sponsor may suspend or discontinue a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may 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. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trials to public registries. In the U.S., information about applicable clinical trials, including clinical trials results, must be submitted within a specific timeframe for publication on the www.clinicaltrials.gov website.

A sponsor who wishes to conduct a clinical trial outside of the U.S. may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. When a foreign clinical study is not conducted under an IND, the sponsor must ensure that the study complies with certain regulatory requirements, including GCP requirements, of the FDA in order to use the study as support for an IND or application for marketing approval. The 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.

Clinical trials to evaluate therapeutic indications to support NDAs and BLAs for marketing approval are typically conducted in three sequential phases, which may overlap or be combined.

- Phase 1—Phase 1 clinical trials involve initial introduction of the investigational product in a limited population of healthy human volunteers or patients with the target disease or condition in the case of some products for severe or life-threatening diseases. These studies are typically designed to test the safety, dosage tolerance, absorption, metabolism, and distribution of the investigational product in humans, evaluate the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness.
- Phase 2—Phase 2 clinical trials typically involve administration of the investigational product to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3—Phase 3 clinical trials typically involve administration of the investigational product to an expanded patient population to further evaluate dosage, to provide substantial evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval. Generally, two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of an NDA or BLA.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication and are commonly intended to generate additional safety data regarding use of the product in a clinical setting. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA or BLA. The mandatory studies are used to confirm clinical benefit in the case of drugs approved under the accelerated approval regulations or to provide additional clinical safety or efficacy data for "full" approvals. Failure to exhibit due diligence with regard to conducting required Phase 4 clinical trials could result in withdrawal of approval for products approved under accelerated approval regulations.

Progress reports detailing the results of clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. 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 studies or animal or *in vitro* testing that suggest a significant risk in humans exposed to the product; and any clinically important increase in the case of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Phase 1, Phase 2, and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. The FDA will typically inspect one or more clinical sites to assure compliance with GCP and the integrity of the clinical data submitted.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the drug or biological characteristics of the product candidate and finalize a process for manufacturing the drug product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and manufacturers must develop, among other things, methods for testing the identity, strength, quality, and purity of the final drug product. 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 and to identify appropriate storage conditions for the product candidates.

***Expanded Access***

Expanded access, also known as compassionate use, is the use of investigational products outside of clinical trials to treat patients with serious or immediately life-threatening diseases or conditions when there are no comparable or satisfactory alternative treatment options. FDA regulations allow access to investigational products on a case-by-case basis for the following groups: individual patients (single-patient INDs for treatment in emergency settings and non-emergency settings); intermediate-size patient populations; and larger populations for use of the investigational product under a treatment protocol or treatment IND.

Under the FDCA, sponsors of one or more investigational products for the treatment of a serious disease or condition must make publicly available their policy for evaluating and responding to requests for expanded access for individual patients. Sponsors are required to make such policies publicly available upon the earlier of initiation of a Phase 2 or Phase 3 clinical trial, or 15 days after the investigational drug or biologic receives designation as a Breakthrough Therapy, Fast Track product, or regenerative medicine advanced therapy.

In the U.S., the Right to Try Act, among other things, provides an additional mechanism for patients with a life-threatening condition who have exhausted approved treatments and are unable to participate in clinical trials to access certain investigational products that have completed a Phase 1 clinical trial, are the subject of an active IND, and are undergoing investigation for FDA approval. Unlike the expanded access framework described above, the Right to Try Act does not require the FDA to review or approve requests for use of the investigational product. There is no obligation for a sponsor to make its investigational products available to eligible patients as a result of the Right to Try Act, but the sponsor must develop an internal policy and respond to patient requests according to that policy.

***FDA Marketing Application Review and Approval Process***

A company seeking marketing approval for a new drug or biologic in the U.S. must submit the results of the preclinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things including payment of a user fee for review of the application, are submitted to the FDA as part of an NDA or BLA requesting approval to market the product for one or more indications. An NDA is a request for approval to market a new drug for one or more specified indications, and a BLA is a request for approval to market a new biologic for one or more specified indications. The NDA or BLA must include all relevant data available from pertinent preclinical studies and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational drug, or the safety, purity and potency of the investigational biologic, to the satisfaction of the FDA. FDA approval of an NDA or BLA must be obtained before a drug or biologic may be marketed in the U.S.

In addition, under the Pediatric Research Equity Act ("PREA"), certain NDAs and BLAs and certain supplements to an NDA or BLA must contain data to assess the safety and effectiveness of the drug or biological product candidate 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 and effective. The Food and Drug Administration Safety and Innovation Act requires that a sponsor who is planning to submit a marketing application or supplement to an application for a drug or biological product that includes a new active ingredient or clinically active component, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan within 60 days after an end-of-Phase 2 meeting or as may be agreed between the sponsor and the FDA. Unless otherwise required by regulation, PREA does not apply to a drug or biological product for an indication for which orphan designation has been granted.

In the U.S., the FDA reviews all submitted NDAs and BLAs to ensure they are sufficiently complete to permit substantive review before it accepts them for filing and may request additional information rather than accepting the application for filing. The FDA may refuse to file any NDA or BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the NDA or BLA must be resubmitted with additional information. Once the submission is accepted for filing, the FDA begins an in-depth review of the marketing application. Applications receive either standard or priority review. Under the current goals mandated under the Prescription Drug User Fee Act (the "PDUFA"), the FDA has ten months in which to complete its initial review of a standard marketing application and respond to the applicant, and six months for a priority marketing application. The FDA does not always meet its PDUFA goal dates for standard or priority marketing applications. The review process and the PDUFA goal date may be extended by three months if the FDA requests or the marketing application sponsor otherwise provides additional substantial information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date. The FDA may further refer an application to an advisory committee for review, evaluation, and recommendation as to whether the application should be approved. Though the FDA is not bound by such recommendations, it considers them carefully when making decisions. If the FDA's evaluations of the marketing application and the clinical and manufacturing procedures and facilities are favorable, the FDA may issue an approval letter. If the FDA finds deficiencies in the marketing application, it may issue a complete response letter, which defines the conditions that must be met in order to secure final approval of the marketing application. If and when those conditions have been met to the FDA's satisfaction, the FDA will issue an approval letter, authorizing commercial marketing of the drug. Sponsors that receive a complete response letter may submit to the FDA information that represents a complete response to the issues identified by the FDA. A resubmission by the marketing application sponsor in response to a complete response letter trigger new review periods of varying length (typically two to six months) based on the content of the resubmission. Before approving an NDA or BLA, the FDA typically will 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 an NDA or BLA, the FDA may inspect one or more clinical trial sites to assure compliance with GCP and other requirements and the integrity of the clinical data submitted to the FDA. To assure GMP and GCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production, and quality control. If the FDA's evaluation of the marketing application and the commercial manufacturing procedures and facilities is not favorable, the FDA may not approve the marketing application.

Even if the FDA approves a product, depending on the specific risk(s) to be addressed, the FDA may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a product's safety or efficacy after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a risk evaluation and mitigation strategy ("REMS"), which can materially affect the potential market and profitability of the product. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use ("ETASU"). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patent registries. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval.

***Orphan Drug Designation and Exclusivity***

Under the Orphan Drug Act, the FDA may grant orphan drug designation ("ODD") to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with either a patient population of fewer than 200,000 individuals in the U.S., or a patient population of greater than 200,000 individuals 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. of that drug or biologic. ODD must be requested before submitting an NDA or BLA. After the FDA grants ODD, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. The granting of ODD does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has received ODD and subsequently receives the first FDA approval for that drug 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 full NDA or BLA, to market the same drug or biologic for the same indication for seven years from the approval of the NDA or BLA, 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. Orphan drug 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 ODD are tax credits for certain research and a waiver of the NDA or BLA application user fee.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received ODD. In addition, orphan drug exclusive marketing rights in the U.S. 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 has historically taken the position that the scope of orphan exclusivity aligns with the approved indication or uses of a product, rather than the disease or condition for which the product received orphan designation. However, on September 30, 2021, the U.S. Court of Appeals for the Eleventh Circuit issued a decision in *Catalyst Pharms., Inc. v. Becerra* holding that the scope of orphan drug exclusivity must align with the disease or condition for which the product received orphan designation, even if the product's approval was for a narrower use or indication. The FDA announced on January 24, 2023 that, despite the *Catalyst* decision, it will continue to apply its longstanding regulations, which tie the scope of orphan exclusivity to the uses or indications for which the drug is approved, rather than to the designation. The FDA's application of its orphan drug regulations post-*Catalyst* could be the subject of future legislation or to further challenges in court.

***Pediatric Studies***

Under PREA, certain NDAs and BLAs and certain supplements to an NDA or BLA must contain data to assess the safety and effectiveness of the drug or biological product candidate 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 and effective. The Food and Drug Administration Safety and Innovation Act requires that a sponsor that is planning to submit a marketing application or supplement to an application for a drug or biological product that includes a new active ingredient or clinically active component, new indication, new dosage form, new dosing regimen, or new route of administration submit an initial Pediatric Study Plan ("PSP") within 60 days after an end-of-Phase 2 meeting or as may be agreed between the sponsor and the FDA. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints, and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach agreement on the PSP prior to submission of a marketing application. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from nonclinical studies, early phase clinical trials, and/or other clinical development programs. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of data or full or partial waivers for pediatric studies. Unless otherwise required by regulation, PREA does not apply to a drug or biological product for an indication for which orphan designation has been granted.

***Expedited Development and Review Programs***

The FDA maintains several programs intended to facilitate and expedite development and review of new drugs and biologics to address unmet medical needs in the treatment of serious or life-threatening diseases or conditions. These programs include Fast Track designation, Breakthrough Therapy designation, priority review and accelerated approval. Fast Track designation, Breakthrough Therapy designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process.

A new drug or biologic is eligible for Fast Track designation if it is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address unmet medical needs for such disease or condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. Fast Track designation provides increased opportunities for sponsor interactions with the FDA during preclinical and clinical development, in addition to the potential for rolling review once a marketing application is filed, meaning that the FDA may initiate review of sections of a Fast Track product's application before the application is complete upon satisfaction of certain conditions.

In addition, a new drug or biological product may be eligible for Breakthrough Therapy designation if it is intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug or biologic, alone or in combination with or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Breakthrough Therapy designation provides all the features of Fast Track designation in addition to intensive guidance on an efficient development program beginning as early as Phase 1, and FDA organizational commitment to expedited development, including involvement of senior managers and experienced review staff in a cross-disciplinary review, where appropriate.

Any product submitted to the FDA for approval, including a product with Fast Track or Breakthrough Therapy designation, may also be eligible for priority review. A product is eligible for priority review if it is intended to treat a serious or life-threatening disease or condition, and if approved, would provide a significant improvement in safety or effectiveness. For original NDAs and BLAs, 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).

The FDA may grant accelerated approval to a product intended to treat a serious or life-threatening disease or condition that generally provides a meaningful therapeutic advantage to patients over available treatments, and demonstrates 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 ("IMM") that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments.

For drugs granted accelerated approval, the FDA generally requires sponsors to conduct, in a diligent manner, adequate and well-controlled post-approval confirmatory studies to verify and describe the product's clinical benefit. Failure to conduct required post-approval studies with due diligence, failure to confirm a clinical benefit during the post-approval studies, or dissemination of false or misleading promotional materials would allow the FDA to withdraw the product approval on an expedited basis. The Food and Drug Omnibus Reform Act of 2022 ("FDORA"), enacted on December 29, 2022, as part of the Consolidated Appropriations Act, 2023, includes numerous reforms to the accelerated approval process for drugs and biologics and enables the FDA to require, as appropriate, that a post-approval study be underway prior to granting accelerated approval. FDORA also expands the expedited withdrawal procedures available to the FDA to allow the agency to use expedited procedures if a sponsor fails to conduct any required post-approval study of the product with due diligence. FDORA also adds the failure of a sponsor of a product approved under accelerated approval to conduct with due diligence any required post-approval study with respect to such product or to submit timely reports with respect to such product to the list of prohibited acts in the FDCA. All promotional materials for product candidates approved under accelerated approval are subject to prior review by the FDA unless the FDA informs the applicant otherwise.

***FDA Approval or Clearance of Companion Diagnostics***

In August 2014, the FDA issued final guidance clarifying the requirements that will apply to the development and approval of therapeutic products intended for use with *in vitro* companion diagnostics. According to the guidance, for novel drugs and biologics, a companion diagnostic device and its corresponding therapeutic should be approved or cleared contemporaneously by the FDA for the use indicated in the therapeutic product's labeling. Approval or clearance of the companion diagnostic device will ensure that the device has been adequately evaluated and has adequate performance characteristics in the intended population. In July 2016, the FDA issued a draft guidance intended to assist sponsors of the therapeutic products and *in vitro* companion diagnostic devices on issues related to co-development of the products. In April 2020, the FDA issued a final guidance on the development and labeling of *in vitro* companion diagnostic devices for oncology therapeutics products.

Under the FDCA, *in vitro* diagnostics, including companion diagnostics, are regulated as medical devices. In the U.S., the FDCA and its implementing regulations, and other federal and state statutes and regulations govern, among other things, medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import, and post-market surveillance. Unless an exemption applies, diagnostic tests require marketing clearance or approval from the FDA prior to commercial distribution.

The FDA previously has required *in vitro* companion diagnostics intended to select the patients who will respond to a product candidate to obtain premarket approval ("PMA"), simultaneously with approval of the therapeutic product candidate. The PMA process, including the gathering of clinical and preclinical data and the submission to and review by the FDA, can take several years or longer. It involves a rigorous premarket review during which the applicant must prepare and provide the FDA with reasonable assurance of the device's safety and effectiveness and information about the device and its components regarding, among other things, device design, manufacturing and labeling. PMA applications are subject to an application fee.

A clinical trial is typically required for a PMA application and, in a small percentage of cases, the FDA may require a clinical study in support of a Premarket Notification under Section 510(k) of the FDCA. A manufacturer that wishes to conduct a clinical study involving the device is subject to the FDA's investigational device exemption ("IDE") regulations. The IDE regulations distinguish between significant and non-significant risk device studies and the procedures for obtaining approval to begin the study differ accordingly. Also, some types of studies are exempt from the IDE regulations. A significant risk device presents a potential for serious risk to the health, safety, or welfare of a subject. Significant risk devices are devices that are substantially important in diagnosing, curing, mitigating, or treating disease or in preventing impairment to human health. Studies of devices that pose a significant risk require both FDA and an IRB approval prior to initiation of a clinical study. Many companion diagnostics are considered significant risk devices due to their role in diagnosing a disease or condition. Non-significant risk devices are devices that do not pose a significant risk to the human subjects. A non-significant risk device study requires only IRB approval prior to initiation of a clinical study.

After a device is placed on the market, it remains subject to significant regulatory requirements. Medical devices may be marketed only for the uses and indications for which they are cleared or approved. Device manufacturers must also establish registration and device listings with the FDA.

In the U.S., device manufacturers are also subject to the FDA's medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur, and the FDA's correction and removal reporting regulations, which require that manufacturers report to the FDA corrections or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health. A medical device manufacturer's manufacturing processes and those of its suppliers are required to comply with the applicable portions of the FDA's Quality System Regulation, which covers the methods and documentation of the design, testing, production, processes, controls, quality assurance, labeling, packaging and shipping of medical devices. Domestic facility records and manufacturing processes are subject to periodic unscheduled inspections by the FDA. The FDA also may inspect foreign facilities that export products to the U.S.

***Post-Approval Requirements for Drugs and Biologics in the U.S.***

In the U.S., drugs and biologics manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, reporting of adverse experiences with the product, complying with promotion and advertising requirements, which include restrictions on promoting products for unapproved uses or patient populations (known as "off-label use") and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe approved products for off-label uses, manufacturers may not market or promote such uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, including not only by Company employees but also by agents of the Company or those speaking on the Company's behalf, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties, including liabilities under the False Claims Act where products carry reimbursement under federal health care programs. Promotional materials for approved drugs and biologics must be submitted to the FDA in conjunction with their first use or first publication. Further, if there are any modifications to the product, including proposed changes to the indication, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new or supplemental NDA or BLA, which may require the development of additional data or preclinical studies and clinical trials.

The FDA may impose a number of post-approval requirements as a condition of approval of an NDA or BLA. For example, the FDA may require post-market testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

The FDA periodically inspects the sponsor's records related to safety reporting and/or manufacturing; the latter including assessment of compliance with cGMP through periodic unannounced inspections. Accordingly, manufacturers and their subcontractors involved in the manufacture and distribution of approved products are required to register their establishments with the FDA and to maintain compliance with ongoing regulatory requirements, including cGMP, requiring continual expenditure of time, money and effort in the area of production and quality control to maintain compliance. Failure to comply with statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as warning letters, suspension of manufacturing, product seizures, injunctions, civil penalties or criminal prosecution. There is also a continuing, annual program fee for any marketed product.

The FDA may withdraw 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, requirements for post-market studies or clinical trials to assess new safety risks, or imposition of distribution or other restrictions under a REMS. 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 Health Care Provider letters, press releases or other communications containing warnings or other safety information about the product;
- mandated modification of promotional materials and labeling and issuance of corrective information;
- fines, warning letters, or untitled letters;
- holds on clinical trials;

- refusal of the FDA to approve applications or supplements to approved applications, or suspension or revocation of product 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 healthcare programs.

***U.S. Patent Term Restoration and Marketing Exclusivity***

Depending upon the timing, duration, and specifics of FDA approval of our current and future product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit restoration of the patent term of up to five years as compensation for patent term lost during the FDA regulatory review process. Patent-term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. The patent-term restoration period is generally one-half the time between the effective date of an IND and the submission date of a marketing application plus the time between the submission date and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant marketing application.

Regulatory exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the U.S. to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application ("ANDA") or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement.

The FDCA also provides three years of exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent for other conditions of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

In addition, both drugs and biologics can also obtain pediatric exclusivity in the U.S. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which attaches to the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

***U.S. Biosimilars and Exclusivity***

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "ACA"), includes a subtitle called the Biologics Price Competition and Innovation Act (the "BPCIA"), which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars in the U.S. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product, and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

Under the BPCIA, a reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product, and an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

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 ACA, 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 regulatory interpretation of the BPCIA remain subject to significant uncertainty.

***Other U.S. Regulatory Matters***

Manufacturing, sales, promotion, and other activities of product candidates following product approval, where applicable, or commercialization are also subject to regulation by numerous regulatory authorities in the U.S. in addition to the FDA, which may include the Centers for Medicare & Medicaid Services ("CMS"), other divisions of the Department of Health and Human Services ("HHS"), the Department of Justice ("DOJ"), the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency, and state and local governments and governmental agencies.

***Other Healthcare Laws in the U.S.***

In the U.S., pharmaceutical manufacturers and their products are subject to extensive regulation, including laws intended to prevent fraud and abuse in the healthcare industry. These laws subject pharmaceutical manufacturers and their products to regulation by national, state and local agencies, including, but not limited to the DOJ, the Office of Inspector General of the U.S. Department of Health and Human Services, and other regulatory bodies. These laws, some of which apply to pharmaceutical manufacturers only after the manufacturers have marketed products, include:

- federal false claims, false statements, and civil monetary penalties laws prohibiting, among other things, any person from knowingly presenting, or causing to be presented, a false claim for payment of government funds or knowingly making, or causing to be made, a false statement to get a false claim paid;
- the federal anti-kickback law, which prohibits, among other things, persons from offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual for, or the purchasing and ordering of a good or service for which payment may be made under federal healthcare programs such as Medicare and Medicaid;
- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which, in addition to privacy protections applicable to healthcare providers and other entities, prohibits executing a scheme to defraud any healthcare benefit program or making false statements related to healthcare matters;
- the FDCA, which among other things, strictly regulates drug marketing, prohibits manufacturers from marketing products prior to approval or for off-label use and regulates the distribution of samples;
- federal laws that require pharmaceutical manufacturers to calculate, report, and certify certain complex product prices and other data to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs, which data may be used in the calculation of reimbursement and/or discounts on approved products;
- the federal Open Payments (or federal "sunshine" law), which requires pharmaceutical and medical device companies to monitor and report certain financial interactions with certain healthcare providers to the Center for Medicare & Medicaid Services within the U.S. Department of Health and Human Services for re-disclosure to the public, as well as ownership and investment interests held by physicians and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, consumer protection and unfair competition laws, and laws governing privacy, security, and breaches of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and
- state laws that require pharmaceutical companies to comply with specific compliance standards, restrict financial interactions between pharmaceutical companies and healthcare providers, report drug product pricing information, financial interactions with health care providers, or marketing expenditures and/or require the registration of pharmaceutical sales representatives.

In addition, pharmaceutical manufacturers may also be subject to U.S. federal and state consumer protection and unfair competition laws and regulations, which broadly regulate marketplace activities and activities that potentially harm consumers.

The distribution of pharmaceutical products is subject to additional requirements and regulation, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

Federal and state enforcement bodies have continued to increase their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring compliance with healthcare laws is time-consuming and costly. Given the breadth of the laws and regulations, limited guidance for certain laws and regulations and evolving government interpretations of the laws and regulations, governmental authorities may possibly conclude that our business practices are non-compliant. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, imprisonment, and the curtailment or restructuring of our operations, any of which could adversely affect our business, financial condition, results of operations, and prospects.

***U.S. Coverage and Reimbursement***

The ability of a pharmaceutical manufacturer to successfully commercialize and achieve market acceptance of a product depends in significant part on adequate coverage and reimbursement from third-party payors, including government healthcare programs, such as Medicare and Medicaid programs, and private entities, such as managed care organizations and private health insurers. In the U.S., no uniform policy of coverage and reimbursement for drug products exists among third-party payors and coverage and reimbursement for drug products can differ significantly from payor to payor. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved.

Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. To obtain or maintain coverage and reimbursement for any approved drug product, a pharmaceutical manufacturer may need to conduct expensive pharmacoeconomic studies or otherwise provide evidence to demonstrate the medical necessity and cost-effectiveness of our product. These studies will be in addition to the studies required to obtain or maintain regulatory approvals. If third-party payors do not consider a product to be cost-effective compared to other available therapies, the payors may not cover the product or, if they do, the level of payment may not be sufficient to allow sale of a product at a profit.

Even if third-party payors provide some coverage, the third-party payors may impose limits on the coverage or controls to manage utilization of products. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication and can exclude drugs from their formularies in favor of competitor drugs or alternative treatments. Payors may also impose step edits that require patients to try alternative, including generic, treatments before authorizing payment for our products, limit the types of diagnoses for which coverage will be provided, require pre-approval (known as "prior authorization") for coverage of a prescription for each patient (to allow the payor to assess medical necessity) or impose a moratorium on coverage for products while the payor makes a coverage decision.

Moreover, a third-party payor's decision to provide coverage for a product does not mean that an adequate reimbursement rate will be approved. We may be required to provide mandatory discounts or rebates to certain purchasers to obtain coverage under federal healthcare programs or to sell products to government purchasers. A pharmaceutical manufacturer may have to offer discounts or rebates to private third-party payors to obtain favorable coverage. Adequate third-party reimbursement may not be available to enable us to maintain net price levels sufficient to realize an appropriate return on our investment in product development.

The containment of healthcare costs has become a priority of federal and state governments, and the prices of products have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption or enhancement of price controls and cost-containment measures could further limit a company's revenue generated from the sale of any approved products. Coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which a company or its collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

***Healthcare Reform***

In the U.S. and some foreign jurisdictions, there have been, and likely will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system directed at broadening the availability of healthcare, improving the quality of healthcare, and containing or lowering the cost of healthcare. For example, in 2010, the U.S. enacted the ACA, which, among other things, subjected biologic products to potential competition by lower-cost biosimilars; addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations; subjected manufacturers to new annual fees and taxes for certain branded prescription drugs; and established a Medicare Part D coverage gap discount program. More generally, the ACA expanded health care coverage through Medicaid expansion and the implementation of the "individual mandate" for health insurance coverage.

Beyond the ACA, there have been ongoing health care reform efforts. Drug pricing and payment reform was a focus of past U.S. presidential administrations and will likely be a focus of the current administration. For example, federal legislation eliminated the statutory cap on Medicaid drug rebate program rebates, currently set at 100% of a drug's "average manufacturer price", effective January 1, 2024. As another example, the Inflation Reduction Act of 2022 (the "IRA") includes a number of changes intended to address rising prescription drug prices in Medicare Parts B and D. These changes, which have varying implementation dates, include caps on Medicare Part D out-of-pocket costs, Medicare Part B and Part D drug price inflation rebates, a new Medicare Part D manufacturer discount drug program, replacing the ACA Medicare Part D coverage gap discount program, and a drug price negotiation program for certain high spend Medicare Part B and D drugs. The focus on health care reform, including reform of drug pricing and payment, has continued in the wake of the IRA. Other potential healthcare reform efforts may affect access to healthcare coverage or the funding of health care benefits. There is significant uncertainty regarding the nature or impact of any such reform implemented through executive action or by Congress.

Healthcare reform efforts have been and may continue to be subject to scrutiny and legal challenge. For example, with respect to the ACA, tax reform legislation was enacted that eliminated the tax penalty established for individuals who do not maintain mandated health insurance coverage beginning in 2019 and, in 2021, the U.S. Supreme Court dismissed the latest judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. As another example, revisions to regulations under the federal anti-kickback statute would remove protection for traditional Medicare Part D discounts offered by pharmaceutical manufacturers to pharmacy benefit managers and health plans. Pursuant to court order, the removal was delayed, and subsequent legislation imposed a moratorium on implementation of the rule until January 2032. As another example, the IRA drug price negotiation program has been challenged in litigation filed by various pharmaceutical manufacturers and industry groups.

There have also been efforts by federal and state government officials or legislators to implement measures to regulate prices or payment for pharmaceutical products, including legislation on drug importation. Recently, there has been considerable public and government scrutiny of pharmaceutical pricing and proposals to address the perceived high cost of pharmaceuticals. There have also been recent state legislative efforts to address drug costs, which generally have focused on increasing transparency around drug costs or limiting drug prices.

General legislative cost control measures may also affect reimbursement for our product candidates. The Budget Control Act, as amended, resulted in the imposition of reductions in Medicare, but not Medicaid, payments to providers in 2013 and will remain in effect into 2032 unless additional Congressional action is taken. Any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented and/or any significant taxes or fees that may be imposed on us could have an adverse impact on our results of operations.

Adoption of new legislation at the federal or state level could affect demand for, or pricing of, any future products if approved for sale. We cannot, however, predict the ultimate content, timing or effect of any federal and state reform efforts. There is no assurance that federal or state health care reform will not adversely affect our future business and financial results.

Outside the U.S., ensuring coverage and adequate payment for a product also involves challenges. Pricing of prescription pharmaceuticals is subject to government control in many countries. Pricing negotiations with government authorities can extend well beyond the receipt of regulatory approval for a product and may require a clinical trial that compares the cost-effectiveness of a product to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in commercialization.

In the European Union (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 the cost-effectiveness of a particular product candidate to currently available therapies or so-called health technology assessments, in order to obtain reimbursement or pricing approval. For example, the EU provides options for its member states to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. An EU member state may approve a specific price for a product, or it may instead adopt a system of direct or indirect controls on the profitability of the Company placing the product on the market. Other member states allow companies to fix their own prices for products but monitor and control prescription volumes and issue guidance on prescribing criteria to physicians, having an effect on restricting prescriptions or usage. Recently, many countries in the EU have increased the amount of discounts required on pharmaceuticals and these efforts could continue as countries attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the EU. The downward pressure on healthcare costs in general, particularly prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU member states, and parallel trade, i.e., arbitrage between low-priced and high-priced member states, can further reduce prices. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any products, if approved in those countries.

In the EU, medicinal products are subject to comprehensive pre- and post-market regulation by both EU and national authorities, ensuring oversight of authorization, safety, efficacy, quality, and ongoing monitoring. Recent reforms introduced through a new directive and regulation (the “EU Pharma Package”) bring significant changes, including streamlined authorization procedures, enhanced measures for access and affordability, stricter management of medicine shortages, strengthened post-market surveillance, and new requirements addressing environmental and ethical considerations. These initiatives are designed to modernize and harmonize medicines regulation, facilitate patient access to innovative therapies, and provide robust oversight of emerging technologies across the EU.

The legislative process for the EU Pharma Package began with the European Commission’s proposal in April 2023, followed by the development of positions by the European Parliament and the European Council. This culminated in trilogue negotiations, with a political agreement reached in December 2025. The agreed text now awaits formal adoption by both the European Parliament and European Council, after which it will be published in the Official Journal of the EU. The new directive and regulation will then enter into force following a transition period of 18 to 36 months, ultimately modernizing EU pharmaceutical law to better support innovation, access, and supply. Under the agreed EU Pharma Package, companies launching new medicines will benefit from eight years of data protection and one year of marketing exclusivity, with a possible additional year for innovative products meeting specific criteria. The package empowers EU countries to require adequate supply of protected medicines to meet patient needs and introduces safeguards to prevent misuse for parallel trade. It provides an intellectual property exemption for generic manufacturers to prepare for immediate market entry post-patent expiry and extends this to procurement submissions. In addition, the European Commission proposed the Biotech Act in December 2025, which seeks to strengthen the competitiveness of the biotechnology sector and facilitate the development and timely market entry of biotechnology innovations, while ensuring high standards for the protection of human health.

***European Drug Development***

In addition to regulations in the U.S., our business is subject to a variety of foreign regulations governing clinical trials, marketing, and distribution of our products. Irrespective of whether it concerns an FDA approved or investigational drug, the commencement of clinical trials and the subsequent marketing of a drug product in foreign countries are subject to preliminary approvals from the corresponding regulatory authorities of such countries. For example, the conduct of clinical trials in the European Union is governed by the Clinical Trials Regulation (EU) No 536/2014 and the principles and guidelines on GCP.

Similar to the U.S., the various phases of preclinical and clinical research in the EU are subject to significant regulatory controls. The currently applicable Regulation (EU) No 536/2014 (the "CTR") requires a clinical trial sponsor to obtain approval from the national competent authority ("NCA") of each European Union member state in which the clinical trial is to be conducted. Furthermore, the sponsor can only start a clinical trial at a specific clinical trial site after the local research ethics committee ("REC") has issued a favorable opinion.

Pursuant to the CTR, a sponsor can submit a single application for a clinical trial authorization ("CTA") through a centralized EU clinical trials portal called the Clinical Trials Information System ("CTIS"). One NCA (the reporting EU member state selected by the sponsor) takes the lead in validating and evaluating the application, as well as consulting and coordinating with the other concerned member states in which the clinical trial is to be conducted. If an application is rejected, it may be amended and resubmitted through CTIS. A concerned member state may in limited circumstances declare an "opt-out" from an approval and prevent the clinical trial from being conducted in that member state.

The EU transition to CTR encompassed a three-year period: from January 31, 2023, the submission of initial CTA applications for a new clinical trial under the CTR via CTIS became mandatory, and by January 31, 2025, all ongoing clinical trials approved under the old regime must comply with the CTR and information relating to such clinical trials must be transitioned to CTIS. All suspected unexpected serious adverse reactions to the investigated drug that occurred during the clinical trial must be reported to the NCA and ECs of the EU member state where they occurred.

***European Drug Marketing***

Much like the Anti-Kickback Statue prohibition in the U.S., the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the EU. The provision of benefits or advantages to induce or reward improper performance generally is governed by the national anti-bribery laws of EU member states, and the Bribery Act 2010 in the UK infringement of these laws could result in substantial fines and imprisonment. EU Directive 2001/83/EC, which governs medicinal products for human use, further provides that, where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy. This provision is reflected in the UK Human Medicines Regulations 2012.

In the EU and UK, the statutory regimes applicable to the advertising of medicinal products are supplemented by self-regulatory regimes set out in the relevant country's industry code of practice; these codes of practice are developed by domestic trade organizations and are only binding on companies which are members of the relevant trade organization. However, since they represent the best practice, many non-members choose to abide by these codes of practices as well. These codes of practice require payments made to physicians to be publicly disclosed. In addition, as a matter of law, payments made to physicians in certain EU member states, such as France, must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU member states. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

***European Drug Review and Approval***

In the European Economic Area (the "EEA"), which is comprised of the member states of the EU together with Norway, Iceland and Liechtenstein, medicinal products can only be commercialized after obtaining a marketing authorization ("MA").

In order to obtain a marketing authorization for a medicinal product in the EU, an applicant is required to submit a marketing authorization application ("MAA") to either (a) the national competent authorities (albeit through the decentralized, mutual recognition, or national procedures) or (b) the EMA (through the centralized authorization procedure). Applicants are required to demonstrate the quality, safety and efficacy of the medicinal product in the application for marketing authorization. In order to support the benefit/risk assessment, an applicant is required to conduct human clinical trials to generate the necessary clinical data. Regulation (EC) No 726/2004 of the European Parliament and of the Council lays down the rules applicable to the centralized procedure for the authorization of medicinal products. Article 3 of Regulation (EC) No 726/2004 defines in which cases the centralized application procedure must (mandatory scope) or may (optional scope) be followed. The centralized procedure is mandatory for medicinal products derived from biotechnological and other high-tech processes, orphan medicinal products, advanced therapy medicinal products and products indicated for the treatment of HIV/AIDS, cancer, diabetes, auto-immune and other immune dysfunctions, viral diseases, and neurodegenerative diseases. For medicinal products that do not fall under any of the aforementioned categories, a submission via the centralized procedure is possible, provided that it concerns (i) a new active substance or (ii) product that can demonstrate a significant therapeutic, scientific, or technical innovation and for which approval would be in the interest of public health. Given the foregoing, our portfolio of product candidates of autoimmune diseases is subject to the mandatory centralized procedure.

The centralized procedure allows pharmaceutical companies to submit a single application to the EMA, which is followed by a single evaluation, resulting in a single approval to market the medicinal product throughout the EEA. Approval via the centralized procedure is a two-step process whereby the Committee for Medicinal Products for Human Use (the "CHMP") first evaluates the MAA and issues an opinion on whether the medicinal product may be authorized or not (step 1). The CHMP opinion is subsequently sent to the EC, which takes a legally binding decision to grant a marketing authorization (step 2). The marketing authorization is valid throughout the EU and is automatically recognized in the EEA states. This allows the marketing authorization holder to market the medicine and make it available throughout the EEA. The timeframe for the first step of the centralized procedure (evaluation by the CHMP) opinion is 210 days from receipt of a valid application. However, the actual time needed to complete this first step is generally longer than the 210 days, since procedural clock stops are required in order for the applicant to respond to additional requests for information by the CHMP. Following a positive CHMP opinion, the EC ordinarily issues its implementing decision within 67 days to grant the marketing authorization. National MAs, which are issued by the NCAs of the EEA member states and only cover their respective territory, are available for products not falling within the mandatory scope of the centralized procedure. Where a product has already been authorized for marketing in a member state of the EEA, this national MA can be recognized in other EEA member states through the mutual recognition procedure. If the product has not received a national MA in any EEA member state at the time of application, it can be approved simultaneously in various EEA member states through the decentralized procedure.

Under the procedures described above, before granting the MA, the EMA or the NCAs of the EEA member states assess the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy. Now that the UK (which comprises Great Britain and Northern Ireland) has left the EU, Great Britain will no longer be covered by centralized MAs. Under the Northern Ireland Protocol, centralized MAs were recognized in Northern Ireland until it was replaced by the Windsor Framework as detailed below.

Accelerated evaluation of the MAA under the centralized procedure is possible in exceptional cases, following a justified request from the applicant, when a medicinal product is of a major public health interest, particularly from the point of view of therapeutic innovation. The CHMP determines what constitutes a major public interest on a case-by-case basis. Justifications must include the major benefits expected and present the arguments to support the claim that the medicinal product introduces new methods of therapy or improves on existing methods, thereby addressing, to a significant extent, the greater unmet needs for maintaining and improving public health. If the applicant provides sufficient justification for an accelerated assessment, the CHMP can reduce the timeframe for review of a MAA to 150 days. The timeframe for the EC to issue its decision remains unaltered.

Similar to the U.S., marketing authorization holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA and/or the national competent authorities of the EU member states. This oversight applies both before and after the granting of manufacturing and marketing authorizations. It includes compliance with EU GMP and GDP rules in relation to such activities as distribution, importing and exporting of medicinal products, rules governing conduct of pharmacovigilance, including good pharmacovigilance practices (“GVP”), and requirements governing advertising, promotion and sale of medicinal products.

The EU is undergoing a revision of its general pharmaceutical legislation to consolidate various legal instruments and introduce significant changes to achieve key policy objectives such as improving patient access to medicines, enhancing supply chain security, promoting innovation, ensuring environmental sustainability, and addressing antimicrobial resistance. The legislative proposal was considered by the European Parliament in April 2024 for a position to be adopted. The legislative process will take considerable time to complete as the proposal will require agreement by the European Parliament and the European Council. It is unlikely that an agreement would be adopted before 2026.

Regulatory approval processes outside of the U.S. and EU vary from country to country and the time may be longer or shorter than timelines for approval outlined above. In addition, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement for market access vary greatly from country to country. In all cases, clinical trials are to be conducted in accordance with GCP, applicable regulatory requirements, and the ethical principles that have their origin in the Declaration of Helsinki.

***European Data and Marketing Exclusivity***

In the EEA, innovative medicinal products (including both small molecules and biological medicinal products) approved on the basis of a complete independent data package consisting of quality, preclinical testing results, and clinical trial data benefit from eight years of data exclusivity upon grant of an MA and an additional two years of market exclusivity. The data exclusivity prevents generic or biosimilar applicants from cross-referencing the innovator's preclinical and clinical trial data contained in the dossier of the reference medicinal product when applying for a generic or biosimilar MA until the data exclusivity period has expired. During the additional two-year period of market exclusivity, a generic or biosimilar MA can be submitted, and the innovator's pre-clinical and clinical data can be cross-referenced, but no generic or biosimilar product can be marketed until the expiration of the market exclusivity period. The overall ten-year period will be extended to a maximum of 11 years if, during the first eight years of those ten years, the MA holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are determined to bring a significant clinical benefit in comparison with currently approved therapies. The UK domestic law follows the same formula of regulatory data and market exclusivity. This period of data and marketing exclusivity may be reduced under the EU legislative proposal as referenced above.

***European Orphan Designation and Exclusivity***

Regulation (EC) No 141/2000 provides that a product can be designated as an orphan medicinal product by the European Commission, upon satisfactory scientific assessment by the EMA's Committee for Orphan Medicinal Products ("COMP"), if the sponsor can establish: that the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition which either affects not more than five in 10,000 persons in the EU, or where it is unlikely that the development of the medicine would generate sufficient return to justify the necessary investment in its development. In each case, no satisfactory method of diagnosis, prevention or treatment must have been authorized (or, if such a method exists, the product in question would be of significant benefit to those affected by the condition). In the UK, the MHRA conducts an equivalent assessment, against criteria which have been tailored for the UK population.

In the EEA, orphan drug designation must be requested before submitting an application for MA. The COMP is required to re-assess the granted orphan designation at the time of MA grant to ensure that it continues to meet the criteria for the designation to be maintained. Otherwise, the orphan designation can be revoked. In relation to the UK, the MHRA does not grant orphan designations during the development of the medicinal product. Instead, the MHRA will decide whether the criteria are satisfied at the point of grant of an MA.

In the EEA and the UK, orphan drug designation/status (as applicable) entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity following MA grant for the orphan product. This period may be reduced to six years if, at the end of the fifth year, it is established that the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. During the period of market exclusivity, MA may only be granted to a "similar medicinal product" for the same therapeutic indication if: (i) a second applicant can establish that its product, although similar to the authorized product, is safer, more effective or otherwise clinically superior; (ii) the MA holder for the authorized product consents to a second orphan medicinal product application; or (iii) the MA holder for the authorized product cannot supply enough orphan medicinal product. A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The period of orphan market exclusivity may be reduced under the EU legislative proposal as referenced above.

***European Pediatric Investigation Plan***

In the EEA, companies developing a new medicinal product must agree upon a pediatric investigation plan ("PIP"), with the EMA's Pediatric Committee (the "PDCO") and must conduct pediatric clinical trials in accordance with that PIP, unless a waiver applies. The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the drug for which MA is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when this data is not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Products that are granted a MA with the results of the pediatric clinical trials conducted in accordance with the PIP (even where such results are negative) are eligible for six months' supplementary protection certificate extension (if any is in effect at the time of approval). In the case of orphan medicinal products, a two-year extension of the orphan market exclusivity may be available. This pediatric reward is subject to specific conditions and is not automatically available when data in compliance with the PIP are developed and submitted.

***European Data Collection***

The collection and use of personal health data in the EEA is governed by the General Data Protection Regulation (the "GDPR"), which became effective May 25, 2018. The GDPR applies to any company established in the EEA and to companies established outside the EEA that process personal data in connection with the offering of goods or services to data subjects in the EEA or the monitoring of the behavior of data subjects in the EEA. The GDPR enhances data protection obligations for data controllers of personal data, including stringent requirements relating to the consent of data subjects, expanded disclosures about how personal data is used, requirements to conduct privacy impact assessments for "high risk" processing, limitations on retention of personal data, special provisions for "sensitive information" including health and genetic information of data subjects, mandatory data breach notification and "privacy by design" requirements, and direct obligations on service providers acting as data processors. The GDPR also imposes strict rules on the transfer of personal data outside of the EEA to countries that do not ensure an adequate level of protection, like the U.S. Failure to comply with the requirements of the GDPR and the related national data protection laws of the EEA member states may result in fines up to 20 million euros or 4% of a company's global annual revenues for the preceding financial year, whichever is higher. Moreover, the GDPR grants data subjects the right to request deletion of personal information in certain circumstances and to claim material and non-material damages resulting from infringement of the GDPR. Given the breadth and depth of changes in data protection obligations, maintaining compliance with the GDPR will require significant time, resources and expense, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. This may be onerous and adversely affect our business, financial condition, results of operations, and prospects.

***Global Drug Development Regulation***

For other countries outside of the U.S. and EU, such as countries in Asia, Australia, and Eastern Europe, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country.

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

**Human Capital Resources**

As of December 31, 2025, we had 109 full-time employees. 38 of our employees have M.D. or Ph.D. degrees. Within our workforce, 76 employees are engaged in research and development and 33 are engaged in business development, finance, legal, and general management and administration. Five of the nine members of our management executive team are women. Across our broader population, approximately 65% of full-time employees are women. 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.

Our offices are located in Cambridge, Massachusetts. We believe our location in the Greater Boston area provides access to a vibrant biotech and pharmaceutical talent pool. We have programs in place to attract and retain talent, including stock-based compensation and cash performance awards, and we believe that our employee compensation is both competitive and equitable. We are also committed to the health, safety, and well-being of our employees at all times, follow federal, state, and local rules and guidelines to ensure the safety of our workforce, and provide resources to assist our employees in managing their overall physical and mental health. Further, we have a performance management and talent development process in which managers provide regular feedback and coaching to develop employees. We believe that open and honest communication among team members, managers, and leadership fosters a work environment where everyone can participate, develop, and thrive. We value career development for all employees, and we provide reimbursement and time for employees to attend professional development courses ranging across technical training, competency-based workshops, and leadership development programs.

As a mission driven organization, we believe the engagement and dedication of our employees is central to our success, and we endeavor to employ talented individuals who have the skills and expertise to help us achieve our goals. Our executive management team places significant focus and attention on matters concerning our human capital assets, including capability development of our workforce. We are committed to creating and maintaining a work environment in which employees are treated fairly, with dignity, decency, respect, and in accordance with all applicable laws. In addition, we value diversity because we believe that our business benefits from the different perspectives that a diverse workforce brings and that a diverse workforce is important to our success.

All employees must adhere to a code of conduct, which defines standards for appropriate behavior, along with a policy prohibiting unlawful harassment, discrimination and retaliation. Our processes in recruitment, hiring, development, training, compensation, and advancement are based on qualifications, performance, skills, and experience without regard to gender, race, ethnicity, sexual orientation, religion, age, disability, or any other legally protected characteristic.

**Corporate Information**

We were incorporated under the laws of the State of Delaware in September 2016. Our principal executive offices are located at One Main Street, Suite 1350, Cambridge, MA 02142, and our telephone number is (617) 410-4650. In April 2024, we changed our name from Cullinan Oncology, Inc. to Cullinan Therapeutics, Inc.

We use various trademarks and trade names in our business, including, without limitation, our corporate name and logo. All other trademarks or trade names referred to in this Annual Report on Form 10-K are the property of their respective owners. Solely for convenience, the trademarks and trade names in this Annual Report on Form 10-K may be referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend our use or display of other companies' trademarks and trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

**Available Information**

Our corporate website address is https://cullinantherapeutics.com. Information contained on or accessible through our website is not a part of this Annual Report on Form 10-K, and the inclusion of our website address in this Annual Report on Form 10-K is as an inactive textual reference only.

Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, including exhibits, proxy and information statements and amendments to those reports filed or furnished pursuant to Sections 13(a), 14, and 15(d) of the Securities Exchange Act of 1934 (as amended, the "Exchange Act"), are available through the "Investors" portion of our website free of charge as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Information on our website is not part of this Annual Report on Form 10-K or any of our other securities filings unless specifically incorporated herein by reference. In addition, our filings with the SEC may be accessed through the SEC's Electronic Data Gathering, Analysis and Retrieval system at https://www.sec.gov. All statements made in any of our securities filings, including all forward-looking statements or information, are made as of the date of the document in which the statement is included, and we do not assume or undertake any obligation to update any of those statements or documents unless we are required to do so by law.

**Item 1A. Risk Factors.**

*The following information should be read in conjunction with the other information in this Annual Report on Form 10-K, including our consolidated financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. The occurrence of any of the events or developments described below could harm our business, financial condition or future results, and such risk factors may not be the only risks we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial also may adversely affect our business, financial condition or future results. See "Special Note Regarding Forward-Looking Statements" in this Annual Report on Form 10-K.*

**Risks Related to the Development of Our Product Candidates**

***Our preclinical studies and clinical trials may fail to demonstrate adequately the safety and efficacy of any of our product candidates, which would prevent or delay development, regulatory approval, and commercialization.***

Before obtaining regulatory approvals for the commercial sale of our current and future product candidates, we must demonstrate the safety and efficacy of our investigational product candidates for use in each target indication through lengthy, complex, and expensive preclinical studies and clinical trials. If the results of our ongoing or future preclinical studies and clinical trials are inconclusive with respect to the safety and efficacy of our product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our product candidates, we may be prevented or delayed in obtaining marketing approval for such product candidates. In some instances, there can be significant variability in safety or efficacy results between different preclinical studies and clinical trials of the same product candidate due to numerous factors, including changes in and adherence to clinical trial procedures set forth in protocols, differences in the size and type of the patient populations, and the rate of dropout among clinical trial participants.

Additionally, we and third parties may have limited preclinical and clinical data, and a more limited understanding generally, with respect to certain indications for which our product candidates are being developed, including autoimmune diseases, and we cannot predict the extent to which the safety and efficacy of a product candidate may vary across indications. We may encounter significant challenges creating appropriate models and assays for evaluating the safety and efficacy of our product candidates and may not be able to provide sufficient data or other evidence, to the satisfaction of regulatory authorities, that certain unexpected results observed in preclinical and clinical testing of our product candidates are not indicative of the potential safety issues of such product candidates. We may develop program plans and timelines for certain product candidates based on our experience with such product candidates in different indications or with other product candidates that incorporate or were developed with the same technologies based on our expectation that such product candidates will perform and act similarly. However, our product candidates may reveal unexpected, important differences, including with respect to safety or efficacy, when developed in different indications or as compared to such other product candidates, including differences that may require changes to the manufacturing process or clinical development plan that require additional time and resources beyond what we initially anticipated. Any such occurrence could require us to adjust or alter our development plans, which could delay, harm, or prevent our ability to develop and commercialize or receive regulatory approval for such product candidates.

In addition to our ongoing clinical trials of zipalertinib, patients have been, and will likely continue to be, treated with zipalertinib under an expanded access or "compassionate use" program. To the extent the experiences of patients being treated in this program are inconsistent with or less favorable than the results of our ongoing or planned company-sponsored clinical trials with zipalertinib, it may negatively affect perceptions of zipalertinib, our other product candidates, or our business. In addition, the United States ("U.S.") Food and Drug Administration (the "FDA"), or foreign regulatory authorities may require us to obtain and submit additional clinical data due to these inconsistent or unfavorable results, which could delay clinical development or marketing approval of zipalertinib or potentially our other product candidates.

***Preclinical and clinical development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future preclinical studies or clinical trial results. If our preclinical studies and clinical trials are not sufficient to support regulatory approval of any of our product candidates, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of such product candidate.***

Our preclinical studies and future clinical trials may not be successful. It is impossible to predict when or if any of our product candidates will prove effective and safe in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical studies and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical development testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in later stage clinical trials even after achieving promising results in earlier stage clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their product candidates.

Additionally, some of the clinical trials we conduct are, and in the future may be, open-label in trial design and may be conducted at a limited number of clinical sites on a limited number of patients. An "open-label" clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect, as investigators and patients in open-label clinical trials are aware when patients are receiving treatment. Open-label clinical trials may be subject to a "patient bias" where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. Moreover, patients selected for early clinical studies often include the most severe sufferers and their symptoms may have been bound to improve notwithstanding the new treatment. In addition, open-label clinical trials may be subject to an "investigator bias" where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. Because some of our clinical trials are open-label in clinical trial design, the results from these clinical trials may not be predictive of future clinical trial results with this or other product candidates for which we conduct an open-label clinical trial when studied in a controlled environment with a placebo or active control.

Moreover, principal investigators for our current and future clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the 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.

If a sufficient number of our product candidates generally prove to be ineffective, unsafe or commercially unviable, our entire pipeline may have little, if any, value, which would have a material and adverse effect on our business, financial condition, results of operations and prospects.

***We may encounter substantial delays in preclinical studies and clinical trials or may not be able to conduct or complete preclinical studies or clinical trials on the expected timelines, if at all.***

We may experience delays in initiating or completing preclinical studies or clinical trials, including as a result of delays in obtaining, or failure to obtain, the FDA's clearance to initiate clinical trials under future investigational new drug applications ("INDs"). Additionally, we cannot be certain that preclinical studies or clinical trials for our product candidates will not require a redesign, enroll an adequate number of subjects on time, or be completed on schedule, if at all. We may experience numerous adverse or unforeseen events during, or as a result of, preclinical studies and clinical trials that could delay or terminate our clinical trials, or delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- we may receive feedback from regulatory authorities that requires us to modify the design or implementation of our preclinical studies or clinical trials, including our ability to commence a clinical trial;

- we may fail or be delayed in reaching agreement on acceptable terms with prospective contract research organizations (“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;
- we may be unable to add or be delayed in adding a sufficient number of clinical trial sites and obtaining institutional review board (“IRB"), or research ethics committee (“REC”) approval at each clinical trial site;
- preclinical studies or clinical trials of our product candidates may fail to show safety or efficacy or otherwise produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials or abandon our research efforts for our other product candidates;
- preclinical studies or clinical trials of our product candidates may not produce differentiated or clinically significant results across indications or tumor types;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of our clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements, fail to maintain adequate quality controls or be unable to provide us with sufficient product supply to conduct and complete preclinical studies or clinical trials of our product candidates in a timely manner, or at all;
- we or our investigators might have to suspend or terminate clinical trials of our product candidates for various reasons, including non-compliance with regulatory requirements, a finding that our product candidates have undesirable side effects or other unexpected characteristics, or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate, for example, if we experience delays or challenges in identifying patients with the mutations required for our clinical trials, we may have to reimburse sites for genetic sequencing costs in order to encourage sequencing of additional patients;
- clinical trial sites may deviate from the clinical trial protocol or drop out of a clinical trial;
- we may be unable to obtain or be delayed in obtaining sufficient product supply of a product candidate for use in preclinical studies or clinical trials from third-party suppliers;
- the quality of our product candidates or other materials necessary to conduct preclinical studies or clinical trials of our product candidates may be insufficient or inadequate, and any transfer of manufacturing activities may require unforeseen manufacturing or formulation changes;
- reports from clinical testing of other therapies may raise safety or efficacy concerns about our product candidates;
- regulators may revise the requirements for development, approval and marketing our product candidates, or such requirements may not be as we anticipate; and
- collaborators may conduct clinical trials in ways they view as advantageous to them but that are suboptimal for us.

If we are required to conduct additional preclinical studies or clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these studies, trials or tests are not positive or are only moderately positive or if there are safety concerns, our business and results of operations may be adversely affected and we may incur significant additional costs.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs, or RECs of the institutions in which such clinical trials are being conducted, by the data safety monitoring board, if any, for such clinical trial or by the FDA or other comparable regulatory authorities. Such authorities may suspend, place on clinical hold, or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical trial protocols, inspection of the clinical trial operations or trial site by the FDA or other comparable regulatory authorities, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from the product candidates, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

***We are early in our development efforts, with the exception of zipalertinib, and are substantially dependent on our lead product candidates. If we are unable to advance these or any of our other current and future product candidates through clinical development, or to obtain regulatory approval and ultimately commercialize any such product candidates, either by ourselves or with or by third parties or if we experience significant delays in doing so, our business may be materially harmed.***

We are early in our development efforts with the exception of zipalertinib. We are developing CLN-978 for patients with autoimmune diseases through an ongoing Phase 1 clinical trial in patients with moderate-to-severe SLE in the U.S., Europe, and Australia, an ongoing Phase 1 clinical trial in patients with active, difficult-to-treat RA in Europe, and an ongoing Phase 1 clinical trial in patients with active, moderate SjD in the U.S. and Europe. In collaboration with an affiliate of Taiho Pharmaceutical Co., Ltd ("Taiho"), we are evaluating zipalertinib in the pivotal Phase 2b portion of the REZILIENT1 clinical trial in patients with EGFR ex20ins non-small cell lung cancer ("NSCLC") who progressed after prior systemic therapy. In February 2026, Taiho completed a rolling submission of a new drug application ("NDA") seeking accelerated approval of zipalertinib for the treatment of patients with relapsed EGFR ex20ins NSCLC. Taiho is also evaluating zipalertinib in a global Phase 3 clinical trial in combination with chemotherapy as a potential first-line treatment for EGFR ex20ins NSCLC adult patients and in a Phase 2 parallel cohort trial. Additionally, CLN-049 is in an ongoing Phase 1 clinical trial in patients with relapsed or refractory acute myeloid leukemia or myelodysplastic syndrome. Our ability to generate product revenues, which we do not expect will occur for years, if ever, and our ability to generate collaboration revenue will depend heavily on the successful clinical development and eventual commercialization of our current and future product candidates, if approved. The success of our current and future product candidates will depend on several factors, including the following:

- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- successful completion of preclinical studies;
- regulator acceptance of and maintenance of INDs, clinical trial authorizations ("CTAs"), or comparable foreign applications that allow commencement and continuation of our planned clinical trials or future clinical trials;
- successful initiation of clinical trials;
- successful patient enrollment in and completion of clinical trials;
- positive results from our preclinical data and clinical trials that support a demonstration of safety and effectiveness and an acceptable risk-benefit profile for our product candidates that are satisfactory to the FDA or any foreign regulatory authority for marketing approval in the intended population;
- receipt of marketing approvals for our product candidates and any companion diagnostics from applicable regulatory authorities;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- making arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our product candidates, if any product candidates are approved;
- establishing sales, marketing, and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- acceptance of our products, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other autoimmune and cancer therapies;
- obtaining and maintaining third-party coverage and adequate pricing and reimbursement decisions; and
- maintaining a continued acceptable safety, tolerability, and efficacy profile of our products following approval.

If we do not succeed in one or more of these factors in a timely manner or at all, we could experience significant delays in our ability to successfully commercialize our current and future product candidates or be unable to commercialize product candidates at all. If we are unable to advance our preclinical-stage product candidates to clinical development, successfully complete clinical trials for our current and future product candidates, obtain regulatory approval, and ultimately commercialize our current and future product candidates, our business may be materially harmed.

There is no guarantee that the results obtained in preclinical studies or our clinical trials of our current and future product candidates will be sufficient to obtain regulatory approval or marketing authorization for such product candidates. Additionally, even if regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND or other applicable regulatory submission, such regulatory authorities may change their requirements or recommendations in the future. The FDA, European Medicines Agency ("EMA") or comparable foreign regulatory authorities may require the analysis of data from clinical trials assessing different doses of a product candidate alone or in combination with other therapies to justify the selected dose prior to the initiation of larger clinical trials in a specific indication. Any delays or failure to obtain regulatory approvals or clearances to initiate our clinical trials may prevent us from completing our clinical trials or commercializing our current and future product candidates on a timely basis, if at all.

Although we believe our product candidates and programs are uncorrelated, negative results in the development process of one product candidate could impact other product candidates or programs. In autoimmune diseases, our product candidates may demonstrate different safety and or efficacy in each of the different diseases we plan on evaluating in our clinical trials. For each of our oncology product candidates, antitumor activity may be different in each of the different tumor types or patient populations we plan on evaluating in our clinical trials. Even as we build clinical experience with our product candidates, we may need to further discuss or meet with the FDA and other comparable foreign regulatory authorities to agree on the optimal patient population, clinical trial design, and size for each clinical trial in order to obtain regulatory approval, any of which may require significant additional resources and delay the timing of our clinical trials and ultimately the approval, if any, of any of our product candidates.

***Difficulty in enrolling patients has delayed, and in the future could delay or prevent, clinical trials of our product candidates and ultimately delay or prevent regulatory approval.***

Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. The timing of completion of our clinical trials depends in part on the speed at which we can recruit patients to participate in testing our product candidates, and we have experienced delays related to enrollment in the past and may experience delays in the future in our clinical trials if we encounter difficulties in enrollment. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll enough eligible patients to participate in these clinical trials as required by the FDA or similar regulatory authorities outside the U.S., or as needed to provide appropriate statistical power for a given clinical trial. For example, in early phase autoimmune disease development, identification of patients with appropriate disease severity and/or willingness to accept the potential risks associated with a novel approach to treating their disease could impair enrollment.

In addition to the potentially small populations, the eligibility criteria of our planned clinical trials for some of our product candidates will further limit the pool of available clinical trial participants as we require that patients have specific characteristics, such as a certain severity or stage of disease progression, to include them in a clinical trial. For example, in the ongoing Phase 1 clinical trial for CLN-978 in patients with moderate to severe SLE in the U.S., we experienced more screening failures than anticipated due to our initial eligibility criteria, which led to a delay in enrollment in the clinical trial.

Additionally, the process of finding eligible patients may prove costly. We also may not be able to identify, recruit, and enroll a sufficient number of patients to complete our clinical studies because of the perceived risks and benefits of the product candidate under clinical trial, the availability and efficacy of competing therapies and clinical trials, the proximity and availability of clinical trial sites for prospective patients, the availability of patients with appropriate disease severity and extent of prior therapy in autoimmune disease indications, the availability of genetic sequencing information for patient tumors so that we can identify patients with the targeted genetic mutations for our oncology studies, and the patient referral practices of physicians. If patients are unwilling to participate in our studies for any reason, the timeline for recruiting patients, conducting studies, and obtaining regulatory approval of potential products may be delayed.

The enrollment of patients further depends on many factors, including:

- the proximity of patients to clinical trial sites;
- the design of the clinical trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- our ability to obtain and maintain patient consents;
- our ability to enroll a diverse patient base in our clinical trials to meet FDA recommended guidance;
- reporting of the preliminary results of any of our clinical trials;
- availability of investigational medicinal product(s);

- the risk that patients enrolled in clinical trials will drop out of the clinical trials before clinical trial completion; and
- factors we may not be able to control, such as future pandemics that may limit patients, principal investigators or staff or clinical site availability.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us because some patients who might have opted to enroll in our clinical trials may instead opt to enroll in a clinical trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. Moreover, because certain of our product candidates represent a departure from more commonly used methods for autoimmune diseases or cancer treatment and because certain of our product candidates have not been tested in humans before, potential patients and their doctors may be inclined to use conventional therapies, such as conventional immune suppressing medications in autoimmune diseases or chemotherapy in oncology, rather than enroll patients in any future clinical trial of our product candidates.

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenue from any of these product candidates could be delayed or prevented.

***Interim, "topline", and preliminary data from our clinical trials that we announce or publish may change as more patient data become available and are subject to confirmation, audit, and verification procedures that could result in material changes in the final data.***

From time to time, we may publicly disclose preliminary or topline data from our preclinical studies and clinical trials, which are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. For example, in April 2024, we announced the expansion of the development of CLN-978 in autoimmune diseases based on the treatment of three patients in a Phase 1 dose escalation trial of CLN-978 in patients with relapsed/refractory B cell non-Hodgkin lymphoma ("B-NHL"). Results from our ongoing Phase 1 clinical trials of CLN-978 in patients with SLE, RA, and SjD or other future trials may differ from the results of our prior Phase 1 trial in CLN-978 in relapsed/refractory B-NHL. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. From time to time, we may also disclose interim data from our clinical trials. Interim data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment and treatment continues and more patient data become available or as patients from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects and our ability to obtain approval for, and commercialize, our product candidates may be harmed. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

***We may not be able to file INDs, IND amendments or other similar regulatory submissions outside of the U.S. to commence additional clinical trials on the timelines we expect, and even if we are able to, the FDA or foreign regulatory authorities may not permit us to proceed.***

Our clinical stage product candidates CLN-978, CLN-049, and zipalertinib have INDs which are currently in effect. However, we may not be able to file future INDs or similar regulatory submissions for our other product candidates on the timelines we expect. Additionally, we may experience manufacturing delays or other delays with IND-enabling studies, or the FDA or other comparable regulatory authorities may require additional preclinical studies that we did not anticipate. Moreover, we cannot be sure that submission of an IND or similar regulatory submissions will result in the FDA or other comparable regulatory authority allowing clinical trials to begin, or that, once begun, issues will not arise that result in a decision by us, by IRBs or independent ethics committees, or by the FDA or other comparable regulatory authorities to suspend or terminate clinical trials, including as a result of a clinical hold. Additionally, even if the FDA or other comparable regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND or other similar regulatory submission, we cannot guarantee that they will not change their requirements or expectations in the future. These considerations also apply to new clinical trials we may submit as amendments to existing INDs or to a new IND. Any failure to file INDs or similar regulatory submissions on the timelines we expect or to obtain regulatory approvals for our clinical trials may prevent us from completing our clinical trials or commercializing our products on a timely basis, if at all.

***Our product candidates may cause undesirable side effects or have other properties that delay or prevent their regulatory approval, limit their commercial potential, or result in significant negative consequences following any potential marketing approval.***

Our product candidates may cause undesirable side effects. Additionally, the administration process or related procedures also can cause adverse side effects. Adverse events that occur in our clinical trials may cause us, or cause the FDA or other comparable regulatory authorities, or IRBs, RECs, or equivalent organizations to order us to halt, delay or amend preclinical development or clinical development of our product candidates and could result in more restrictive labeling or the denial of regulatory approval of our product candidates for any or all targeted indications. Even if serious adverse events are unrelated to study treatment, such occurrences could affect patient enrollment or the ability of enrolled patients to complete the clinical trial. In addition, if any of our product candidates are tested or used in combination with other drugs, these combinations may have additional side effects, which could be more severe than those caused by either therapy alone.

Furthermore, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of our product candidates or those of our competitors may only be uncovered when a significantly larger number of patients have been exposed to the product candidate. For example, while we believe that CLN-978, zipalertinib, and CLN-049 have demonstrated manageable tolerability profiles thus far, there can be no assurance that they or any of our other product candidates will not cause more severe side effects in a greater proportion of patients.

Moreover, if we elect, or are required, to delay, suspend or terminate any clinical trial of any of our product candidates, the commercial prospects of such product candidates or our other product candidates may be harmed, and our ability to generate product revenues from any of these product candidates may be delayed or eliminated. Any of these occurrences may harm our ability to develop other product candidates and may harm our business, financial condition, results of operations, and prospects significantly.

If our product candidates receive marketing approval and we or others identify undesirable side effects caused by such product candidates (or any other similar drugs or biologics) after such approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of such product candidates;
- regulatory authorities may require the addition of labeling statements, such as a “boxed” warning or a contraindication;
- we may be required to change the way such product candidates are distributed or administered, conduct additional clinical trials or change the labeling of the product candidates with the potential restriction of their clinical use;
- regulatory authorities may require a Risk Evaluation and Mitigation Strategy ("REMS") plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools;
- we may be subject to regulatory investigations and government enforcement actions;
- we may decide to remove such product candidates from the marketplace;
- personal injury claims, actions, lawsuits and proceedings that may arise from exposure to or taking our product candidates; and
- our reputation may suffer.

We believe that any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidates and could substantially increase the costs of commercializing our product candidates, if approved, and significantly impact our ability to successfully commercialize our product candidates and generate revenues.

***Since the number of patients that have been and will be dosed in our ongoing clinical trials is small, the results from such clinical trials, once completed, may be less reliable than results achieved in larger clinical trials, which may hinder our efforts to obtain regulatory approval for our product candidates.***

The preliminary results of clinical trials with smaller sample sizes can be disproportionately influenced by various biases associated with the conduct of small clinical trials, such as the potential failure of the smaller sample size to accurately depict the characteristics of the broader patient population, which limits the ability to generalize the results across a broader community, thus making the clinical trial results less reliable than clinical trials with a larger number of patients. As a result, there may be less certainty that such product candidates would achieve a statistically significant effect in any future clinical trials. Further, the FDA or other comparable regulatory authorities may require us to conduct additional and larger clinical trials than we may plan to support applications for marketing authorization. If we conduct any future clinical trials of our current and future product candidates, we may not achieve a positive or statistically significant result or the same level of statistical significance, if any, that we might have anticipated based on prior results.

***We are currently conducting and may in the future conduct clinical trials for product candidates outside the U.S., and the FDA and comparable foreign regulatory authorities may not accept data from such trials.***

We are conducting clinical trials for our product candidates outside the U.S., including in Europe and Australia, and Genrix is conducting a clinical trial for velinotamig in China, for which we intend to use the data generated to accelerate global clinical development of the program. The acceptance of study data from clinical trials conducted outside the U.S. or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. If data from foreign clinical trials are intended to serve as the 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, and (ii) the clinical trials were performed by clinical investigators of recognized competence and pursuant to good clinical practice ("GCP") regulations. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory authorities have similar approval requirements. In addition, foreign clinical trials are subject to the applicable local laws of the foreign jurisdictions where the clinical trials are conducted. We would need to conduct additional trials if the FDA or any comparable foreign regulatory authority does not accept data from clinical trials conducted outside of the U.S. or the applicable foreign jurisdiction, which could be costly and time-consuming, and which may result in product candidates that we may develop not receiving approval for commercialization in the U.S. or any such foreign jurisdiction.

***We may develop product candidates in combination with other therapies, which would expose us to additional risks.***

We may develop product candidates in combination with one or more approved or unapproved therapies to treat cancer or other diseases. Even if any product candidate we develop were to receive marketing approval for use in combination with other approved therapies, the FDA, the EMA, or comparable foreign regulatory authorities outside of the U.S. could still revoke approval of the therapy used in combination with our product. If the therapies used in combination with our product candidates are replaced as the standard of care for the indications we choose for any of our product candidates, the FDA, EMA or comparable foreign regulatory authorities may require us to conduct additional clinical trials. The occurrence of any of these risks could result in our own products, if approved, being removed from the market or being less successful commercially.

Further, we will not be able to market and sell any product candidate we develop in combination with an unapproved therapy for a combination indication if that unapproved therapy does not ultimately obtain marketing approval either alone or in combination with our product. In addition, unapproved therapies face the same risks described with respect to our product candidates currently in development and clinical trials, including the potential for serious adverse effects, delay in their clinical trials and lack of FDA approval.

If the FDA, EMA or comparable foreign regulatory authorities do not approve these other products or revoke their approval of, or if safety, efficacy, quality, manufacturing or supply issues arise with the products we choose to evaluate in combination with our product candidate, we may be unable to obtain approval of or market such combination therapy.

***If we are unable to successfully validate, develop, and obtain regulatory approval for any required companion diagnostic tests for our product candidates or experience significant delays in doing so, we may fail to obtain approval or may not realize the full commercial potential of these product candidates.***

In connection with the clinical development of our product candidates for certain indications, we may need to develop or obtain access to *in vitro* companion diagnostic tests to identify patient subsets within a disease category who may derive benefit from our product candidates, as we are targeting certain genetically defined populations for our treatments. Such companion diagnostics may be used during our clinical trials and may be required in connection with the FDA approval of our product candidates. To be successful, we or our collaborators will need to address a number of scientific, technical, regulatory, and logistical challenges. Companion diagnostics are subject to regulation by the FDA, the EMA, and other comparable regulatory authorities as medical devices and require separate regulatory approval prior to commercialization.

Given our limited experience in developing and commercializing diagnostics, we may rely on third parties for the design, development, and manufacture of companion diagnostic tests for our product candidates that may require such tests. If we enter into such collaborative agreements, we will be dependent on the sustained cooperation and effort of our future collaborators in developing and obtaining approval for these companion diagnostics. We and our future collaborators may encounter difficulties in developing and obtaining approval for the companion diagnostics, including issues relating to selectivity/specificity, analytical validation, reproducibility, or clinical validation of companion diagnostics. We and our future collaborators also may encounter difficulties in developing, obtaining regulatory approval for, manufacturing, and commercializing companion diagnostics similar to those we face with respect to our product candidates themselves, including issues with achieving regulatory clearance or approval, production of sufficient quantities at commercial scale and with appropriate quality standards, and in gaining market acceptance. If we are unable to successfully develop companion diagnostics for these product candidates, or experience delays in doing so, the development of these product candidates may be adversely affected or these product candidates may not obtain marketing approval or such approval may be delayed, and we may not realize the full commercial potential of any of these product candidates that obtain marketing approval. As a result, our business, results of operations, and financial condition could be materially harmed. In addition, a diagnostic company with whom we contract may decide to discontinue developing, selling or manufacturing the companion diagnostic test that we anticipate using in connection with development and commercialization of our product candidates or our relationship with such diagnostic company may otherwise terminate. We may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative diagnostic test for use in connection with the development and commercialization of our product candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of our product candidates.

**Risks Related to Our Financial Condition and Capital Requirements**

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

We began substantive operations in 2017. Our operations to date have involved organizing and staffing our company, business planning, raising capital, identifying, acquiring, and investing in potential product candidates, undertaking clinical trials, building our intellectual property portfolio, and establishing arrangements and collaborating with third parties for identification, discovery and research activities, preclinical studies, clinical trials, and the manufacture of initial quantities of our product candidates and component materials. We have not yet demonstrated our ability to successfully conduct late-stage clinical trials, obtain marketing approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales, marketing, and distribution activities necessary for successful product commercialization.

Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

***We have incurred significant losses since inception, and we expect to incur losses over the next several years and may not be able to achieve or sustain revenues or profitability in the future.***

Investment in biopharmaceutical product development is a highly speculative undertaking and entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval, and become commercially viable. With the exception of zipalertinib, we are still in the early stages of development. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. We have financed our operations primarily through the sale of equity securities.

We have a history of significant net losses since we began substantive operations. For 2025 and 2024, we reported a net loss of $219.9 million and $167.4 million, respectively. As of December 31, 2025, we had an accumulated deficit of $588.1 million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase substantially if and as we:

- continue our research and development efforts and submit INDs or other regulatory filings for our current and future product candidates;
- conduct preclinical studies and clinical trials for our current and future product candidates;
- experience any delays or encounter any issues with any of the above, including but not limited to failed studies, complex results, safety issues, or other regulatory challenges;
- develop the necessary processes, controls, and manufacturing capabilities to obtain marketing approval for our product candidates and to support manufacturing on a commercial scale;
- seek regulatory approvals for any product candidates that successfully complete clinical trials, if any;
- hire and retain additional personnel, such as non-clinical, clinical, pharmacovigilance, quality assurance, regulatory affairs, manufacturing, distribution, legal, compliance, medical affairs, finance, general and administrative, commercial, and scientific personnel;
- establish a sales, marketing, and distribution infrastructure and scale-up manufacturing capabilities, whether alone or with third parties, to commercialize any current and future product candidates for which we may obtain regulatory approval; and
- develop, maintain, expand, and protect our intellectual property portfolio.

Because of the numerous risks and uncertainties associated with developing pharmaceutical product candidates, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development and other expenditures to develop and seek regulatory approval for additional product candidates or additional indications. We may encounter unforeseen expenses, difficulties, complications, delays, and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

***We have not generated any revenue from the sale of our product candidates and may never be profitable.***

Our ability to become profitable depends upon our ability to generate revenue. Other than a previous licensing agreement, we have not generated any other license or collaboration revenue or any sales revenue from any of our product candidates. We do not expect to generate significant sales revenue or commercial revenue from the sale or license of one or more of our preclinical programs or product candidates unless or until we successfully complete clinical development and obtain regulatory approval of, and then successfully commercialize, at least one of our product candidates or, alternatively, enter into agreements with third parties for the purchase, collaboration, or license of one of our product candidates. We are currently advancing CLN-978, CLN-049, and zipalertinib (pursuant to the co-development agreement with an affiliate of Taiho) in clinical development, in addition to our other programs that are in the preclinical stages of development and will require additional preclinical studies. All of our product candidates will require additional clinical development, regulatory review and approval, substantial investment, access to sufficient commercial manufacturing capacity, and significant marketing efforts before we can generate any revenue from product sales.

Our ability to generate revenue depends on a number of factors, including, but not limited to:

- timely completion of our preclinical studies and clinical trials, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- our ability to complete IND-enabling studies and successfully submit INDs or comparable applications for our product candidates;
- whether we are required by the FDA or similar foreign regulatory authorities to conduct additional clinical trials or other studies beyond those planned to support the approval and commercialization of our current and future product candidates;
- our ability to timely seek and obtain regulatory and marketing approvals for any of our current and future product candidates;

- the prevalence, duration, and severity of potential side effects or other safety issues experienced by patients receiving our current and future product candidates;
- the willingness of physicians, operators of clinics, and patients to utilize or adopt any of our current and future product candidates over alternative or more conventional therapies, such as chemotherapy;
- the actual and perceived availability, cost, risk profile, and efficacy of our current and future product candidates, if approved, relative to existing and future alternative therapies and competitive product candidates and technologies;
- the equal cost-sharing structure for clinical development and commercialization costs of zipalertinib in the U.S. and the equal profit-sharing structure from potential future U.S. sales of zipalertinib, each pursuant to the co-development agreement with an affiliate of Taiho, subject to certain adjustments for any approved indications independently developed by Taiho;
- our ability and the ability of third parties with whom we contract to manufacture adequate clinical and commercial supplies of our current and future product candidates, remain in good standing with regulatory authorities and develop, validate, and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practices ("cGMP");
- our ability to successfully develop a commercial strategy and thereafter commercialize our current and future product candidates in the U.S. and internationally, if approved for marketing, reimbursement, sale, and distribution in such countries and territories, whether alone or in collaboration with others;
- patient demand for our current and future product candidates, if approved; and
- our ability to establish and enforce intellectual property rights in and for our current and future product candidates.

Many of the factors listed above are beyond our control and could cause us to experience significant delays or prevent us from obtaining regulatory approvals or commercializing our current and future product candidates. Even if we are able to commercialize our current and future product candidates, we may not achieve profitability soon after generating product sales, if ever. If we are unable to generate sufficient revenue through the commercial sale of our current and future product candidates, or from agreements with third parties for the purchase, collaboration, or license of one or more of our product candidates, we may be unable to continue operations without continued funding.

***We will require substantial additional funding to develop and commercialize our current and future product candidates. If we are unable to raise capital when needed, we would be compelled to delay, reduce, or eliminate our product development programs or other operations.***

The development of pharmaceutical products is capital intensive. We are currently advancing CLN-978, CLN-049, and zipalertinib (pursuant to the co-development agreement with an affiliate of Taiho) in clinical development and making further investments in our preclinical programs. We expect our expenses to increase in parallel with our ongoing activities, as described above under the risk factor entitled “We have incurred significant losses since inception, and we expect to incur losses over the next several years and may not be able to achieve or sustain revenues or profitability in the future.” We have estimated our current additional funding needs based on assumptions that may prove to be wrong. Changing circumstances may cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. We cannot be certain that additional funding will be available on acceptable terms, or at all. Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of public or private equity offerings, debt financings, governmental funding, collaborations, strategic partnerships, and alliances, or marketing, distribution, or licensing arrangements with third parties. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce, or eliminate our identification, discovery, and preclinical or clinical development programs, or any future commercialization efforts.

As of December 31, 2025, we had cash, cash equivalents, and short-term investments of $377.9 million, and long-term investments and interest receivable of $61.1 million. We believe that, based upon our current operating plan, our existing capital resources will be sufficient to fund our anticipated operations into 2029.

Our future capital requirements will depend on many factors, including:

- the scope, progress, results, and costs of drug discovery, laboratory testing, manufacturing and preclinical and clinical development for our current and future product candidates;
- the extent to which we enter into additional collaboration arrangements with regard to product discovery or acquire or in-license products or technologies;

- the equal cost-sharing structure for clinical development and commercialization costs of zipalertinib in the U.S. and the equal profit-sharing structure from potential future U.S. sales of zipalertinib, each pursuant to the co-development agreement with an affiliate of Taiho;
- our ability to establish additional discovery collaborations on favorable terms, if at all;
- the costs, timing, and outcome of regulatory review of our product candidates;
- the costs of future commercialization activities, including product sales, marketing, manufacturing, and distribution, for any of our product candidates for which we receive marketing approval;
- revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval, or from licensing or collaboration agreements pursuant to which we may receive milestone, royalty, or other revenue from third parties developing or commercializing our product candidates; and
- the costs of preparing, filing, and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims.

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

We have a co-development agreement with an affiliate of Taiho for zipalertinib. Pursuant to the terms of the co-development agreement, development costs for zipalertinib are shared equally between us and Taiho, with each party receiving 50% of any future pre-tax profits from potential U.S. sales of zipalertinib, subject to certain adjustments for any additional indications independently developed by Taiho. Additionally, we have a license agreement with Chongqing Genrix Biopharmaceutical Co., Ltd. ("Genrix") pursuant to which we in-licensed velinotamig.

We intend to engage in various acquisitions and strategic partnerships in the future, including licensing or acquiring products, intellectual property rights, technologies, or businesses. Any acquisition or strategic partnership, including the co-development agreement with an affiliate of Taiho and our license agreement with Genrix, may entail numerous risks to us, including:

- increased operating expenses and cash requirements;
- the assumption of indebtedness or contingent liabilities;
- the issuance of equity securities which would result in dilution;
- assimilation of operations, intellectual property, products, and product candidates of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of financial and managerial resources from our existing product programs and initiatives in pursuing such an acquisition or strategic partnership;
- retention of key personnel, the loss of institutional knowledge, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals;
- our inability to generate revenue from acquired intellectual property, technology, and/or products sufficient to meet our objectives or even to offset the associated transaction and maintenance costs;
- risk of conducting research and development activities in new therapeutic areas or treatment modalities in which we have little to no experience;
- successfully negotiating a proposed acquisition, in-license or investment in a timely manner and at a price or on terms and conditions favorable to us;
- successfully combining and integrating a potential acquisition into our existing business to fully realize the benefits of such acquisition;
- the impact of regulatory reviews on a proposed acquisition, in-license or investment; and
- the outcome of any legal proceedings that may be instituted with respect to the proposed acquisition, in-license or investment.

If we fail to properly evaluate potential acquisitions, in-licenses, investments or other transactions associated with the creation of new research and development programs or the maintenance of existing ones, we might not achieve the anticipated benefits of any such transaction, we might incur costs in excess of what we anticipate, and management resources and attention might be diverted from other necessary or valuable activities.

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

To the extent that we raise additional capital through the sale of equity or convertible debt securities, existing ownership interests will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of our stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through strategic partnerships with third parties, we may have to relinquish valuable rights to our technologies or product candidates, future revenue streams, research programs or product candidates or grant licenses on terms that are not favorable to us. If we are unable to raise additional capital when needed, we would be required to delay, limit, reduce or terminate our product development or commercialization efforts for our current and future product candidates.

***Our stockholders will experience substantial additional dilution if outstanding stock options are exercised for common stock.***

As of February 18, 2026, the number of shares of our common stock outstanding excludes approximately 17.3 million shares of common stock issuable upon the exercise of stock options, having a weighted-average exercise price of $14.51 per share. The exercise of outstanding stock options for common stock would be substantially dilutive to existing stockholders. As of February 18, 2026, the number of shares of our common stock outstanding also excludes approximately 2.0 million shares of common stock issuable upon vesting of restricted stock units, approximately 1.1 million shares of common stock reserved for future issuance under our 2021 Stock Option and Incentive Plan and 2.7 million shares of common stock reserved for future issuance under our 2021 Employee Stock Purchase Plan. Any dilution or potential dilution may cause our stockholders to sell their shares, which may contribute to a downward movement in the stock price of our common stock.

***Our operations and financial condition have been and could continue to be adversely affected by global and regional economic conditions in ways we may not be able to predict or control.***

Our operations and financial condition have been and could continue to be adversely affected by global or regional economic conditions if markets decline in the future, whether related to a public health crisis similar to the COVID-19 pandemic, changes in international relations or global conflicts, higher inflation or interest rates, recession, natural disasters, impacts of and issues related to climate change, business disruptions, our ability to adequately staff operations or otherwise. Additionally, escalation in interest rates, in conjunction with banking failures, may lead to financial institutions being more prudent with capital deployment and tightening lending, especially in relation to construction and real estate development.

Additionally, the U.S. government has made statements and taken actions that have led to certain changes and may lead to additional changes to U.S. and international trade policies. For example, the Trump administration has imposed or signaled to impose a series of tariffs on certain products manufactured outside the United States, including pharmaceutical products and raw materials and components for pharmaceutical products, and it is unknown whether and to what extent additional tariffs (or other new laws or regulations) will be adopted, or the effect that any such actions would have on us or our industry. Such unfavorable government policies on international trade, such as export controls, capital controls or tariffs, may affect the import and export of materials and products used in our development efforts. These policies may also affect the demand for our product candidates, the competitive position of our product candidates, and clinical manufacturing and future commercial activities. If any new tariffs, export controls, legislation and/or regulations are implemented, or if existing trade agreements are renegotiated or if the U.S. government takes retaliatory trade actions due to the ongoing trade tensions, such changes could have an adverse effect on our business, financial condition and operations.

***Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.***

Our operations, and those of our CROs, contract manufacturing organizations ("CMOs") and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

**Risks Related to Our Corporate Structure**

***We may not be successful in our efforts to build a pipeline of product candidates with commercial value.***

We may not be successful in our efforts in building a pipeline of product candidates for the treatment of various autoimmune diseases and cancers through acquisitions, licensing or through internal development or in progressing these product candidates through clinical development. Although we analyze whether we can replicate scientific results observed prior to our acquisition or investment in a product candidate, we may not be successful in doing so after our investment. For example, pharmacodynamic activity of B cell depleting agents such as CLN-978 has not always been associated with sufficient anti-disease activity to support broad development in indications of sufficient commercial opportunity. Similarly, we may not be successful in identifying additional genetic mutations which are oncogenic and which can be "basketed" into a group that is large enough to present a sufficient commercial opportunity or that is druggable with one chemical compound.

An element of our strategy is to form or seek strategic alliances, create joint ventures or collaborations, or enter into licensing arrangements with third parties for programs, product candidates, technologies or intellectual property that we believe are novel, employ differentiated mechanisms of action, are more advanced in development than competitors, or have a combination of these attributes. We face significant competition in seeking appropriate strategic partners and licensing and acquisition opportunities, and the negotiation process is time-consuming and complex. Identifying, selecting, and acquiring promising product candidates requires substantial technical, financial and human resources expertise. Efforts to do so may not result in the actual acquisition or license of a successful product candidate, potentially resulting in a diversion of our management's time and the expenditure of our resources with no resulting benefit. For example, if we are unable to identify programs that ultimately result in approved products, we may spend material amounts of our capital and other resources evaluating, acquiring, and developing products that ultimately do not provide a return on our investment. We have terminated programs and expect to terminate programs in the future if they do not meet our criteria for advancement. For example, following a review of the emerging clinical data in patients with NSCLC and multiple myeloma, we decided not to pursue further development of CLN-619, and after a review of the emerging clinical data in patients with advanced solid tumors, we decided not to pursue further development of CLN-617.

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

Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. If we do so, we may never realize the anticipated benefits of these decisions and, as a result, we may be required to forego or delay other opportunities. In addition, our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

***Certain agreements provide our licensors, collaborators, or other shareholders in our CLN-049 development subsidiary with rights that could delay or impact the potential sale of our development subsidiaries or could impact our ability to sell assets, or enter into strategic alliances, collaborations, or licensing arrangements with other third parties.***

We license intellectual property from third parties for several of our product candidates and have raised capital from third-party investors for CLN-049. These third parties have certain rights that could delay collaboration, licensing or other arrangement with another third party, and the existence of these rights may adversely impact the ability to attract an acquirer or partner. These rights include rights of negotiation and fees payable upon a sale of assets or change of control of a subsidiary that are contained in license agreements, as well as rights such as drag-along rights in agreements with shareholders of the subsidiary.

In addition, we will also owe the licensor of CLN-049 a success fee in the event of a sale or other disposition of the majority of the assets of the CLN-049 development subsidiary. This fee will reduce the net proceeds we receive from any such sale or disposition of assets.

We have also entered into investor rights and voting agreements with third-party investors, which may delay or impact our ability to sell our equity interests in or the assets of our CLN-049 development subsidiary. For example, we would need to comply with certain notice and other provisions, such as a drag-along provision in the event of sale of the subsidiary, which may delay or prevent a specific transaction or make transacting with us less attractive to third parties.

We may enter into similar agreements with future partners or investors that in each case may contain similar provisions or other terms that are not favorable to us.

***Our reliance on a limited number of employees presents operational challenges that may adversely affect our business.***

As of December 31, 2025, we had 109 full-time employees upon which we rely for various research and development, administrative and other support services. The small size of our team may limit our ability to devote adequate personnel, time, and resources to our research and development activities, and the management of financial, accounting, and reporting matters. If our team fails to provide adequate research and development, administrative, or other services, our business, financial condition, and results of operations could be harmed.

***We are a "smaller reporting company," and we cannot be certain if the reduced reporting requirements applicable to smaller reporting companies will make our common stock less attractive to investors.***

As of January 1, 2025, we were a large accelerated filer and were subject to all of the related compliance or disclosure requirements applicable to a large accelerated filer. Based on the market value of our common stock that was held by non-affiliates as of June 30, 2025 and our annual revenues for the fiscal year ended December 31, 2024, we became a smaller reporting company effective December 31, 2025 and are able to immediately avail ourselves of the reduced disclosure requirements permitted for smaller reporting companies. As a smaller reporting company, we are permitted and intend to rely on exemptions from certain compliance and disclosure requirements that are applicable to other public companies that are not smaller reporting companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We may take advantage of scaled disclosures available to smaller reporting companies until the fiscal year following the determination that either (i) the market value of our voting and non-voting common stock held by non-affiliates is greater than $700 million, as measured on the last business day of the most recently completed second fiscal quarter, or (ii) the market value of our voting and non-voting common stock held by non-affiliates, as measured on the last business day of our most recently completed second fiscal quarter, is less than $700 million but greater than $250 million and our annual revenues during our most recently completed fiscal year are greater than $100 million. 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 our stock price may be more volatile.

**Risks Related to Potential Commercialization**

***Even if we obtain regulatory approval of our product candidates, the products may not gain market acceptance among physicians, patients, hospitals, treatment centers, and others in the medical community.***

The use of T cell engagers in immunology and oncology is a recent development and may not become broadly accepted by physicians, patients, hospitals, treatment centers, and others in the medical community. Various factors will influence whether our product candidates are accepted in the market, including:

- the clinical indications for which our product candidates are licensed;
- physicians, hospitals, treatment centers, and patients considering our product candidates as a safe and effective treatment;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the prevalence and severity of any side effects caused by our product candidates;
- the prevalence and severity of any side effects for other precision medicines and public perception of other precision medicines;
- product labeling or product insert requirements of the FDA or other comparable regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA;
- the timing of market introduction of our product candidates as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate coverage, reimbursement and pricing by third-party payors and government authorities;

- the willingness of patients to pay out-of-pocket in the absence of coverage by third-party payors and government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

If our product candidates are licensed but fail to achieve market acceptance among physicians, patients, hospitals, treatment centers or others in the medical community, we will not be able to generate significant revenue.

Even if our product candidates achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete.

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

The biotechnology and pharmaceutical industries are characterized by the rapid evolution of technologies and understanding of disease etiology, intense competition, and a strong emphasis on intellectual property. We face, and will continue to face, competition from companies focused on more traditional therapeutic modalities, such as small-molecule inhibitors. We believe that our differentiated business model, approach, scientific capabilities, know-how, and experience provide us with competitive advantages. However, we expect substantial competition from multiple sources, including major pharmaceutical, specialty pharmaceutical, and existing or emerging biotechnology companies, academic research institutions, governmental agencies, and public and private research institutions worldwide. Many of our competitors, either alone or through collaborations, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These companies also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and recruiting patients in clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. As a result, our competitors may discover, develop, license or commercialize products before or more successfully than we do.

Product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. The key competitive factors affecting the success of all of our product candidates, if approved, are likely to be their efficacy, safety, convenience, price, the level of generic competition, and the availability of reimbursement from government and other third-party payors. Our competitors may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. The availability of reimbursement from government and other third-party payors will also significantly affect the pricing and competitiveness of our products. Our competitors may also obtain FDA or other comparable regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. If our competitors develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient to administer, are less expensive or with a more favorable label than our product candidates, we could see a reduction or elimination in our commercial opportunity. For additional information regarding our competition, see the section of this Annual Report on Form 10-K titled "Business—Competition."

***The insurance coverage and reimbursement status of newly-approved products is uncertain. Our product candidates may become subject to unfavorable pricing regulations, third-party coverage and reimbursement practices, or healthcare reform initiatives, which would harm our business. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue.***

The regulations that govern marketing approvals, pricing, coverage, and reimbursement for new drugs vary widely from country to country. Some countries require approval of the sale price of a drug before the product can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product candidate in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenue we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if any product candidates we may develop obtain marketing approval.

In the U.S. and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental authorities or healthcare programs, such as Medicare and Medicaid, and private payors, such as health plans, is critical to new product acceptance. Our ability to successfully commercialize our product candidates will depend in part on the extent to which adequate coverage and reimbursement for these products and related treatments will be available from government authorities and programs as well as private health plans and other organizations. Government authorities and other third-party payors decide which products will be covered and establish reimbursement levels for the products (or the services provided using the products). If coverage and reimbursement is not available, or is available but limited, we may not be able to successfully commercialize our product candidates. Under such circumstances, we may not be able to establish or maintain pricing sufficient to realize a sufficient return on our investment.

Within the U.S., no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Coverage and reimbursement for new drug products is uncertain and, if applicable, can differ significantly from payor to payor. New products face particular coverage and reimbursement challenges. To obtain or maintain coverage and reimbursement for any approved drug product, we may need to conduct expensive pharmacoeconomic studies or otherwise provide evidence to demonstrate the medical necessity and cost-effectiveness of our product. These studies will be in addition to the studies required to obtain or maintain regulatory approvals. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover the product or, if they do, the level of payment may not be sufficient to allow sale of a product at a profit.

Even if third-party payors provide some coverage, the third-party payors may impose limits on the coverage or controls to manage utilization of products. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication and can exclude drugs from their formularies in favor of competitor drugs or alternative treatments. Payors may also impose step edits that require patients to try alternative, including generic, treatments before authorizing payment for our products, limit the types of diagnoses for which coverage will be provided, require pre-approval (known as "prior authorization") for coverage of a prescription for each patient (to allow the payor to assess medical necessity) or impose a moratorium on coverage for products while the payor makes a coverage decision.

Moreover, a third-party payor's decision to provide coverage for a product does not mean that an adequate reimbursement rate will be approved. We may be required to provide mandatory discounts or rebates to certain purchasers to obtain coverage under federal healthcare programs, or to sell products to government purchasers. We also may have to offer discounts or rebates to private third-party payors to obtain favorable coverage. There has been significant consolidation in the health insurance industry, increasing the leverage of large insurers and pharmacy benefit managers in pricing and other negotiations and potentially impacting potential drug product sales, business and results of operations.

Reimbursement rates may also vary according to the use of the drug and the clinical setting in which the drug is used; rates may be based on reimbursement levels already set for lower cost drugs or rates may be incorporated into existing payments for other services.

The containment of healthcare costs has become a priority of federal and state governments, and the prices of products have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption or enhancement of price controls and cost-containment measures could further limit a company's revenue generated from the sale of any approved products. Coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which a company or its collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved products we may develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize product candidates, and our overall financial condition.

Outside the U.S., governmental authorities and other third-party payors have also attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In general, the prices of medicines under such systems are substantially lower than in the U.S. Other countries allow companies to fix their own prices for medicines, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the U.S., the reimbursement for products may be reduced compared with the U.S. and may be insufficient to generate commercially reasonable revenues and profits.

Additionally, we may develop companion diagnostic tests for use with our product candidates. We, or our collaborators, may be required to obtain coverage and reimbursement for these tests separate and apart from the coverage and reimbursement we seek for our product candidates, once approved. Even if we obtain regulatory approval or clearance for such companion diagnostics, there is significant uncertainty regarding our ability to obtain coverage and adequate reimbursement for the same reasons applicable to our product candidates. Our inability to promptly obtain coverage and adequate reimbursement from both third-party payors for the companion diagnostic tests that we develop and for which we obtain regulatory approval could have a material and adverse effect on our business, financial condition, results of operations and prospects.

We expect ongoing initiatives from government and private payors to control utilization and costs of healthcare generally and drug products specifically, which initiatives could reduce demand for any product candidates for which we obtain marketing approval or limit the prices that we may charge for such products.

***Healthcare legislative measures aimed at reducing healthcare costs may have a material adverse effect on our business and results of operations.***

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 or any future product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell a product for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

The containment of healthcare costs also has become a priority of federal, state and foreign governments. In the U.S., in recent years, the pharmaceutical industry has been a particular focus of such reform efforts and has been significantly affected by major legislative, administrative and executive initiatives. For example, the Inflation Reduction Act of 2022 (the "IRA") included a number of changes intended to address rising prescription drug prices in Medicare Parts B and D. These changes included caps on Medicare Part D out-of-pocket costs, Medicare Part B and Part D drug price inflation rebates, a new Medicare Part D manufacturer discount drug program (replacing the previous coverage gap discount program) and a drug price negotiation program for certain high-spend Medicare Part B and D drugs. The IRA has had and will likely continue to have a significant impact on the pharmaceutical industry. Beyond the IRA, changes to Medicaid effective in 2024 eliminated the Medicaid rebate cap. Additionally, changes to certain Medicare price reporting requirements for drugs beginning in 2026 will likely increase the administrative and compliance burden for manufacturers.

Recently, drug pricing and payment has been subject to a number of reform initiatives. For example, President Trump issued an Executive Order in April 2025 with multiple directives aimed at lowering drug prices, including refining the Medicare drug price negotiation program established by the IRA; accelerating competition for high-cost prescription drugs by accelerating approval of generics and biosimilars and facilitating the process for re-classifying prescription drugs as over-the-counter drugs; and increasing drug importation. In May 2025, President Trump issued another Executive Order that directed government agencies and officials to identify most-favored nation pricing targets for prescription drugs (and looked to pharmaceutical manufacturers to make significant progress towards delivering target prices to patients); prevent foreign countries from disproportionately shifting the cost of global pharmaceutical research and development to the United States; and facilitate direct-to-consumer purchasing programs for pharmaceutical manufacturers to sell their products to patients at the most-favored-nation price. In the wake of the Executive Orders and related executive initiatives, a number of pharmaceutical manufacturers have announced direct-to-consumer offerings with discounted prices and/or reached agreement with the federal government regarding pricing for drugs, including prices for Medicaid drugs and newly launched products. A website sponsored by the federal government offering pharmaceutical direct-to-consumer channels has also been launched. Federal agencies are developing new drug pricing pilot programs, such as a voluntary Medicaid initiative which would authorize the federal government to negotiate Medicaid supplemental rebates with participating manufacturers on behalf of state Medicaid programs, in exchange for standardized coverage criteria for participating manufacturer drugs, and the proposed Medicare Part B and Part D pilot models that, if finalized as proposed, would replace existing inflation-based Medicare rebates with rebates determined on the basis of international prices, for drugs and patients subject to the model. Many of these reform initiatives would require additional legal and/or administrative action to implement and may be subject to legal challenge.

Other federal healthcare reform efforts or actions may affect access to healthcare coverage or the funding of health care benefits, although the full impact of such efforts or actions cannot be predicted. For example, the Congressional Budget Office has estimated that Medicaid provisions in the 2025 budget reconciliation legislation, including restrictions in eligibility and funding for Medicaid, as well as changes to the healthcare marketplace such as the elimination of certain subsidies, will increase the number of uninsured.

At the state level, individual states are increasingly implementing initiatives 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 measures to encourage importation from other countries and bulk purchasing. For example, certain states have formed Prescription Drug Affordability Boards that assert authority to set reimbursement rates and/or drug pricing in the state. States are also increasingly expanding or changing Medicaid supplemental rebate programs to secure additional rebates from manufacturers in exchange for drug coverage and to limit coverage of certain drugs for certain Medicaid patients or to all Medicaid patients. These and other future state-level reform activities could negatively affect Medicaid coverage and reimbursement for our products.

The continuing efforts of the government as well as third-party payors to limit access to healthcare, reduce the scope of coverage of healthcare, contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain coverage and reimbursement approval for a product;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Other recent government actions also may affect prices or payments for prescription drugs. For example, the Trump administration's recently announced tariff on branded or patented drugs may adversely impact our ability to realize an adequate return on the sale of drug products (if approved) that are imported from abroad or manufactured using products or materials imported from abroad. The timeline for implementation of this tariff has not yet been finalized. As another example, the Budget Control Act, as amended, resulted in the imposition of reductions in Medicare (but not Medicaid) payments to providers in 2013 and will remain in effect into 2032 unless additional Congressional action is taken. Any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented and/or any significant taxes or fees that may be imposed on us could have an adverse impact on our results of operations.

Reform efforts have been and may continue to be subject to scrutiny and legal challenge, which increases uncertainty. For example, the IRA drug price negotiation program has been challenged in litigation filed by various pharmaceutical manufacturers and industry groups.

We expect that current and future reform efforts in the U.S. or abroad may result in more rigorous coverage criteria, new payment methodologies, restrictions on access and additional downward pressure on the payment that we receive or price that we may charge for any approved product. The implementation of such reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates, if approved.

***If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.***

We face an inherent risk of product liability litigation as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even a 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 our product candidates or products that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;

- a diversion of management's time and our resources;
- substantial monetary awards to clinical trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any product candidate; and
- a decline in our share price.

Failure to obtain or retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of product candidates we develop, alone or with corporate collaborators. Although we have clinical trial insurance, our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

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

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

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

***The market opportunities for our product candidates and forecasts of market growth may not be accurate, and the actual market for our products may be smaller than we estimate, and even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, or at all.***

The precise incidence and prevalence for all the conditions we aim to address with our product candidates are unknown. Our estimates of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including sales of our competitors, scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect in general, or as to their applicability to our company. Further, new trials may change the estimated incidence or prevalence of these diseases. Even if the markets in which we compete meet our size estimates and growth forecasts, our business may not grow at similar rates, or at all. The total addressable market across all of our product candidates will ultimately depend upon, among other things, the diagnosis criteria included in the final label for each of our product candidates approved for sale for these indications, the ability of our product candidates to improve on the safety, convenience, cost and efficacy of competing therapies or therapies in development, acceptance by the medical community and patients, drug pricing and reimbursement. The number of patients in the U.S., other major markets and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our product candidates or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our business, financial condition, results of operations and prospects. Further, even if we obtain significant market share for our product candidates, because some of our potential target populations are very small, we may never achieve profitability despite obtaining such significant market share.

***We currently have no marketing and sales organization and have no experience in marketing products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, if approved, we may not be able to generate product revenue.***

We currently have no sales, marketing or distribution capabilities and have no experience in marketing products. If we commercialize ourselves any of our product candidates that may be approved, we will need to develop an in-house marketing organization and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel.

If we are unable or decide not to establish internal sales, marketing and distribution capabilities, we will pursue arrangements with third-party sales, marketing, and distribution collaborators regarding the sales and marketing of our products, if approved. However, there can be no assurance that we will be able to establish or maintain such arrangements on favorable terms or at all, or if we are able to do so, that these third-party arrangements will provide effective sales forces or marketing and distribution capabilities. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates.

There can be no assurance that we will be able to develop in-house sales and distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any product in the U.S. or overseas.

**Risks Related to Government Regulation**

***If we are not able to obtain, or are delayed in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize, or will be delayed in commercializing, our product candidates, and our ability to generate revenue will be materially impaired.***

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import, and export are subject to comprehensive regulation by the FDA and other comparable regulatory agencies in the U.S. and by comparable authorities in other countries. Before we can commercialize any of our product candidates, we must obtain marketing approval. Whether the results from our current ongoing clinical trials and other trials will suffice to obtain approval will be a review issue and the FDA may not grant approval and may require that we conduct one or more controlled clinical trials to obtain approval. Additionally, even if the FDA grants approval for one or more of our product candidates, it may be for a narrower indication than we seek. Regulatory authorities, including the FDA, also may impose significant limitations in the form of narrow indications, warnings, or a REMS. These regulatory authorities may require labeling that includes precautions or contra-indications with respect to conditions of use, or they may grant approval subject to the performance of costly post-marketing clinical trials. In addition, regulatory authorities may not approve the labeling claims that are necessary or desirable for the successful commercialization of any product candidates we may develop. To date, we have had interactions with various regulatory authorities globally.

Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Further, our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining regulatory approvals, both in the U.S. and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity, and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted IND, CTA, Biologics License Application ("BLA"), New Drug Application ("NDA"), marketing authorization application, or equivalent application type, may cause delays in the approval or rejection of an application. The FDA and other competent authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies.

Our product candidates could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- the FDA or comparable foreign regulatory authorities may disagree with our development strategy;

- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication or a related companion diagnostic is suitable to identify appropriate patient populations;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a BLA, NDA or other submission or to obtain regulatory approval in the U.S. or elsewhere;
- the FDA or comparable foreign regulatory authorities may determine that the manufacturing processes or controls or the facilities of third-party manufacturers with which we contract for clinical and commercial supplies are inadequate; and
- the policies or regulations of the FDA or comparable foreign regulatory authorities regarding development, approval, and marketing of biological products may significantly change, including, but not limited to, as a result of the 2024 U.S. presidential election, and our clinical data may be rendered insufficient for approval or we may not be able to market our product candidates in the manner in which we anticipate.

Of the large number of product candidates in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations, and prospects.

The U.S. Supreme Court's June 2024 decision in *Loper Bright Enterprises v. Raimondo* overturned the longstanding *Chevron* doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The *Loper* decision could result in additional legal challenges to regulations and guidance issued by federal agencies, including the FDA, on which we rely. Any such legal challenges, if successful, could have a material impact on our business. Additionally, the *Loper* decision may result in increased regulatory uncertainty, inconsistent judicial interpretations, and other impacts to the agency rulemaking process, any of which could adversely impact our business and operations. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action or as a result of legal challenges, either in the U.S or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, our business could be materially harmed.

***We may be unable to obtain or maintain orphan drug status for our current and future product candidates, or to maintain the benefits associated with orphan drug status, including market exclusivity, which may cause our revenue, if any, to be reduced.***

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. Orphan drug designation must be requested before submitting a BLA or NDA. 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 or biologic 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 for a particular drug 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 or NDA, to market the same drug 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 one of our product candidates receives orphan exclusivity, that exclusivity may not effectively protect the product candidate from competition because different product candidates can be approved for the same condition. In addition, even after an orphan drug is approved, the FDA can subsequently approve a later product candidate that is the same drug as the drug with orphan exclusivity for the same condition if the FDA concludes that the later product candidate is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care compared with the product that has orphan exclusivity. Orphan drug exclusivity may also be lost if the FDA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of the patients with the rare disease or condition. The FDA has historically taken the position that the scope of orphan exclusivity aligns with the approved indication or use of a product, rather than the disease or condition for which the product received orphan designation. However, on September 30, 2021, the U.S. Court of Appeals for the Eleventh Circuit issued a decision in *Catalyst Pharms., Inc. v. Becerra* holding that the scope of orphan drug exclusivity must align with the disease or condition for which the product received orphan designation, even if the product's approval was for a narrower use or indication.

We may not be granted orphan drug designation for some of our current and future product candidates in additional orphan indications in which there is a medically plausible basis for the use of these products. Even if we obtain 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 the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. In addition, although we intend to seek orphan drug designation for other product candidates, we may never receive such designations. For example, the FDA has expressed concerns regarding the regulatory considerations for orphan drug designation as applied to tumor-agnostic therapies, and the FDA may interpret the federal Food, Drug and Cosmetic Act, as amended (the "FDCA"), and regulations promulgated thereunder in a way that limits or blocks our ability to obtain orphan drug designation or orphan drug exclusivity, if our product candidates are approved, for our targeted indications.

On August 18, 2017, the FDA Reauthorization Act of 2017 ("FDARA") was enacted. FDARA, among other things, codified the FDA's pre-existing regulatory interpretation, to require that a drug sponsor demonstrate the clinical superiority of an orphan drug that is otherwise the same as a previously approved drug for the same rare disease in order to receive orphan drug exclusivity. The legislation was made in response to a court ruling holding that the Orphan Drug Act unambiguously requires that the FDA recognize the orphan exclusivity period of a company obtains approval of a drug designated as an orphan drug, regardless of a showing of clinical superiority. Moreover, in the Consolidated Appropriations Act, 2021, Congress did not further change this interpretation when it clarified that the interpretation codified in FDARA would apply in cases where the FDA issued an orphan designation before the enactment of FDARA but where product approval came after the enactment of FDARA. Additionally, the Catalyst decision regarding interpretation of the Orphan Drug Act's exclusivity provisions as applied to drugs and biologics approved for orphan indications being narrower than the product's orphan designation has the potential to significantly broaden the scope of orphan exclusivity for such products. The FDA announced on January 24, 2023 that despite the Catalyst decision, it will continue to apply its longstanding regulations, which tie the scope of orphan exclusivity to the uses or indications for which the drug is approved, rather than to the designation. The FDA's application of its orphan drug regulations post-Catalyst could be the subject of future legislation or to further challenges in court, which could impact our ability to obtain or seek to work around orphan exclusivity and might affect our ability to retain orphan exclusivity that the FDA previously has recognized for our product candidates. The FDA and legislators may further reevaluate the Orphan Drug Act and its regulations and policies. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

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

If a drug or biologic is intended for the treatment of a serious or life-threatening condition and the product demonstrates the potential to address unmet medical needs for this condition, the product sponsor may apply for FDA Fast Track designation for a particular indication. In December 2025, the FDA granted Fast Track designation to CLN-049 for the treatment of relapsed/refractory AML. We may seek Fast Track designation for other current or future product candidates, but there is no assurance that the FDA will grant this status to any of our other proposed product candidates. Marketing applications filed by sponsors of products in Fast Track development may qualify for priority review under the policies and procedures offered by the FDA, but the Fast Track designation does not assure any such qualification or ultimate marketing approval by the FDA. The FDA has broad discretion whether or not to grant Fast Track designation, so even if we believe a particular product candidate is eligible for this designation, there can be no assurance that the FDA would decide to grant it. In any event, the receipt of Fast Track designation for CLN-049 or any other product candidate may not result in a faster development process, review or approval compared to conventional FDA procedures, and it does not provide assurance of ultimate FDA approval. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. In addition, the FDA may withdraw any Fast Track designation at any time.

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

In January 2022, the FDA granted Breakthrough Therapy designation for zipalertinib for the treatment of patients with locally advanced or metastatic NSCLC harboring epidermal growth factor exon 20 insertion mutations who have previously received platinum-based systemic chemotherapy. We may also seek Breakthrough Therapy designation for certain current or future product candidates. 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. Sponsors of product candidates that have been designated as Breakthrough Therapies are eligible to receive more intensive FDA guidance on developing an efficient drug development program, an organizational commitment involving senior managers, and eligibility for rolling review and priority review. Drugs and biologics designated as Breakthrough Therapies by the FDA may also be eligible for other expedited approval programs, including accelerated approval.

Designation as a Breakthrough Therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy designation for zipalertinib or any other product candidate may not result in a faster development process, review or approval compared to candidate products developed and considered for approval that have not received Breakthrough Therapy designation and does not assure ultimate approval by the FDA. Even though we may seek Breakthrough Therapy designation for some or all of our current or future product candidates for the treatment of various autoimmune diseases or cancers, there can be no assurance that we will receive Breakthrough Therapy designation for such product candidates.

***Seeking accelerated approval by the FDA, even if requested for zipalertinib or any other current or future product candidates, may not lead to a faster regulatory review and does not increase the likelihood that our product candidates will receive marketing approval.***

We and our collaboration partners are seeking accelerated approval of zipalertinib for treatment of patients with locally advanced or metastatic EGFR ex20ins NSCLC who have previously received platinum-based systemic chemotherapy, and we may also seek approval of certain of our other current and future product candidates using the FDA's accelerated approval pathway. A product may be eligible for accelerated approval if it treats a serious or life-threatening condition, generally provides a meaningful advantage over available therapies, and demonstrates an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. As a condition of approval, the FDA requires that a sponsor of a product receiving accelerated approval perform a post-marketing confirmatory clinical trial or trials. These confirmatory trials must be completed with due diligence. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. The Food and Drug Omnibus Reform Act of 2022 ("FDORA"), enacted on December 29, 2022 as part of the Consolidated Appropriations Act, 2023, includes numerous reforms to the accelerated approval process for drugs and biologics and enables the FDA to require, as appropriate, that a post-approval study be underway prior to granting accelerated approval. FDORA also expands the expedited withdrawal procedures already available to the FDA to allow the agency to use expedited procedures if a sponsor fails to conduct any required post-approval study of the product with due diligence. FDORA also adds the failure of a sponsor of a product approved under accelerated approval to conduct with due diligence any required post-approval study with respect to such product or to submit timely reports with respect to such product to the list of prohibited acts in the FDCA. Even if we do receive accelerated approval, we may not experience a faster regulatory review, and receiving accelerated approval does not provide assurance of ultimate full FDA approval. In connection with the receipt of accelerated approval, we may be required to complete additional confirmatory clinical trials. Conducting such additional confirmatory clinical trials could delay or prevent our ability to receive full approval of our product. Accelerated approval may also be withdrawn if, among other things, a confirmatory trial required to verify the predicted clinical benefit of the product fails to verify such benefit or if such trial is not conducted with due diligence.

***If approved, our investigational products regulated as biologics may face competition from biosimilars approved through an abbreviated regulatory pathway.***

Most of our current product candidates, with the exception of zipalertinib, will be regulated by the FDA as biologics, which must be licensed by the FDA prior to marketing under a BLA. The ACA includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 (the "BPCIA"), which created an abbreviated approval pathway for biologic products that are biosimilar to or interchangeable with an FDA-licensed reference biologic product. Under the BPCIA, a reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of the other company's product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty.

In December 2022, Congress clarified through 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 approved as a biologic product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our investigational medicines to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once licensed, will be substituted for any one of our reference products 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 marketing approval for biosimilars referencing our products, our products may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences.

Even if a product is considered to be a reference product eligible for exclusivity, 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 preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of the product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. There have been recent government proposals to reduce the 12-year reference product exclusivity period, but none has been enacted to date. Since passage of the BPCIA, many states have passed laws or amendments to laws, which address pharmacy practices involving biosimilar products.

The Consolidated Appropriations Act, which was enacted on December 27, 2020 required that the "patent dance" lists be made public in the FDA's Database of Licensed Biological Products (the "Purple Book"). In particular, within 30 days of exchanging a patent list (patents with expiry dates) with a biosimilar applicant, reference product BLA holders must submit that patent list, as well as any supplemental lists, to the FDA. This information was previously maintained as confidential as between the BLA holder and biosimilar applicant. A BLA holder may still assert other patents against future filers, and publication of these lists does not exclude enforcement of newly granted patents. Additionally, under the Consolidated Appropriations Act, 2021, the FDA must now update the Purple Book every 30 days and publish in the Purple Book the following information about patented biological products:

- a list of each biological product, by nonproprietary name, for which a biologics license is in effect;
- the date of licensure and the application number;
- the licensure status and, as available, the marketing status; and
- exclusivity periods.

***If the FDA or comparable foreign regulatory authorities approve generic versions of any of our small-molecule investigational products that receive marketing approval, or such authorities do not grant our products appropriate periods of exclusivity before approving generic versions of those products, the sales of our products, if approved, could be adversely affected.***

Once an NDA is approved, the product covered thereby becomes a "reference listed drug" in the FDA's publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the Orange Book. Manufacturers may seek approval of generic versions of reference listed drugs through submission of abbreviated new drug applications ("ANDAs"), in the U.S. In support of an ANDA, a generic manufacturer need not conduct clinical trials to assess safety and efficacy. Rather, the applicant generally must show that its product has the same active ingredient(s), dosage form, strength, route of administration and conditions of use or labeling as the reference listed drug and that the generic version is bioequivalent to the reference listed drug, meaning it is absorbed in the body at the same rate and to the same extent. Generic products may be significantly less costly to bring to market than the reference listed drug and companies that produce generic products are generally able to offer them at lower prices. Thus, following the introduction of a generic drug, a significant percentage of the sales of any branded product or reference listed drug is typically lost to the generic product.

The FDA may not approve an ANDA for a generic product until any applicable period of non-patent exclusivity for the reference listed drug has expired. The FDCA provides a period of five years of non-patent exclusivity for a new drug containing a new chemical entity. Specifically, in cases where such exclusivity has been granted, an ANDA may not be submitted to the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification that a patent covering the reference listed drug is either invalid or will not be infringed by the generic product, in which case the applicant may submit its application four years following approval of the reference listed drug.

Generic drug manufacturers may seek to launch generic products following the expiration of any applicable exclusivity period we obtain if our products are approved, even if we still have patent protection for such products. Competition that our products could face from generic versions of our products could materially and adversely affect our future revenue, profitability, and cash flows and substantially limit our ability to obtain a return on the investments we have made in those product candidates.

***Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.***

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing, and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the U.S., including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the U.S., a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the U.S. have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. 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 products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

***Even if we receive regulatory approval of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.***

Any product candidate for which we obtain marketing approval will be subject to extensive and ongoing regulatory requirements governing, among other things, the research, development, testing, manufacturing, labeling, packaging, distribution, storage, advertising, promotion, import, export, recordkeeping, monitoring, and reporting of our products. These requirements include submissions of safety and other post-marketing information and reports, facility registration and drug listing requirements, as well as continued compliance with cGMPs, good laboratory practices, regulations, and GCPs, for any clinical trials that we conduct post-approval. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product.

The FDA may require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market or voluntary or mandatory product recalls;
- manufacturing delays and supply disruptions where regulatory inspections identify observations of noncompliance requiring remediation;
- revisions to the labeling, including limitation on approved uses or the addition of additional warnings, contraindications or other safety information, including boxed warnings;
- imposition of a REMS, which may include distribution or use restrictions;
- requirements to conduct additional post-market clinical trials to assess the safety of the product;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of approvals;
- product seizure or detention, or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's and other comparable regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U.S. or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

***The FDA and other comparable regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.***

The FDA and other regulatory agencies closely regulate the post-approval marketing and promotion of products to ensure that they are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA and other comparable regulatory agencies impose stringent restrictions on manufacturers' communications regarding off-label use. If any of our product candidates are approved and we are found to have promoted such off-label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. Violation of the FDCA, and other statutes, including the False Claims Act (the "FCA") and equivalent legislation in other countries relating to the promotion and advertising of prescription products may also lead to investigations or allegations of violations of federal and state and other countries' health care fraud and abuse laws and state consumer protection laws. Even if it is later determined we were not in violation of these laws, we may be faced with negative publicity, incur significant expenses defending our actions and have to divert significant management resources from other matters.

***Inadequate funding for the FDA, the SEC and other government agencies, including from government shut downs, or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.***

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities. During the 2025 government shutdown, which has since ended, the FDA was not accepting new marketing applications that require a user fee, included NDAs. If a prolonged government shutdown or other disruption occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns or other disruptions could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

***Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements which could have a significant adverse impact on our business.***

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to: comply with the regulations of the FDA and other similar foreign regulatory authorities, provide true, complete and accurate information to the FDA and other similar foreign regulatory authorities, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws in the U.S. and similar foreign fraudulent misconduct laws, or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the U.S., our potential exposure under such laws and regulations will increase significantly, and our costs associated with compliance with such laws and regulations are also likely to increase. These laws may impact, among other things, our current activities involving principal investigators and research patients, as well as proposed and future sales, marketing and education programs. We adopted a code of conduct applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, 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 comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

***We are or may become subject to additional healthcare regulation and enforcement by various government entities, and our failure to strictly adhere to these regulatory regimes could have a significant adverse impact on our business.***

Pharmaceutical manufacturers and their products are subject to extensive federal and state regulation, including laws intended to prevent fraud and abuse in the healthcare industry. These laws may constrain the business or financial arrangements and relationships through which we conduct business, including how we conduct research regarding, market, sell, and distribute our products. In the U.S., these laws include, but are not limited to the following, some of which are likely to apply only if or when we obtain marketing approval for a product candidate:

- federal false claims, false statements, and civil monetary penalties laws prohibiting, among other things, any person from knowingly presenting, or causing to be presented, a false claim for payment of government funds or knowingly making, or causing to be made, a false statement to get a false claim paid;
- the federal anti-kickback law, which prohibits, among other things, persons from offering, soliciting, receiving, or providing remuneration, directly or indirectly, to induce either the referral of an individual for, or the purchasing or ordering of, a good or service for which payment may be made under federal healthcare programs such as Medicare and Medicaid;
- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which, in addition to privacy protections applicable to healthcare providers and other entities, prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the FDCA, which among other things, strictly regulates drug marketing, prohibits manufacturers from marketing products prior to approval or for off-label use and regulates the distribution of samples;
- federal laws that require pharmaceutical manufacturers to calculate, report and certify certain complex product prices and other data to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs, which data may be used in the calculation of reimbursement and/or discounts on approved products;
- the federal Open Payments (or federal "sunshine" law), which requires pharmaceutical and medical device companies to monitor and report certain financial interactions with certain healthcare providers to the Center for Medicare & Medicaid Services within the U.S. Department of Health and Human Services for re-disclosure to the public, as well as ownership and investment interests held by physicians and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- analogous state laws and regulations, including state anti-kickback and false claims laws, consumer protection and unfair competition laws and laws governing privacy, security and breaches of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and
- state laws that require pharmaceutical companies to comply with specific compliance standards, restrict financial interactions between pharmaceutical companies and healthcare providers, report drug product pricing information, financial interactions with health care providers, or marketing expenditures and/or require the registration of pharmaceutical sales representatives.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

Ensuring compliance is time-consuming and costly. Given the breadth of the laws and regulations, limited guidance for certain laws and regulations and evolving government interpretations of the laws and regulations, governmental authorities may possibly conclude that our business practices are non-compliant. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, imprisonment, and the curtailment or restructuring of our operations, any of which could adversely affect our business, financial condition, results of operations, and prospects.

Outside the U.S., our activities may also be subject to extensive regulation, including anti-kickback and false claims laws. The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the EU. The provision of benefits or advantages to induce or reward improper performance generally is usually governed by the national anti-bribery laws of EU member states, and the Bribery Act 2010 in the UK. Infringement of these laws could result in substantial fines and imprisonment. EU Directive 2001/83/EC, which is the EU Directive governing medicinal products for human use, further provides that, where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy. This provision has been transposed into the Human Medicines Regulations 2012 and so remains applicable in the UK despite its departure from the EU. Payments made to physicians in certain EU member states must be publicly disclosed.

Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU member states. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the EU member states.

Failure to comply with these requirements could result in administrative, civil and criminal penalties, damages, fines, disgorgement, the exclusion from participation in federal and state healthcare programs, individual imprisonment, reputational harm, and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws.

***Data collection is governed by restrictive regulations governing the use, processing and cross-border transfer of personal information.***

We may be subject to additional data privacy restrictions as we continue to enroll subjects in our ongoing or future clinical trials. The collection, use, storage, disclosure, transfer, or other processing of personal data regarding individuals in the EEA, including personal health data, is subject to the EU General Data Protection Regulation (the "GDPR") which became effective on May 25, 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that are established in the EEA or which are not established in the EEA but collect and use personal data in relation to (i) offering goods or services to, or (ii) monitoring the behavior of, individuals located in the EEA. The GDPR imposes stringent operational requirements for controllers and processors of personal data, including, for example, requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing and maintaining a process to address data subject rights, implementing safeguards to protect the security and confidentiality of personal data, providing notification to data subjects and government authorities of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to most countries outside the EEA, including the U.S., and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. The GDPR increased our responsibility and potential liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries within the EEA. Compliance with the GDPR will continue to be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European data processing activities. Following the UK's exit from the EU, our processing of personal data of persons located in the United Kingdom subjects us to the UK Data Protection Act 2018 and the "UK GDPR" as defined by the Data Protection Act 2018, as amended by the Data Protection, Privacy and Electronic Communications (Amendments etc.) (EU Exit) Regulations 2019 (SI 2019/419) ("UK GDPR"). The UK GDPR imposes similar obligations on data controllers and processors to those found in the GDPR and carries with it fines similar to those of the GDPR. The UK's data protection authority, the Information Commissioner's Office, had indicated that it will continue to enforce the UK GDPR in line with the enforcement of GDPR in the EU, and currently the UK GDPR and EU GDPR are broadly aligned. On June 19, 2025, the UK's Data (Use and Access) Act took effect, which introduces certain relatively minor amendments to the data protection regime in the UK, and therefore creates slight divergences between the EU and UK data protection regimes.

Recent legal developments in the EU and UK have also created complexity and uncertainty regarding transfers of personal data from the EEA and the UK to the U.S. and other countries. On July 10, 2023, the European Commission issued an EU-U.S. data adequacy decision on the basis of the new framework for transatlantic data flows, the EU-U.S. Data Privacy Framework ("DPF"). Companies must self-certify to the U.S. Department of Commerce that they comply with the principles of the DPF in order to benefit from the new mechanism to transfer personal data from the EU (and the UK and Switzerland under the respective extensions to the DPF) and the U.S. Companies who have not certified to the DPF will continue to be subject to the current rules on international transfers under the GDPR and UK GDPR, including, for example, ensuring that the Standard Contractual Clauses, published by the European Commission in 2021, and the UK Addendum, or the UK International Data Transfer Agreement ("UK IDTA"), published by the UK Government in 2022, are in place where required. Prior to entering into the Standard Contractual Clauses or the UK IDTA, organizations are required to conduct a case-by-case assessment of the relevant data transfer(s) in order to assess the legal regime applicable in the destination country. The DPF has already been subjected to legal challenge, and it is likely to be subjected to further challenges in the future. The impact of these developments on the ability to lawfully transfer personal information from the EEA and UK to the U.S. and other countries has led to increased scrutiny on data transfers out of the EEA and UK and may increase our costs of compliance with data privacy legislation.

The U.S. Department of Justice, pursuant to Executive Order 14117, has put into effect a data security program (the "Data Security Program") that restricts, and in some cases prohibits, access by certain countries of concern such as the People's Republic of China (including Hong Kong and Macau) to certain U.S. government-related data and bulk human 'omic, geolocation, biometric, health, financial, and other sensitive personal data, even if those data are de-identified, anonymized or encrypted. Entities organized under the laws of the United States as well as U.S. persons are restricted in their ability to provide access to such data to such countries as well as "covered persons" that have certain nexuses to such countries, and they are also required to prohibit foreign parties from making an "onward transfer" of such data to countries of concern and covered persons. These restrictions may result in an inability to realize the full value of such data, to use such data effectively or efficiently, or to engage in some data transactions that would otherwise be available to entities not subject to the Data Security Program. These international data restrictions may also limit our ability to develop insights and transfer data as our business would otherwise find more desirable and they may limit potential investments. Failure to comply with these restrictions could lead to civil or criminal penalties.

In addition, the U.S. federal government and various states and governmental agencies have adopted or are considering adopting various laws, regulations and standards regarding the collection, use, retention, security, disclosure, transfer and other processing of sensitive and personal information. In some states, such as California and Washington, state privacy laws are even more protective than HIPAA and special statutes such as the Washington My Health My Data Act are particularly restrictive. These laws and regulations are not necessarily preempted by HIPAA, particularly if a state affords greater protection to individuals than HIPAA. In addition to fines and penalties imposed upon violators, some of these state laws also afford private rights of action to individuals who believe their personal information has been misused. Most notably, the California Consumer Privacy Act, as amended by the California Privacy Rights Act (together, the "CCPA") gives California residents certain privacy rights in the collection and use of their personal information and requires businesses to make certain disclosures, limit their use of personal information, and take certain other acts in furtherance of those rights. Failure to comply with the CCPA may result in, among other things, civil penalties of up to $7,500 per violation, as well as a private right of action for certain data breaches. Additionally, California has created a data protection agency authorized to implement and enforce the CCPA, which could result in increased enforcement.

While there are currently exceptions in the CCPA for protected health information that is subject to HIPAA and information collected in research studies, including clinical trials, that are conducted in accordance with certain regulations, we may process other personal information that is subject to the CCPA. In addition, almost 20 other states have now passed comprehensive privacy laws that have taken effect or will come into effect at various times over the next few years. These comprehensive state privacy laws also provide exemptions for protected health information subject to HIPAA or exempt covered entities and business associates entirely. All of these evolving compliance and operational requirements impose significant costs that are likely to increase over time, may require us to modify our data processing practices and policies, divert resources from other initiatives and projects and could restrict the way services involving data are offered, all of which may adversely affect our results of operations. Certain state laws may be more stringent or broader in scope, or offer greater individual rights, than federal or other state laws, and such laws may differ from each other, which may complicate compliance efforts. We will need to continue to evaluate our privacy program as the implementation of these laws evolves and may need to make further modifications to our programs, which, if we fail to do so as required, may expose us to liability.

Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), class action litigation and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend and could result in adverse publicity that could harm our business.

***Regulations regarding the use and development of artificial intelligence ("AI") are being introduced in various jurisdictions globally.***

We may be currently, and may become, subject to a range of current and future regulations relating to the use and/or development of AI technology or systems. Regulations related to AI may impose certain obligations on organizations, and the costs of monitoring and responding to such regulations, as well as the consequences of non-compliance, could have an adverse effect. Several governmental authorities have already proposed or enacted laws and other guidance governing AI.

In the UK, the government has pledged to implement legislation imposing obligations on developers of the most powerful AI models. This framework is expected to take the form of a principles-based regime intended to foster growth and development of AI technologies, however, there have been delays with this proposal and a UK AI bill is not expected until mid-2026 at the earliest. Sector-specific guidance on AI has already been published by regulators in the UK, including the Competition and Markets Authority and the Information Commissioner's Office.

In the EU, by contrast, the Artificial Intelligence Act (Regulation (EU) 2024/1689) (the "EU AI Act") represents the world's first comprehensive legislative framework for AI. The EU AI Act came into force on August 1, 2024 and the obligations have taken, and will take, effect in stages between February 2025 and August 2027 (with the majority of obligations enforceable from August 2, 2026). Classifying AI systems according to risk, the EU AI Act imposes a range of obligations on developers, importers, distributors and users of AI systems, and also imposes prohibitions on certain high-risk AI practices. It also carries a range of enforcement powers for the European Commission's newly established AI Office to exercise, including fines of up to EUR 35,000,000 or 7% of an organization's annual turnover for the previous year, and the authority to recall or restrict AI systems and require corrective action. On November 19, 2025, the European Commission published the Digital Omnibus Package – a proposal intended to streamline the EU's digital framework, including the EU AI Act. There could therefore be future changes in the applicable obligations and steps needed for compliance under the EU AI Act.

U.S. legislation related to AI technologies has also been introduced at the federal level and is advancing at the state level. For instance, California enacted seventeen new laws in 2024 that further regulate use of AI technologies and provide consumers with additional protections around companies' use of AI technologies, such as requiring companies to disclose certain uses of generative AI. Other states have also passed AI-focused legislation. For example, Utah passed the Utah AI Policy Act, which took effect in May 2024, imposing certain disclosure requirements on the use of AI, and Colorado enacted the Colorado AI Act, which took effect in February 2026. Further, the California Privacy Protection Agency recently finalized regulations under the CCPA regarding the use of automated decision-making. Such additional regulations may impact our ability to develop, use, procure and commercialize AI technologies in the future.

In January 2026, the FDA and EMA jointly published "Guiding Principles of Good AI Practice in Drug Development," which acknowledge the growing use of AI in drug development and set forth potential areas of focus for regulators and international standards organizations.

Preparing for and complying with current and upcoming regulations related to AI systems could involve material compliance costs and/or adversely affect the operations or performance of our business. These and other developing obligations may prevent or make it harder for us to conduct or enhance our business using AI, or lead to regulatory fines, penalties, or other liability. Further, use of AI systems could lead to unintended consequences, such as cybersecurity risks or unintended biases, impact our ability to protect confidential data and intellectual property, and expose us to intellectual property infringement claims by third parties, any of which may have a material adverse effect on our operations, financial condition, and prospects.

**Risks Related to Our Intellectual Property**

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

Our success depends in large part on our ability to obtain and maintain patent and other intellectual property protection in the U.S. and other countries with respect to our product candidates, their respective components, formulations, combination therapies, methods used to manufacture them and methods of treatment and development that are important to our business, as well as successfully defending these patents against third-party challenges. If we do not adequately protect our intellectual property rights, competitors may be able to erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability.

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

To protect our proprietary position, we have filed or in-licensed, and plan to file or in-license, patents and patent applications in the U.S. and abroad relating to our product candidates that are important to our business. Our ability to stop unauthorized third parties from making, using, selling, offering to sell, or importing our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. If we are unable to secure or maintain patent protection with respect to any of our current or future product candidates, or any other proprietary products and technology we develop, our business, financial condition, results of operations, and prospects would be materially harmed.

The degree of patent protection we require to successfully compete in the marketplace may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We cannot provide any assurances that any patents we may own, have licensed, or in-license in the future will have, or that any of our patent applications that mature into issued patents will include, claims with a scope sufficient to protect our current and future product candidates or otherwise provide any competitive advantage. In addition, to the extent that we currently or in the future in-license intellectual property, we cannot assure you that those licenses will remain in force. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the U.S. Furthermore, patents have a limited lifespan, and the term of any patents we may own or in-license may be inadequate to protect our competitive position of our product candidates or technology for an adequate amount of time. In the U.S., the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized.

Even if they are unchallenged, our patent applications, if issued, and any patents we may own or in-license, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent any patents we may own or in-license by developing similar or alternative technologies or therapeutics in a non-infringing manner. For example, a third party may develop a competitive therapy that provides benefits similar to one or more of our product candidates but that uses a formulation and/or a device that falls outside the scope of any patent protection we may have in the future. If the patent protection provided by our patent applications or any patents, we may pursue with respect to our product candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize our product candidates could be negatively affected, which would harm our business.

Patent positions of life sciences companies can be uncertain and involve complex factual and legal questions. Changes in either the patent laws or their interpretation in any jurisdiction that we seek patent protection may diminish our ability to protect our inventions, maintain and enforce our intellectual property rights; and, more generally, may affect the value of our intellectual property, including the narrowing of the scope of our patent applications or any patents we may own or in-license.

The patent prosecution process is complex, expensive, time-consuming, and inconsistent across jurisdictions. Patent license negotiations also can be complex and protracted, with uncertain results. We may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent rights at a commercially reasonable cost or in a timely manner. In addition, we may not pursue or obtain patent protection in all relevant markets. It is possible that we will fail to identify important patentable aspects of our research and development efforts in time to obtain appropriate or any patent protection. While we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development efforts, including for example, our employees, corporate collaborators, external academic scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose results before a patent application is filed, thereby endangering our ability to seek patent protection. In addition, publications of discoveries in the scientific and scholarly literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Consequently, we cannot be certain that we were the first to file for patent protection on the inventions claimed in our patent applications.

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

Additionally, we cannot be certain that the claims in our patent applications covering composition of matter of our product candidates or technology will be considered patentable by the U.S. Patent and Trademark Office (the "USPTO") or by patent offices in foreign countries, or that the claims in any issued patents we may own or in-license will be considered patentable by courts in the U.S. or foreign countries.

Method of use patents protect the use of a product for the specified method. These types of patents do 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 induce or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

The patent position of pharmaceutical and biotechnology companies generally is highly uncertain and involves complex legal and factual questions for which many legal principles remain unresolved. In recent years, patent rights have been the subject of significant litigation. As a result, the issuance, scope, validity, enforceability, and commercial value of any rights we may have from our patent applications are highly uncertain. Our patent applications may not result in patents being issued in the U.S. or in other jurisdictions which protect our technology or products, or which effectively prevent others from commercializing competitive technologies and products. Moreover, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art, including our own previously filed patent applications and scientific publications, allow our inventions to be patentable over the prior art. Even if our patent applications issue as patents, third parties could challenge the validity of such patents based on such scientific publications and we could potentially lose valuable patent rights. Further, the scope of the invention claimed in a patent application can be significantly reduced before the patent is issued, and this scope can be reinterpreted after issuance. Even where our patent applications, whether owned or in-licensed, 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 a competitive advantage. Any patents that eventually issue may be challenged, narrowed, or invalidated by third parties. Consequently, we do not know whether any of our product candidates will be protectable or remain protected by valid and enforceable patent rights. Our competitors or other third parties may be able to evade any rights we may have by developing new compounds or alternative technologies or products in a non-infringing manner.

The issuance or grant of a patent is not irrefutable as to its inventorship, scope, validity, or enforceability, and any of our current or future patents, whether owned or in-licensed may be challenged in the courts or patent offices in the U.S. and abroad. Such challenges may result in the patent claims of any such patents being narrowed, invalidated, or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. We may in the future, become subject to a third-party pre-issuance submission of prior art or opposition, derivation, revocation, re-examination, post-grant and *inter partes* review, or interference proceeding and other similar proceedings challenging any rights we may have from our patent applications or the patent rights of others in the USPTO or other foreign patent office, or in declaratory judgment actions or counterclaims. An unfavorable determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, any rights we may have from our patents or patent applications, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or extinguish our ability to manufacture or commercialize products without infringing third-party patent rights.

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

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

We are currently, and may in the future be, party to license or collaboration agreements with third parties to advance our research or allow commercialization of our product candidates. Our current agreements impose, and we expect that future agreements may impose numerous obligations, such as development, diligence, payment, commercialization, funding, milestone, royalty, sublicensing, insurance, patent prosecution, enforcement and other obligations on us and may require us to meet development timelines, or to exercise commercially reasonable efforts to develop and commercialize licensed products, in order to maintain the licenses. If our licensors conclude that we have materially breached our license agreements they may seek to terminate the license agreements, thereby removing or limiting our ability to develop and commercialize products and technologies covered by these license agreements.

Any termination of these licenses, or if the underlying patents fail to provide the intended exclusivity, could result in the loss of significant rights and could harm our ability to commercialize our product candidates, and competitors or other third parties would have the freedom to seek regulatory approval of, and to market, products identical to ours and we may be required to cease our development and commercialization of certain of our product candidates. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including:

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

In addition, licensing agreements are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. For example, we will owe the licensor of CLN-049 a success fee in the event of a sale or other disposition of the majority of the assets of the development subsidiaries holding these product candidates. These fees will reduce the net proceeds we receive from any such sale or disposition of assets.

Moreover, if disputes over intellectual property prevent or impair our ability to maintain licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations and prospects.

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

In addition to the protection afforded by our owned and in-licensed patents, we seek to rely on trade secret protection, confidentiality agreements, and license agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our product identification, discovery, and development processes, that involve proprietary know-how, information, or technology that is not covered by patents. Although we require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, trade secrets can be difficult to protect, and we have limited control over the protection of trade secrets used by our collaborators and suppliers. We cannot be certain that we have or will obtain these agreements in all circumstances, and we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary information. Any party with whom we have executed such an agreement may breach that agreement 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. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. Further, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such third party, or those to whom they communicate such technology or information, 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, our business and competitive position could be harmed.

***Third-party claims of intellectual property infringement, misappropriation or other violations may be costly and time consuming and may prevent or delay our product identification, discovery and development efforts.***

The intellectual property landscape around precision medicine is crowded, and 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 have a material adverse effect on the success of our business. Our commercial success depends upon our ability, or the ability of our third parties, to develop, manufacture, market and sell our current and future product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including derivation, interference, reexamination, *inter partes* review, and post grant review proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We or any of our licensors or strategic partners may be party to, exposed to, or threatened with, future adversarial proceedings or litigation by third parties having patent or other intellectual property rights alleging that our current or future product candidates and/or proprietary technologies infringe, misappropriate or otherwise violate their intellectual property rights. We cannot assure you that our product candidates and other technologies that we have developed, are developing or may develop in the future do not or will not infringe, misappropriate or otherwise violate existing or future patents or other intellectual property rights owned by third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our product candidates, technologies, or methods.

If a third party claims that we infringe, misappropriate or otherwise violate its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement, misappropriation and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business and may impact our reputation;
- substantial damages for infringement, misappropriation or other violations, which we may have to pay if a court decides that the product candidate or technology at issue infringes, misappropriates or violates the third party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;
- a court prohibiting us from developing, manufacturing, marketing or selling our current and future product candidates, or from using our proprietary technologies, unless the third party licenses its product rights to us, which it is not required to do, on commercially reasonable terms or at all;
- if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights for our products, or the license to us may be non-exclusive, which would permit third parties to use the same intellectual property to compete with us;
- redesigning our product candidates or processes so they do not infringe, misappropriate or violate third-party intellectual property rights, which may not be possible or may require substantial monetary expenditures and time; and
- 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.

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

We may choose to challenge the patentability of claims in a third party's U.S. patent by requesting that the USPTO review the patent claims in an *ex-parte* re-exam, *inter partes* review or post-grant review proceedings. These proceedings are expensive and may consume our time or other resources. We may choose to challenge a third party's patent in patent opposition proceedings in the European Patent Office (the "EPO") or other foreign patent office. The costs of these opposition proceedings could be substantial, and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO or other patent office then we may be exposed to litigation by a third party alleging that the patent may be infringed by our product candidates or proprietary technologies.

Third parties may assert that we are employing their proprietary technology without authorization. Patents issued in the U.S. by law enjoy a presumption of validity that can be rebutted only with evidence that is "clear and convincing," a heightened standard of proof. There may be issued third-party patents of which we are currently unaware with claims to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Patent applications can take many years to issue. In addition, because some patent applications in the U.S. may be maintained in secrecy until the patents are issued, patent applications in the U.S. and many foreign jurisdictions are typically not published until 18 months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications covering our product candidates or technology. If any such patent applications issue as patents, and if such patents have priority over our patent applications or patents we may own or in-license, we may be required to obtain rights to such patents owned by third parties which may not be available on commercially reasonable terms or at all, or may only be available on a non-exclusive basis. There may be currently pending patent applications which may later result in issued patents that may be asserted in infringement claims against our current and future product candidates. It is also possible that patents owned by third parties of which we are aware, but which we do not believe are relevant to our current and future product candidates or other technologies, could be found by a court of competent jurisdiction to be infringed by our product candidates or other technologies. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Moreover, we may fail to identify relevant patents or incorrectly conclude that a patent is invalid, not enforceable, exhausted, or not infringed by our activities. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, molecules used in or formed during the manufacturing process, or any final product itself, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Defense of these claims, regardless of their merit, could involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement, misappropriation or other violation against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need or may choose to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly.

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

We own five patent families related to CLN-978. We own four patent families related to velinotamig. We have in-licensed seven patent families related to zipalertinib as part of our co-development agreement with an affiliate of Taiho. We own one patent family and have in-licensed one patent family related to CLN-049.

Because additional product candidates may require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in-license or use these proprietary rights.

Our product candidates may also require specific formulations to work effectively and efficiently, and these rights may be held by others. Similarly, efficient production or delivery of our product candidates may also require specific compositions or methods, and the rights to these may be owned by third parties. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm our business. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be nonexclusive, thereby giving our competitors access to the same technologies licensed to us. In such circumstances, we may be required to expend significant time and resources to develop or license replacement technology. Moreover, the molecules that will be used with our product candidates may be covered by the intellectual property rights of others.

Additionally, we sometimes collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. In certain cases, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program and allowing third parties to compete with us. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of such program and our business and financial condition could suffer.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and companies, which may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to in-license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of such program and our business, results of operations, financial condition and prospects could suffer.

***We may be involved in lawsuits to protect or enforce our owned or in-licensed intellectual property rights, which could be expensive, time-consuming and unsuccessful.***

Competitors may infringe any patents we may own or in-license. In addition, any patents we may own, or in-license may become involved in inventorship, priority, validity or unenforceability disputes. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, in an infringement proceeding, a court may decide that one or more of any patents we may own or in-license is not valid or is unenforceable or that the other party's use of our technology that may be patented falls under the safe harbor to patent infringement under 35 U.S.C. §271(e)(1). There is also the risk that, even if the validity of these patents is upheld, the court may refuse to stop the other party from using the technology at issue on the grounds that any of our owned or in-licensed patents do not cover the technology in question or that such third party's activities do not infringe our patents. An adverse result in any litigation or defense proceedings could put one or more of our owned or in-licensed patents at risk of being invalidated, held unenforceable, or interpreted narrowly, or could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. 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 and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

Post-grant proceedings provoked by third parties or brought by the USPTO may be necessary to determine the validity or priority of inventions with respect to our owned or in-licensed patents or patent applications. These proceedings are expensive and an unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if a party prevailing against us does not offer us a license on commercially reasonable terms. In addition to potential USPTO review proceedings, we may become a party to patent opposition proceedings in the EPO or similar proceedings in other foreign patent offices, where our foreign patents are challenged. The costs of these opposition or similar proceedings could be substantial, and may result in a loss of scope of some claims or a loss of the entire patent. An unfavorable result at the USPTO, EPO or other patent office may result in the loss of our right to exclude others from practicing one or more of our inventions in the relevant country or jurisdiction, which could have a material adverse effect on our business.

Litigation or post-grant proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the U.S.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

We may not be able to detect infringement against any of our owned or in-licensed patents. Even if we detect infringement by a third party, we may choose not to pursue litigation against or settlement with the third party. If we later sue such third party for patent infringement, the third party may have certain legal defenses available to it, which otherwise would not be available except for the delay between when the infringement was first detected and when the suit was brought. Such legal defenses may make it impossible for us to enforce any patents we may own or in-license against such third party.

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

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and following the issuance of a patent. While an inadvertent lapse can in some cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market with similar or identical products or platforms, which could have a material adverse effect on our business prospects and financial condition.

***Changes to patent law in the U.S. and in foreign jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.***

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity, and are therefore costly, time-consuming and inherently uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we might obtain in the future. For example, in the case *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.,* the U.S. Supreme Court held that certain claims to DNA molecules are not patentable. Any adverse changes in the patent laws of other jurisdictions could have a material adverse effect on our business and financial condition. Changes in the laws and regulations governing patents in other jurisdictions could similarly have an adverse effect on our ability to obtain and effectively enforce any rights we may have in our patent applications or any patents we may own or in-license.

Recent or future patent reform legislation could also increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of any patents we may own or in-license. The U.S. has enacted and implemented wide-ranging patent reform legislation. On September 16, 2011, the Leahy-Smith America Invents Act, was signed into law, which includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, may affect patent litigation, establish a new post-grant review system and switch the U.S. patent system from a "first-to-invent" system to a "first-to-file" system. Under a "first-to-file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier.

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

We may not be able to pursue generic coverage of our product candidates outside of the U.S. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and intellectual property rights in some countries outside the U.S. can be less extensive than those in the U.S. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the U.S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from selling or importing products made using our inventions in and into the U.S. or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but where enforcement is not as strong as that in the U.S. These products may compete with our product candidates and in jurisdictions where we do not have any issued patents or patent applications or other intellectual property rights, we may not have effective or sufficient protection to prevent them from competing. Our patent portfolio is at the very early stages of prosecution. We will need to decide whether and in which jurisdictions to pursue protection for the various inventions in our portfolio prior to applicable deadlines.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biopharmaceutical products, which could make it difficult for us to stop the infringement of any patents we may own or in-license or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce any rights we may have in our patents and patent applications in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put any of our owned or in-licensed patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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

***We may be subject to claims challenging the inventorship or ownership of any intellectual property, including any patents we may own or in-license.***

We may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates or other technologies. We generally enter into confidentiality and intellectual property assignment agreements with our employees, consultants, and contractors. These agreements generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, those agreements may not be honored and may ineffectively assign intellectual property rights to us. Moreover, there may be some circumstances where we are unable to negotiate for such ownership rights. Disputes regarding ownership or inventorship of intellectual property can also arise in other contexts, such as collaborations and sponsored research. If we are subject to a dispute challenging our rights in or to patents or other intellectual property, such a dispute could be expensive and time consuming. Litigation may be necessary to defend against these and other claims challenging inventorship of any of our owned or in-licensed patents, trade secrets or other intellectual property. If we were unsuccessful, in addition to paying monetary damages, we could lose valuable rights in intellectual property that we regard as our own, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates and other technologies. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

***We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information or alleged trade secrets of third parties or competitors or are in breach of non-competition or non-solicitation agreements with our competitors.***

We have received confidential and proprietary information from third parties. In addition, as is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors, in some cases until recently. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information or trade secrets of these third parties or our employees' former employers or our consultants' or contractors' current or former clients or customers. In addition, we may become subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation or arbitration may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation or other legal proceedings relating to intellectual property claims and possible aftermath could result in substantial cost and be a distraction to our management and employees. Any litigation or the threat thereof may adversely affect our ability to hire employees. A loss of key personnel or their work product could hamper or prevent our ability to commercialize product candidates, which could have an adverse effect on our business, results of operations and financial condition. In 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. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property related proceedings could adversely affect our ability to compete in the marketplace.

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

Depending upon the timing, duration and specifics of any FDA marketing approval of any of our current or future product candidates we may develop, one or more U.S. patents we may own or in-license may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Amendments"). The Hatch-Waxman Amendments permit a patent term extension of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is shorter than what we request, our competitors may obtain approval of competing products following expiration of any patents that issue from our patent applications, and our business, financial condition, results of operations, and prospects could be materially harmed.

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

Our trademarks or trade names may be challenged, infringed, diluted, circumvented, or declared generic or determined to be infringing on other marks. We intend to rely on both registration and common law protection for our trademarks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During the trademark registration process, we may receive Office Actions from the USPTO objecting to the registration of our trademark. Although we would be given an opportunity to respond to those objections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and/or to seek the cancellation of registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to obtain a registered trademark or establish name recognition based on our trademarks and trade names, we may not be able to compete effectively, and our business may be adversely affected.

**Risks Related to Our Reliance on Third Parties**

***We currently rely and expect to continue to rely on the outsourcing of the majority of our development functions to third parties to conduct our preclinical 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 utilize and depend upon independent investigators and collaborators, such as medical institutions, CROs, CMOs, and strategic partners to conduct and support our preclinical studies and clinical trials under agreements with us and expect to rely on such parties in the future.

We negotiate budgets and contracts with CROs, clinical trial sites and CMOs, and we may not be able to do so on favorable terms, which may result in delays to our development timelines and increased costs. We rely heavily on these third parties over the course of our preclinical studies and clinical trials, and we control only certain aspects of their activities. As a result, we have less direct control over the conduct, timing and completion of our preclinical studies and clinical trials and the management of data developed through preclinical studies and clinical trials than would be the case if we relied entirely upon our own staff. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with good manufacturing, clinical, laboratory practices ("GxPs"), which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GxPs through periodic inspections of clinical trial sponsors, principal investigators and clinical trial sites. If we or any of these third parties fail to comply with applicable GxP regulations, 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 before approving our marketing applications. We cannot assure you that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GxP regulations. In addition, our clinical trials must be conducted with pharmaceutical product produced under GxP regulations and will require a large number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may delay ongoing or planned clinical trials or require us to repeat clinical trials, which would delay the regulatory approval process. Failure by us or by third parties we engage to comply with regulatory requirements can also result in fines, adverse publicity, and civil and criminal sanctions. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting our preclinical studies and clinical trials are not and will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our current and future preclinical studies and clinical trials. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Switching or adding third parties to conduct our preclinical studies and clinical trials involves substantial cost and requires extensive time and focus of our management. In addition, there is a natural transition period when a new third party commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines.

Additionally, we do not directly control the manufacturing facilities where our product candidates are made, and we must depend on CMOs to make our product candidates according to standards for quality and reliability. We do not own any manufacturing facilities or equipment. We cannot provide assurance that we will be able to obtain qualified contract manufacturing services on reasonable terms. If any CMO with whom we contract fails to perform its obligations or has challenges sourcing raw materials, we may be forced to enter into an agreement with a different CMO, which we may not be able to do on reasonable terms, if at all. In such a scenario, our clinical trials supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original CMO 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 CMOs for any reason, we will be required to verify that the new CMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. We may need to verify, such as through a manufacturing comparability or bridging study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another comparable regulatory authority. The delays associated with the verification of a new CMO could negatively affect our ability to advance clinical trials or otherwise develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a CMO may possess technology related to the manufacture of our product candidate that such CMO owns independently, which may increase our reliance on such CMO or require us to obtain a license from such CMO in order to have another CMO manufacture 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 our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require us to conduct further additional clinical trials.

***In addition to our existing collaborations, we may form or seek additional collaborations or strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such collaborations, alliances or licensing arrangements.***

As noted above, we may receive up to $130.0 million from Taiho upon the achievement of certain U.S. regulatory milestones related to zipalertinib. There is no guarantee that these milestones will be achieved or that we will receive any of the $130.0 million. We have a co-development agreement with an affiliate of Taiho to co-develop zipalertinib. Pursuant to the terms of the co-development agreement, we each equally contribute to the clinical development costs of zipalertinib in the U.S., and will each receive 50% of any future pre-tax profits from potential U.S. sales of zipalertinib. There is no guarantee that the co-development and commercialization will be successful or that we will receive any net profits, and we could lose money.

We may form or seek additional strategic alliances, create joint ventures or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business.

Further, collaborations involving our product candidates are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization of our product candidates based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our product candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and
- collaborators may own or co-own intellectual property covering our product candidates that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

As a result, if we enter into additional collaboration agreements and strategic partnerships or license our product candidates, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new collaborations or strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

***We currently rely and expect to rely in the future on third parties to manufacture our product candidates. Our business could be harmed if the third-party manufacturers fail to provide us with sufficient quantities of our product candidates or fail to do so on acceptable timelines or at acceptable quality levels or prices.***

We do not currently own any facility that may be used as our clinical-scale manufacturing and processing facility and must currently rely on outside vendors to manufacture our product candidates. We will need to negotiate and maintain contractual arrangements with these outside vendors for the supply of our product candidates, and we may not be able to do so on favorable terms. We have not yet caused CLN-978, CLN-049 or velinotamig to be manufactured on a commercial scale and may not be able to do so for any of our product candidates.

Our anticipated reliance on a limited number of third-party manufacturers exposes us to a number of risks, including the following:

- we may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA, or comparable foreign regulatory authorities, must inspect any manufacturers for cGMP compliance as part of our marketing application;
- a new manufacturer would have to be educated in, or develop substantially equivalent processes for, the production of our current and future product candidates;
- our third-party manufacturers might be unable to timely manufacture our current and future product candidates or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- contract manufacturers may not be able to execute our manufacturing procedures and other logistical support requirements appropriately;
- our future contract manufacturers may not perform as agreed, may not devote sufficient resources to our current and future product candidates or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store, and distribute our products, if any;
- manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies, as well as foreign regulatory authorities, to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards and we have no control over third-party manufacturers' compliance with these regulations and standards;
- we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our current and future product candidates;
- our third-party manufacturers could breach or terminate their agreements with us;
- raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier, may not be available or may not be suitable or acceptable for use due to material or component defects; and
- our contract manufacturers and critical reagent suppliers may be subject to inclement weather, as well as natural or man-made disasters.

Each of these risks could delay or prevent the completion of our clinical trials or the approval of any of our current and future product candidates by the FDA, or comparable foreign regulatory authorities, resulting in higher costs or adversely impact commercialization of our current and future product candidates. In addition, we will rely on third parties to perform certain specification tests on our product candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm and the FDA, or comparable foreign regulatory authorities, could place significant restrictions on our company until deficiencies are remedied.

Significant non-compliance could also result in the imposition of sanctions, including warning or untitled letters, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation and our business.

Additionally, for some of our product candidates, we rely on third parties located in China to manufacture and supply certain raw materials, drug substances, and/or drug products, and we expect to continue to use such third-party manufacturers as needed. A natural disaster, epidemic or pandemic disease outbreak, trade war, political unrest or other event(s) in China or in adjacent geopolitical territories could disrupt the business or operations of our CMOs with whom we conduct business now or in the future. Any disruption in China or in adjacent geopolitical territories that significantly impacts such third parties, including their ability to produce and deliver materials according to our contracts in adequate quantities to meet our needs could impede, delay, limit, or prevent the research and development of our current and future product candidates. In addition, for any activities conducted in China, we are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies of the U.S. or Chinese governments, political unrest or unstable economic conditions in China. For example, the recently enacted BIOSECURE Act limits US governmental procurement from and grants to certain named Chinese CMOs. Any unfavorable government policies on international trade, such as export controls, capital controls or tariffs, new legislation or regulations, renegotiation of existing trade agreements, or any retaliatory trade actions due to recent trade tension, may impede, delay, limit, or increase the cost of manufacturing our product candidates. Such events could have an adverse effect on our business, financial condition and results of operations.

***The manufacture of drug products, and particularly biologics, is complex, and our third-party manufacturers may encounter difficulties in production. If any of our third-party manufacturers encounter such difficulties, our ability to provide supply of our current and future product candidates, if approved, could be delayed or prevented.***

Manufacturing drugs, particularly biologics, especially in large quantities, is often complex and may require the use of innovative technologies to handle living cells. Each lot of an approved biologic must undergo thorough testing for identity, strength, quality, purity, and potency. Manufacturing biologics requires facilities specifically designed for and validated for this purpose, and sophisticated quality assurance and quality control procedures are necessary. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping, and quality control testing, may result in lot failures, product recalls or spoilage. When changes are made to the manufacturing process, we may be required to provide preclinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes. If microbial, viral or other contaminations are discovered at the facilities of our manufacturers, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely harm our business.

In addition, there are risks associated with large scale manufacturing for clinical trials or commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, compliance with good manufacturing practices, lot consistency and timely availability of raw materials. Even if we obtain marketing approval for any of our current and future product candidates, there is no assurance that our manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other comparable foreign regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential commercial launch of the product or to meet potential future demand. If our manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

***If our third-party manufacturers use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.***

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials, by our third-party manufacturers. Our manufacturers are subject to federal, state and local laws and regulations in the U.S. governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

**Risks Related to Managing Growth and Employee Matters**

***We are highly dependent on our key personnel. If we are not successful in retaining highly qualified personnel, we may not be able to successfully implement our business strategy.***

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our senior management, including scientific and medical personnel, and other key employees. While we expect to engage in an orderly transition process as we integrate newly appointed officers and managers, we face a variety of risks and uncertainties relating to management transition, including diversion of management attention from business concerns, failure to retain other key personnel or loss of institutional knowledge. In addition, the loss of the services of any of our executive officers, other key employees, and other scientific and medical advisors, and an inability to find suitable replacements could result in delays in product development and harm our business. In particular, due to our small number of employees, the loss of one employee may have a larger impact on our business than compared to a loss at one of our peers.

We conduct our operations at our facilities in Cambridge, Massachusetts. The Massachusetts region is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. Changes to U.S. immigration and work authorization laws and regulations, including those that restrain the flow of scientific and professional talent, can be significantly affected by political forces and levels of economic activity. Our business may be materially adversely affected if legislative or administrative changes to immigration or visa laws and regulations impair our hiring processes and goals or projects involving personnel who are not U.S. citizens.

To encourage valuable employees to remain at our company, in addition to salary and cash incentives, we have provided equity that vests over time. The value to employees of stock options that vest over time may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific, and development teams may terminate their employment with us on short notice. Although we have employment agreements with our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. Our success also depends on our ability to continue to attract, retain, and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel.

***We will need to grow the size of our organization, and we may experience difficulties in managing this growth.***

As of December 31, 2025, we had 109 full-time employees. As our development and commercialization plans and strategies develop, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and FDA review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to commercialize our current and future product candidates that are approved for marketing will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and potentially commercialize our current and future product candidates and, accordingly, may not achieve our research, development and commercialization goals.

***Our internal computer systems, or those used by our third-party CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption to the development programs of our current and future product candidates.***

Despite the implementation of security measures, our internal computer systems and those of our current and future CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, and telecommunication and electrical failures. While we have not experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of data from completed or future preclinical studies and 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 have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed.

***We may be unable to adequately protect our information systems from cyberattacks, which could result in the disclosure of confidential or proprietary information, including personal data, damage our reputation, and subject us to significant financial and legal exposure.***

We rely on information technology systems that we or our third-party providers operate to process, transmit and store electronic information in our day-to-day operations. In connection with our product discovery efforts, we may collect and use a variety of personal data, such as name, mailing address, email addresses, phone number and clinical trial information. A successful cyberattack could result in the theft or destruction of intellectual property, data, or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and disrupt our operations. Cyberattacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Hackers are also making increased use of AI agents that can significantly increase the speed and harm of their attacks. Use of AI systems may also lead to new vulnerabilities such as prompt injection attacks that may compromise these systems and other operations that depend on these systems. We also continue to provide for remote work for our employees, which may increase our vulnerability to cyber and other information technology risks. Cyberattacks could include wrongful conduct by hostile foreign governments, industrial espionage, wire fraud and other forms of cyber fraud, the deployment of harmful malware, denial-of-service, ransomware, business email compromise, phishing attacks, social engineering fraud or other means to threaten data security, confidentiality, integrity and availability. A successful cyberattack could cause serious negative consequences for us, including, without limitation, the disruption of operations, the misappropriation of confidential business information, including financial information, trade secrets, financial loss and the disclosure of corporate strategic plans. As cybersecurity threats continue to evolve, we may be required to expend significant additional resources to continue to modify or enhance our protective measures or to investigate and remediate any information security vulnerabilities. The inability to implement, maintain and upgrade adequate safeguards could have a material adverse effect on our business. Although we have implemented measures designed to protect our information systems, there can be no assurance that our efforts will prevent information security breaches that would result in business, legal, financial or reputational harm to us, or would have a material adverse effect on our results of operations and financial condition. Any failure to comply with applicable laws relating to information security and/or prevent or mitigate security breaches or improper access to, use of, or disclosure of personal data, including our clinical data or patients' personal data could result in significant liability under state (e.g., state breach notification laws), federal (e.g., HIPAA, as amended by HITECH), and international law (e.g., the GDPR/UK GDPR and the EU Network and Information Security Directive) and may cause a material adverse impact to our reputation, affect our ability to conduct new studies and potentially disrupt our business. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In some cases, data cannot be reproduced. To the extent that any disruption or security breach was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur material legal claims and liability, damage to our reputation, and the further development of our devices and drugs or any future product candidate could be delayed. If a security breach results in the exposure or unauthorized disclosure of personal information, we can be subject to requirements to notify regulatory authorities and affected individuals within strict statutory timeframes, and could incur additional costs associated with data breach notification and remediation expenses, investigation costs, regulatory penalties and fines, and legal proceedings. Our insurance coverage may not be adequate to cover all the costs related to such breaches or attacks. Furthermore, we cannot be sure that insurance will continue to be available to us on commercially reasonable terms, if at all, or that any insurer will not deny coverage as to any future claim.

In addition, the computer systems of various third parties on which we rely, including our CROs and other contractors, consultants and law and accounting firms, may sustain damage from computer viruses, unauthorized access, data breaches, phishing attacks, cybercriminals, natural disasters (including hurricanes and earthquakes), terrorism, war and telecommunication and electrical failures. We rely on our third-party providers to implement effective security measures and identify and correct for any such failures, deficiencies or breaches. If we or our third-party providers fail to maintain or protect our information technology systems and data integrity effectively or fail to anticipate, plan for or manage significant disruptions to our information technology systems, we or our third-party providers could have difficulty preventing, detecting and controlling such cyber-attacks and any such attacks could result in losses described above as well as disputes with physicians, patients and our partners, litigation (including class claims), regulatory sanctions or penalties, increases in operating expenses, expenses or lost revenues or other adverse consequences, any of which could have a material adverse effect on our business, results of operations, financial condition, prospects and cash flows. Any failure by such third parties to prevent or mitigate security breaches or improper access to or disclosure of such information could have similarly adverse consequences for us. If we are unable to prevent or mitigate the impact of such data breaches, we could be exposed to litigation and governmental investigations, which could lead to a potential disruption to our business.

**Risks Related to Ownership of Our Common Stock**

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

The trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Annual Report on Form 10-K, these factors include:

- the results of our ongoing, planned or any future preclinical studies, clinical trials or clinical development programs;
- the commencement, enrollment, or results of clinical trials of our current and future product candidates, or changes in the development status of our product candidates;
- adverse results or delays in preclinical studies and clinical trials, including as a result of clinical holds;
- our decision to initiate a clinical trial, not to initiate a clinical trial, or to terminate an existing clinical trial;
- any delay in our regulatory filings or any adverse regulatory decisions, including failure to receive regulatory approval of our current and future product candidates;
- changes in laws or regulations applicable to our products, including but not limited to clinical trial requirements for approvals;
- adverse developments concerning our manufacturers or our manufacturing plans;
- our inability to obtain adequate product supply for any licensed product or inability to do so at acceptable prices;
- our inability to establish collaborations if needed;
- our failure to commercialize our current and future product candidates;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our current and future product candidates;
- introduction of new products or services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- the size and growth of our initial target markets;
- our ability to successfully treat additional types of autoimmune diseases or cancers or at different stages;
- actual or anticipated variations in quarterly operating results;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;

- publication of research reports about us or our industry, or immunotherapy in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- disputes or other developments relating to intellectual property or proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including intellectual property or stockholder litigation;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and The Nasdaq Global Select Market and market for biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, financial condition, results of operation and future prospects.

We expect our financial condition and results of operations to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

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

We currently anticipate that we will retain future earnings for the development, operation, and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, we may enter into agreements that prohibit us from paying cash dividends without prior written consent from our contracting parties, or which other terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Any return to stockholders will therefore be limited to the appreciation of their stock, which may never occur.

***Our principal stockholders and management own a significant percentage of our stock and could be able to exert significant influence over matters subject to stockholder approval.***

Our executive officers, directors, and 5% stockholders beneficially owned approximately 56.0% of our voting stock, based on 60,543,903 shares of our common stock deemed to be outstanding as of December 31, 2025, which assumes conversion of 299,767 shares of outstanding convertible preferred stock into shares of common stock. These stockholders could have the ability to influence us through their ownership position and significantly affect the outcome of all matters requiring stockholder approval. For example, these stockholders may be able to significantly affect the outcome of elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

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

As of December 31, 2025, we had U.S. federal and state NOL carryforwards of $312.6 million and $317.7 million, respectively. As of December 31, 2025, $311.2 million of our federal NOLs can be carried forward indefinitely and $1.4 million, which were generated prior to 2018, expire in 2037. As of December 31, 2025, state NOL carryforwards begin to expire in 2031. As of December 31, 2025, we had federal and state research and development tax credit carryforwards of $8.7 million and $2.7 million, respectively. As of December 31, 2025, our federal research and development tax credit carryforwards begin to expire in 2036, $0.3 million of our state research and development tax credit carryforwards can be carried forward indefinitely, and the remaining $2.4 million of our state research and development tax credit carryforwards expires beginning in 2036. In general, our ability to use our NOLs and tax credit carryforwards to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income, and we cannot predict with certainty when, or whether, we will generate sufficient taxable income to use all of our NOLs and tax credit carryforwards. Federal NOLs generated post-2017 are not subject to expiration but are not be permitted to be carried back. In addition, the amount of post-2020 NOLs that we are permitted to deduct in any taxable year is limited to 80% of our taxable income in such year, where taxable income is determined without regard to the NOL deduction itself. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state income taxes owed.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change" (generally defined as a greater than 50% change (by value) in its equity ownership by 5% stockholders over a three-year period), the corporation's ability to use its pre-change net operating loss ("NOL") carryforwards and other pre-change tax attributes to offset its post-change taxable income may be limited. We have experienced ownership changes in the past, and we may also experience additional ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our net operating loss carryforwards or other pre-change tax attributes is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

***Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control, which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.***

Our second amended and restated certificate of incorporation and third amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the board of directors acting pursuant to a resolution approved by the affirmative vote of a majority of the directors then in office;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than two-thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our second amended and restated certificate of incorporation and third amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer, or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

***Our third amended and restated bylaws designate specific courts as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us.***

Pursuant to our third amended and restated bylaws, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for state law claims for (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, or other employees to us or our stockholders; (3) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law or our certificate of incorporation or bylaws; (4) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or bylaws; or (5) any action asserting a claim governed by the internal affairs doctrine, or the Delaware Forum Provision. The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act or the Exchange Act. Our third amended and restated bylaws will further provide that unless we consent in writing to the selection of an alternative forum, the U.S. District Court for the District of Delaware will be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, or the Federal Forum Provision, as the Company is incorporated in the State of Delaware. In addition, our third amended and restated bylaws will provide that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of and consented to the Delaware Forum Provision and the Federal Forum Provision; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the U.S. federal securities laws and the rules and regulations thereunder.

The Delaware Forum Provision and the Federal Forum Provision in our third amended and restated bylaws may impose additional litigation costs on stockholders in pursuing any such claims. Additionally, these forum selection clauses may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage the filing of lawsuits against us and our directors, officers and employees, even though an action, if successful, might benefit our stockholders. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court are "facially valid" under Delaware law, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the U.S. District Court for the District of Delaware may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

***If we fail to establish and maintain proper and effective internal control over financial reporting, our operating results and our ability to operate our business could be harmed.***

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be re-evaluated frequently. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles.

If we fail to adequately staff our accounting and finance function to address the additional demands that are applicable to us as a public company, including the requirements of the Sarbanes-Oxley Act of 2002, or fail to maintain adequate internal control over financial reporting, it could prevent our management from concluding our internal control over financial reporting is effective and impair our ability to prevent material misstatements in our financial statements, which could cause our business to suffer.

Implementing any appropriate changes to our internal controls may distract our officers and employees, entail substantial costs to modify our existing processes, and take significant time to complete. These changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and harm our business. In addition, investors' perceptions that our internal controls are inadequate or that we are unable to produce accurate financial statements on a timely basis may harm our stock price.

***If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.***

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. In the event one or more of the analysts who cover us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

**Item 1B. Unresolved Staff Comments.**

None.

**Item 1C. Cybersecurity.**

Our board of directors recognizes the critical importance of maintaining the trust and confidence of our vendors, partners, and employees. The Board is actively involved in oversight of our risk management program, and cybersecurity represents an important component of our overall approach. Our cybersecurity standards, processes, and practices are based on recognized frameworks established by the National Institute of Standards and Technology and the International Organization for Standardization, and other applicable industry standards. In general, we seek to address cybersecurity risks through a comprehensive, cross-functional approach that is focused on preserving the confidentiality, security, and availability of the information that we collect and store by identifying, preventing, and mitigating cybersecurity threats and effectively responding to cybersecurity incidents when they occur.

***Risk Management and Strategy***

As one of the critical elements of our overall risk management approach, our cybersecurity program is focused on the following key areas:

- Governance: As discussed in more detail under the heading below titled, "Governance", the Board's oversight of cybersecurity risk management is supported by the audit committee's regular interactions with our Head of Information Technology and other members of management or a subcommittee thereof.
- Collaborative Approach: We have developed a comprehensive, cross-functional approach to identifying, preventing, and mitigating cybersecurity threats and incidents, while also developing tools and processes that provide for the prompt escalation of certain cybersecurity incidents so that decisions regarding the public disclosure and reporting of such incidents can be made by management in a timely manner.
- Technical Safeguards: We deploy technical safeguards that are designed to protect our information systems from cybersecurity threats, including firewalls, intrusion prevention and detection systems, antimalware functionality, and access controls, which are evaluated and improved through vulnerability assessments and cybersecurity managed detection and response.
- Incident Response and Recovery Planning: We have developed a comprehensive incident response and recovery plan that addresses our response to a cybersecurity incident.
- Third-Party Risk Management: We have various controls relating to cybersecurity threats originating from third parties, including vendors, service providers and other external users of our systems, as well as the systems of third parties that could adversely impact our business in the event of a cybersecurity incident affecting those third-party systems.
- Education and Awareness: We provide regular, mandatory training for personnel regarding cybersecurity threats to equip our personnel with tools to address cybersecurity threats, and to communicate our information technology policies, standards, processes, and practices.

We engage in the periodic assessment and testing of our policies, standards, processes and practices that are designed to address cybersecurity threats and incidents. These efforts include a wide range of activities, assessments, vulnerability testing, and other exercises focused on evaluating the effectiveness of our cybersecurity measures and planning. We regularly engage third parties to perform assessments on our cybersecurity measures. The results of such assessments are reported to the audit committee, and we adjust our cybersecurity policies, standards, processes and practices as necessary based on the information provided by these assessments.

***Governance***

The audit committee of the Board oversees our risk management program, including the management of risks arising from cybersecurity threats. The audit committee receives regular presentations and reports on cybersecurity risks, which address a wide range of topics including recent developments, evolving standards, the threat environment, technological trends, and information security considerations arising with respect to our peers and third parties. When necessary, the Board receives prompt and timely information regarding any material cybersecurity incident, as well as ongoing updates regarding any such incident until it has been addressed. On a periodic basis, the audit committee of the Board discusses our approach to cybersecurity risk management with our Head of Information Technology.

Our Head of Information Technology, in coordination with the Board and audit committee, works collaboratively to implement and execute a program designed to protect our information systems from cybersecurity threats and to promptly respond to any cybersecurity incidents in accordance with our incident response and recovery approach. To facilitate the success of our cybersecurity risk management program, our Head of Information Technology and his team monitor the prevention, detection, mitigation, and remediation of cybersecurity threats and incidents in real time and, when necessary, report such threats and incidents to the Board. Our Head of Information Technology has served in various roles in information technology and information security for over 20 years, including serving as the Head of Information Technology of another clinical-stage biopharmaceutical company. Our Head of Information Technology holds undergraduate and graduate degrees in mathematics and computer information systems, respectively.

Cybersecurity threats, including as a result of any previous cybersecurity incidents, have not materially affected us, including our business strategy, results of operations, or financial condition.

**Item 2. Properties.**

Our corporate headquarters is located in Cambridge, Massachusetts, where we lease and occupy approximately 14,000 square feet of office space in a multi-tenant building. The current term of our Cambridge lease expires in September 2028. We believe our existing facilities are sufficient for our needs for the foreseeable future.

**Item 3. Legal Proceedings.**

From time to time, we may become involved in litigation or other legal proceedings. We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are probable to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on our business, financial condition, results of operations and prospects because of defense and settlement costs, diversion of management resources and other factors.

**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.

Our common stock is publicly traded on the Nasdaq Global Select Market under the symbol "CGEM".

**Stockholders**

As of December 31, 2025, there were 9 stockholders of record of our common stock. The actual number of holders of our common stock 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 or held by other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

**Dividend Policy**

We have never paid or declared any cash dividends on our common stock, and we do not anticipate paying any cash dividends on our common stock in the foreseeable future. We intend to retain all available funds and any future earnings to fund the development and expansion of our business. Any future determination to pay dividends will be at the discretion of our board of directors and will depend upon a number of factors, including our results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors that our board of directors deems relevant.

**Equity Compensation Plans**

The information required by Item 5 of Form 10-K regarding equity compensation plans will be included in our Definitive Proxy Statement to be filed with the Securities and Exchange Commission (the "SEC") with respect to our 2026 Annual Meeting of Stockholders and is incorporated herein by reference.

**Issuer Purchases of Equity Securities**

We did not purchase any of our registered equity securities during the period covered by this Annual Report on Form 10-K.

### Item 6. Reserved

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

*You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes appearing elsewhere in this Annual Report on Form 10-K. This discussion and other parts of this Annual Report on Form 10-K contain forward-looking statements that involve risks and uncertainties, such as statements regarding our plans, objectives, expectations, intentions and projections. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the "Risk Factors" section of this Annual Report on Form 10-K.*

**Overview**

We are a biopharmaceutical company developing potential first- or best-in-class, high-impact therapies for autoimmune diseases and cancer. We pursue promising therapeutic targets while leveraging core expertise in T cell engagers, which are established in oncology and are now advancing into autoimmune diseases. With a clinical-stage pipeline built on a rigorous scientific approach and purposeful innovation, we are advancing our mission to deliver new standards of care for patients.

***Immunology***

- CLN-978 is a CD19xCD3 bispecific T cell engager that we are developing for autoimmune diseases. In the Phase 1 OUTRACE Program, CLN-978 is being evaluated in patients with systemic lupus erythematosus ("SLE"), rheumatoid arthritis ("RA"), and Sjögren's disease ("SjD"). The OUTRACE SLE Study is an ongoing global Phase 1 clinical trial in patients with moderate to severe SLE. The OUTRACE RA Study is a Phase 1 clinical trial in patients with active, difficult-to-treat RA, which is ongoing in Europe. We plan to share initial clinical data in SLE RA in the second quarter of 2026 and repeat dosing data in RA in the third quarter of 2026. The OUTRACE SjD Study is an ongoing global Phase 1 clinical trial in patients with active, moderate to severe Sjögren's disease. We plan to share initial clinical data in Sjögren's disease in the fourth quarter of 2026.
- Velinotamig is a BCMAxCD3 bispecific T cell engager that we are developing for autoimmune diseases. Chongqing Genrix Biopharmaceutical Co., Ltd. ("Genrix"), from which we licensed velinotamig, is enrolling a Phase 1 clinical trial in China in patients with autoimmune diseases, initially in patients with SLE, followed by planned future expansion into other indications, and initial clinical data will be shared in the fourth quarter of 2026. We intend to use the data generated from this Phase 1 clinical trial to accelerate global clinical development. Following the completion of the Genrix Phase 1 clinical trial, we will conduct all further development of velinotamig in autoimmune diseases.

***Oncology***

- CLN-049 is a FLT3xCD3 bispecific T cell engager. CLN-049 is being evaluated in an ongoing Phase 1 clinical trial in patients with relapsed/refractory acute myeloid leukemia ("AML") or myelodysplastic syndrome ("MDS"). At the 2025 American Society for Hematology ("ASH") Annual Meeting, we shared monotherapy efficacy data from the ongoing dose escalation portion of the trial in a heavily pretreated all-comer population of patients with relapsed/refractory AML. We plan to share a clinical data update from the dose escalation portion of the trial in the second half of 2026. We also plan to begin enrolling dose expansion cohorts in the second quarter of 2026 and expect to complete enrollment in the fourth quarter of 2026 to determine the recommended Phase 2 dose for an expected single-arm pivotal registrational trial.
- Zipalertinib (CLN-081/TAS6417), on which we are collaborating with an affiliate of Taiho Pharmaceutical Co., Ltd. ("Taiho"), is an orally-available small-molecule, irreversible epidermal growth factor receptor ("EGFR") inhibitor that is designed to selectively target cells expressing EGFR exon 20 insertion mutations ("EGFR ex20ins") with relative sparing of cells expressing wild-type EGFR.
    - We are evaluating zipalertinib in the pivotal Phase 2b portion of the REZILIENT1 clinical trial in patients with EGFR ex20ins non-small cell lung cancer ("NSCLC") who progressed after prior systemic therapy. In February 2026, based on the primary efficacy data from REZILIENT1, Taiho completed a rolling submission of a new drug application ("NDA") seeking accelerated approval of zipalertinib for the treatment of patients with locally advanced or metastatic EGFR ex20ins NSCLC who have previously received platinum-based systemic chemotherapy.
    - Taiho is evaluating zipalertinib in a global Phase 3 clinical trial ("REZILIENT3") in combination with chemotherapy as a potential first-line treatment for locally advanced or metastatic EGFR ex20ins NSCLC adult patients. Taiho completed enrollment of the trial in February 2026 and expects to obtain top-line results by the end of 2026.

- Taiho is also evaluating zipalertinib in a Phase 2 parallel cohort trial ("REZILIENT2"). Taiho shared emerging data from certain REZILIENT2 cohorts at the International Association for the Study of Lung Cancer ("IASLC") 2025 World Conference on Lung Cancer ("WCLC") and European Society for Medical Oncology ("ESMO") Congress 2025.

***Preclinical Programs***

In addition to the product candidates described above, we are actively developing several preclinical programs in autoimmune diseases and oncology.

***Recently Discontinued Program***

CLN-619 is a MICA/B monoclonal antibody that we were previously evaluating in Phase 1 clinical trials. In May 2025, following a review of the CLN-619 data from the disease-specific expansion cohorts for endometrial and cervical cancers, we announced discontinuation of further development of CLN-619 in patients with gynecological cancers as preliminary results did not meet our internal threshold for advancement. In November 2025, after a review of the emerging clinical data in patients with NSCLC and multiple myeloma, we discontinued further development of CLN-619.

CLN-617 is an interleukin-2 and interleukin-12 fusion protein that we were previously evaluating in a Phase 1 clinical trial. In November 2025, after a review of the emerging clinical data in patients with advanced solid tumors, we discontinued further development of CLN-617.

CLN-418 is a B7H4x4-1BB bispecific antibody that we licensed from Harbour BioMed US Inc. ("Harbour") and were previously evaluating in a Phase 1 clinical trial. In August 2024, following a review of the data from the Phase 1 clinical trial in solid tumors, we notified Harbour of our decision to terminate the license and collaboration agreement for CLN-418 (the "Harbour License Agreement"), effective November 2024. In connection with the termination of the Harbour License Agreement, we discontinued development of CLN-418 and returned development and commercial rights for CLN-418 to Harbour.

***Intellectual Property***

We directly hold the worldwide intellectual property rights for CLN-978. We hold the worldwide, excluding mainland China, Hong Kong, Macau and Taiwan (collectively referred to as "greater China"), intellectual property rights for velinotamig. We hold the worldwide intellectual property rights for CLN-049 through a development subsidiary that we had a 98% ownership interest in as of December 31, 2025. We are co-developing zipalertinib, for which Taiho holds the intellectual property rights, with an affiliate of Taiho. We hold the worldwide intellectual property rights or exclusive options for worldwide intellectual property for our early-stage programs.

***Financing and Business Operations***

Since our inception in 2016, we have focused all of our efforts and financial resources on raising capital, organizing and staffing our company, identifying, acquiring or in-licensing and developing product and technology rights, establishing and protecting our intellectual property portfolio, and developing and advancing our programs. We do not have any products approved for sale and have not generated any revenue from product sales.

We have funded our operations primarily through the sale of equity securities and from licensing or selling the rights to our product candidates. As of December 31, 2025, we have received net proceeds of $842.2 million from equity financings, $275.0 million from the sale of our equity interest in our zipalertinib development subsidiary to Taiho, and $18.9 million in revenue from a previous license agreement.

As of December 31, 2025, we had cash, cash equivalents, and short-term investments of $377.9 million, and long-term investments and interest receivable of $61.1 million. Interest receivable is included in prepaid expenses and other current assets on the consolidated balance sheets and represents accrued and unpaid interest on our marketable securities. We have a history of significant operating losses and have had negative cash flows from operations since our inception. As of December 31, 2025, we had an accumulated deficit of $588.1 million. We expect to continue to generate operating losses for the foreseeable future. Our future viability is dependent on the success of our research and development and our ability to access additional capital to fund our operations. There can be no assurance that our current operating plan will be achieved or that additional funding will be available on terms acceptable to us, or at all.

We are subject to risks and uncertainties common to early-stage companies in the biotechnology industry including, but not limited to, new technological innovations, protection of proprietary technology, dependence on key personnel, compliance with government regulations and the ability to obtain additional capital to fund operations. Our current and future product candidates will require significant additional research and development efforts, including preclinical and clinical testing and regulatory approval prior to commercialization. These efforts require additional capital, adequate personnel and extensive compliance-reporting capabilities. There can be no assurance that our research and development will be successfully completed, that adequate protection for our intellectual property will be obtained, that any products developed will obtain necessary government regulatory approval or that any approved products will be commercially viable.

**Components of Our Results of Operations**

***Revenue***

We have not generated any revenue from the sale of products since our inception.

***Research and Development Expenses***

Research and development expenses consist primarily of costs incurred in connection with the research and development of our product candidates and programs. These expenses include:

- compensation costs for employees engaged in research and development functions;
- expenses incurred under agreements with organizations that support our drug discovery and development activities;
- expenses incurred in connection with the preclinical and clinical development of our product candidates and programs, including under agreements with contract research organizations ("CROs");
- costs related to contract manufacturing organizations that are primarily engaged to provide drug substance, raw materials, and drug product for our clinical trials, research and development programs, as well as investigative sites and consultants that conduct our clinical trials, nonclinical studies, and other scientific development services;
- the costs of acquiring and manufacturing nonclinical and clinical trial materials, including manufacturing registration and validation batches;
- costs related to compliance with quality and regulatory requirements;
- payments made under third-party licensing agreements; and
- direct and allocated costs related to facilities, information technology, personnel and other overhead.

Pursuant to a co-development agreement, we are collaborating with a Taiho affiliate to develop zipalertinib for the treatment of a genetically defined subset of patients with NSCLC, and Taiho will commercialize zipalertinib. For the agreed-upon indication, we and Taiho share development costs equally, and each party will receive 50% of any future potential pre-tax profits from U.S. sales of zipalertinib. For any additional indications that Taiho chooses to develop independently, Taiho will bear all development costs until they have sufficient data from such indication to support a commercial purpose or submission of zipalertinib for the additional indication. At such time, 50% of Taiho’s independent development costs, subject to certain adjustments, will be deducted from future pre-tax profits for potential U.S. sales of zipalertinib. In November 2025, Taiho independently initiated an ongoing global Phase 3 clinical trial evaluating zipalertinib in an additional indication.

***General and Administrative Expenses***

General and administrative expenses consist primarily of compensation costs for personnel in executive management, finance, legal, corporate and business development, and other administrative functions. General and administrative expenses also include legal fees relating to patent and corporate matters; professional fees for accounting, auditing, tax, and administrative consulting services; insurance costs; administrative travel expenses; marketing expenses; and other operating costs.

***Other Income***

Other income consists primarily of interest income earned on our cash, cash equivalents, and investments.

***Income Taxes***

In July 2025, the U.S enacted the budget reconciliation bill H.R. 1 into law, which included significant changes to U.S. income tax laws. We have assessed the impacts of H.R. 1 for 2025 and determined that there was no impact on our 2025 effective tax rate. Income taxes consist primarily of federal and state income taxes.

**Results of Operations**

***Comparison of 2025 and 2024***

The following table presents our results of operations for 2025 and 2024 (in thousands):

| | 2025 | 2024 |
|---|---|---|
| Operating expenses: | | |
| Research and development | $ 187,402 | $ 142,903 |
| General and administrative | 54,246 | 54,016 |
| Total operating expenses | 241,648 | 196,919 |
| Loss from operations | (241,648) | (196,919) |
| Other income (expense): | | |
| Interest income | 22,212 | 29,660 |
| Other income (expense), net | (443) | (199) |
| Net loss before income taxes | (219,879) | (167,458) |
| Income tax expense | — | 117 |
| Net loss | (219,879) | (167,575) |
| Net loss attributable to noncontrolling interests | — | (192) |
| Net loss attributable to Cullinan | $ (219,879) | $ (167,383) |

*Research and Development Expenses*

The following table summarizes our research and development expenses for 2025 and 2024 (in thousands):

| | 2025 | 2024 |
|---|---|---|
| CLN-049 | $ 17,088 | $ 7,508 |
| CLN-418 | — | 6,471 |
| CLN-617 | 6,778 | 4,403 |
| CLN-619 | 23,118 | 25,096 |
| CLN-978 | 23,074 | 14,833 |
| Velinotamig | 1,619 | — |
| Zipalertinib | 33,548 | 31,875 |
| Clinical-stage product candidates | 105,225 | 90,186 |
| Early-stage programs | 6,286 | 5,938 |
| Research and development personnel and operations | 39,986 | 31,532 |
| License agreement obligations | 20,303 | 100 |
| Equity-based compensation | 15,602 | 15,147 |
| Total research and development expenses | $ 187,402 | $ 142,903 |

The $44.5 million increase in research and development expenses in 2025 compared to 2024 was primarily due to the one-time upfront in-licensing fee for velinotamig ($20.0 million), increases in clinical development costs ($21.9 million), personnel costs relating to higher average headcount during 2025 ($8.2 million), and equity-based compensation expense ($0.5 million), offset partially by decreases in preclinical costs ($3.7 million), and chemistry, manufacturing and controls costs ($2.4 million).

*General and Administrative Expenses*

The $0.2 million increase in general and administrative expenses in 2025 compared to 2024 was primarily due to increases in professional fees ($1.7 million), and legal costs ($1.6 million), offset partially by decreases in equity-based compensation expense ($2.2 million), and personnel costs ($1.0 million).

*Other Income*

The $7.7 million decrease in other income in 2025 compared to 2024 was primarily related to lower interest income earned.

*Income Tax Expense (Benefit)*

We did not record income tax expense or benefit in 2025 due to our net loss before income taxes in the current year and expected losses in future years. The income tax expense recognized for 2024 was driven by the finalization of estimates upon filing our 2023 tax return for the utilization of federal research and development credits generated during 2023 that were carried back to tax year 2022.

*Net Loss Attributable to Noncontrolling Interests*

Net loss attributable to noncontrolling interests is determined as the difference in the noncontrolling interests in the consolidated balance sheets between the start and end of each reporting period, after taking into account any capital transactions between our development subsidiaries and third parties.

**Liquidity and Capital Resources**

***Overview***

We have a history of significant operating losses and have had negative cash flows from operations since our inception and expect to continue to generate operating losses for the foreseeable future. We have not yet commercialized any products, and we do not expect to generate revenue from sales of products for several years, if at all. To date, we have funded our operations primarily with proceeds from the sale of equity securities and from licensing or selling the rights to our product candidates. As of December 31, 2025, we had cash, cash equivalents, and short-term investments of $377.9 million, and long-term investments and interest receivable of $61.1 million.

Based on our current operational plans and assumptions, we expect that our current cash, cash equivalents, investments, and interest receivable will be sufficient to fund operations into 2029. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. We cannot guarantee that we will be able to raise additional capital on reasonable terms or at all.

In June 2025, we entered into a license agreement with Genrix (the "Genrix License Agreement"), pursuant to which Genrix granted us a global (excluding greater China), exclusive license to develop and commercialize velinotamig, a BCMAxCD3 bispecific T cell engager, in all fields of use. Under the terms of the Genrix License Agreement, we paid Genrix an upfront license fee of $20.0 million in June 2025. Refer to Note 6 of our notes to the consolidated financial statements in this Annual Report on Form 10-K for additional detail regarding the Genrix License Agreement.

In April 2024, we completed a private placement (the "2024 Private Placement") in which we issued approximately 14.4 million shares of our common stock and pre-funded warrants to purchase approximately 0.3 million additional shares of our common stock. We received net proceeds of $262.7 million from the 2024 Private Placement, after deducting offering costs of $17.3 million. Refer to Note 7 of our notes to the consolidated financial statements in this Annual Report on Form 10-K for additional detail regarding the 2024 Private Placement.

We have an at-the-market equity offering program (the "ATM") through an agreement established with Cowen and Company, LLC (“Cowen”) in May 2023, pursuant to which we may offer and sell up to $125.0 million of our common stock from time to time through Cowen, acting as our sales agent. We made no sales under the ATM in 2025. Through December 31, 2025, we have sold approximately 3.3 million shares under the ATM and received net proceeds of $38.4 million, after deducting commissions. As of December 31, 2025, we had $85.6 million in shares of our common stock remaining under the ATM.

Cullinan is eligible to receive a $30.0 million payment from Taiho upon U.S. regulatory approval of zipalertinib for the treatment of patients with locally advanced or metastatic EGFR ex20ins NSCLC who have previously received platinum-based systemic chemotherapy. Cullinan is also eligible to receive up to a $100.0 million payment from Taiho upon U.S. regulatory approval of zipalertinib for the first-line treatment for adult patients with locally advanced or metastatic EGFR ex20ins NSCLC. We and Taiho will each receive 50% of any future pre-tax profits from potential U.S. sales of zipalertinib.

***Cash Flows***

***Comparison of 2025 and 2024***

The following table summarizes our sources and uses of cash for 2025 and 2024 (in thousands):

| | 2025 | 2024 |
|---|---|---|
| Net cash used in operating activities | $ (175,750) | $ (145,303) |
| Net cash provided by (used in) investing activities | 179,989 | (136,314) |
| Net cash provided by financing activities | 1,088 | 266,188 |
| Net decrease in cash and cash equivalents | $ 5,327 | $ (15,429) |

*Cash Flow from Operating Activities*

During 2025, our operating activities used $175.8 million of cash, which primarily consisted of our operating expenses, excluding non-cash items, of $205.3 million, partially offset by interest income, excluding accretion on marketable securities, of $15.9 million, $11.1 million net change in our non-tax operating assets and liabilities, and income tax refunds of $3.0 million. The non-cash operating expenses primarily consisted of equity-based compensation expense.

During 2024, our operating activities used $145.3 million of cash, which primarily consisted of our operating expenses, excluding non-cash items, of $158.8 million and a $2.8 million net change in our non-tax operating assets and liabilities, partially offset by interest income, excluding accretion on marketable securities, of $14.2 million, and an income tax refund of $2.3 million. The non-cash operating expenses primarily consisted of equity-based compensation expense.

*Cash Flow from Investing Activities*

During 2025, our investing activities provided $180.0 million, which consisted primarily of $416.6 million of proceeds from the maturities of marketable securities, partially offset by $236.5 million of purchases of marketable securities.

During 2024, our investing activities used $136.3 million, which consisted of $721.1 million of purchases of marketable securities, partially offset by $584.8 million of proceeds from the maturities of marketable securities.

*Cash Flow from Financing Activities*

During 2025, our financing activities provided $1.1 million of cash, which consisted of net proceeds from the issuance of common stock under equity-based compensation plans.

During 2024, our financing activities provided $266.2 million, which consisted of $262.7 million of net proceeds from the issuance of common stock under our 2024 Private Placement and $8.0 million in net proceeds from the issuance of common stock under our equity-based compensation plans, partially offset by $4.4 million paid to acquire shares and options to purchase shares of our CLN-619 development subsidiary that were held by noncontrolling interests.

***Future Funding Requirements***

We expect our expenses to continue to increase in connection with our ongoing activities, particularly as we:

- continue research and development of our current and future product candidates and programs;
- conduct preclinical studies and clinical trials for our current and future product candidates;
- experience any delays or encounter any issues with any of the above, including but not limited to failed studies, or trials, complex results, safety issues, or other regulatory challenges;
- develop the necessary processes, controls, and manufacturing capabilities to obtain marketing approval for our current and future product candidates and to support manufacturing on a commercial scale;
- develop and implement plans to establish and operate in-house manufacturing operations and facilities, if deemed appropriate;
- seek regulatory approvals for our current and future product candidates that successfully complete clinical trials;
- hire and retain additional personnel, such as nonclinical, clinical, pharmacovigilance, quality assurance, regulatory affairs, manufacturing, distribution, legal, compliance, medical affairs, finance, general and administrative, commercial, and scientific personnel; and
- develop, maintain, expand, and protect our intellectual property portfolio.

Based on our current operational plans and assumptions, we expect that our current cash, cash equivalents, investments, and interest receivable will be sufficient to fund operations into 2029. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. As we progress with our development programs and the regulatory review process, we expect to incur significant expenses related to product manufacturing, pre-commercial activities and commercialization. We may also require additional capital to pursue in-licenses or acquisitions of other programs to further expand our pipeline.

Because of the numerous risks and uncertainties associated with research, development and commercialization of our product candidates and programs, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on and could increase significantly as a result of many factors, including:

- the scope, progress, results, and costs of drug discovery, laboratory testing, and preclinical and clinical development for our current and future product candidates;
- timely completion of our preclinical studies and clinical trials, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- the prevalence, duration, and severity of potential side effects or other safety issues experienced by patients receiving our current and future product candidates;
- our ability to establish and maintain collaborations and license agreements on favorable terms, if at all, and the extent to which we acquire or in-license technologies or programs, if at all;
- our ability to enroll clinical trials in a timely manner and to quickly resolve any delays or clinical holds that may be imposed on our development programs;
- the costs of expanding our facilities to accommodate our expected growth in personnel;
- our ability and the ability of third parties with whom we contract to manufacture adequate clinical and commercial supplies of our current and future product candidates, remain in good standing with regulatory authorities and develop, validate, and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practices;
- the costs of preparing, filing, and prosecuting patent applications, maintaining and enforcing our intellectual property rights, and defending intellectual property-related claims;
- the extent to which we acquire or in-license technologies or programs;
- the sales price and availability of adequate third-party coverage and reimbursement for our product candidates, if and when approved; and
- the ongoing costs of operating as a public company.

Until such time, if ever, that we can generate product revenue sufficient to achieve profitability, we expect to finance our cash needs through equity offerings, debt financings, government or other third-party funding, marketing and distribution arrangements, and other collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity, current ownership interests will be diluted. If we raise additional funds through government or third-party funding, collaboration agreements, strategic alliances, licensing arrangements, or marketing and distribution arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. Debt 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 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 products or product candidates that we would otherwise prefer to develop and market ourselves.

**Contractual Obligations and Other Commitments**

We have certain contractual obligations under various license and collaboration agreements. Under these agreements, we will be required to make milestone payments upon successful completion and achievement of certain intellectual property, clinical, regulatory, and sales milestones, and we will be required to make milestone and royalty payments in connection with the sale of products developed under these agreements. In addition, under our co-development agreement, if Taiho generates sufficient data to support commercial purposes or a regulatory submission for new zipalertinib indications that it independently develops, half of Taiho's independent development costs, subject to certain adjustments, will be deducted from future pre-tax profits related to potential U.S. sales of zipalertinib. As the achievement and timing of these future contractual obligations are not probable or estimable, such amounts have not been included in our consolidated balance sheets as of December 31, 2025 and 2024.

As of December 31, 2025, total future minimum lease payments were $3.1 million, with $1.0 million payable within 12 months. See Note 12 of our consolidated financial statements included in this Annual Report on Form 10-K for further detail on our lease obligations and the timing of expected future payments.

In addition, we enter into agreements in the normal course of business with CROs for clinical trials and with other vendors for preclinical studies, manufacturing services, and other services and products for operating purposes, which are generally cancelable upon written notice.

**Critical Accounting Policies and Estimates**

Our consolidated financial statements are prepared in accordance with U.S. generally accepted accounting principles ("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, 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 of our consolidated financial statements included in 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 Contract Costs and Accruals***

Research and development costs are expensed as incurred. We record accrued liabilities for estimated costs of research and development activities conducted by third-party service providers, which include the conduct of preclinical studies, clinical trials and contract manufacturing activities. We record the estimated costs of research and development activities based upon the estimated amount of services provided but not yet invoiced and include these costs in accrued research and development liabilities in our consolidated balance sheets and within research and development expense in our consolidated statements of operations and comprehensive income (loss). These costs are a significant component of our research and development expenses.

We accrue for these costs based on factors such as estimates of the amount of work completed through discussions with internal personnel and external service providers as to the progress or stage of completion of the services and in accordance with agreements established with our third-party service providers for such services. We make significant judgments and estimates in determining the accrued research and development liabilities balance at each reporting period. As actual costs become known, we adjust our accrued estimates. Although we do not expect our estimates to be materially different from amounts actually incurred, the status and timing of services performed, the number of patients enrolled in clinical trials and the rate of patient enrollment may vary from our estimates and could result in us reporting amounts that are too high or too low in any particular period. Our accrued expenses are dependent, in part, upon the receipt of timely and accurate reporting from clinical research organizations and other third-party service providers. We record advance payments to service providers as prepaid assets, which are expensed as the contracted services are performed.

***Equity-Based Compensation Expense***

We estimate the fair value of stock options using the Black-Scholes option pricing model, which requires the input of objective and subjective assumptions. Certain assumptions used, including our expected stock price volatility, represent management’s estimates and involve inherent uncertainties and the application of management’s judgment. As a result, if factors change and management uses different assumptions, equity-based compensation expense could be materially different for future awards.

We do not have sufficient historical or implied volatility data for our common stock necessary to estimate expected volatility over a period of time commensurate with the expected term of our stock option awards. We use a blended rate to calculate expected volatility that combines our historical volatility with the historical volatilities of the stock prices of similar entities within our industry over a period of time commensurate with the expected term assumption.

***Income Taxes***

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. A reduction in the carrying value of the deferred tax assets is required when it is not more likely than not that such deferred tax assets are not realizable. Judgment is required to if certain income tax positions are more likely than not of being sustained and may change from period to period when there is a change in judgment.

**Recently Issued and Adopted Accounting Pronouncements**

A description of recently issued and adopted accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 of our consolidated financial statements included in this Annual Report on Form 10-K.

**Item 7A. Quantitative and Qualitative Disclosures About Market Risk.**

We are a smaller reporting company as defined by Item 10 of Regulation S-K and are not required to provide the information otherwise required under this Item.

**Item 8. Financial Statements and Supplementary Data.**

The financial statements required to be filed pursuant to this Item 8 are appended to this Annual Report on Form 10-K. An index of those financial statements is found in Item 15, Exhibits and Financial Statement Schedules, of this Annual Report on Form 10-K.

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

There has been no change of accountants nor any disagreements with accountants on any matter of accounting principles or practices of financial disclosure required to be reported under this Item.

**Item 9A. Controls and Procedures.**

**Evaluation of Disclosure Controls and Procedures**

Based on an evaluation under the supervision and with the participation of our management, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (as amended, the "Exchange Act") were effective as of December 31, 2025 to provide reasonable assurance that information required to be disclosed by us in reports that we file or submit under the Exchange Act is (i) recorded, processed, summarized, and reported within the time periods specified in the SEC rules and forms and (ii) accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

**Inherent Limitations on Internal Controls**

Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP. The Company's internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that receipts and expenditures are being made only in accordance with the authorizations of management and directors; and
- provide reasonable assurance regarding the prevention or timely detection of unauthorized acquisition, use or disposition of assets that could have a material effect on our financial statements.

Our management, including the Chief Executive Officer and Chief Financial Officer, do not expect that our internal controls will prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can only provide reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system reflects resource constraints, and the benefits of controls must be considered relative to their costs. Because there are inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. Also, any evaluation of the effectiveness of controls in future periods are subject to the risk that those internal controls may become inadequate because of changes in business conditions, or that the degree of compliance with the policies or procedures may deteriorate.

**Management's Annual Report on Internal Control Over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework provided in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on the results of its evaluation, management has concluded that our internal control over financial reporting was effective as of December 31, 2025 to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with GAAP.

**Changes in Internal Control over Financial Reporting**

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) or 15(d)-15(f) under the Exchange Act) that occurred during the fiscal 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.**

*Rule 10b5-1 Trading Plans*

During the fiscal quarter ended December 31, 2025, none of our directors and officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted, modified, or terminated a "Rule 10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement," as those terms are defined in Item 408(a) of Regulation S-K.

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

Not Applicable.

## PART III

**Item 10. Directors, Executive Officers and Corporate Governance.**

*Insider Trading Policies and Procedures*

We have an insider trading policy which governs the purchase, sale and/or other dispositions of the Company's securities by the Company's directors, officers, employees, consultants, and other covered persons and is designed to promote compliance with insider trading laws, rules and regulations, and listing standards applicable to the Company. The Company's Insider Trading Policy is included as an exhibit to this Annual Report on Form 10-K.

The other information required by this Item 10 will be included in our Definitive Proxy Statement to be filed with the Securities and Exchange Commission (the "SEC"), with respect to our 2026 Annual Meeting of Stockholders and is incorporated herein by reference.

**Item 11. Executive Compensation.**

The information required by this Item 11 will be included in our Definitive Proxy Statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders and is incorporated herein by reference.

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

The information required by this Item 12 will be included in our Definitive Proxy Statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders and is incorporated herein by reference.

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

The information required by this Item 13 will be included in our Definitive Proxy Statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders and is incorporated herein by reference.

**Item 14. Principal Accountant Fees and Services.**

The information required by this Item 14 will be included in our Definitive Proxy Statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders and is incorporated herein by reference.

## PART IV

**Item 15. Exhibits and Financial Statement Schedules.**

(1) For a list of the financial statements included herein, see Index to the Consolidated Financial Statements on page F-1 of this Annual Report on Form 10-K, incorporated into this Item by reference.

(2) Financial statement schedules have been omitted because they are either not required or not applicable or the information is included in the consolidated financial statements or the notes thereto included in this Annual Report on Form 10-K.

(3) The exhibits filed as part of this Annual Report on Form 10-K are set forth on the Exhibit Index immediately following our consolidated financial statements. The Exhibit Index is incorporated herein by reference.

**Item 16. Form 10-K Summary.**

None.

**CULLINAN THERAPEUTICS, INC.**

**INDEX TO FINANCIAL STATEMENTS**

**Report of Independent Registered Public Accounting Firm**

To the Stockholders and the Board of Directors
Cullinan Therapeutics, Inc.:

*Opinion on the Consolidated Financial Statements*

We have audited the accompanying consolidated balance sheets of Cullinan Therapeutics, Inc. and subsidiaries (the Company) as of December 31, 2025 and 2024, the related consolidated statements of operations and comprehensive income (loss), stockholders' equity, and cash flows for the years then ended, and the related notes (collectively, 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 U.S. generally accepted accounting principles.

*Basis for Opinion*

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these 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 in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit 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.

*Critical Audit Matters*

Critical audit matters are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ KPMG LLP

We have served as the Company's auditor since 2018.

Boston, Massachusetts
March 10, 2026

**CULLINAN THERAPEUTICS, INC.**
**CONSOLIDATED BALANCE SHEETS**
**(in thousands, except share amounts)**

| | December 31, | |
|---|---|---|
| | 2025 | 2024 |
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 88,332 | $ 83,005 |
| Short-term investments | 289,564 | 315,972 |
| Prepaid expenses and other current assets | 8,860 | 15,691 |
| Total current assets | 386,756 | 414,668 |
| Property and equipment, net | 421 | 683 |
| Operating lease right-of-use assets | 2,630 | 1,667 |
| Other assets | 297 | 366 |
| Long-term investments | 58,270 | 204,440 |
| Total assets | $ 448,374 | $ 621,824 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 841 | $ 1,682 |
| Accrued expenses and other current liabilities | 36,120 | 27,663 |
| Operating lease liabilities, current | 780 | 1,302 |
| Total current liabilities | 37,741 | 30,647 |
| Long-term liabilities: | | |
| Operating lease liabilities, net of current portion | 1,903 | 849 |
| Total liabilities | 39,644 | 31,496 |
| Commitments and contingencies (Note 11) | | |
| Stockholders' equity: | | |
| Preferred stock, $0.0001 par value, 10,000,000 shares authorized as of December 31, 2025 and 2024; 555,935 and 647,500 shares issued and outstanding as of December 31, 2025 and 2024, respectively. | — | — |
| Common stock, $0.0001 par value, 150,000,000 shares authorized as of December 31, 2025 and 2024; 60,244,136 and 58,510,610 shares issued and outstanding as of December 31, 2025 and 2024, respectively. | 6 | 6 |
| Additional paid-in capital | 995,823 | 958,695 |
| Accumulated other comprehensive gain (loss) | 1,020 | (133) |
| Accumulated deficit | (588,119) | (368,240) |
| Total Cullinan stockholders' equity | 408,730 | 590,328 |
| Noncontrolling interests | — | — |
| Total stockholders' equity | 408,730 | 590,328 |
| Total liabilities and stockholders' equity | $ 448,374 | $ 621,824 |

See accompanying notes to the consolidated financial statements.

**CULLINAN THERAPEUTICS, INC.**
**CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)**
**(in thousands, except per share amounts)**

| | 2025 | 2024 |
|---|---|---|
| Operating expenses: | | |
| Research and development | $ 187,402 | $ 142,903 |
| General and administrative | 54,246 | 54,016 |
| Total operating expenses | 241,648 | 196,919 |
| Loss from operations | (241,648) | (196,919) |
| Other income (expense): | | |
| Interest income | 22,212 | 29,660 |
| Other income (expense), net | (443) | (199) |
| Net loss before income taxes | (219,879) | (167,458) |
| Income tax expense | — | 117 |
| Net loss | (219,879) | (167,575) |
| Net loss attributable to noncontrolling interests | — | (192) |
| Net loss attributable to Cullinan | $ (219,879) | $ (167,383) |
| | | |
| Comprehensive income (loss): | | |
| Net loss | $ (219,879) | $ (167,575) |
| Unrealized gain (loss) on investments | 1,153 | (4) |
| Comprehensive loss | (218,726) | (167,579) |
| Comprehensive loss attributable to noncontrolling interests | — | (192) |
| Comprehensive loss attributable to Cullinan | $ (218,726) | $ (167,387) |
| | | |
| Basic and diluted net loss per share attributable to Cullinan: | | |
| Common stock | $ (3.36) | $ (2.78) |
| Preferred stock | $ (33.57) | $ (27.78) |
| Weighted-average shares used in computing basic and diluted net loss per share attributable to Cullinan: | | |
| Common stock | 59,050 | 53,771 |
| Preferred stock | 645 | 648 |

See accompanying notes to the consolidated financial statements.

**CULLINAN THERAPEUTICS, INC.**
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**
**(in thousands, except share amounts)**

| | Preferred Stock | | Common Stock | | Additional Paid-In | Accumulated Other Comprehensive | Accumulated | Noncontrolling Interests in | Total Stockholders' |
|---|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | Capital | Income (Loss) | Deficit | Subsidiaries | Equity |
| Balances at December 31, 2023 | 647,500 | $ — | 42,900,083 | $ 4 | $ 654,685 | $ (129) | $ (200,857) | $ 192 | $ 453,895 |
| Issuance of common stock and pre-funded warrants, net of issuance costs | — | — | 14,421,070 | 1 | 262,651 | — | — | — | 262,652 |
| Issuance of common stock under equity-based compensation plans | — | — | 1,189,457 | 1 | 7,983 | — | — | — | 7,984 |
| Equity-based compensation | — | — | — | — | 37,824 | — | — | — | 37,824 |
| Acquisition of noncontrolling interests | — | — | — | — | (4,448) | — | — | — | (4,448) |
| Unrealized loss on investments | — | — | — | — | — | (4) | — | — | (4) |
| Net loss | — | — | — | — | — | — | (167,383) | (192) | (167,575) |
| Balances at December 31, 2024 | 647,500 | — | 58,510,610 | 6 | 958,695 | (133) | (368,240) | — | 590,328 |
| Issuance of common stock upon conversion of preferred stock | (91,565) | — | 915,650 | — | — | — | — | — | — |
| Issuance of common stock under equity-based compensation plans | — | — | 502,128 | — | 1,088 | — | — | — | 1,088 |
| Issuance of common stock upon exercise of pre-funded warrants | — | — | 315,748 | — | — | — | — | — | — |
| Equity-based compensation | — | — | — | — | 36,040 | — | — | — | 36,040 |
| Unrealized gain on investments | — | — | — | — | — | 1,153 | — | — | 1,153 |
| Net loss | — | — | — | — | — | — | (219,879) | — | (219,879) |
| Balances at December 31, 2025 | 555,935 | $ — | 60,244,136 | $ 6 | $ 995,823 | $ 1,020 | $ (588,119) | $ — | $ 408,730 |

See accompanying notes to the consolidated financial statements.

**CULLINAN THERAPEUTICS, INC.**
**CONSOLIDATED STATEMENTS OF CASH FLOWS**
**(in thousands)**

| | 2025 | 2024 |
|---|---|---|
| Operating activities: | | |
| Net loss | $ (219,879) | $ (167,575) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Equity-based compensation expense | 36,040 | 37,824 |
| Accretion on marketable securities | (6,306) | (15,469) |
| Depreciation and amortization | 311 | 306 |
| Changes in operating assets and liabilities: | | |
| Prepaid expenses and other current assets | 6,897 | (2,472) |
| Accounts payable | (839) | (812) |
| Accrued expenses and other liabilities | 8,026 | 2,895 |
| Net cash used in operating activities | (175,750) | (145,303) |
| Investing activities: | | |
| Maturities of marketable securities | 416,572 | 584,817 |
| Purchase of marketable securities | (236,534) | (721,131) |
| Purchase of property and equipment | (49) | — |
| Net cash provided by (used in) investing activities | 179,989 | (136,314) |
| Financing activities: | | |
| Issuance of common stock under equity-based compensation plans | 1,088 | 7,984 |
| Issuance of common stock and pre-funded warrants, net of issuance costs | — | 262,652 |
| Acquisition of noncontrolling interests | — | (4,448) |
| Net cash provided by financing activities | 1,088 | 266,188 |
| Net decrease in cash and cash equivalents | 5,327 | (15,429) |
| Cash and cash equivalents at beginning of period | 83,005 | 98,434 |
| Cash and cash equivalents at end of period | $ 88,332 | $ 83,005 |
| **SUPPLEMENTAL NONCASH DISCLOSURE** | | |
| Non-cash investing and financing activities and supplemental cash flow information | | |
| Cash refunded for income taxes | $ (2,970) | $ (2,274) |

See accompanying notes to consolidated financial statements.

## (1) Nature of Business and Basis of Presentation

### *Organization*

Cullinan Therapeutics, Inc., together with its consolidated subsidiaries ("Cullinan" or "the Company"), is a clinical-stage biopharmaceutical company developing therapies for autoimmune diseases and cancer that was incorporated in September 2016 and has a principal place of business in Cambridge, Massachusetts. In April 2024, the Company changed its name from Cullinan Oncology, Inc. to Cullinan Therapeutics, Inc.

### *Liquidity*

The Company has a history of significant operating losses and has had negative cash flows from operations since its inception and expects to continue to generate operating losses for the foreseeable future. Cullinan's ultimate success depends on the outcome of its research and development activities as well as its ability to commercialize the Company's product candidates. Cullinan is subject to a number of risks including, but not limited to, the need to obtain adequate additional funding for the ongoing and planned clinical development of its product candidates. Due to the numerous risks and uncertainties associated with pharmaceutical development, government regulation, potential commercialization, intellectual property, and our reliance on third parties the Company is unable to accurately predict the timing or amount of funds required to complete development of its product candidates, and costs could exceed Cullinan's expectations for a number of reasons, including reasons beyond the Company's control.

Since inception, Cullinan has funded its operations primarily through the sale of equity securities and from licensing or selling the rights to its product candidates. The Company expects that its cash, cash equivalents, and short-term investments of $377.9 million, and long-term investments and interest receivable of $61.1 million as of December 31, 2025, will be sufficient to fund its operating expenses and capital expenditure requirements through the next twelve months from the date of issuance of these consolidated financial statements.

### *Basis of Presentation*

The accompanying consolidated financial statements of the Company have been prepared in conformity with accounting principles generally accepted in the United States ("U.S. GAAP") for financial reporting.

## (2) Summary of Significant Accounting Policies

### *Principles of Consolidation*

The accompanying consolidated financial statements include the accounts of Cullinan and consolidated subsidiaries. The Company considers its voting rights, effective economic control, or other control over an entity when evaluating whether to consolidate an entity for financial reporting.

### *Use of Estimates*

The preparation of Cullinan's consolidated financial statements and accompanying notes in conformity with U.S. GAAP requires the Company's management to make estimates and judgments that affect the amounts reported in the financial statements. On an ongoing basis, Cullinan's management evaluates its estimates, which include, but are not limited to, estimates related to prepaid and accrued research and development expenses, equity-based compensation, income taxes, and the fair value of royalty transfer agreements. Management's estimates could change period to period based on changes in facts and circumstances. The Company's management bases its estimates on historical experience and on other relevant assumptions that are believed to be reasonable. Actual results may differ materially from these estimates.

### *Concentration of Risk*

Cullinan had no significant concentration of credit risk as of December 31, 2025. Cash and cash equivalents are primarily maintained with three financial institutions in the U.S. as of December 31, 2025. Deposits at banks may exceed the federally insured limits. To date, the Company has not experienced any losses on such accounts. Under our investment policy, the Company limits amounts invested in such securities by investment type, credit rating, maturity, industry group and issuer. The goals of our investment policy are (i) safety and preservation of principal and diversification of risk and (ii) liquidity of investments sufficient to meet cash flow requirements.

Cullinan is subject to certain risks and uncertainties and believes that changes in any of the following areas could have a material adverse effect on future financial position or results of operations: ability to conduct and complete preclinical and clinical trials of our current and future product candidates; ability to obtain future financing; ability to build a successful pipeline of product candidates, including efficient expenditures of its resources; regulatory approval and market acceptance of, and reimbursement for, current and future product candidates; protection of Cullinan's intellectual property, including litigation or claims against the Company based on intellectual property, patent, product, regulatory or other factors; performance of third-party clinical research organizations and manufacturers upon which the Company relies; and Cullinan's ability to attract and retain employees necessary to support its growth.

The Company is dependent and expects to continue to be dependent on a small number of third-party manufacturers to supply drug product and drug substance for research and development activities in its programs. These programs could be adversely affected by a significant interruption in supply.

***Cash and Cash Equivalents***

The Company considers all highly liquid investments with original maturities of three months or less at the time of purchase to be cash equivalents. As of December 31, 2025 and 2024, cash equivalents consist of government-backed money market funds.

***Investments***

Cullinan generally holds investments in marketable securities. Investments not classified as cash equivalents with maturities of less than twelve months are classified as short-term investments in the consolidated balance sheets. Investments with maturities greater than twelve months for which the Company has the intent and ability to hold the investment for greater than twelve months are classified as long-term investments in the consolidated balance sheets.

The amortized cost of marketable securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion is included in interest income. Dividends are also included in interest income. Interest receivable is included in prepaid expenses and other current assets on the consolidated balance sheets and represents accrued and unpaid interest on Cullinan's marketable securities.

The Company periodically reviews its investments for impairment based on a security-specific analysis as of each balance sheet date. If the fair value of a security is below its amortized cost, the Company first assesses whether it intends to sell the security or is more likely than not required to sell it before recovery of its amortized cost. If neither condition is met, the Company evaluates whether a portion of the decline is attributable to credit loss. Any credit-related impairment is recorded as an allowance for credit losses through earnings, with non-credit-related unrealized losses recorded in other comprehensive income (loss).

***Fair Value of Financial Instruments***

Cullinan has certain financial assets and liabilities recorded at fair value which have been classified as Level 1, 2 or 3 within the fair value hierarchy as described in the accounting standards for fair value measurements. The three levels of the fair value hierarchy are described below:

Level 1—Unadjusted quoted prices for identical assets or liabilities in active markets that the Company has the ability to access;

Level 2—Quoted prices for similar assets and liabilities in active markets or other market-observable inputs such as interest rates, yield curves and foreign currency spot rates; and

Level 3—Pricing or valuations that require inputs that are both significant to the fair value measurement and unobservable.

There were no transfers of financial assets or liabilities measured at fair value between Level 1 and Level 2, and there were no Level 3 investments during 2025 or 2024.

Cullinan's financial assets recorded at fair value consist of investments. The fair value of the Company's investments is primarily determined using market quotations or prices obtained from independent pricing sources.

***Property and Equipment, net***

Property and equipment is stated at cost less accumulated depreciation. Depreciation expense is recognized using the straight-line method over the estimated useful life of each asset as follows:

| Asset Class | Estimated Useful Life |
|---|---|
| Office furniture and equipment | 5 years |
| Leasehold improvements | Shorter of the useful life of the asset or the lease term |

Maintenance and repairs that do not improve or extend the life of the assets are expensed when incurred. Upon disposal or retirement of assets, the cost and accumulated depreciation and amortization are removed from the consolidated balance sheets and any resulting gain or loss is reflected in the consolidated statements of operations and comprehensive income (loss).

***Leases***

Cullinan determines if an arrangement is a lease at inception. A contract is or contains a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration. The Company classifies leases at the lease commencement date as operating or finance leases and records a right-of-use asset ("ROU") and a lease liability on the consolidated balance sheets for all leases with an initial lease term of greater than 12 months. Leases with an initial term of 12 months or less are not recorded in the balance sheet, and payments are recognized as expense on a straight-line basis over the lease term.

Cullinan enters into contracts that contain both lease and non-lease components. Non-lease components may include maintenance, utilities and other operating costs. The Company combines the lease and non-lease components of fixed costs in its lease arrangements as a single lease component. Variable costs, such as utilities or maintenance costs, are not included in the measurement of ROU assets and lease liabilities but rather are expensed when the event determining the amount of variable consideration to be paid occurs.

Operating lease assets and liabilities are recognized at the lease commencement date based on the present value of the lease payments over the lease term using the discount rate implicit in the lease. If the discount rate is not readily determinable, Cullinan utilizes an estimate of its incremental borrowing rate based upon the available information at the lease commencement date. Operating lease assets are further adjusted for prepaid or accrued lease payments. Operating lease payments are expensed using the straight-line method as an operating expense over the lease term. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that Cullinan will exercise that option.

***Impairment of Long-Lived Assets***

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated. Impairment charges are recognized at the amount by which the carrying amount of an asset exceeds the fair value of the asset. Assets to be disposed of are reported at the lower of the carrying amount or the fair value less costs to sell.

***Noncontrolling Interests***

Noncontrolling interests represent third-party interests in the Company's subsidiaries. Cullinan determines the amount of the noncontrolling interests in the net assets of the Company's subsidiaries at each balance sheet date using the hypothetical liquidation at book value ("HLBV") method. Under the HLBV method, the amounts reported as noncontrolling interests in the consolidated balance sheets represent the amounts third parties would hypothetically receive at each balance sheet date under the liquidation provisions of the subsidiaries, assuming the net assets of the subsidiaries were liquidated at their recorded amounts determined in accordance with U.S. GAAP and distributed to the owners of the subsidiaries. Net loss attributable to noncontrolling interests on the consolidated statements of operations and comprehensive income (loss) is determined as the difference in the noncontrolling interest in the consolidated balance sheets between the start and end of each reporting period, after taking into account any capital transactions between the subsidiaries and third parties.

***Revenue Recognition***

Revenue is recognized when a customer obtains control of promised goods or services. The amount of revenue recognized reflects the consideration to which Cullinan expects to be entitled in exchange for these goods and services. To achieve this core principle, the Company applies the following five steps: 1) identify the customer contract; 2) identify the contract's performance obligations; 3) determine the transaction price; 4) allocate the transaction price to the performance obligations; and 5) recognize revenue when or as a performance obligation is satisfied.

Licensing arrangements are analyzed to determine whether the promised goods or services, which could include licenses and research and development materials and services, are distinct or whether they must be accounted for as part of a combined performance obligation.

The transaction price is determined based on the consideration to which Cullinan will be entitled. The transaction price may include fixed amounts, variable amounts, or both. The Company reevaluates the probability of realizing such variable consideration and any related constraints at each reporting period. Cullinan includes variable consideration in the transaction price to the extent it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur.

The Company allocates the transaction price based on the estimated standalone selling price of the underlying performance obligations. Cullinan must develop assumptions that require judgment to determine the standalone selling price for each performance obligation identified in the contract. The Company utilizes key assumptions to determine the standalone selling price, which may include other comparable transactions, pricing considered in negotiating the transaction and the estimated costs to complete the respective performance obligation. Cullinan also utilizes judgment in assessing whether or not variable consideration is constrained or if it can be allocated specifically to one or more performance obligations in the arrangement.

When a performance obligation is satisfied, revenue is recognized for the amount of the transaction price allocated to that performance obligation on a relative standalone selling price basis, which excludes estimates of variable consideration that are constrained. Significant management judgment is required in determining the level of effort required under an arrangement and the period over which the Company is expected to complete its performance obligations under an arrangement.

For performance obligations consisting of licenses and other promises, Cullinan utilizes judgment to assess whether the combined performance obligation is satisfied over time or at a point in time and the recognition pattern for the portion of the transaction price allocated to the performance obligation.

***Research and Development Expenses***

Research and development costs are expensed as incurred. Research and development expenses consist primarily of employee compensation costs and amounts incurred with third parties for the provision of services for product candidate development, clinical and preclinical development and related supply and manufacturing costs, and regulatory compliance costs. 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 received or services are performed. At the end of each reporting period, the Company conducts a thorough review of ongoing research and development activities to identify goods received or services rendered in order to establish an estimate of the associated costs incurred. The Company compares payments made to its vendors to its estimate of costs incurred to determine the resulting prepaid or accrual position. Significant judgments and estimates are made in determining the prepaid and accrued balances at the end of any reporting period. Such estimates are subject to change as additional information becomes available, and actual results could differ from the Company’s estimates.

Costs incurred to obtain licenses are recognized as research and development expense if the technology licensed has no alternative future use.

***Patent Costs***

All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty about the recovery of the expenditure. Amounts incurred are classified as general and administrative expenses in the consolidated statements of operations and comprehensive income (loss).

***Equity-Based Compensation***

Equity-based compensation is measured at the grant date for all equity-based awards using the fair value of the awards and is recognized as expense over the requisite service period, which is generally the vesting period. Forfeitures are recognized as they occur. Cullinan classifies equity-based compensation in its consolidated statements of operations and comprehensive income (loss) in the same manner in which the award recipient’s payroll costs or service payments are classified.

The fair value of service-based restricted stock units ("RSUs") is the closing market price of the Company's common stock on the grant date. The fair value of market-based RSUs is measured on the grant date using a Monte Carlo simulation model. Cullinan estimated the fair value of stock options using the Black-Scholes option pricing model. Both the Monte Carlo simulation model and the Black-Scholes option pricing model require the input of objective and subjective assumptions. Certain assumptions used, including the Company’s expected stock price volatility, involve inherent uncertainties and the application of management’s judgment. As a result, if factors change and management uses different assumptions, equity-based compensation expense could be materially different for future awards.

***Income Taxes***

Cullinan recognizes the effect of income tax positions only if those positions are more likely than not of being sustained. Recognized income tax positions are measured at the largest amount of benefit that is greater than fifty percent likely to be realized upon settlement. Changes in measurement are reflected in the period in which the change in judgment occurs.

***Net Loss per Share Attributable to Cullinan***

Cullinan computes net loss per share attributable to Cullinan using the two-class method required for multiple classes of common stock. The Company has determined that the preferred stock does not have preferential rights over the Company's common stock and, accordingly, is considered to be a second class of common stock for purposes of calculating net loss per share attributable to Cullinan. Basic net loss per share attributable to Cullinan is calculated by dividing the net loss attributable to Cullinan allocated to each share class by the weighted-average number of shares outstanding during the period for that share class. Diluted net loss per share attributable to Cullinan is determined by dividing net loss attributable to Cullinan allocated to each share class by the weighted-average number of shares outstanding during the period for that share class, adjusted for the dilutive effect of shares of common stock equivalents as determined using the treasury stock method for equity awards and the if-converted method for preferred stock.

***Recently Adopted Accounting Pronouncements***

In December 2023, the Financial Accounting Standards Board (the "FASB") issued an accounting standards update to enhance transparency about income tax information through improvements to income tax disclosures primarily related to the rate reconciliation and income taxes paid information. The main provisions in this update require companies to disclose, on an annual basis, specific categories in the rate reconciliation and provide additional information for reconciling items that meet a quantitative threshold. This update also requires companies to disclose, on an annual basis, the amount of income taxes paid, income (or loss) from continuing operations before income tax expense (or benefit), and income tax expense (or benefit) from continuing operations, disaggregated between federal, state and foreign jurisdictions. Cullinan adopted this standard on a retrospective basis effective January 1, 2025 for 2025 annual reporting and interim periods beginning in 2026.

***Recently Issued Accounting Pronouncements***

In November 2024, the FASB issued an accounting standards to improve disclosures regarding the types of expenses included in commonly presented expense captions, including disaggregating the amounts of employee compensation, depreciation and amortization included within each income statement expense caption. This standard is effective for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027, with early adoption permitted. Cullinan will adopt this standard on January 1, 2027 for 2027 annual reporting and interim periods beginning in 2028 and is evaluating the impact of adopting this standard on its consolidated financial statements and disclosures.

## (3) Financial Instruments

*Investments*

Cullinan recognized its investments by security type at December 31, 2025 as follows (in thousands):

| | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Estimated Fair Value |
|---|---|---|---|---|
| Short-term investments | | | | |
| U.S. government notes | $ 159,632 | $ 683 | $ — | $ 160,315 |
| Corporate notes | 119,368 | 119 | (7) | 119,480 |
| Asset-backed securities | 9,717 | 52 | — | 9,769 |
| Total short-term investments | 288,717 | 854 | (7) | 289,564 |
| Long-term investments | | | | |
| Corporate notes | 48,134 | 90 | (2) | 48,222 |
| U.S. government notes | 9,963 | 85 | — | 10,048 |
| Asset-backed securities | — | — | — | — |
| Total long-term investments | 58,097 | 175 | (2) | 58,270 |
| Total investments | $ 346,814 | $ 1,029 | $ (9) | $ 347,834 |

Cullinan recognized its investments by security type at December 31, 2024 as follows (in thousands):

| | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Estimated Fair Value |
|---|---|---|---|---|
| Short-term investments | | | | |
| Corporate notes | $ 211,584 | $ 343 | $ (6) | $ 211,921 |
| U.S. government notes | 78,874 | 81 | — | 78,955 |
| Asset-backed securities | 25,084 | 12 | — | 25,096 |
| Total short-term investments | 315,542 | 436 | (6) | 315,972 |
| Long-term investments | | | | |
| U.S. government notes | 118,423 | 88 | (188) | 118,323 |
| Corporate notes | 77,196 | 9 | (472) | 76,733 |
| Asset-backed securities | 9,384 | — | — | 9,384 |
| Total long-term investments | 205,003 | 97 | (660) | 204,440 |
| Total investments | $ 520,545 | $ 533 | $ (666) | $ 520,412 |

All of the Company's long-term investments as of each of December 31, 2025 and 2024 had maturities between one and two years from the respective balance sheet date. The Company did not recognize any credit loss relating to its investments during 2025 or 2024.

*Fair Value of Financial Instruments*

The following table sets forth the fair value of Cullinan's financial assets that were measured at fair value on a recurring basis as of December 31, 2025 (in thousands):

| | Level 1 | Level 2 | Level 3 | Total |
|---|---|---|---|---|
| Short-term investments | | | | |
| U.S. government notes | $ — | $ 160,315 | $ — | $ 160,315 |
| Corporate notes | — | 119,480 | — | 119,480 |
| Asset-backed securities | — | 9,769 | — | 9,769 |
| Total short-term investments | — | 289,564 | — | 289,564 |
| Long-term investments | | | | |
| Corporate notes | $ — | $ 48,222 | $ — | $ 48,222 |
| U.S. government notes | — | 10,048 | — | 10,048 |
| Asset-backed securities | — | — | — | — |
| Total long-term investments | — | 58,270 | — | 58,270 |
| Total investments | $ — | $ 347,834 | $ — | $ 347,834 |

The following table sets forth the fair value of Cullinan's financial assets that were measured at fair value on a recurring basis as of December 31, 2024 (in thousands):

| | Level 1 | Level 2 | Level 3 | Total |
|---|---|---|---|---|
| Short-term investments | | | | |
| Corporate notes | $ — | $ 211,921 | $ — | $ 211,921 |
| U.S. government notes | — | 78,955 | — | 78,955 |
| Asset-backed securities | — | 25,096 | — | 25,096 |
| Total short-term investments | — | 315,972 | — | 315,972 |
| Long-term investments | | | | |
| U.S. government notes | — | 118,323 | — | 118,323 |
| Corporate notes | — | 76,733 | — | 76,733 |
| Asset-backed securities | — | 9,384 | — | 9,384 |
| Total long-term investments | — | 204,440 | — | 204,440 |
| Total investments | $ — | $ 520,412 | $ — | $ 520,412 |

As of December 31, 2025 and 2024, the fair values of cash and cash equivalents, prepaid expenses and other current assets, accounts payable, accrued expenses and other current liabilities approximated their carrying values due to the short-term nature of these instruments.

**(4) Property and Equipment, net**

Property and equipment, net consisted of the following as of December 31, 2025 and 2024 (in thousands):

| | December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Office furniture and equipment | $ 814 | $ 765 |
| Leasehold improvements | 576 | 576 |
| Total property and equipment, gross | 1,390 | 1,341 |
| Less: accumulated depreciation | (969) | (658) |
| Total property and equipment, net | $ 421 | $ 683 |

Depreciation expense was $0.3 million in each of 2025 and 2024.

**(5) Accrued Expenses and Other Current Liabilities**

Accrued expenses and other current liabilities consisted of the following as of December 31, 2025 and 2024 (in thousands):

| | December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Contracted research and development expenses | $ 16,388 | $ 10,297 |
| Employee compensation | 9,952 | 9,935 |
| Due to Taiho under collaboration agreement, net | 8,784 | 5,994 |
| Other current liabilities | 996 | 1,437 |
| | $ 36,120 | $ 27,663 |

**(6) License and Collaboration Agreements**

***Genrix License Agreement***

In June 2025, the Company and Chongqing Genrix Biopharmaceutical Co., Ltd. (“Genrix”) entered into a license agreement (the “Genrix License Agreement”), pursuant to which Genrix granted Cullinan a global (excluding mainland China, Hong Kong, Macau and Taiwan), exclusive license to develop and commercialize velinotamig, a BCMAxCD3 bispecific T cell engager, in all fields of use.

Under the terms of the Genrix License Agreement, Cullinan paid Genrix an upfront license fee of $20.0 million. Genrix will be eligible to receive up to $292.0 million in milestone payments based on the achievement of certain clinical and regulatory milestones. Genrix is also eligible to receive up to an additional $400.0 million in net sales-based milestones as well as tiered royalties ranging from mid-single digit to mid-teens, as a percentage of net sales of licensed products.

Unless earlier terminated, the Genrix License Agreement will continue in effect on a country-by-country basis until the expiration of Cullinan’s royalty obligations in such country. The Genrix License Agreement may be terminated by either party for a material breach by the other party, subject to notice and cure provisions, or in the event of the other party’s insolvency. Additionally, subject to a notice period, Cullinan may terminate the Genrix License Agreement for convenience. In the Genrix License Agreement, each party made customary representations and warranties and agreed to customary covenants, including, without limitation, with respect to indemnification, for transactions of this type.

Cullinan evaluated the Genrix License Agreement and determined that the exclusive license to develop and commercialize velinotamig represented an asset acquisition of in-process research and development. The Company also determined that the asset had no alternative future use at the time of acquisition, and therefore, the upfront license fee of $20.0 million was recorded within research and development expenses in 2025.

***Taiho Agreements***

Cullinan has a co-development agreement with an affiliate of Taiho Pharmaceutical Co., Ltd ("Taiho"), pursuant to which the Company is collaborating to develop zipalertinib for the treatment of a genetically defined subset of patients with NSCLC, and Taiho will commercialize zipalertinib. For the agreed-upon indication, Cullinan and Taiho share development costs equally, and each party will receive 50% of any future pre-tax profits from potential U.S. sales of zipalertinib. For any additional indications that Taiho chooses to develop independently, Taiho will bear all development costs until they have sufficient data from such indication to support a commercial purpose or submission of zipalertinib for such indication. At such time, 50% of Taiho’s independent development costs, subject to certain adjustments, will be deducted from future pre-tax profits for potential U.S. sales of zipalertinib. In November 2025, Taiho independently initiated an ongoing global Phase 3 clinical trial evaluating zipalertinib in an additional indication.

The Company concluded that the co-development agreement with Taiho is a collaborative arrangement because Cullinan is an active participant in the development of zipalertinib, and in the oversight of commercialization for zipalertinib. Amounts due to or from Taiho for zipalertinib development activities after the execution of the co-development agreement are recorded within research and development expenses or general and administrative expenses based on the nature of the activity. The following table summarizes each party's respective share of costs incurred and paid by the other party for zipalertinib development activities for 2025 and 2024 (in thousands):

| | 2025 | 2024 |
|---|---|---|
| Cullinan's share of zipalertinib research and development costs incurred by Taiho | $ 28,401 | $ 24,909 |
| Cullinan's share of general and administrative costs incurred by Taiho | $ 3,247 | $ 2,051 |
| Taiho's share of research and development costs incurred by Cullinan | $ 7,640 | $ 9,549 |

Under a separate agreement, Cullinan is also eligible to receive up to $130.0 million from Taiho tied to epidermal growth factor receptor exon 20 non-small-cell lung cancer U.S. regulatory milestones. As of December 31, 2025, no milestone payments have been received under this agreement.

***DKFZ/Tübingen License Agreement***

The Company has exclusive worldwide rights to CLN-049, its bispecific T cell engager targeting FLT3 and CD3, pursuant to an exclusive license agreement (the "DKFZ/Tübingen License Agreement") with Deutsches Krebsforschungszentrum ("DKFZ"), Eberhard Karls University of Tübingen, Faculty of Medicine, and Universitätsmedizin Gesellschaft für Forschung und Entwicklung mbH, Tübingen. Pursuant to the DKFZ/Tübingen License Agreement, DKFZ and the University of Tübingen, collectively referred to as the Licensor, granted to Cullinan an exclusive worldwide, milestone- and royalty-bearing license under certain licensed patent rights, applications, technical information and know-how, with the right to grant sublicenses through multiple tiers to research, develop, commercialize or otherwise exploit licensed products within the field.

The Company shall pay certain non-refundable, non-creditable milestone payments to the Licensor upon the occurrence of certain clinical and regulatory events related to a licensed product. Each milestone payment is paid one time only up to a certain payment amount.

Furthermore, Cullinan is required to pay running low to mid-single digit royalty percentage on net sales of each licensed product on a country-by-country and product-by-product basis during the royalty term, subject to certain offsets or reductions. The aggregate, worldwide royalties due to Licensor for net sales of any licensed product in a calendar year shall not be reduced to an amount less than low to mid-single digit percentages. Such royalty obligations will expire on a country-by-country and product-by-product basis upon the later of (a) the expiration of the last valid claim of a patent which covers a product in such country and (b) a low double digit anniversary following the first commercial sale of a product in such country. Under certain conditions upon a first change in control in the Company's CLN-049 development subsidiary, Cullinan shall pay a non-refundable, non-creditable mid-single digit percent of sale proceeds, provided, however, that such payment shall not be required following consummation of an initial public offering of the Company's CLN-049 development subsidiary.

Either party may terminate the agreement upon a material breach by the other party or insolvency of the other party. Cullinan may terminate the DKFZ/Tübingen License Agreement for any or no reason after the first filing of an investigational new drug application or clinical trial agreement by providing prior written notice. Licensor may terminate the agreement by providing prior written notice, if the Company or any of its affiliates challenges the validity of certain patent rights. Unless earlier terminated, the DKFZ/Tübingen License Agreement continues perpetually. As of December 31, 2025, no milestone obligations have been incurred under the DKFZ/Tübingen License Agreement.

***Adimab***

Cullinan has a collaboration agreement with Adimab, LLC ("Adimab") (the "Adimab Collaboration Agreement"). Pursuant to the Adimab Collaboration Agreement, the Company selected a single-digit number of biological targets against which Adimab used its proprietary platform technology to discover and/or optimize antibodies, including antibody components that were used to generate CLN-978, based upon mutually agreed-upon research plans. Under the Adimab Collaboration Agreement, Cullinan has the ability to select additional biological targets against which Adimab will provide additional antibody discovery and optimization services for delivery of binders with a specified range of binding affinities.

During the research term and evaluation term for a given research program with Adimab, the Company has a non-exclusive worldwide license under Adimab's technology to perform certain research activities and to evaluate the program antibodies to determine whether Cullinan wants to exercise its option to obtain a royalty-free, fully paid, non-exclusive license to exploit such antibodies and sublicense through multiple tiers (the "Adimab Option").

Under the Adimab Collaboration Agreement, Cullinan paid a one-time, non-creditable, non-refundable technology access fee. Cullinan is also required to pay an annual access fee and research funding fees, which are creditable against the annual access fee for Adimab's performance of its' research obligations under the Adimab Collaboration Agreement. Cullinan is also obligated to make certain research delivery, clinical and sales milestone payments to Adimab in an aggregate amount of up to $15.8 million for each product, on a product-by-product basis, subject to certain reductions and discounts. As of December 31, 2025, Cullinan has incurred and paid a cumulative $0.5 million of milestone obligations for CLN-978 under the Adimab Collaboration Agreement.

Cullinan is obligated to pay certain royalty payments on a product-by-product basis at a low single-digit percentage of annual aggregate worldwide net sales. Such royalty obligations will expire on a country-by-country and product-by-product basis upon the later of (a) a certain low double-digit number of years after the first commercial sale of such product in such country and (b) the expiration of the last issued and not expired, permanently revoked, or invalid claim within a program patent covering such product.

Cullinan may terminate the Adimab Collaboration Agreement at any time, for any reason, upon a specified period advance written notice. The term of the Adimab Collaboration Agreement expires upon the last research program's evaluation term in the event no Adimab Option is exercised or in the event an Adimab Option is exercised, after the royalty term expires at the later of a specified period or invalid patent coverage of the relevant product.

During 2025 and 2024, Cullinan did not incur any milestone obligations under the Adimab Collaboration Agreement.

***Massachusetts Institute of Technology***

The Company had an exclusive patent license agreement (the "MIT License Agreement") for the technology underlying CLN-617 with MIT through its development subsidiary, Cullinan Amber Corp. ("Cullinan Amber"). Under the terms of the MIT License Agreement, Cullinan has incurred and paid $0.7 million of milestone obligations through December 31, 2025. In November 2025, after a review of the emerging clinical data in patients with advanced solid tumors, Cullinan decided not to pursue further development of CLN-617. In connection with the decision not to pursue further development of CLN-617, the Company notified MIT of its decision to terminate the MIT License Agreement. In connection with the termination of the MIT License Agreement, Cullinan returned the licensed patent rights for the technology underlying CLN-617 to MIT.

During 2025 and 2024, Cullinan did not incur any milestone obligations under the MIT License Agreement.

***Harbour License Agreement***

The Company and Harbour BioMed US Inc. ("Harbour") were party to a license and collaboration agreement pursuant to which Harbour granted Cullinan an exclusive license for the development, manufacturing and commercialization of HBM7008 (CLN-418) in the U.S. In August 2024, following a review of the data from the Phase 1 clinical trial of CLN-418, the Company notified Harbour of its decision to terminate the license and collaboration agreement, effective November 2024. In connection with the termination, the Company discontinued development of CLN-418 and returned development and commercial rights for CLN-418 to Harbour.

## (7) Stockholders' Equity

***Common Stock***

Each share of common stock entitles the holder to one vote and to receive dividends when and if declared by the board of directors of the Company. No dividends have been declared through December 31, 2025.

*2024 Private Placement*

In April 2024, Cullinan completed a private placement (the "2024 Private Placement") in which Cullinan issued approximately 14.4 million shares of its common stock and pre-funded warrants to purchase approximately 0.3 million additional shares of its common stock. Cullinan received net proceeds of $262.7 million from the 2024 Private Placement, after deducting offering costs of $17.3 million. Refer to the discussion under the heading "Warrants" below for further detail regarding the pre-funded warrants.

*At-the-Market Equity Offering Program*

Cullinan has an at-the-market equity offering program (the "ATM") through an agreement with Cowen and Company, LLC ("Cowen") pursuant to which the Company may offer and sell up to $125.0 million of its common stock from time to time through Cowen, acting as its sales agent. The Company made no sales under the ATM in 2025. Through December 31, 2025, the Company has sold approximately 3.3 million shares under the ATM and received net proceeds of $38.4 million after deducting commissions. As of December 31, 2025, Cullinan had $85.6 million in shares of its common stock remaining under the ATM.

***Preferred Stock***

Each share of preferred stock is convertible into ten shares of common stock at the option of the holder at any time, subject to certain limitations, including that the holder is prohibited from converting preferred stock into common stock if, as a result of such conversion, the holder, together with its affiliates, would beneficially own a number of shares of common stock more than 9.99% of the total common stock then issued and outstanding immediately following the conversion of such shares of preferred stock. Holders of the preferred stock are permitted to increase this percentage to an amount not to exceed 19.99% upon 60 days notice.

Shares of preferred stock generally have no voting rights, except as required by law and except that the consent of a majority of the holders of the outstanding preferred stock will be required to amend the terms of the preferred stock. In the event of the Company's liquidation, dissolution or winding up, holders of preferred stock will participate pari passu with any distribution of proceeds to holders of common stock. Holders of preferred stock are entitled to receive when, as, and if dividends are declared and paid on the common stock, an equivalent dividend, calculated on an as-converted basis. Shares of preferred stock are otherwise not entitled to dividends.

The preferred stock ranks (i) senior to any class or series of capital stock of Cullinan created specifically ranking by its terms junior to the preferred stock; (ii) on parity with the common stock and any class or series of capital stock of the Company created specifically ranking by its terms on parity with the preferred stock; and (iii) junior to any class or series of capital stock of Cullinan created specifically ranking by its terms senior to any preferred stock, in each case, as to distributions of assets upon liquidation, dissolution or winding up of the Company, whether voluntarily or involuntarily.

The Company determined that the preferred stock should be classified as permanent equity.

***Noncontrolling Interests in Subsidiaries***

Certain of the Company's current and former clinical-stage product candidates are held through development subsidiaries in which the Company has controlling interests. The following table shows the Company's ownership interest as of December 31, 2025 and 2024, respectively, in product candidates in which the Company has a controlling interest:

| Product Candidate | December 31, 2025 | December 31, 2024 |
|---|---|---|
| CLN-619 | 99% | 99% |
| CLN-049 | 98% | 98% |
| CLN-617 | 96% | 96% |

During 2024, Cullinan paid $4.4 million to acquire shares and options to purchase shares of its CLN-619 development subsidiary that were held by noncontrolling interests.

***Warrants***

In April 2025, all outstanding pre-funded warrants were exercised on a cashless basis in exchange for 0.3 million shares of common stock.

Cullinan determined that the pre-funded warrants should be equity-classified when they were issued. The Company also determined that the pre-funded warrants should be included in the weighted-average shares used in computing basic net loss per share attributable to common stockholders of Cullinan.

## (8) Equity-Based Compensation

The Company recorded equity-based compensation in the following expense categories in the consolidated statements of operations and comprehensive income (loss) in 2025 and 2024 (in thousands):

| | 2025 | 2024 |
|---|---|---|
| General and administrative | $ 20,438 | $ 22,677 |
| Research and development | 15,602 | 15,147 |
| Total equity-based compensation | $ 36,040 | $ 37,824 |

***2021 Stock Option and Incentive Plan***

Cullinan grants equity awards in the form of stock options and RSUs to its employees and non-employees directors, through the 2021 Stock Option and Incentive Plan (the "2021 Stock Plan"). Cullinan has also granted equity awards outside of the 2021 Stock Plan in the form of stock options as an inducement material to an individual's entering into employment with the Company. As of December 31, 2025, there were approximately 2.1 million shares remaining for future grants under the 2021 Stock Plan.

The 2021 Stock Plan provides that the number of shares reserved and available for issuance under the 2021 Stock Plan will automatically increase each January 1 by 5% of the outstanding number of shares of Cullinan's common stock on the immediately preceding December 31 or such lesser number of shares as determined by Cullinan's board of directors or compensation committee. On January 1, 2026, the total number of shares available for issuance under the 2021 Stock Plan increased by approximately 3.0 million shares under this provision.

The options granted have a ten-year term and were issued with an exercise price equal to the closing market price of Cullinan's common stock on the grant date. For equity awards with service-based vesting conditions, Cullinan recognizes compensation expense over the vesting period, which is generally over a four-year period. For equity awards with a market-based vesting condition, the Company recognizes compensation expense over the requisite service period. The number of shares awarded, if any, when a market-based award vests will depend on the degree of achievement of the corporate stock price metrics within the performance period of the award.

*Determining Fair Value of Options*

The fair value of options is estimated using the Black-Scholes option pricing model, which takes into account inputs such as the exercise price, the value of the underlying common stock at the grant date, expected term, expected volatility, risk-free interest rate and dividend yield. The fair value of each grant of options during 2025 and 2024 were determined using the methods and assumptions discussed below:

- The expected term of options is determined using the "simplified" method, as prescribed in the SEC Staff Accounting Bulletin (SAB) No. 107, whereby the expected life equals the arithmetic average of the vesting term and the original contractual term of the option due to Cullinan's lack of sufficient historical data.
- The risk-free interest rate is based on implied yields available from U.S. Treasury securities with a remaining term equal to the expected term assumed at the grant date.
- The expected volatility used in the Black-Scholes option pricing model for new options was based on a blended rate that combines the Company's historical volatility with the historical volatilities of the stock prices of similar entities within Cullinan's industry over a period of time commensurate with the expected term assumption.
- The estimated annual dividend yield was based on the Company's expectation of not paying dividends on its common stock in the foreseeable future.

For 2025 and 2024, the weighted-average grant date fair value of the options granted were $6.01 and $12.28 per share, respectively. The grant date fair value was estimated at the time of grant using the Black-Scholes option-pricing model using the following weighted-average assumptions in 2025 and 2024:

| | 2025 | 2024 |
|---|---|---|
| Risk-free interest rate | 4.3% | 4.2% |
| Expected term (in years) | 6.0 | 6.0 |
| Expected volatility | 69.8% | 70.3% |
| Expected dividend yield | 0.0% | 0.0% |

*Stock Options*

The following table summarizes 2025 stock option activity (options and aggregate intrinsic value in thousands):

| | Number of Options | Weighted-Average Exercise Price | Weighted-Average Remaining Contractual Term (in Years) | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Outstanding as of December 31, 2024 | 11,633 | $ 16.35 | | |
| Granted | 2,734 | $ 9.18 | | |
| Exercised | (56) | $ 9.62 | | |
| Forfeited | (501) | $ 11.52 | | |
| Outstanding as of December 31, 2025 | 13,810 | $ 15.13 | 6.95 | $ 10,266 |
| Exercisable as of December 31, 2025 | 9,448 | $ 16.15 | 6.20 | $ 7,497 |

As of December 31, 2025, there was $36.1 million in unrecognized compensation costs that are expected to be recognized over a remaining weighted-average period of 2.4 years.

The aggregate intrinsic value of options is calculated as the difference between the exercise price of the options and the fair value of Cullinan's common stock for those options that had exercise prices lower than the fair value of the Company's common stock at the measurement date. The total intrinsic value of options exercised in 2025 and 2024 was $0.1 million and $10.4 million, respectively.

*RSUs*

The following table summarizes the activity related to RSUs during 2025 (shares in thousands):

| | Number of Shares | Weighted-Average Grant Date Fair Value |
|---|---|---|
| Outstanding unvested as of December 31, 2024[(1)] | 1,297 | $ 15.24 |
| Granted | 980 | $ 9.43 |
| Vested | (361) | $ 14.78 |
| Forfeited | (271) | $ 12.71 |
| Outstanding unvested as of December 31, 2025 | 1,645 | $ 12.30 |

(1) The number outstanding represents the number of shares issuable upon vesting of service-based and market-based RSUs, assuming the Company achieves its corporate stock price metrics at the target achievement level.

As of December 31, 2025, there was $15.5 million in unrecognized compensation cost related to RSUs expected to be recognized over a remaining weighted-average period of 2.6 years. The total fair value of RSUs that vested during 2025 and 2024 was $3.4 million and $2.9 million, respectively.

***2021 Employee Stock Purchase Plan***

The 2021 Employee Stock Purchase Plan (the "ESPP") authorizes the issuance of shares of common stock to participating eligible employees and provides for two six-month offering periods each year. As of December 31, 2025, there were approximately 2.1 million shares remaining for future purchases under the ESPP.

The ESPP provides that the number of shares reserved and available for issuance under the ESPP will automatically increase each January 1 by the lesser of 0.8 million shares of the Company's common stock, 1% of the outstanding number of shares of Cullinan's common stock on the immediately preceding December 31, or such lesser number of shares as determined by the Company's compensation committee. On January 1, 2026, the total number of shares available for issuance under the ESPP increased by approximately 0.6 million shares under this provision.

During each of 2025 and 2024, Cullinan issued less than 0.1 million shares of its common stock pursuant the ESPP.

## (9) Royalty Transfer Agreements

The Company's CLN-049 development subsidiary is party to royalty transfer agreements with two charitable foundations. Under these royalty transfer agreements, the charitable foundations are collectively entitled to receive a low single digit royalty percentage of all global net sales of any products developed by the development subsidiary, subject to limitations after patent expirations and on intellectual property developed after a change of control. Cullinan has deemed these royalty transfer agreements to be freestanding financial instruments that should be accounted for at fair value. The Company concluded that these instruments had no value at the inception of the agreements.

Cullinan has not had any applicable net sales from its products and as a result, has not paid or incurred any royalties under these agreements as of December 31, 2025. Given the early-stage nature of the underlying technologies and inherent risks associated with obtaining regulatory approval and achieving commercialization, the Company ascribed no value to the royalty transfer agreements as of December 31, 2025 and 2024.

## (10) Income Taxes

Cullinan did not record income tax expense or benefit in 2025 due to its net loss before income taxes in the current year and expected losses in future years. During 2024, the Company recorded a current federal income tax expense of $0.1 million. The income tax expense recorded for 2024 was driven by the finalization of the federal research and development credits generated during 2023 that were carried back to tax year 2022. The Company's net loss before income taxes consists solely of domestic losses in each of 2025 and 2024. As of December 31, 2024, Cullinan had recorded $3.0 million within prepaid expenses and other current assets on its consolidated balance sheets for the Company's tentative refund from the carryback of 2023 federal research and development credits to tax year 2022.

During 2025, Cullinan was refunded $3.0 million for federal income taxes from the carryback of 2023 federal research and development credits to tax year 2022. During 2024, Cullinan paid $1.6 million for federal income taxes due to a refund payment from the Internal Revenue Service (the "IRS") that was in excess of the Company's 2022 federal refund claim and was refunded $3.9 million for Massachusetts state income taxes from 2022 state refund claims.

A reconciliation of the Company's statutory income tax rate to its effective income tax rate in 2025 and 2024 is as follows:

| | 2025 | | 2024 | |
|---|---|---|---|---|
| | Amount | Percentage | Amount | Percentage |
| Federal statutory tax rate | $ (46,175) | 21.00% | $ (35,313) | 21.00% |
| State and local income taxes, net of federal income tax effect[1] | — | —% | 2,132 | (1.27)% |
| Research and development credits | (3,342) | 1.52% | (3,700) | 2.20% |
| Nontaxable or nondeductible items | | | | |
| Other | 2,174 | (0.99)% | 1,427 | (0.85)% |
| Other adjustments | 13,870 | (6.31)% | 2,130 | (1.26)% |
| Valuation allowance | 33,473 | (15.22)% | 33,441 | (19.89)% |
| Effective tax rate | $ — | —% | $ 117 | (0.07)% |

(1) Massachusetts makes up the majority (greater than 50 percent) of the State taxes, net of federal benefit category.

As of December 31, 2025 and 2024, the net deferred income tax asset balance related to the following (in thousands):

| | December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Deferred tax assets: | | |
| Net operating losses | $ 85,763 | $ 32,148 |
| Capitalized research and development | 57,378 | 65,606 |
| Research and development credits | 11,414 | 6,970 |
| Equity-based compensation | 9,562 | 21,035 |
| Licenses | 5,723 | 694 |
| Accrued expenses | 2,280 | 2,699 |
| Basis difference on gain on 2022 sale of zipalertinib development subsidiary | 1,638 | 1,700 |
| Lease liability | 709 | 590 |
| Capitalized organizational and start-up expenses | 83 | 101 |
| Gross deferred tax assets | 174,550 | 131,543 |
| Valuation allowance | (173,785) | (130,939) |
| Net deferred tax asset | 765 | 604 |
| Deferred tax liability | | |
| ROU asset | 695 | 457 |
| Depreciation and amortization | 70 | 147 |
| Net deferred tax asset | $ — | $ — |

The Company's net operating loss ("NOL") and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service ("IRS") and state tax authorities. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, as well as similar state provisions, NOL and tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50%. The rules generally operate by focusing on changes in ownership among stockholders considered by the rules as owning, directly or indirectly, 5% or more of the stock of a company and any change in ownership arising from new issuances of stock by the company.

As of December 31, 2025 and 2024, the Company had federal NOL carryforwards, of $312.6 million and $125.3 million, respectively, which may be available to offset future income tax liabilities. As of December 31, 2025, $311.2 million of Cullinan's federal NOL carryforwards can be carried forward indefinitely, and the remaining $1.4 million expires in 2037. As of December 31, 2025 and 2024, the Company had state NOL carryforwards of $317.7 million and $128.2 million, respectively, which may be available to offset future income tax liabilities. As of December 31, 2025, Cullinan's state NOL carryforwards begin to expire in 2031.

As of December 31, 2025 and 2024, the Company had federal research and development tax credit carryforwards of $8.7 million and $5.4 million, respectively. As of December 31, 2025, Cullinan’s federal research and development tax credit carryforwards begin to expire in 2036. As of each of December 31, 2025 and 2024, the Company had state research and development tax credit carryforwards of $2.7 million and $2.0 million, respectively. As of December 31, 2025, $0.3 million of Cullinan's state research and development tax credit carryforwards can be carried forward indefinitely, and the remaining $2.4 million expires beginning in 2036.

Cullinan has evaluated the positive and negative evidence bearing upon its ability to realize the deferred tax assets, which primarily consist of capitalized research and development costs, temporary differences on equity-based compensation, and NOL carryforwards. The Company has considered its history of cumulative net losses, estimated future taxable income and prudent and feasible tax planning strategies and has concluded that it is more likely than not that Cullinan will not realize the benefits of its deferred tax assets. As a result, as of December 31, 2025, the Company has maintained a full valuation allowance against its remaining net deferred tax assets.

Cullinan’s valuation allowance increased in 2025 primarily due to the valuation allowance on NOLs generated during the year and in 2024 primarily due to the valuation allowance on capitalized research and development costs and NOLs generated during the year. The following table summarizes activity in Cullinan’s valuation allowance during 2025 and 2024 (in thousands):

| | 2025 | 2024 |
|---|---|---|
| Valuation allowance at beginning of year | $ 130,939 | $ 87,371 |
| Increases recorded to income tax provision | 42,846 | 43,568 |
| Increases (decreases) recorded to equity | — | — |
| Valuation allowance at end of year | $ 173,785 | $ 130,939 |

The calculation of the Company's tax liabilities involves dealing with uncertainties in the application of complex tax laws and regulations for both federal taxes and the states in which Cullinan operates or does business in.

The Company recognizes a tax benefit from an uncertain tax position when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, on the basis of the technical merits. Cullinan records uncertain tax positions as liabilities and adjusts these liabilities when its judgment changes as a result of the evaluation of new information not previously available. Due to the complexity of some of these uncertainties, the ultimate resolution may result in a payment that is materially different from the Company's current estimate of the unrecognized tax benefit liabilities. These differences will be reflected as increases or decreases to income tax expense in the period in which new information is available. As of December 31, 2025 and 2024, Cullinan has not recorded a liability for any uncertain tax positions in its consolidated financial statements.

The Company recognizes interest and penalties related to unrecognized tax benefits on the income tax expense line in the accompanying consolidated statements of operations and comprehensive income (loss). As of December 31, 2025 and 2024, no accrued interest or penalties are included in the consolidated balance sheets.

Cullinan files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions in the U.S. There are currently no pending tax examinations. Cullinan's federal and state income tax returns are generally subject to tax examinations for tax years 2022 and later. To the extent that the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the IRS and the state tax authorities to the extent utilized in a future period.

## (11) Commitments and Contingencies

The Company enters into contracts in the normal course of business with contract research organizations, contract manufacturing organizations, and other third parties for preclinical research studies, clinical trials and testing and manufacturing services. These agreements generally include cancellation clauses.

***Indemnification Agreements***

In the ordinary course of business, Cullinan may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors and executive officers that will require Cullinan, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in certain cases, unlimited. To date, Cullinan has not incurred any material costs as a result of such indemnifications. The Company is not aware of any indemnification arrangements that could have a material effect on its financial position, results of operations or cash flows, and it has not accrued any liabilities related to such obligations in its consolidated financial statements as of December 31, 2025 and 2024.

***Legal Proceedings***

Cullinan is not currently party to, or aware of, any material legal proceedings. At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. Cullinan expenses as incurred the costs related to such legal proceedings.

## (12) Leases

Cullinan has an operating lease for approximately 14,000 square feet of office space in a multi-tenant building in Cambridge, Massachusetts, which commenced in August 2022 and was scheduled to expire in July 2026. In October 2025, Cullinan extended its operating lease through September 2028. Cullinan determined that the lease extension constituted a modification of the existing lease, which required remeasurement of the lease liability and a corresponding adjustment to the right-of-use-asset. Lease expense consisted of operating lease costs of $1.2 million for each of 2025 and 2024.

The following table summarizes supplemental cash flow information for 2025 and 2024 (in thousands):

| | 2025 | 2024 |
|---|---|---|
| Cash paid for amounts included in measurement of lease liabilities: | | |
| Operating cash flows from operating leases | $ 1,461 | $ 1,738 |
| ROU asset obtained in exchange for an operating lease liability | $ 1,797 | $ — |

The following table summarizes Cullinan's future minimum lease payments as of December 31, 2025 (in thousands):

| | December 31, 2025 |
|---|---|
| 2026 | $ 1,029 |
| 2027 | 1,190 |
| 2028 | 906 |
| Total future minimum lease payments | 3,125 |
| Less: imputed interest | (442) |
| Total lease liabilities at present value | $ 2,683 |

The following table summarizes the weighted-average lease term and discount rate as of December 31, 2025 and 2024:

| | 2025 | 2024 |
|---|---|---|
| Weighted-average remaining lease term (in years) | 2.8 | 1.6 |
| Weighted-average discount rate | 11.8% | 11.0% |

As Cullinan's operating leases did not provide an implicit rate, the Company used its incremental borrowing rate based on the information available in determining the present value of lease payments. Cullinan's incremental borrowing rate was based on the term of the lease, the economic environment and reflects the rate the Company would have had to pay to borrow on a secured basis.

**(13) Net Loss per Share Attributable to Cullinan**

The Company computes net loss per share attributable to Cullinan for its common stock and preferred stock using the two-class method required for multiple classes of common stock. The two-class method is an earnings (loss) allocation method under which earnings (loss) per share is calculated for each class of common stock.

The following table sets forth the calculation of basic and diluted net loss per share attributable to Cullinan for 2025 and 2024 (in thousands, except per share data):

| | 2025 | | 2024 | |
|---|---|---|---|---|
| | Common Stock | Preferred Stock | Common Stock | Preferred Stock |
| Numerator: | | | | |
| Net loss attributable to Cullinan - basic and diluted | $ (198,212) | $ (21,667) | $ (149,393) | $ (17,990) |
| Denominator: | | | | |
| Weighted-average shares outstanding - basic and diluted | 59,050 | 645 | 53,771 | 648 |
| Net loss per share attributable to Cullinan: | | | | |
| Basic and diluted | $ (3.36) | $ (33.57) | $ (2.78) | $ (27.78) |

Cullinan used the treasury stock method for equity awards and the if converted method for preferred stock to determine the number of dilutive shares outstanding in each period. The following table sets forth potential common shares that were excluded from the computation of diluted net loss per share attributable to common stockholders of Cullinan for 2025 and 2024 because their effect would have been anti-dilutive (in thousands):

| | 2025 | 2024 |
|---|---|---|
| Stock options | 12,958 | 8,989 |
| Preferred stock | 6,455 | 6,475 |
| RSUs | 1,644 | 292 |
| ESPP | 4 | 6 |
| Total | 21,061 | 15,762 |

**(14) Segment Reporting**

The Company operates and manages the business as one reporting and one operating segment, which is the business of developing immunology and oncology therapies. Cullinan has determined that its Chief Executive Officer is the chief operating decision maker ("CODM"). Cullinan's CODM reviews financial information on an aggregate basis and uses net loss attributable to Cullinan as presented in the consolidated statement of operations and comprehensive income (loss) for purposes of allocating resources and evaluating financial performance.

Financial information of the Company's reportable segment for 2025 and 2024 are as follows (in thousands):

| | 2025 | 2024 |
|---|---|---|
| Research and development ("R&D") programs: | | |
| CLN-049 | $ 17,088 | $ 7,508 |
| CLN-418 | — | 6,471 |
| CLN-617 | 6,778 | 4,403 |
| CLN-619 | 23,118 | 25,096 |
| CLN-978 | 23,074 | 14,833 |
| Early-stage programs | 6,286 | 5,938 |
| Velinotamig | 1,619 | — |
| Zipalertinib | 33,548 | 31,875 |
| Total R&D program expense | 111,511 | 96,124 |
| Equity-based compensation | 36,040 | 37,824 |
| R&D personnel and operations | 39,986 | 31,532 |
| General and administrative personnel | 13,572 | 14,578 |
| License agreement obligations | 20,303 | 100 |
| Other segment expenses[(1)] | 20,236 | 16,761 |
| Loss from operations | (241,648) | (196,919) |
| Other income (expense): | | |
| Interest income | 22,212 | 29,660 |
| Other income (expense), net | (443) | (199) |
| Net loss before income taxes | (219,879) | (167,458) |
| Income tax expense (benefit) | — | 117 |
| Net loss | (219,879) | (167,575) |
| Net loss attributable to noncontrolling interests | — | (192) |
| Net loss attributable to Cullinan | $ (219,879) | $ (167,383) |

(1) Other segment expenses for 2025 and 2024 include legal fees relating to patent and corporate matters; professional fees for accounting, auditing, tax, and administrative consulting services; insurance costs; marketing expenses; depreciation; and other operating costs.

All of the Company's long-lived assets were located in the U.S. as of each of December 31, 2025 and 2024. Expenditures for additions to long-lived assets included purchases of property and equipment for 2025. There were no expenditures for long-lived assets in 2024.

## EXHIBIT INDEX

| Exhibit Number | Description |
|---|---|
| 3.1 | Second Amended and Restated Certificate of Incorporation of the Registrant, as amended by the Certificate of Amendment, effective as of April 15, 2024 (incorporated by reference to Exhibit 3.1 of the Registrant's Quarterly Report on Form 10-Q filed with the SEC on May 15, 2024). |
| 3.2 | Third Amended and Restated Bylaws of the Registrant, effective as of April 15, 2024 (incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K filed with the SEC on April 16, 2024). |
| 3.3 | Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed with the SEC on January 19, 2023). |
| 4.1 | Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 of the Registrant's Registration Statement on Form S-3 (File No. 333-279452) filed with the SEC on May 16, 2024. |
| 4.2 | Registration Rights Agreement, dated January 7, 2021, among the Registrant and certain of its stockholders (incorporated by reference to Exhibit 4.2 of the Registrant's Annual Report on Form 10-K for the year ended December 31, 2020 filed with the SEC on March 30, 2021). |
| 4.3 | Description of Securities (incorporated by reference to Exhibit 4.3 of the Registrant's Annual Report on Form 10-K for the year ended December 31, 2020 filed with the SEC on March 30, 2021). |
| 4.4 | Form of Registration Rights Agreement, dated April 15, 2024, by and among the Registrant and the purchasers party thereto (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed with the SEC on April 16, 2024). |
| 4.5 | Form of Pre-Funded Warrant (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed with the SEC on April 16, 2024). |
| 4.6 | Form of Stock Purchase Agreement, dated April 15, 2024, by and among the Registrant and the purchasers party thereto (incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed with the SEC on April 16, 2024). |
| 10.1# | 2021 Stock Option and Incentive Plan and form of award agreements thereunder (incorporated by reference to Exhibit 10.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-251512) filed with the SEC on January 4, 2021). |
| 10.2# | 2021 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.2 of the Registrant's Registration Statement on Form S-1 (File No. 333-251512) filed with the SEC on January 4, 2021). |
| 10.3# | Senior Executive Cash Incentive Bonus Plan (incorporated by reference to Exhibit 10.3 of the Registrant's Registration Statement on Form S-1 (File No. 333-251512) filed with the SEC on December 18, 2020). |
| 10.4# | Form of Indemnification Agreement, between the Registrant and each of its directors (incorporated by reference to Exhibit 10.4 of the Registrant's Registration Statement on Form S-1 (File No. 333-251512) filed with the SEC on December 18, 2020). |
| 10.5# | Form of Indemnification Agreement, between the Registrant and each of its executive officers (incorporated by reference to Exhibit 10.5 of the Registrant's Registration Statement on Form S-1 (File No. 333-251512) filed with the SEC on December 18, 2020). |

| | |
|---|---|
| 10.6† | Exclusive Patent License Agreement, dated December 12, 2019, as amended on April 3, 2020, by and between Massachusetts Institute of Technology and Cullinan Amber Corp. (incorporated by reference to Exhibit 10.6 of the Registrant's Registration Statement on Form S-1 (File No. 333-251512) filed with the SEC on December 18, 2020). |
| 10.7† | Collaboration Agreement, dated November 28, 2018, by and between Adimab, LLC and the Registrant (incorporated by reference to Exhibit 10.7 of the Registrant's Registration Statement on Form S-1 (File No. 333-251512) filed with the SEC on December 18, 2020). |
| 10.8† | Amendment One to the Collaboration Agreement, dated April 30, 2024, by and between Adimab, LLC and the Registrant (incorporated by reference to Exhibit 10.8 of the Registrant's Annual Report on Form 10-K filed with the SEC on February 27, 2025). |
| 10.9† | Amendment Two to the Collaboration Agreement, dated July 11, 2024, by and between Adimab, LLC and the Registrant (incorporated by reference to Exhibit 10.8 of the Registrant's Annual Report on Form 10-K filed with the SEC on February 27, 2025). |
| 10.10† | Amendment Three to the Collaboration Agreement, dated July 11, 2024, by and between Adimab, LLC and the Registrant. (incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q filed with the SEC on May 8, 2025). |
| 10.11† | Share Purchase Agreement, dated May 11, 2022, by and among the Registrant, Taiho Pharmaceutical Co. Ltd. and Cullinan Pearl Corp. (incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q filed with the SEC on August 10, 2022). |
| 10.12† | Co-Development Agreement, dated June 21, 2022, by and between the Registrant and Taiho Oncology, Inc. (incorporated by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q filed with the SEC on August 10, 2022). |
| 10.13† | Exclusive License Agreement, dated August 31, 2020, by and among Deutches Krebsforschungszentrum, Eberhard Karls University of Tuebingen, Faculty of Medicine, Universitatsmedizin Gesellschaft fur Forschung und Entwicklung mbH, Tubingen and Cullinan Florentine Corp. (incorporated by reference to Exhibit 10.9 of the Registrant's Registration Statement on Form S-1 (File No. 333-251512) filed with the SEC on December 18, 2020). |
| 10.14# | Form of Executive Employment Agreement (incorporated by reference to Exhibit 10.13 of the Registrant's Registration Statement on Form S-1 (File No. 333-251512) filed with the SEC on December 18, 2020). |
| 10.15 | Form of Voting Agreement (incorporated by reference to Exhibit 10.18 of the Registrant's Registration Statement on Form S-1 (File No. 333-251512) filed with the SEC on December 18, 2020). |
| 10.16 | Form of Investors Rights Agreement (incorporated by reference to Exhibit 10.19 of the Registrant's Registration Statement on Form S-1 (File No. 333-251512) filed with the SEC on December 18, 2020). |
| 10.17 | Form of Services Agreement (incorporated by reference to Exhibit 10.20 of the Registrant's Registration Statement on Form S-1 (File No. 333-251512) filed with the SEC on December 18, 2020). |
| 10.18 | Form of Royalty Transfer Agreements (incorporated by reference to Exhibit 10.21 of the Registrant's Registration Statement on Form S-1 (File No. 333-251512) filed with the SEC on December 18, 2020). |
| 10.19 | Form of Contribution Agreement (incorporated by reference to Exhibit 10.22 of the Registrant's Registration Statement on Form S-1 (File No. 333-251512) filed with the SEC on January 4, 2021). |
| 10.20#* | Non-Employee Director Compensation Policy. |

| | |
|---|---|
| 10.21# | Employment Agreement, effective February 28, 2022, between the Registrant and Jeffrey Jones (incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed with the SEC on March 3, 2022). |
| 10.22# | Performance Stock Unit Award Agreement, dated June 9, 2022, by and between the Registrant and Nadim Ahmed (incorporated by reference to Exhibit 10.3 of the Registrant's Current Report on Form 10-Q filed with the SEC on August 10, 2022). |
| 10.23 | Form of Stock Purchase and Transfer Agreement for Institutional Transferors (incorporated by reference to Exhibit 10.24 of the Registrant's Annual Report on Form 10-K filed with the SEC on March 9, 2023). |
| 10.24 | Form of Stock Purchase and Transfer Agreement for Individual Transferors (incorporated by reference to Exhibit 10.25 of the Registrant's Annual Report on Form 10-K filed with the SEC on March 9, 2023). |
| 10.25† | Second Amendment to Exclusive Patent License Agreement, dated December 20, 2022, by and between the Massachusetts Institute of Technology and Cullinan Amber Corp. (incorporated by reference to Exhibit 10.26 of the Registrant's Annual Report on Form 10-K filed with the SEC on March 9, 2023). |
| 10.26 | Amendment Number 1 to Royalty Transfer Agreement, dated June 6, 2022, by and among the Registrant, MPM Oncology Charitable Foundation, Inc., and the UBS Optimus Foundation (incorporated by reference to Exhibit 10.27 of the Registrant's Annual Report on Form 10-K filed with the SEC on March 9, 2023). |
| 10.27 | Exchange Agreement, dated January 17, 2023, by and among the Registrant and the Stockholders named therein (incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed with the SEC on January 19, 2023). |
| 10.28† | License and Collaboration Agreement, dated February 13, 2023, by and between the Registrant and Harbour BioMed US Inc. (incorporated by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q filed with the SEC on May 11, 2023). |
| 10.29 | Sales Agreement by and between the Registrant and Cowen and Company, LLC, dated as of May 11, 2023 (incorporated by reference to Exhibit 1.2 of the Registrant's Registration Statement on Form S-3 filed with the SEC on May 11, 2023). |
| 10.30# | Employment Agreement, effective as of October 18, 2021, by and between the Registrant and Nadim Ahmed (incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed with the SEC on October 18, 2021). |
| 10.31# | Amendment No. 1 to Employment Agreement, by and between the Registrant and Nadim Ahmed (incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 8, 2023). |
| 10.32 | Form of Restricted Stock Unit Award Agreement (incorporated by reference to Exhibit 10.32 of the Registrant's Annual Report on Form 10-K filed with the SEC on March 14, 2024). |
| 10.33# | Employment Agreement, effective April 29, 2024, by and between the Registrant and Mary Kay Fenton (incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed with the SEC on April 29, 2024). |
| 10.34† | Third Amendment to Exclusive Patent License Agreement, dated December 20, 2023, by and between the Massachusetts Institute of Technology and Cullinan Amber Corp (incorporated by reference to Exhibit 10.34 of the Registrant's Annual Report on Form 10-K filed with the SEC on February 27, 2025). |
| 10.35† | License Agreement, dated as of June 4, 2025, by and between Cullinan Therapeutics, Inc. and Chongqing Genrix Biopharmaceutical Co., Ltd. (incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q filed with the SEC on August 7, 2025). |

| | |
|---|---|
| 19.1* | Insider Trading Policy. |
| 21.1* | List of Subsidiaries of the Registrant. |
| 23.1* | Consent of KPMG LLP, the Registrant's 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 and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 97.1 | Policy for Recoupment of Incentive Compensation (incorporated by reference to Exhibit 97.1 of the Registrant's Annual Report on Form 10-K filed with the SEC on March 14, 2024). |
| 101.INS | Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document) |
| 101.SCH | Inline XBRL Taxonomy Extension Schema Document With Embedded Linkbase Documents |
| 104 | Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101) |

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* Filed herewith.
** Furnished herewith.
# Indicates a management contract or compensatory plan, contract or arrangement.
† Portions of this exhibit (indicated by asterisks) have been omitted because the Registrant has determined they are not material and would likely cause competitive harm to the Registrant if publicly disclosed.

## SIGNATURES

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

**Cullinan Therapeutics, Inc.**

Date: March 10, 2026

By: /s/ Nadim Ahmed
Name: Nadim Ahmed
Title: President and Chief Executive Officer

## POWER OF ATTORNEY

Each person whose individual signature appears below hereby authorizes and appoints Nadim Ahmed and Mary Kay Fenton, and each of them, with full power of substitution and resubstitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this annual report on Form 10-K and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his substitute or substitutes may lawfully do or cause to be done by virtue thereof.

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/ Nadim Ahmed<br>**Nadim Ahmed** | President, Chief Executive Officer and Director (Principal Executive Officer) | March 10, 2026 |
| /s/ Mary Kay Fenton<br>**Mary Kay Fenton** | Chief Financial Officer (Principal Financial and Accounting Officer) | March 10, 2026 |
| /s/ Andrew Allen, M.D., Ph.D.<br>**Andrew Allen, M.D., Ph.D.** | Director | March 10, 2026 |
| /s/ Mittie Doyle, M.D., FACR<br>**Mittie Doyle, M.D., FACR** | Director | March 10, 2026 |
| /s/ David Meek<br>**David Meek** | Director | March 10, 2026 |
| /s/ Anthony Rosenberg<br>**Anthony Rosenberg** | Director | March 10, 2026 |
| /s/ Mary Thistle<br>**Mary Thistle** | Director | March 10, 2026 |
| /s/ Stephen Webster<br>**Stephen Webster** | Director | March 10, 2026 |