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, 2022

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 ONCOLOGY, 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 **Suite 1350** **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 stock held by non-affiliates of the Registrant as of June 30, 2022 was $375.6 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 March 1, 2023 was 39,327,298.

The number of shares of the Registrant's preferred stock outstanding as of March 1, 2023 was 647,500, which are excluded from the above aggregate market value. Each share of the preferred stock will be convertible into 10 shares of common stock at the option of the holder at any time, subject to certain limitations, including that the holder will be 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. Shares of preferred stock will 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. The Preferred Stock ranks (i) senior to any class or series of capital stock of the Company hereafter 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 the Company 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.

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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 (the "Exchange Act") 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 Exchange Commission (the "SEC"), including the following:

- the success, cost and timing of our clinical-stage product candidates, including zipalertinib (CLN-081/TAS6417), CLN-049, CLN-619, CLN-418, and CLN-978;
- the initiation, timing, progress, results and cost of our research and development programs and our current and future preclinical and clinical studies, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available, and our research and development programs;
- 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;
- our ability to compete with companies currently marketing or engaged in the development of treatments that our product candidates are designed to target;
- 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 oncology diseases and any of our current product candidates or other product candidates we may identify and pursue, 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 product candidates and any other product candidates we may identify and pursue, if approved, including our ability to successfully build a specialty sales force and commercial infrastructure to market our current product candidates and any other product candidates we may identify and pursue;
- our ability to identify research priorities and apply a risk-mitigated strategy to efficiently discover and develop 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 and reimbursement;
- our estimates of our expenses, ongoing losses, capital requirements and our needs for or ability to obtain additional financing;
- the milestone payments that we may receive from Taiho Pharmaceutical Co., Ltd.;
- the anticipated development and commercialization of zipalertinib;
- the development of our commercial infrastructure;
- potential investments in our pipeline and the potential for such product candidates;
- our cash runway;

- 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;
- our financial performance;
- developments and projections relating to our competitors or our industry; and
- the effect of the COVID-19 pandemic, including mitigation efforts and economic effects, on any of the foregoing or other aspects of our business operations, including but not limited to our preclinical studies and future clinical trials.

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.

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, zipalertinib, CLN-049, CLN-619, and CLN-418. If we are unable to advance these or any of our other 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 will be materially harmed.
- Difficulty in enrolling patients 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 product candidates and identify and invest in new 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.
- Our subsidiaries are party to certain agreements that provide our licensors, collaborators, or other shareholders in our subsidiaries with rights that could delay or impact the potential sale of our subsidiaries or could impact the ability of our subsidiaries to sell assets, or enter into strategic alliances, collaborations, or licensing arrangements with other third parties.
- Our ability to realize value from our subsidiaries may be impacted if we reduce our ownership to a minority interest or otherwise cede control to other investors through contractual agreements or otherwise.
- A single or limited number of subsidiaries may comprise a large proportion of our value.
- Our reliance on a central team consisting of 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 zipalertinib, CLN-049, CLN-619, and CLN-418 or any other 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.
- COVID-19 has and may continue to adversely impact our business.
- 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 clinical-stage biopharmaceutical company focused on modality-agnostic targeted oncology. Our strategy is to identify high-impact cancer targets and then select what we believe is the optimal therapeutic modality for those targets. We source innovation both internally and externally, focusing on product candidates with novel technology platforms or differentiated mechanisms. Before we advance a product candidate into clinical development, we evaluate its potential for anti-tumor activity as a single agent as well as its ability to generate an immune system response or to inhibit oncogenic processes. Using this strategy, we have built a broad and deep pipeline of targeted oncology programs that includes six distinct product candidates, of which five are clinical-stage, as well as multiple research and discovery programs.

Zipalertinib (CLN-081/TAS6417) which we are co-developing with an affiliate of Taiho Pharmaceutical, Co. Ltd ("Taiho"), is an orally bioavailable small-molecule, irreversible epidermal growth factor receptor ("EGFR") inhibitor that is designed to selectively target cells expressing EGFR exon 20 insertion ("EGFRex20ins") mutations with relative sparing of cells expressing wild-type EGFR. The United States Food and Drug Administration (the "FDA") has granted Breakthrough Therapy designation to zipalertinib. In the fourth quarter of 2022, in collaboration with our partners at Taiho, we initiated a pivotal Phase 2b study in patients with EGFR exon 20 non-small-cell lung cancer ("NSCLC") who progressed after prior systemic therapy. In June 2022, Taiho acquired our equity interest in our partially-owned subsidiary, Cullinan Pearl Corp. (“Cullinan Pearl”), which provided Taiho with worldwide rights to zipalertinib outside of Japan and Greater China, for an upfront payment of $275.0 million. As part of the sale, we are also eligible to receive up to an additional $130.0 million tied to EGFR exon 20 NSCLC regulatory milestones. Concurrently with the closing of the sale of our equity interest in Cullinan Pearl, we entered into a co-development and co-commercialization agreement for zipalertinib with an affiliate of Taiho, pursuant to which we will collaborate to develop zipalertinib and will retain the option to co-commercialize zipalertinib in the United States ("U.S."). Development costs for, and any future pre-tax profits from potential U.S. sales of, zipalertinib shall be shared equally between us and Taiho.

In addition to zipalertinib, our portfolio includes four other clinical-stage product candidates and one product candidate that is pending FDA clearance for its investigational new drug application ("IND"):

- CLN-049 is a FLT3/CD3 T cell engaging bispecific antibody being investigated in patients with relapsed/refractory acute myeloid leukemia ("AML") or myelodysplastic syndrome ("MDS"). CLN-049 is currently in an ongoing Phase 1 study with initial clinical data expected in mid-2023.
- CLN-619 is a monoclonal antibody that stabilizes expression of MICA/B on the tumor cell surface to promote tumor cell lysis mediated by both cytotoxic innate and adaptive immune cells. CLN-619 has broad therapeutic potential and is being investigated as both monotherapy and in combination with checkpoint inhibitor therapy in an ongoing Phase 1 study in patients with advanced solid tumors with initial clinical data expected in mid-2023.
- CLN-418 is a B7H4/4-1BB bispecific antibody that induces tumor-specific immune activation and is being investigated in an ongoing Phase 1 study in patients with advanced solid tumors with initial clinical data expected in 2024.
- CLN-978 is a CD19/CD3 T cell engaging antibody construct with a human serum albumin ("HSA") binding domain to increase serum half-life. In January 2023, the FDA cleared our IND for CLN-978. We will initially evaluate CLN-978 in a Phase 1 study for the treatment of relapsed/refractory B-cell non-Hodgkin lymphoma ("B-NHL").
- CLN-617 is a fusion protein combining two potent antitumor cytokines, interleukin-2 ("IL-2") and interleukin-12 ("IL-12") with tumor retention domains for the treatment of solid tumors. In February 2023, we filed the IND for CLN-617 and intend to initiate a Phase 1 study by the end of 2023, pending IND clearance.

In addition to the product candidates described above, we are actively developing several preclinical oncology programs, all in the discovery stage, including our collaboration with Icahn School of Medicine at Mount Sinai for the development of novel hematopoietic progenitor kinase 1 ("HPK1") degraders.

Our mission is to create new standards of care for patients with cancer. We seek to achieve our mission through our differentiated approach to drug development, which is guided by the following core elements:

- Rapidly advance only candidates that we believe have first- and/or best-in-class potential.

- Seek clear evidence of monotherapy activity early in preclinical and clinical development, which we believe will de-risk later stage drug development.
- Innovate without borders: Remain open to finding what we believe are the optimal modalities and drug candidates either through in-house discovery or through licensing and collaborations.

Our Pipeline

Our pipeline includes oncology product candidates and programs that are diversified by target, mechanism, technology platform, and modality. We rigorously assess each of our programs to justify continued investment and determine proper capital allocation. When certain programs do not meet our de-risking criteria for advancement, we terminate those programs and preserve our capital and resources to invest in programs with greater potential. As a result, our pipeline will continue to be dynamic. We believe that each program candidate has differentiating design features or mechanisms of action, as well as first- and/or best-in-class potential. Our current pipeline is summarized in the diagram below:

Our Business Strategy and Objectives

Our strategic focus is on what we call "modality-agnostic targeted oncology": We first identify high-impact cancer targets and then select what we believe is the optimal therapeutic modality for those targets. As a result, we are not dependent upon a singular technological platform or product. We define "high-impact" biological targets as those that play key roles as either oncogenic drivers or immune system activators. From there, we advance only molecules that we believe have first- and/or best-in-class potential and that can generate a robust anti-tumor response as a single agent *in vivo*. Through this disciplined approach, we believe we will bring forward differentiated molecules with the potential to create new standards of care for patients with cancer. Key objectives we aim to achieve with our strategy are as follows:

- **Advance zipalertinib, which we are co-developing with an affiliate of Taiho, toward potential regulatory approval for the targeted treatment of NSCLC patients with EGFRex20ins mutations.** In the fourth quarter of 2022, in collaboration with our partners at Taiho, we initiated a pivotal study of zipalertinib in EGFR exon 20 NSCLC patients who progressed after prior systemic therapy. In collaboration with Taiho, we also intend to initiate a pivotal study of zipalertinib for the first line treatment of patients with metastatic or locally advanced disease. We intend to continue leveraging zipalertinib's Breakthrough Therapy designation to support our ongoing development activity and future interactions with the FDA.

- **Advance CLN-049, CLN-619, and CLN-418, which are all being evaluated in ongoing clinical studies, through late-stage clinical development.** We believe these molecules are representative of our modality-agnostic, targeted approach to oncology drug discovery and development. For example, each candidate is designed to engage with important targets found in the tumor microenvironment: CLN-049 targets FLT3, a known oncogenic driver on AML cells, and CD3 on T cells in order to direct cell-mediated lysis of tumor cells; CLN-619 targets MICA/B, which are ligands expressed on tumor cells, in order to restore immune recognition and lysis of tumor cells via multiple mechanisms of action; finally, CLN-418 is a bispecific antibody designed to deliver conditional activation of 4-1BB by targeting B7H4, an antigen expressed on tumor cells. FLT3, MICA/B and B7H4 all have relatively higher expression on tumor cells compared to healthy cells, potentially allowing for a wide therapeutic window and limiting on-target, off-tumor toxicity. Furthermore, each target's expression profile identifies what we believe is potentially a large addressable patient population: both MICA/B and B7H4 are expressed in a broad range of tumor types, and FLT3, whether mutant or wild-type, is expressed on approximately 80% of AML cells. We intend to provide a clinical update for CLN-049 and CLN-619 in mid-2023 and for CLN-418 in 2024.
- **Continue to advance our pipeline through our rigorous and differentiated approach to drug development.** In addition to the programs listed above, we are advancing two candidates that are both designed to address limitations of approved oncology therapies. CLN-978 is a half-life extended, humanized, single-chain T cell engaging antibody that we believe has the potential to improve on some of the limitations of the approved CD3/CD19 bispecific T cell engager, blinatumomab, and to compete with CD19-targeted CAR-T cell therapies. In January 2023, the FDA cleared our IND for CLN-978. We believe the second candidate, CLN-617, is the only single agent immunotherapy in development combining IL-2 and IL-12 with a collagen-binding domain to enhance retention of cytokines within the tumor microenvironment. In February 2023, we filed the IND for CLN-617 and intend to initiate a Phase 1 study by the end of 2023, pending IND clearance.
- **Expand our pipeline through research collaborations, business development, and internally designed programs.** Our management team is comprised of leaders in oncology drug discovery, clinical development, and commercial operations. Their proven track records and longstanding relationships in the life sciences industry provide us with access to programs from around the world, including zipalertinib, CLN-049, CLN-619, and CLN-418, each of which were sourced externally. In addition, their experiences and deep understanding of molecular oncology and cancer immunotherapy also enable us to translate novel concepts into internally designed product candidates, such as CLN-978, or those that contain both internal and externally sourced innovation, such as CLN-617. We are evaluating both external and internal opportunities to continue to expand our pipeline, while balancing the desire to maintain ample cash runway beyond key program milestones.

Our Structure

We are developing product candidates through Cullinan Oncology, Inc. ("Cullinan") and through established development subsidiaries that we have created. Cullinan holds U.S. co-development and co-commercialization rights to zipalertinib, as well as U.S. rights to CLN-418, and worldwide rights to CLN-978. Previously, we established development subsidiaries when we licensed or acquired exclusive worldwide rights to intellectual property for several of our drug candidates, including Cullinan Florentine Corp. ("Cullinan Florentine") for CLN-049, Cullinan MICA Corp. ("Cullinan MICA") for CLN-619, and Cullinan Amber Corp. ("Cullinan Amber") for CLN-617. Cullinan currently owns 96% of Cullinan Florentine, 95% of Cullinan Mica, and 94% of Cullinan Amber. The structure of our financing arrangements with each subsidiary enables us to increase our economic ownership when we provide additional capital.

We historically created development subsidiaries as a private company in order to grow and advance our portfolio efficiently. As a publicly held company, we do not intend to create new development subsidiaries in the future. Further information about our subsidiaries, including ownership and governance, is included in the "Management's Discussion and Analysis" section of this Annual Report on Form 10-K.

Our Programs

Zipalertinib

Overview

Zipalertinib is an orally bioavailable small-molecule designed as a next generation, irreversible EGFR inhibitor being developed in collaboration with an affiliate of Taiho for the treatment of a genetically defined subset of patients with NSCLC. In January 2022, the FDA granted Breakthrough Therapy designation to zipalertinib and in November 2022, in collaboration with our partners at Taiho, we initiated a pivotal Phase 2b trial evaluating zipalertinib in adult NSCLC patients with EGFRex20ins mutations who progressed after prior systemic therapy. We have a co-development and co-commercialization agreement for zipalertinib with an affiliate of Taiho, pursuant to which we will collaborate to develop zipalertinib and will retain the option to co-commercialize zipalertinib in the U.S. Development costs for zipalertinib shall be shared equally between us and Taiho with each party receiving 50% of any future pre-tax profits from potential U.S. sales of zipalertinib.

In June 2022, we provided a clinical update at the American Society for Clinical Oncology meeting that included safety and efficacy data from 73 evaluable NSCLC patients with EGFRex20ins mutations enrolled in a Phase 1/2a trial across five dose levels, ranging from 30 to 150 milligrams ("mg") twice daily. At the 100 mg twice-daily dose, we observed the following efficacy and safety highlights, which we believe reflect zipalertinib's differentiated clinical profile:

- 16 of 39 (41%) response evaluable patients achieved a confirmed partial response.
- 38 of 39 (97%) response evaluable patients achieved a best response of partial response or stable disease.
- The median progression-free survival ("PFS") was 12 months.
- No Grade 3 or greater treatment-related adverse events ("TRAEs") of rash or diarrhea, which are associated with EGFR tyrosine kinase inhibitor ("TKI") therapies.

Background on NSCLC and EGFR mutations

Lung cancer is by far the leading cause of cancer deaths among both men and women, comprising almost 25% of all cancer deaths. The American Cancer Society estimated that in 2023, there will be approximately 238,340 new cases of lung cancer and approximately 127,070 deaths from lung cancer in the U.S. The most common subtype of lung cancer is NSCLC, which represents approximately 80% to 85% of all lung cancers.

EGFR is a receptor tyrosine kinase ("RTK"), that normally functions to trigger cell division when growth factors bind to the receptor. Oncogenic mutations in the tyrosine kinase domain can induce growth factor-independent activation of EGFR, resulting in uncontrolled cell growth and proliferation. Ultimately, these aberrant signals can contribute to the development of NSCLC. EGFR mutations are present in approximately 15% to 25% of U.S. and Western European NSCLC patients and approximately 30% to 50% of Asian NSCLC patients. Given its important role and prevalence in cancer, mutant EGFR is a critical target in lung cancer therapy. Exon 19 deletion and exon 21 L858R substitution mutations, collectively referred to as classical EGFR mutations, are the most common and account for over 75% of EGFR mutations in NSCLC. Multiple EGFR inhibitors, including gefitinib, erlotinib, afatinib, and osimertinib, target these common mutations and have been approved as first-line therapies, thus validating mutant EGFR as a target for the treatment of NSCLC.

Exon 20 insertions, which account for 7% to 13% of all EGFR mutations in NSCLC patients, are the most prevalent after the classical EGFR mutations. We estimate an incidence of approximately 2,000 to 5,000 NSCLC patients in the U.S. and approximately 1,000 to 3,000 patients in France, Germany, Italy, Spain, and the United Kingdom (the "UK") with EGFRex20ins mutations. Preclinical studies have shown that exon 20 insertions, as well as classical EGFR mutations, have the characteristics of oncogenic driver mutations, which are responsible for both tumorigenesis and the progression of cancer. However, in contrast to classical EGFR mutations, exon 20 insertions do not sensitize the kinase domain to treatment with approved EGFR inhibitors.

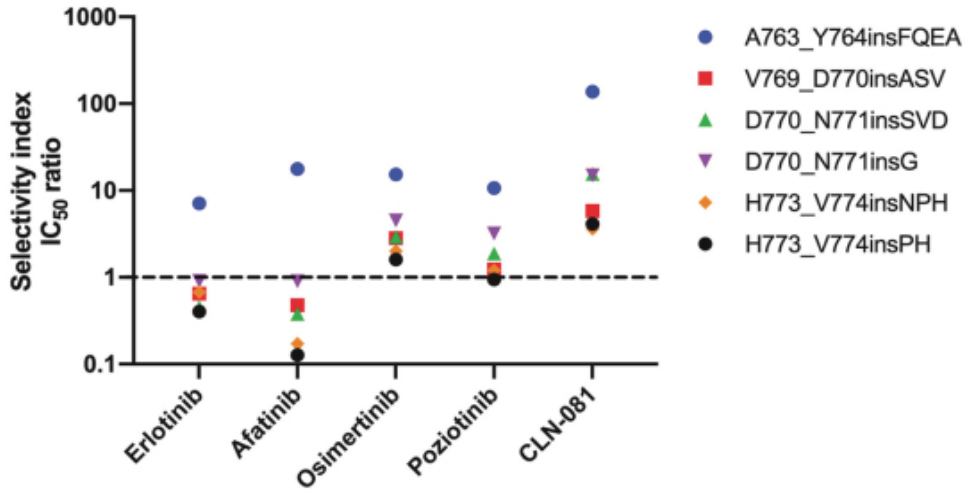
Currently, there are two targeted therapies with accelerated approval for NSCLC patients with EGFRex20ins mutations whose disease has progressed on or after platinum-based chemotherapy: amivantamab-vmjw (Rybrevant) and mobocertinib (Exkivity). Despite these accelerated approvals, we believe significant unmet need remains for NSCLC patients with EGFRex20ins mutations. Specifically, we believe there is an opportunity for an oral therapy with strong selectivity for mutant versus wild-type EGFR, which could potentially lead to an improved safety and tolerability profile, especially with respect to treatment-related adverse events such as rash, diarrhea, and infusion site reactions, as well as cardiovascular events.

Zipalertinib

Zipalertinib is a small molecule that was designed as an irreversible EGFR inhibitor with a novel pyrrolopyrimidine scaffold, which is unique among the therapies in development that are targeting EGFRex20ins mutations. 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. In preclinical studies, zipalertinib demonstrated high selectivity and inhibition of EGFR in cells expressing mutant EGFR proteins, with substantially less inhibition in cells expressing wild-type EGFR.

The selectivity index of zipalertinib versus competing EGFR inhibitors was evaluated *in vitro* as measured by the ratio of the half-maximal growth inhibition ("IC50") value of cells expressing wild-type EGFR versus cells expressing exon 20 insertion mutant EGFR. As shown below, zipalertinib demonstrated the highest selectivity index among a panel of EGFR targeted therapies, suggesting that zipalertinib may be capable of achieving clinically relevant inhibition of EGFRex20ins mutations with relative sparing of wild-type EGFR.

Zipalertinib Demonstrated Superior Selectivity Across Multiple EGFRex20ins Mutations



Clinical Development

Phase 1/2a Study

We initiated our ongoing Phase 1/2a trial of zipalertinib in the fourth quarter of 2019. This first-in-human, open-label, multi-center trial was designed to evaluate the safety and tolerability, pharmacokinetics, pharmacodynamics, and preliminary efficacy of zipalertinib in adult NSCLC patients with EGFRex20ins mutation who progressed after prior systemic therapy. The trial included two major components: dose escalation and cohort expansion. Dose escalation began with a single patient accelerated titration design and transitioned to rolling six decision rules upon the first occurrence of a Grade 2 or greater TRAE, which occurred at the 100 mg twice-daily dose level. This trial had a flexible, adaptive design that included 30, 45, 65, 100, and 150 mg twice-daily dose cohorts and allowed for expansion of any given cohort, gated by acceptable safety and pre-specified efficacy criteria. Per original protocol, cohorts could be expanded to six, then 13, then 36 patients, gated by these criteria. We expanded cohorts at the 65 mg, 100 mg, and the 150 mg twice-daily dose levels, although we subsequently discontinued enrollment at the 150 mg level after 11 patients based on assessment of the overall clinical profile at this dose level. We enrolled a total of 39 patients at the 100 mg twice-daily dose level, which includes the original protocol maximum of 36 patients plus an additional three patients that were reassigned following our decision to discontinue enrollment at the 150 mg twice-daily dose level. We enrolled patients across sites in the U.S., the Netherlands, Singapore, Hong Kong, and Taiwan.

The study enrolled a total of 73 patients who received at least one dose of zipalertinib. 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 study entry (i.e. third line of therapy or greater). Further, 36% of patients received prior treatment with an EGFR inhibitor, including 4% that received prior treatment with poziotinib or Exkivity, TKIs that target exon 20 insertion mutations. Over half (55%) of the patients received prior treatment with immunotherapy.

Phase 1/2a Safety and Pharmacokinetic Data

The following table provides a summary of treatment-related safety and tolerability events, including rash and diarrhea, which are toxicities related to inhibition of wild-type EGFR, as well as laboratory abnormalities including anemia and transaminase elevations across all twice-daily dose levels for comparison, as well as the overall safety population in our Phase 1/2a trial. We believe that this safety and tolerability profile compares favorably to other EGFR exon 20 inhibitors, in particular with respect to the incidence and severity of diarrhea.

Differentiated Safety and Tolerability Profile of Zipalertinib at 100mg Twice-Daily

Dose BID	≤65 mg (N = 23)		100 mg (N = 39)		150 mg (N = 11)		Overall (N = 73)	
AE Term, n (%)	All grade[1]	Grade ≥ 3	All grade	Grade ≥ 3	All grade	Grade ≥ 3	All grade	Grade ≥3
Rash	19 (83)	0	32 (82)	0	7 (64)	1 (9)	58 (80)	1 (1)
Paronychia	6 (26)	0	12 (31)	0	5 (45)	0	23 (32)	0
Diarrhea	4 (17)	0	14 (36)	0	4 (36)	2 (18)	22 (30)	2 (3)
Fatigue	5 (22)	0	8 (21)	0	2 (18)	0	15 (21)	0
Anemia	7 (30)	4 (17)	5 (13)	1 (3)	2 (18)	2 (18)	14 (19)	7 (10)
Dry skin	6 (26)	0	7 (18)	0	0	0	13 (18)	0
Nausea	5 (22)	0	4 (10)	0	3 (27)	0	12 (16)	0
Stomatitis	2 (9)	0	5 (13)	0	3 (27)	1 (9)	10 (14)	1 (1)
Alopecia	3 (13)	0	6 (15)	0	0	0	9 (12)	0
Dry eye	1 (4)	0	7 (18)	0	1 (9)	0	9 (12)	0
AST increased	3 (13)	1 (4)	3 (8)	1 (3)	2 (18)	1 (9)	8 (11)	3 (4)
Decreased appetite	4 (17)	0	4 (10)	0	0	0	8 (11)	0
Dose Interruptions	5 (22)		13 (33)		6 (55)		24 (33)	
Dose Reductions	2 (9)		5 (13)		3 (27)		10 (14)	
Dose Discontinuations	2 (9)		2 (5)		2 (18)		6 (8)	

[1]Common Terminology Criteria for Adverse Events v5.0

In the 39 safety-evaluable patients in the Phase 1/2a trial treated at the 100 mg twice daily dose level, none experienced Grade 3 or greater treatment-related rash or diarrhea. At this dose level, 82% and 36% of patients experienced treatment-related rash and diarrhea, respectively, of either Grade 1 or 2 severity; however, the ratio of patients who experience Grade 1 versus Grade 2 events is approximately 3:1 for both rash and diarrhea. Both events were manageable with conventional supportive care, and implementation of systematic gastrointestinal prophylaxis was not required for diarrhea management. As has been seen with other EGFR TKIs, a case of Grade 3 treatment-related pneumonitis was observed at this dose level, although the patient had recent treatment with checkpoint inhibitor therapy and the concurrent presence of a significant hydropneumothorax, not related to treatment, in the contralateral lung.

Key observations in 11 safety-evaluable patients at the 150 mg twice-daily dose level included treatment-related Grade 3 diarrhea in two patients, Grade 3 rash in one patient, and two patients with Grade 3 and Grade 4 transaminitis. In addition, one patient who was off treatment with zipalertinib for more than three weeks because of progressive disease was reported as having Grade 3 treatment-related pneumonitis; the patient had a concurrent *Pneumocystis jirovecii* infection. In addition, an increase in rates of dose reduction and dose discontinuation were observed among patients treated at the 150 mg twice-daily compared to the 100 mg twice-daily dose level. These observations informed our decision to discontinue further enrollment of patients at 150 mg twice-daily, after 11 patients.

Preliminary pharmacokinetic data demonstrated a near dose-dependent trend in exposure, as measured by unbound area under the curve ("AUC") and C_{max} values. Furthermore, the target AUC required to achieve tumor regression in preclinical studies was reached starting at the initial dose of 30 mg twice daily. Notable features of the zipalertinib pharmacokinetic profile include sustained pharmacokinetic exposure over the concentration required for 50% growth inhibition ("GI50") for EGFRex20ins mutations for eight hours post dose, limited interpatient heterogeneity, and limited exposure above the GI50 for wild-type EGFR at doses at or below 100 mg twice daily. Consistent with the clinical safety profile at 100 mg twice-daily dose compared with the 150 mg twice-daily dose, at the 150 mg twice-daily dose we observed zipalertinib concentrations above wild-type EGFR GI50 ratios for approximately four hours.

Phase 1/2a Efficacy Data

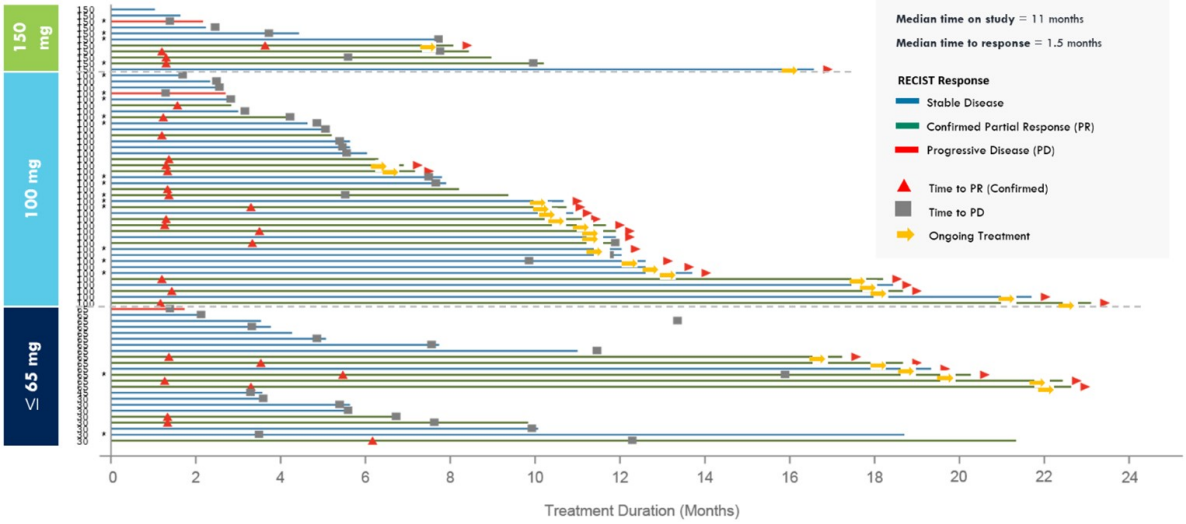
The following table summarizes best response characteristics for response-evaluable patients treated at 65mg or below (N=23), 100 mg (N=39), and 150 mg (N=11) twice-daily dose levels as well as the overall population across dose levels in aggregate (N=73) as of a May 9, 2022 data cutoff. Among patients treated at 100 mg twice daily, 16 patients achieved a confirmed partial response, indicating a 41% confirmed overall response rate ("ORR"). This confirmed ORR was higher than the 36% confirmed ORR among 11 patients at the 150 mg twice-daily dose cohort. At the 100 mg twice-daily dose cohort, median PFS was 12 months compared to a PFS of only 8 months at the 150mg twice-daily dose. As discussed above, Grade 3 or higher rash and diarrhea as well as dose reductions and dose discontinuations all favored the 100mg twice-daily dose cohort.

Zipalertinib: Superior Safety and Efficacy Observed at 100mg Twice-Daily Dose

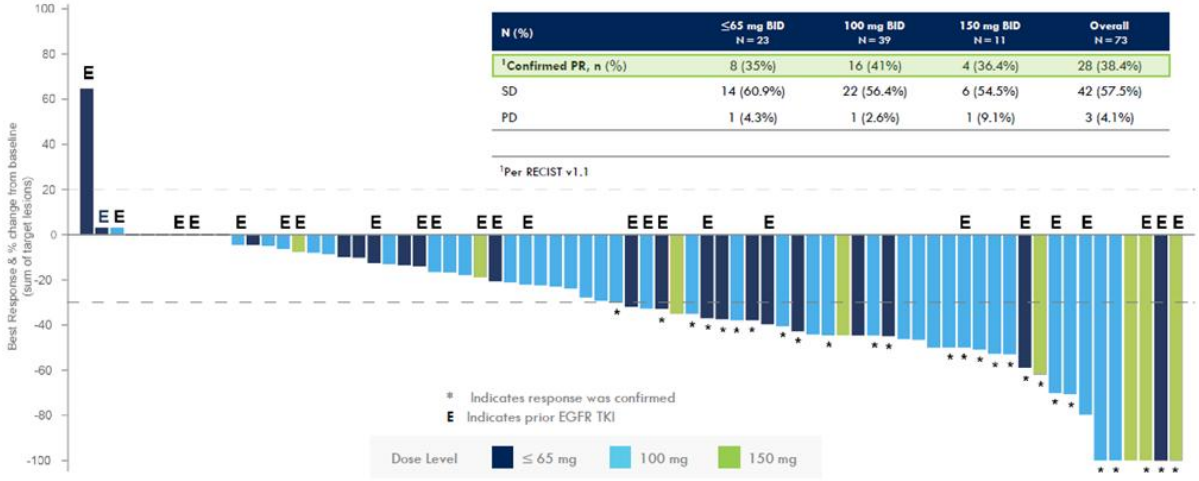
	<65 mg (N=23)	100 mg (N=39)	150 mg (N=11)	Total (N=73)
ORR	8 (35%)	16 (41%)	4 (36%)	28 (38%)
Median PFS	8 mo	12 mo	8 mo	10 mo
Gr3+ Rash	0	0	1 (9%)	1 (1%)
Gr3+ Diarrhea	0	0	2 (18%)	2 (3%)
Dose Reductions	2 (9%)	5 (13%)	3 (27%)	10 (14%)
Dose Discontinuations	2 (9%)	2 (5%)	2 (18%)	6 (8%)

Below are additional efficacy analyses for the 73 patients including a swimmer's chart (A) and a waterfall chart with percentage best change from baseline (B). We have also included a Kaplan-Meier curve showing median PFS (C). Patients in the trial have their initial tumor imaging performed after approximately six weeks of treatment, and then every nine weeks thereafter. Based on these analyses, we believe that zipalertinib has shown substantial antitumor activity with broad EGFR exon 20 variant coverage; a rapid onset of action; and encouraging response quality as measured by PFS.

(A) Preliminary Efficacy Results from Ongoing Phase 1/2a Trial of Zipalertinib



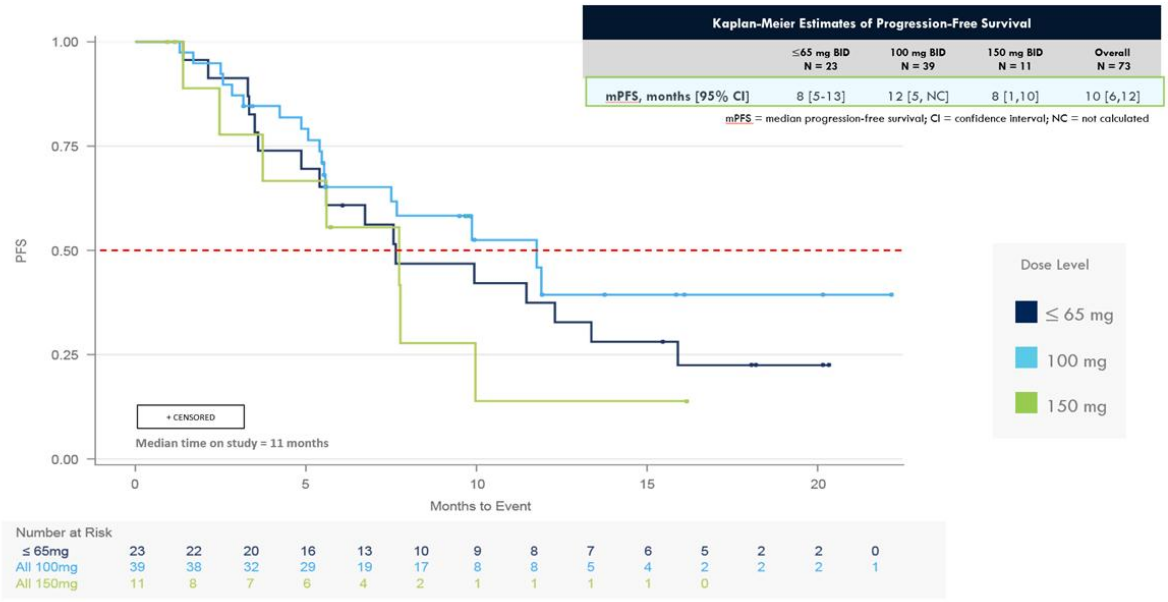
(B) Best Response % Change from Baseline (target lesion)



N (%)	≤65 mg BID N = 23	100 mg BID N = 39	150 mg BID N = 11	Overall N = 73
[1]Confirmed PR, n (%)	8 (35%)	16 (41%)	4 (36.4%)	28 (38.4%)
SD	14 (60.9%)	22 (56.4%)	6 (54.5%)	42 (57.5%)
PD	1 (4.3%)	1 (2.6%)	1 (9.1%)	3 (4.1%)

[1]Per RECIST v1.1

(C) Estimated Median Progression-Free Survival



Phase 1/2a Food Effect Study

In addition to the Phase 1/2a trial described above, in 2022 we completed a 16 patient preliminary food effect module evaluating the single-dose pharmacokinetics (PK) of a single dose of 150 mg zipalertinib in an all-comer solid tumor population. Employing a randomized cross-over design, each patient received 150 mg zipalertinib in both the fed and fasted state in order to assess the effect of taking the drug with food on exposure. The results showed that co-administering the drug with food did not meaningfully change zipalertinib exposure. Consistent with decision rules reviewed by the FDA, we will explore the safety and efficacy of the 150 mg twice-daily dose in a fed state as part of the pivotal Phase 2b portion of the study, as described below.

Pivotal Phase 2b Study

In November 2022, in collaboration with our partners at Taiho, we initiated an ongoing, pivotal Phase 2b study of zipalertinib in adult NSCLC patients with EGFRex20ins mutations who progressed after prior systemic therapy, a patient population consistent with the Phase 1/2a trial. The pivotal portion of the Phase 2b study consists of two parallel, non-randomized dosing cohorts: one cohort of patients receiving a 100 mg twice-daily dose of zipalertinib in the fasted state and a second cohort of patients receiving a 150 mg twice-daily dose of zipalertinib in the fed state. Rigorous stopping rules are being applied to the 150 mg cohort in which this dose must show superior efficacy and safety relative to the Phase 1/2a results for the 100 mg fasted dose. If the 150 mg cohort fails to show superiority on both safety and efficacy criteria, we will stop enrollment and continue enrolling patients only at the 100 mg twice-daily fasted dose. The trial protocol also includes a separate cohort intended to evaluate zipalertinib at the 100 mg fasted dose level in adult NSCLC patients with EGFRex20ins mutations who have received prior treatment with an approved exon 20 therapy.

CLN-049

Overview

CLN-049, is a humanized bispecific antibody that we are developing for the treatment of AML and MDS. We are currently evaluating CLN-049 in a multi-ascending dose trial in adult patients with relapsed or refractory AML (“r/r AML") and MDS. 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. FLT3 is a proto-oncogene and a validated target, and several kinase inhibitors targeting mutant FLT3 are approved for the treatment of r/r AML, but their use is limited to approximately 25% of the AML population with FLT3 mutations. By targeting the extracellular domain of FLT3, CLN-049 has the potential to address up to approximately 80% of AML patients that express mutant or wild-type FLT3. Preclinically, we have observed that CLN-049 led to highly potent FLT3-dependent killing of leukemic cells *in vitro* at a wide range of FLT3 expression levels on AML cells regardless of FLT3 mutational status. In preclinical studies, treatment with CLN-049, even at low doses, led to survival benefit in an AML xenograft model and elimination of leukemic blasts in mouse models implanted with AML cell lines or primary patient leukemic cells.

Background on Acute Myeloid Leukemia and FLT3

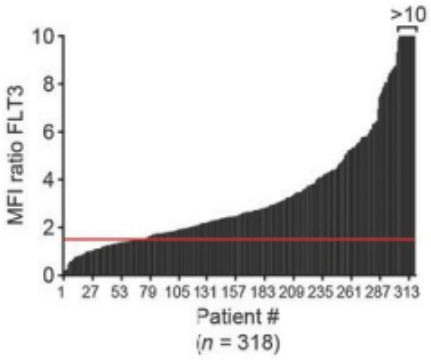
The American Cancer Society estimates that, in 2023, there will be approximately 20,380 newly diagnosed patients with AML and approximately 11,310 deaths from AML in the U.S. AML is a complex hematologic malignancy characterized by uncontrolled proliferation of malignant immature myeloid blast cell populations. These blasts may completely infiltrate and replace the bone marrow, resulting in major disruption of normal hematopoiesis and pancytopenia, very high numbers of circulating blasts in the peripheral blood, and infiltration of visceral organs as well as the skin. In addition, patients with AML may be susceptible to bleeding complications due to thrombocytopenia and experience complications from treatment with cytotoxic chemotherapy. These patients may also be severely immuno-compromised secondary to their disease and experience prolonged periods of neutropenia and lymphopenia. As a result, these patients are often susceptible to life-threatening infections that also contribute to severe morbidity and mortality.

Despite advancements in the treatment of AML, there continues to be a high unmet need in these patients. Eligible newly diagnosed patients are typically treated with intensive induction chemotherapy (“IC”), which may include continuous infusion of cytarabine with an anthracycline, in an attempt to achieve a complete remission. The majority of patients that experience complete remission undergo hematopoietic stem cell transplantation ("HSCT"). This regimen is the only currently available curative therapy for AML. However, 85% of patients over 60 years old are ineligible for IC and HSCT. Given an average age of diagnosis of 68 years old, curative therapy is not available for most AML patients. Despite aggressive first-line combination chemotherapy, the recent approvals of multiple targeted small molecules for molecularly defined AML patient subsets, and the use of HSCT in patients with a suitable matched donor, the prognosis of patients with AML remains extremely poor. Although 60% to 85% of younger adult patients achieve complete remissions, patients older than 60 years of age have inferior complete response rates of 40% to 60%. In addition, approximately 40% of all patients relapse following HSCT and approximately 10% of relapsed patients survive at least five years. Therefore, a significant unmet need remains for a broadly applicable, well-tolerated therapy that can produce high rates of durable responses.

FLT3 is a Class III RTK with a well-recognized and essential role in hematopoiesis. In healthy individuals, expression of FLT3 is restricted to a subpopulation of hematopoietic stem and progenitor cells ("HSPCs"), inducing their proliferation and differentiation into monocytes, dendritic cells, B cells, and T cells. FLT3 has been identified as a proto-oncogene and plays a key role in promoting leukemic cell proliferation and survival. Several small-molecule kinase inhibitors targeting FLT3 mutations are in development or have been approved for the treatment of AML. However, these product candidates and approved therapies only address approximately 25% of AML patients who have intracellular FLT3 genetic mutations but do not address the larger subset of patients with extracellular expression of FLT3 regardless of mutational status on the surface of cancer cells.

Studies using flow cytometry have shown that FLT3 is expressed on AML blasts in approximately 80% of AML patients, regardless of mutational status. In one study, leukemic bulk cells from 318 newly diagnosed or relapsed AML patients were evaluated for cell surface FLT3 protein expression, and 78% were found positive for FLT3, as shown in the figure below. This broad expression of FLT3 in AML patients suggests that targeting FLT3 with a biologic agent, namely a T cell engaging bispecific antibody that recruits T cells to kill tumor cells expressing FLT3 on the cell surface, could address a larger AML patient population than the targeted small-molecule inhibitors targeting the mutated version of the intracellular signaling domain of FLT3 that are approved or in development. Compared to other tumor surface antigens identified in AML, such as CD33 and CD123, FLT3 expression is generally restricted to a subpopulation of bone marrow HSPCs and circulating dendritic cells. FLT3 plays a key role in driving leukemogenesis and malignant progression of AML, promoting leukemic cell proliferation and survival. We believe that the expression of FLT3 on the surface of leukemic blasts in most AML patients and its role as a known oncogenic driver make it an attractive therapeutic target for a T cell engager approach.

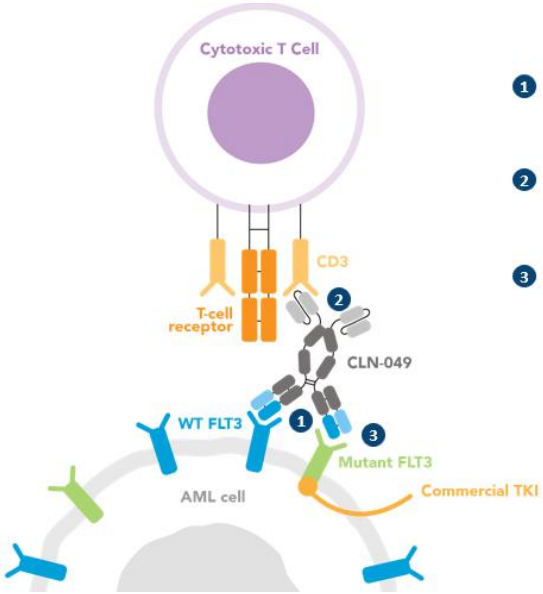
Approximately 80% of AML Patients Show Positive Cell Surface FLT3 Protein Expression



CLN-049

As shown below, CLN-049 is a humanized bispecific antibody construct comprised of two FLT3-binding domains, an Fc-silenced humanized immunoglobulin G1 ("IgG1") backbone, and CD3-binding single-chain variable fragment domains ("scFvs"), fused to the C-terminus of the antibody's heavy chain. In multiple preclinical studies, CLN-049 has demonstrated the ability to redirect T cells to lyse FLT3-expressing AML cells *in vitro* and potent antitumor activity *in vivo*. By targeting extracellular FLT3, regardless of mutant or wild-type status, we believe CLN-049 has the potential to address up to approximately 80% of AML patients, a broader patient population than existing small-molecule FLT3 kinase inhibitors acting on the intracellular domain, which are limited to a subset of approximately 25% of AML patients with FLT3 mutations.

CLN-049 Mechanism Potentially Allows for Broad FLT3 Depended AML Blast Killing

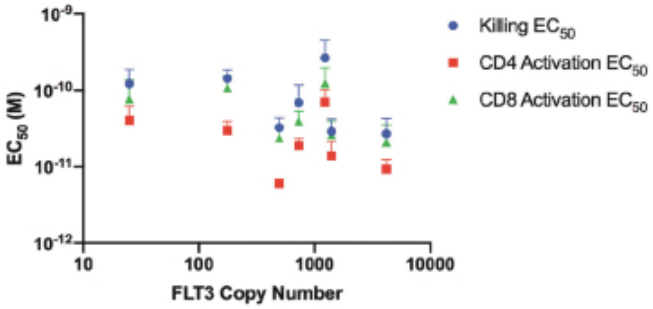


1. Redirects lysis of AML cells expressing mutant or wildtype FLT3
2. Functionally monovalent CD3 binding domains prevent T-cell activation in absence of target cells
3. Two FLT3 binding domains drives potent elimination of AML blasts even at low FLT3 expression levels

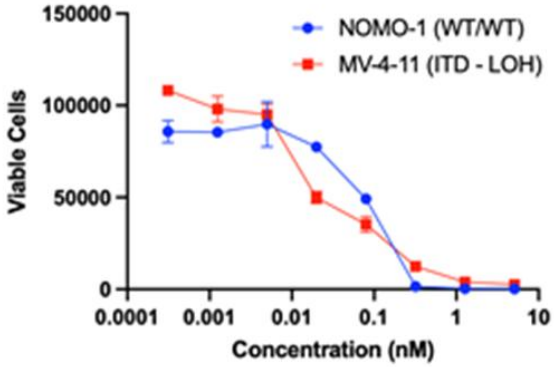
Preclinical Data

Given the observed variability in FLT3 expression levels among patients, we characterized the killing potential of CLN-049 across multiple cell lines expressing differing levels of FLT3 on the cell surface. As shown in the figures below, CLN-049 was observed to mediate robust target-dependent cell killing *in vitro* across all AML cell lines tested. Importantly, we observed that the drug concentration at which 50% of target cells are killed (the "EC50 value"), was in the sub-nanomolar range and did not seem to be dependent on the number of FLT3 receptor molecules found on AML target cells. In particular, we observed potent target cell killing even when those cells expressed fewer than 100 copies of the FLT3 receptor per cell. We also observed potent redirected lysis of AML cell lines with wild-type or mutant FLT3 expression. Based on these results, we believe CLN-049 may effectively kill AML target cells with even low levels of FLT3 expression, regardless of wild-type or mutant status, which could potentially translate into deeper and more durable responses in the clinic and may allow us to treat a larger subset of AML patients.

CLN-049 Demonstrated Killing of Target Cells Expressing a Range of FLT3, *in vitro*

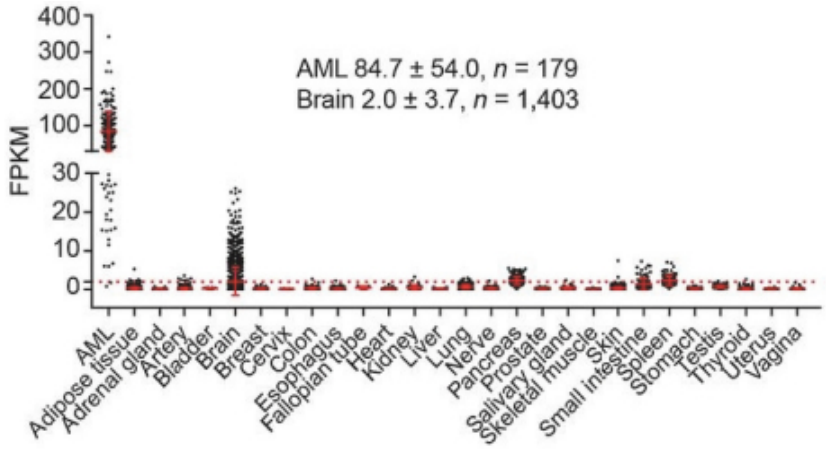


CLN-049 Demonstrated Killing of Target Cells Expressing Wild-Type and Mutant FLT3, *in vitro*



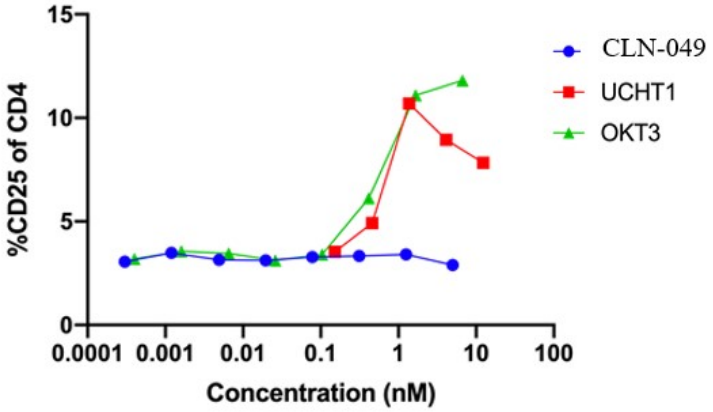
FLT3 is not widely expressed on normal immune cells, but rather is restricted to certain hematopoietic stem cell precursors in the bone marrow and dendritic cell subsets in the periphery. As shown in the figure below, a recent study found that the expression level of FLT3 transcript was significantly higher on AML cells compared to normal tissues.

FLT3 Transcript Level is Higher on AML Cells Than on Normal Human Solid Tissues



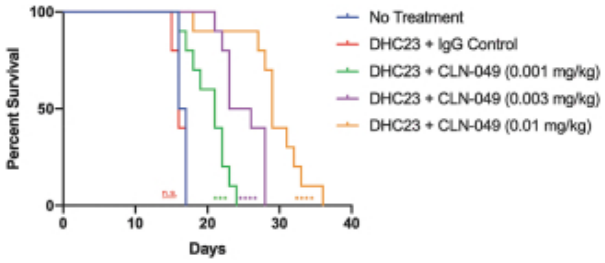
CLN-049 has two CD3-binding arms that can potentially crosslink CD3 on T cells, which may result in target cell-independent T cell activation and systemic cytokine-related toxicities. In preclinical studies, we examined whether CLN-049 can lead to spurious T cell activation in the absence of target cells. As shown below, incubation of purified human T cells with CLN-049 in the absence of target-expressing cells did not induce T cell activation markers CD25 and CD69 on either $CD4^+$ or $CD8^+$ T cells as opposed to positive control anti-CD3 antibodies OKT3 and UCHT1 (CLN-049 parental anti-CD3 antibody) that induced T cell activation.

No T Cell Activation by CLN-049 in the Absence of Target Cells



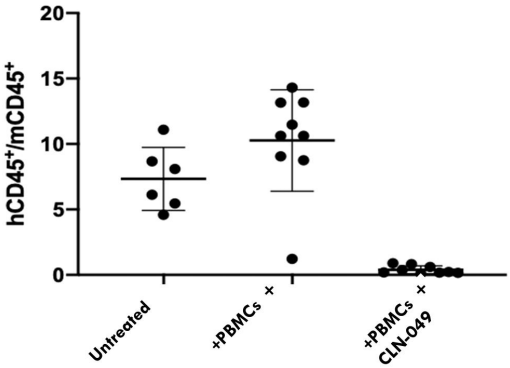
The potential efficacy of CLN-049 was evaluated in a humanized mouse model where a human AML cell line was implanted systemically. As shown in the figure below, CLN-049 controlled AML leukemic burden in mice engrafted with human peripheral blood mononuclear cells ("PBMC") and led to improved survival of the mice in a dose-dependent manner beginning at very low doses. We believe CLN-049 effected this result by redirecting the T cells in the human PBMC population to kill the target AML cells.

Increased Survival of Engrafted Mice Starting at Very Low Doses of CLN-049



The anti-leukemic activity of CLN-049 was also evaluated using patient-derived AML or acute lymphoblastic leukemia ("ALL") blasts and PBMCs in disseminated humanized mouse models. As shown in the figure below, treatment with CLN-049 resulted in a significant reduction in the overall leukemic burden in the bone marrow in both the primary AML model and the primary ALL model. In contrast, a control T cell engaging bispecific antibody having the same format as CLN-049 but containing a non-specific target-binding domain did not impact the leukemic burden as compared to untreated control.

CLN-049 Demonstrated Potent Elimination of Patient-Derived AML Blasts in Mice



Ongoing Clinical Development

In December 2021, we initiated a Phase 1 clinical trial evaluating CLN-049 in r/r AML patients. The study is designed to primarily evaluate the pharmacokinetics and safety of the administration of CLN-049. We completed the single ascending dose portion of the Phase 1 trial testing intravenous administration of CLN-049 and initiated a multi-ascending dose portion of the study utilizing subcutaneous dosing in December 2022. We expect to present initial clinical data in mid-2023.

CLN-619

Overview

CLN-619 is a MICA/B-targeted, humanized IgG1 monoclonal antibody that we intend to initially develop for the treatment of solid tumors. CLN-619 was designed to promote an antitumor response through multiple mechanisms of action, including inhibition of MICA/B shedding, mediation of antibody-dependent cell-mediated cytotoxicity ("ADCC"), antibody-dependent cellular phagocytosis ("ADCP"), and enhancement of NKG2D receptor binding to MICA/B. The MICA/B receptor, NKG2D, is expressed on both innate and adaptive immune cell populations. Although several companies have disclosed preclinical MICA/B targeting programs, we are unaware of any clinical stage, antibody-based programs engaging this target, implying CLN-619 has first-in-class potential. In multiple *in vivo* preclinical tumor models, CLN-619 administration was associated with antitumor activity and reduced levels of serum MICA/B.

We believe CLN-619 has the potential to become a novel backbone agent for immuno-oncology therapy given the broad expression of MICA/B across tumor types and the biological rationale for combining CLN-619 with other agents. We are currently evaluating CLN-619 in an ongoing clinical trial for patients with advanced solid tumors. The trial design includes parallel evaluation of CLN-619 as a monotherapy and in combination with checkpoint-inhibitor therapy.

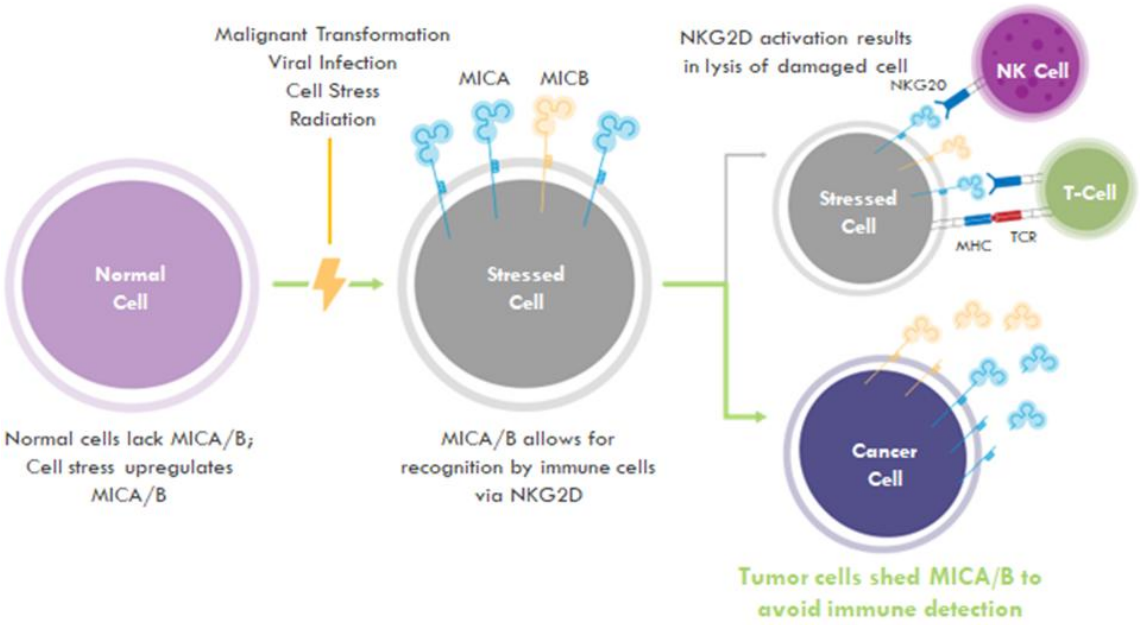
Background on NKG2D and MICA/B

NKG2D is a key activating receptor on NK cells responsible for cytolysis upon binding to ligands expressed on target cells. NKG2D is also expressed on other types of immune cells, including $CD8^+$ ß T cells, natural killer T cells, and T cells, and can prime such cells for activation and enhance their antitumor activity as a co-activating receptor. Healthy cells do not normally express ligands of NKG2D, but will do so in response to cellular stress, such as oxygen or nutrient deprivation, radiation, viral infection, or oncogenic transformation.

MICA/B proteins are broadly recognized by NK cells, T cells, and $CD8^+$ ß T cells via the NKG2D receptor. The engagement between the NKG2D receptor and MICA/B proteins triggers the effector cytolytic responses of NK cells and T cells against tumor cells expressing MICA/B. In the case of $CD8^+$ ß T cells, effector responses mediated by the T cell receptor are enhanced by NKG2D-MICA/B interactions. NKG2D-mediated stimulation also results in the induction of cytokines, which further promotes the recruitment and the proliferation of immune cells and bolsters the immune response.

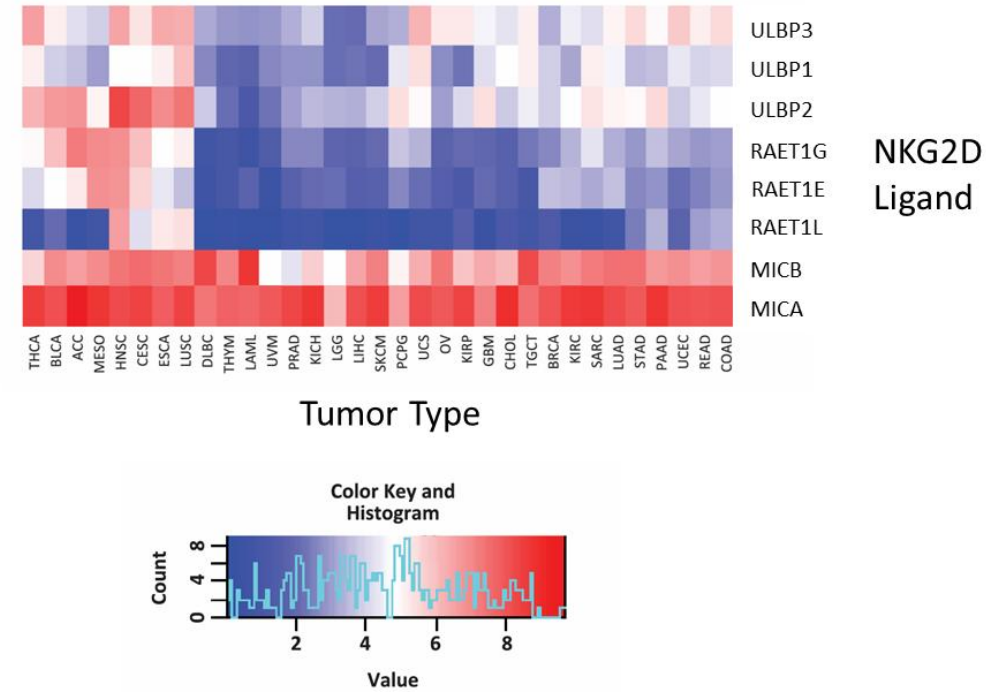
To evade potential cytotoxic destruction by NK cells and T cells, tumor cells expressing MICA/B have adopted shedding of MICA/B from their cell surface as a key evasion mechanism. The MICA/B alpha-3 domain contains a stretch of amino acids that allows for protease cleavage of an extracellular portion of MICA/B and subsequent release from the cell surface, thereby reducing the ability of MICA/B to interact with NKG2D and resulting in decreased NKG2D-mediated killing of tumor cells. This mechanism also concomitantly increases the amount of circulating serum MICA/B ("sMICA/B"). The mechanisms underlying this biology are illustrated below. Below, the top pathway shows the normal mechanism by which tumor-associated ligands of NKG2D, such as MICA/B, can induce the killing of stressed cells. The bottom pathway shows how tumor cells, through the proteolytic cleavage of MICA/B, can escape immune surveillance and immune cell-mediated killing.

MICA/B Serves as a Warning Signal to the Immune System to Eliminate Potentially Dangerous Cells



An analysis of the expression of the NKG2D ligands in The Cancer Genome Atlas ("TCGA"), shows that MICA and MICB are the two ligands for NKG2D that are most frequently expressed across a wide range of tumor types. In the results of the TCGA analysis shown below, the red shading indicates high expression levels of NKG2D ligands and blue shading indicates low expression levels. We believe the positive expression profile of MICA/B in many tumor types provides attractive development opportunities across a wide range of indications.

MICA/B are the Most Highly Expressed NKG2D Ligands Across a Wide Array of Tumor Types



Disease name	Cohort
THCA	Thyroid carcinoma
BLCA	Bladder Urothelial Carcinoma
ACC	Adrenocortical carcinoma
MESO	Mesothelioma
HNSC	Head and Neck squamous cell carcinoma
CESC	Cervical squamous cell carcinoma and endocervical adenocarcinoma
ESCA	Esophageal carcinoma
LUSC	Lung squamous cell carcinoma
DLBC	Lymphoid Neoplasm Diffuse Large B-cell Lymphoma
THYM	Thymoma
LAML	Acute Myeloid Leukemia
UVM	Uveal Melanoma
PRAD	Prostate adenocarcinoma
KICH	Kidney Chromophobe
LGG	Brain Lower Grade Glioma
LIHC	Liver hepatocellular carcinoma
SKCM	Skin Cutaneous Melanoma
PCPG	Pheochromocytoma and Paraganglioma
UCS	Uterine Carcinosarcoma
OV	Ovarian serous cystadenocarcinoma
KIRP	Kidney renal papillary cell carcinoma
GBM	Glioblastoma multiforme
CHOL	Cholangiocarcinoma
TGCT	Testicular Germ Cell Tumors
BRCA	Breast invasive carcinoma
KIRC	Kidney renal clear cell carcinoma
SARC	Sarcoma
LUAD	Lung adenocarcinoma
STAD	Stomach adenocarcinoma
PAAD	Pancreatic adenocarcinoma
UCEC	Uterine Corpus Endometrial Carcinoma
READ	Rectum adenocarcinoma
COAD	Colon adenocarcinoma

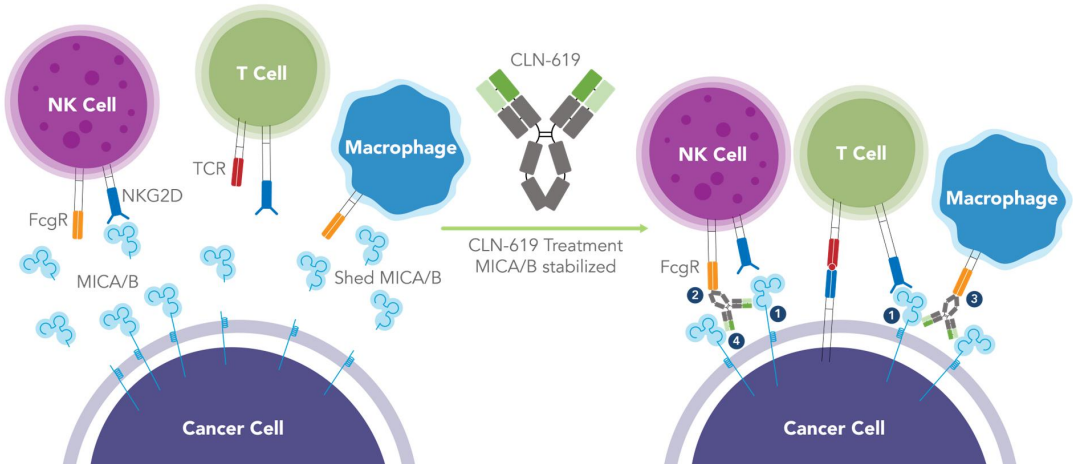
Data generated via analysis of TCGA database by Monoceros Biosystems.

CLN-619

CLN-619 is a MICA/B-targeted humanized IgG1 antibody with a competent Fc gamma 1 domain capable of mediating effector cell functions through binding to Fc gamma receptors on innate immune cells.

We believe CLN-619 may affect antitumor activity through a multi-pronged mechanism of action. First, we believe that CLN-619 may prevent the proteolytic cleavage of MICA and MICB on cancer cells by proteases commonly found in the tumor microenvironment (noted as "1" in the figure below). This mechanism would enable the accumulation of MICA/B on the surface of cancer cells. In preclinical studies, treatment with a parental CLN-619 clone resulted in increased cell surface expression and reduced serum levels of MICA/B in various tumor cell lines, while CLN-619 treatment *in vivo* led to reduced serum levels of MICA/B. Elevated expression of MICA/B on the surface of cancer cells is expected to enhance killing of cancer cells by NK cells via binding of their NKG2D receptor to MICA/B. MICA/B also interacts with NKG2D expressed on gd T cells and natural killer T cells, where NKG2D can play the role of a co-activating receptor, lowering the threshold for T cell-mediated cancer cell lysis. Second, CLN-619 has a human IgG1 backbone with a wild-type Fc gamma domain, which allows it to engage NK cells by binding to their FcgRIIIa, leading to ADCC (noted as "2" in the figure below). In preclinical studies, treatment with CLN-619 was shown to induce ADCC *in vitro*. Third, the wild-type Fc gamma domain of CLN-619 enables it to mediate ADCP of target tumor cells via macrophage engagement (noted as "3" in the figure below). Finally, our preliminary preclinical data suggests that CLN-619 may have the potential to enhance the binding of MICA/B to NKG2D receptors on NK cells or other immune cells to provide for improved cancer cell lysis (noted as "4" in the figure below). We believe that all of these mechanisms may be acting in a coordinated manner to engage NK cells and other immune cells, which could result in the cancer cell lysis observed in the preclinical studies described below.

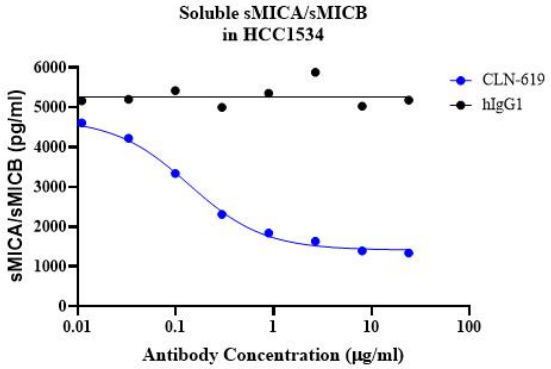
Three CLN-619 Modes of Action



Preclinical Data

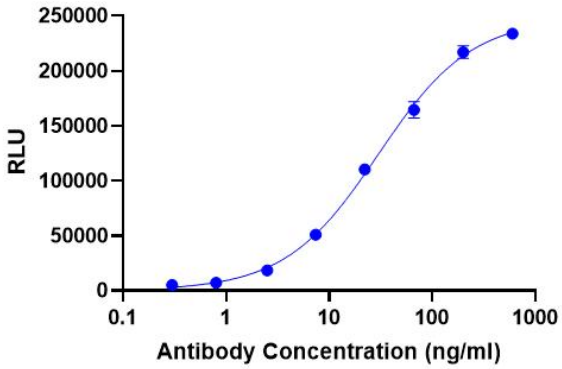
The key mechanistic underpinning of CLN-619's antitumor activity is its ability to stabilize and prevent the shedding of MICA/B expressed on the surface of cancer cells. In preclinical studies, CLN-619 prevented shedding across a variety of cancer cell lines. In a representative hepatoma PLC/PRF/5 cell line, soluble MICA in the supernatant decreased following treatment with CLN-619 compared to a control antibody as shown in the figure below.

CLN-619 Inhibits MICA/B Shedding from Tumor Cells



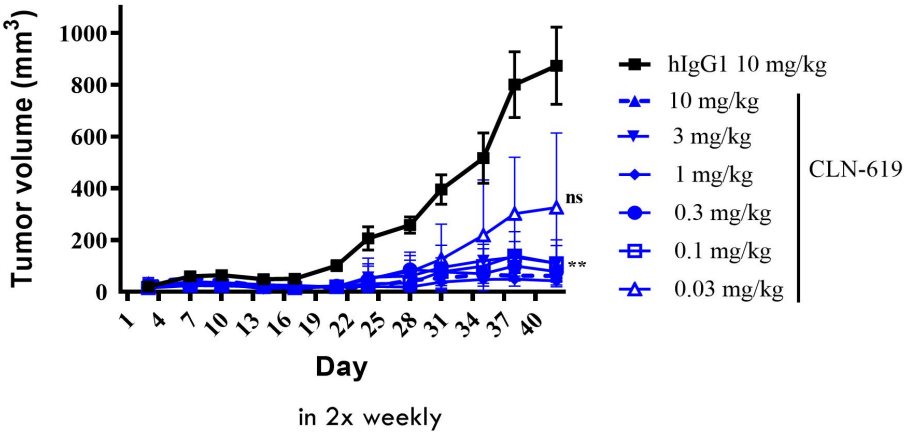
CLN-619 also demonstrated the ability to enhance NK cell-mediated killing of MICA/B expressing cancer cells *in vitro*. In an ADCC reporter bioassay, the parental clone of CLN-619, which has antibody variable region sequences from a mouse hybridoma from which CLN-619 was derived, induced ADCC in a dose-dependent and MICA/B binding-dependent manner, as shown in the figure below, where killing activity was measured by the relative luminescence units ("RLU"). Such ADCC activity was abrogated when mutations in the Fc region were introduced into h3F9-DANA, which eliminated the binding to Fc RIIIa on NK cells that is key to mediating ADCC. An isotype control also failed to trigger ADCC, demonstrating the requirement of MICA/B target engagement.

Parental Clone of CLN-619 Induces Cell Killing at Low Concentrations



The antitumor activity of CLN-619 was further evaluated in multiple mouse tumor models. In a representative lung cancer xenograft model, CLN-619 treatment as a single agent resulted in tumor growth inhibition at all doses tested, as shown in the figure below. We also observed suppression of MICA shedding at all doses tested as measured by soluble MICA serum levels.

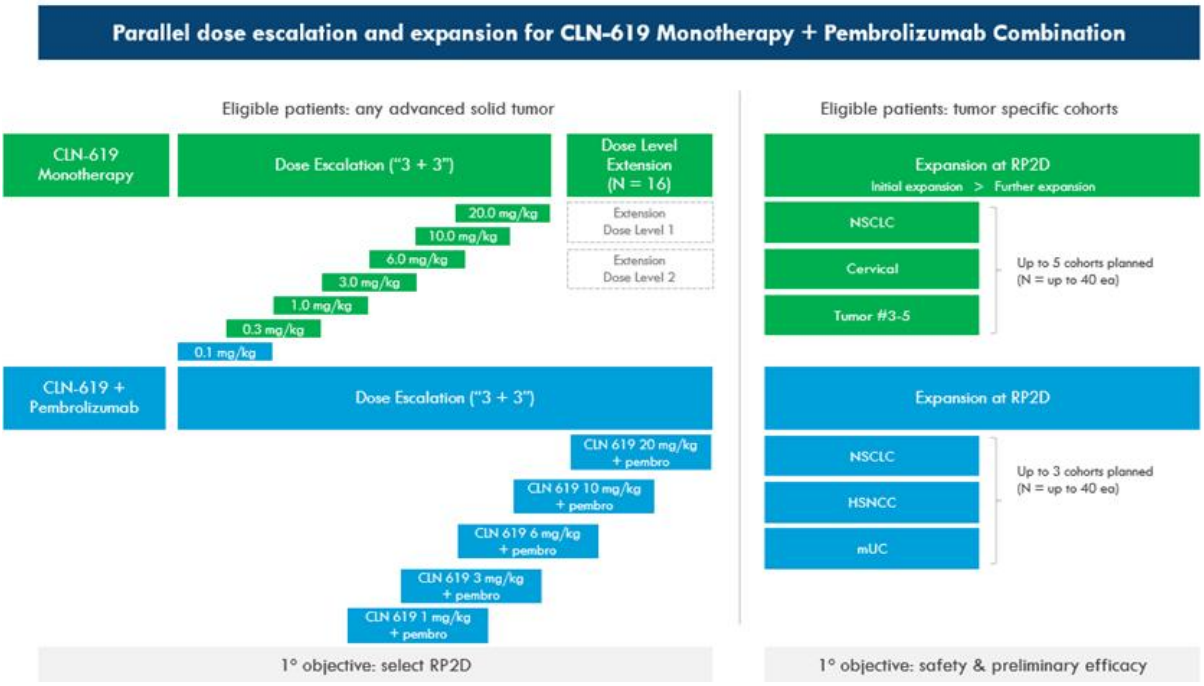
CLN-619 Demonstrated Tumor Growth Inhibition in a HCC1534 Lung Cancer Xenograft Model



Ongoing Clinical Development Plan

We are currently evaluating CLN-619 in a global Phase 1 clinical trial in patients with advanced solid tumors. The trial design includes initial evaluation of CLN-619 as a monotherapy and in combination with checkpoint inhibitor therapy in parallel dose-escalation cohorts. Upon establishing a recommended Phase 2 dose, the trial design includes several expansion cohorts to evaluate the preliminary efficacy of CLN-619 as both a monotherapy and in combination with checkpoint inhibitor therapy in patients with multiple solid tumor types. Planned monotherapy expansion cohorts include one in NSCLC, one in cervical cancer, and up to three additional cohorts to be determined based on observations from the dose escalation portion of the study. Planned combination expansion cohorts include NSCLC, head and neck squamous cell carcinoma, and metastatic urothelial cancer. In addition, we will collect and analyze biomarkers, including sMICA, to inform the future development of CLN-619. Monotherapy dose escalation was initiated in December 2021 and the dose escalation with checkpoint inhibitor therapy was initiated as planned in 2022 after the 3 mg/kg monotherapy dose level cleared evaluation for dose-limiting toxicity. We expect to present initial clinical data in mid-2023.

Global Phase 1 Clinical Trial Design of CLN-619



CLN-418

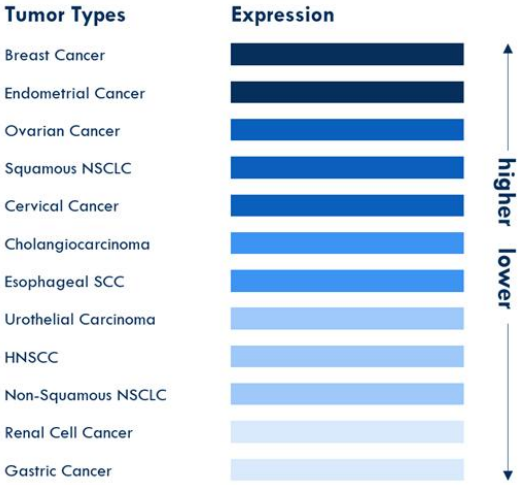
Overview

CLN-418 is a fully human bispecific antibody targeting B7H4 and 4-1BB. In February 2023, we licensed from Harbour BioMed US Inc. ("Harbour") the exclusive rights to develop and commercialize CLN-418 in the U.S. in exchange for an upfront license fee of $25 million, plus up to $148 million in development and regulatory milestone payments, up to $415 million in sales-based milestone payments, and tiered royalties up to high teens on potential U.S. commercial sales. We are currently evaluating CLN-418 in a Phase 1 clinical study being conducted at U.S. and Australian sites in patients with advanced solid tumors.

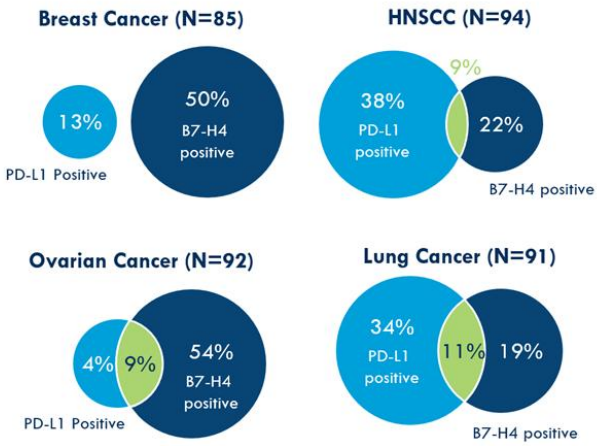
Background on B7H4 and 4-1BB

We believe that B7H4 represents an attractive target for cancer immunotherapy. B7H4 is a member of the B7 family of immune regulatory proteins that includes important immune inhibitory ligands like PD-L1. B7H4 is expressed on the cell surface of tumor cells and has been shown to play an immunosuppressive role by inhibiting T cell proliferation and expansion. Expression of B7H4 in patient tumor samples has been correlated with advanced stages of disease, poor prognosis, and lower overall patient survival. While B7H4 is expressed at potentially clinically relevant levels across a range of solid tumors, including triple-negative breast cancer, NSCLC, and ovarian cancer, its expression is limited on normal tissues, indicating the potential for a wide therapeutic window. Finally, B7H4 often has minimal overlap with PD-L1 expression, which we believe creates the potential to address so-called “cold tumors” for which current PD-1 pathway immunotherapy approaches have demonstrated limited efficacy. The panel below includes B7H4 expression data from various studies conducted by Harbour.

B7H4 expression across solid tumor types



B7H4 relative to PD-L1 expression across solid tumor cells

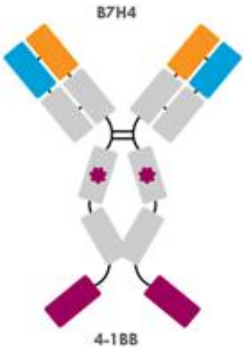


4-1BB is a key costimulatory molecule expressed on T cells and NK cells and has emerged as an attractive immunotherapy target. Mechanistically, 4-1BB activation induces T cell proliferation and survival, stimulates the secretion of inflammatory cytokines, and can promote anti-tumor immunity. Monoclonal agonistic antibodies targeting 4-1BB have been shown to have the ability to stimulate immune cells and generate antitumor responses in patients, but not without challenging toxicity issues often associated with non-specific 4-1BB immune cell activation, such as liver toxicity which is thought to be caused by Fc-mediated cross-linking enabled by Fc gamma receptor expressing cells present in the liver.

CLN-418

CLN-418 is a fully human bispecific antibody that contains human B7H4 and 4-1BB binding domains that were selected to have high binding affinity to B7H4 and designed to enable B7H4-crosslinking dependent 4-1BB activation. CLN-418 includes a silenced Fc domain designed to avoid cross-linking mediated by Fc gamma receptor-expressing cells. By targeting B7H4 on tumor cells, we believe CLN-418 represents a unique approach to enable the conditional activation of 4-1BB in the tumor microenvironment. Because of this mechanism and because CLN-418 lacks an active Fc domain, we believe CLN-418 has the potential to avoid toxicities associated with non-specific 4-1BB activation seen with Fc-functional monoclonal 4-1BB agonist antibodies. Also, CLN-418 may have the potential to synergize with other cancer therapies, particularly immunotherapy approaches, making it a strong candidate for combination therapy.

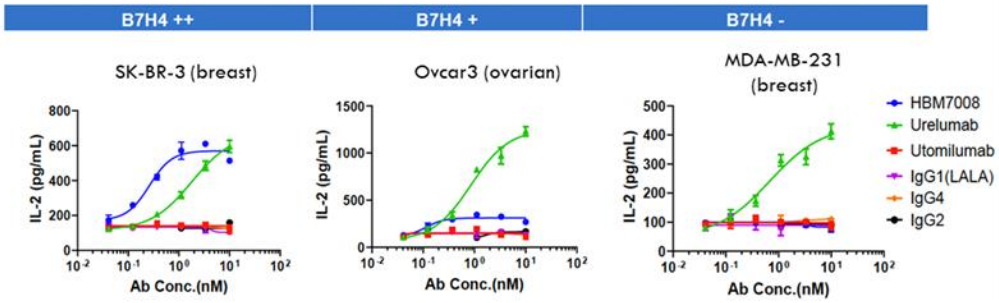
CLN-418 Structure



Preclinical Data

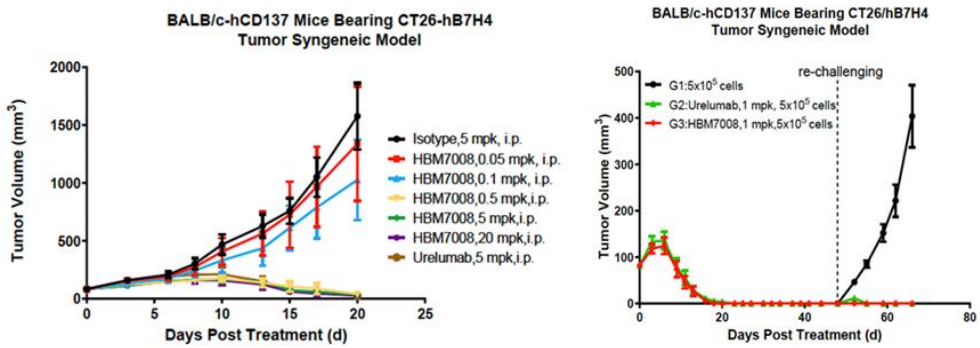
Preclinical studies of CLN-418 in multiple tumor cell lines, summarized below, have demonstrated 4-1BB T cell activation, as measured by induction of IL-2, contingent on the presence of B7H4, unlike monoclonal 4-1BB agonistic antibodies, such as urelumab and utomilumab.

CLN-418 only elicits T-cell activation in the presence of B7H4



Preclinically, CLN-418 showed the ability as a single agent to eradicate tumors *in vivo* and drive a memory response that prevented tumor growth upon re-challenge in the mice. An example of these results is shown below in a syngeneic mouse tumor model, whereby CLN-418 demonstrates a dose-dependent inhibition of tumor growth, and mice with an initial complete response following treatment with CLN-418 are subsequently immune upon tumor re-challenge.

CLN-418 clears tumors in mice and drives a memory response that prevents tumor growth upon re-challenge



Ongoing Clinical Development Plan

We are currently evaluating CLN-418 in a Phase 1 clinical study being conducted at U.S. and Australian sites in patients with advanced solid tumors. The part 1 dose escalation will test up to seven dose levels of CLN-418, from 0.03 to 20 mg per kilogram, dosed once every three weeks. Once a proposed Phase 2 dose is determined, the part 2 dose expansion will evaluate up to 30 patients in each of three tumor specific expansion cohorts: one in NSCLC, one in breast cancer, and a third to be determined by the efficacy signals observed in part 1 of the clinical study. In parallel, we are exploring opportunities to expand the trial to include one or more combination arms, which may include approved immunotherapy agents or other emerging therapeutic candidates in investigational studies. Initial data from part 1 of the ongoing trial is expected in 2024.

CLN-978

Overview

CLN-978 is a half-life extended, humanized, single-chain bispecific antibody designed to simultaneously engage CD19 on cancer cells and CD3 on T cells, triggering redirected T cells to lyse the target cancer cells. In addition, CLN-978 has an HSA binding domain designed to prolong its serum half-life. CLN-978 mediated CD19-dependent cell lysis *in vitro* of target cell lines with a range of CD19 target expression levels. In preclinical *in vivo* studies, treatment with CLN-978, at extremely low and infrequent doses, led to inhibition of tumor growth and tumor regression in a humanized lymphoma xenograft mouse model. We intend to initially evaluate CLN-978 as a novel treatment for B-NHL and are currently preparing to enter Phase 1 clinical studies in 2023.

We designed CLN-978 based on a bispecific T cell engager-like format using tandemly arranged scFvs for CD19 and CD3, similar to blinatumomab. In addition, we incorporated a third domain in the form of a single-domain antibody (VHH) for binding to HSA. We believe that binding of CLN-978 to albumin has the potential to extend its serum half-life. An illustration of the CLN-978 structure is shown in the following figure.

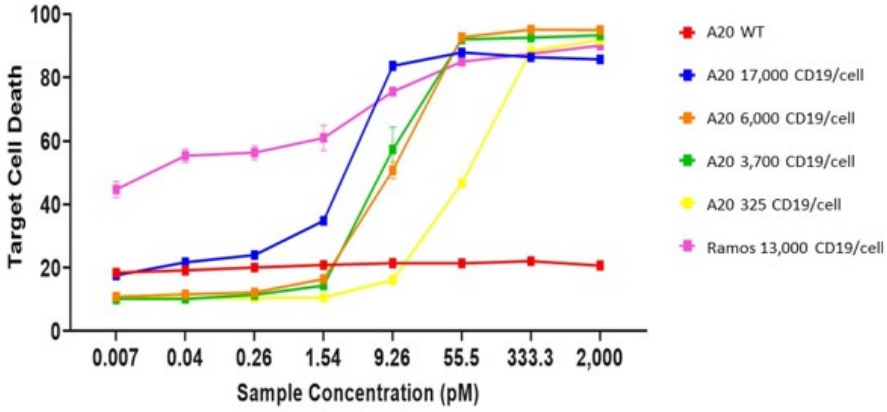
Design of CLN-978, a CD19/CD3-bispecific T Cell Engager with Extended Serum Half-life

We have engaged with Adimab, LLC ("Adimab") to generate antibody-derived binding domains specific for CD19, CD3, and HSA with optimized biophysical and biochemical properties, tailored binding affinities as well as other parameters that are key to developability, manufacturability and preclinical testing of drug candidates. In preclinical studies, CLN-978 has demonstrated potent antitumor activity both in terms of redirecting T cells to lyse low-CD19 expressing cells *in vitro* and significant tumor growth inhibition *in vivo*. We believe these preclinical results support further evaluation of CLN-978 for its potential to improve upon the clinical efficacy of existing therapies. In addition, we believe the ability to target cells with low CD19 expression would potentially enable us to address patients such as those patients that progress following CAR-T therapy.

Preclinical Data

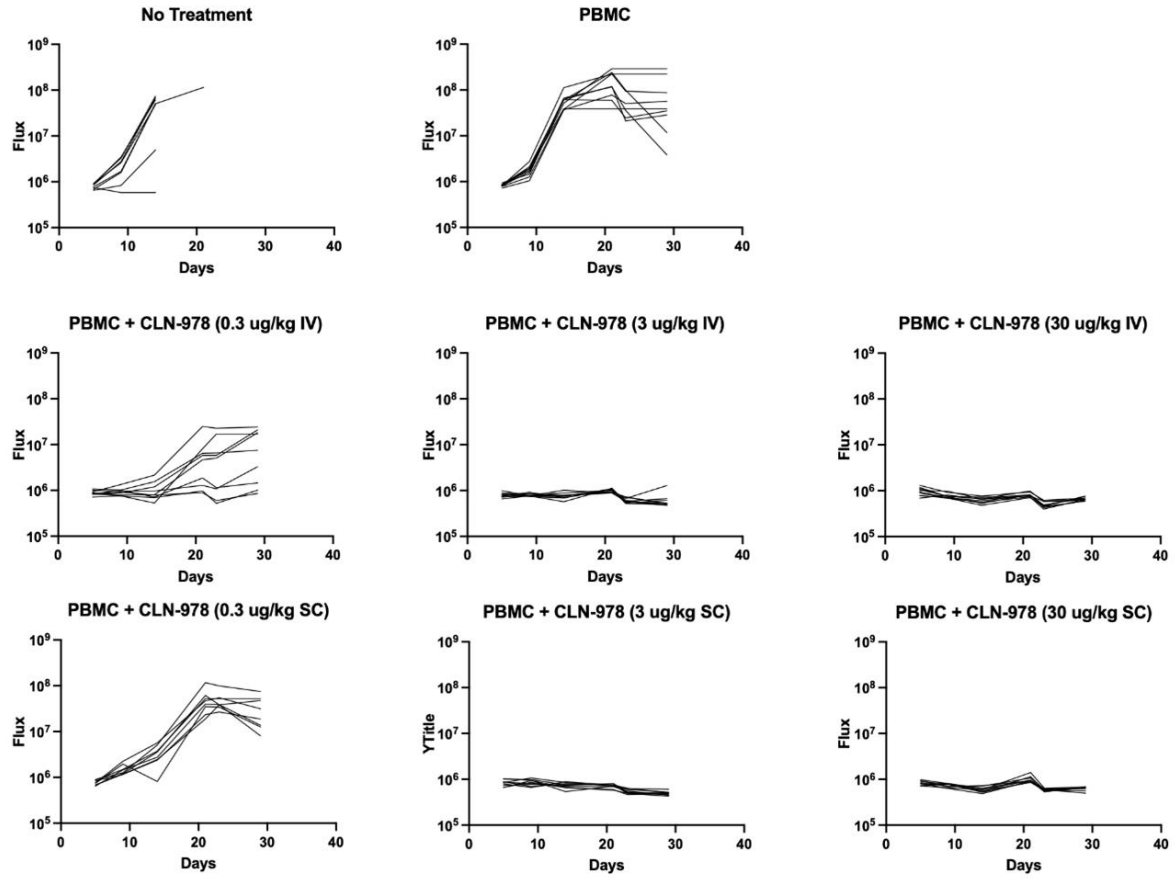
CLN-978 incorporates a CD19 binding domain that was engineered to achieve picomolar binding affinity to CD19 as measured using plasmon resonance, which we believe may contribute to cytolytic potency against low CD19-expressing cell lines in *in vitro* studies. As shown in the figure below, CLN-978 targets a range of CD19 expression levels in the engineered A20 cell lines evaluated as measured by both the picomolar EC50 values of redirected cell lysis and the maximum percentage of lysis. We believe this observation supports our hypothesis that CLN-978 may have the potential to more adequately address the patient population with lower levels of CD19 expression and/or patients in which CD19 expression is downregulated as a resistance mechanism to CD19-targeted therapies. It was also shown that the robust lysis of target cells was dependent on CD19 expression, as the A20 parental cell line, which lacks CD19 expression, was not susceptible to lysis at any of the drug concentrations tested.

CLN-978 Redirects Cell Lysis of Low CD19-expressing Cell Lines *in vitro* Cytotoxicity Assays



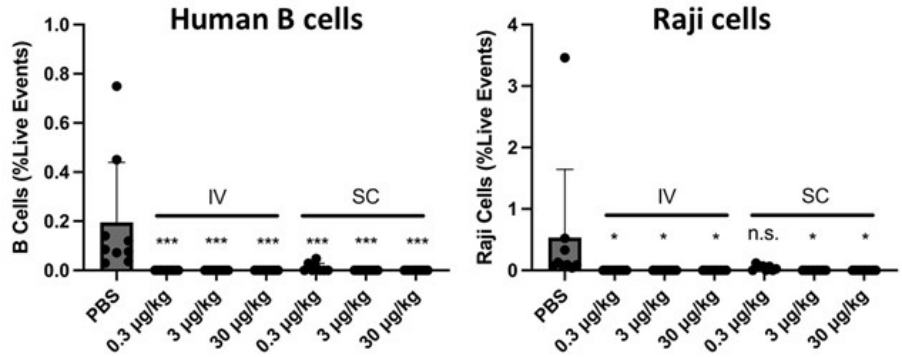
CLN-978 has also demonstrated antitumor activity *in vivo* in a humanized model, where the mice were implanted with a human Raji-luciferase lymphoma cell line (Raji B.luc) and human PBMC. As shown in the figure below, CLN-978 demonstrated significant tumor growth inhibition at every dose level tested, both via intravenous ("IV") or subcutaneous ("SC") administration. Furthermore, at the 3 microgram per kilogram dose level and above, CLN-978 treatment resulted in a complete response in 100% of treated mice, regardless of route of administration.

Antitumor Activity of CLN-978 in a Raji-luciferase human PBMC mouse model



Consistent with the tumor growth inhibition, we observed a statistically significant reduction in the number of both Raji B.luc cells and normal human $CD19^{+}$ B cells in all CLN-978 treated groups as shown in the figure below.

Reduction in normal B cells and tumor cells in peripheral blood after treatment with CLN-978 in the huPBMC Raji B.luc mouse model



Ongoing Clinical Development Plan

We submitted an IND for CLN-978 in the fourth quarter of 2022. The FDA cleared our IND in January 2023. We remain on track to begin a Phase 1 clinical trial in 2023 evaluating CLN-978 in patients with relapsed/refractory B-NHL.

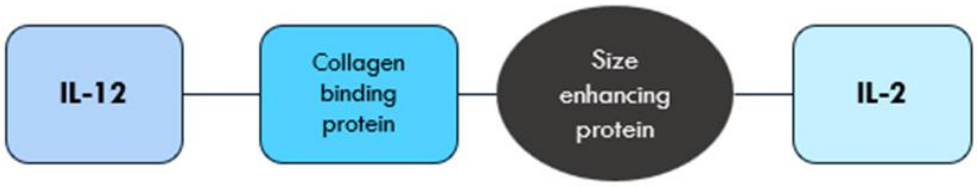
CLN-617

Overview

CLN-617 is a fusion protein uniquely combining, in a single agent, two potent antitumor cytokines, IL-2 and IL-12, with a collagen-binding domain for the treatment of solid tumors. The combination of IL-2 and IL-12 therapeutic administration has previously been shown to synergistically enhance T and NK cell functions *in vitro* and mediated pronounced therapeutic activity in preclinical tumor models, even in well-established mouse models with primary and/or metastatic tumors. For nearly five decades, clinical researchers have studied the powerful role cytokines play in stimulating an immune response to cancer. However, severe toxicities associated with systemic cytokine administration and a short serum half-life have hindered their clinical development and broader commercial uptake. Despite numerous advancements in protein engineering, delivery and targeting mechanisms, there are currently only two FDA-approved cytokine-based cancer therapies, with the most recent approval occurring over twenty years ago.

We have included multiple differentiating features in CLN-617's design in order to address the historical limitations of cytokine-based therapy. First, tumor retention following intratumoral injection is enabled by the collagen-binding domain, due to the presence of collagen in all solid tumors, and by HSA, which increases the molecular weight to further reduce the rate of diffusion out of the tumor tissue. Retention may help minimize the systemic dissemination and associated toxicities of IL-2 and IL-12 and prolong their immunostimulatory antitumor activity in the tumor. Second, CLN-617 is the only product candidate that we are aware of that co-delivers IL-2 and IL-12 proteins, functionally enabling synergistic T and NK cell activation. Third, CLN-617's construct uses fully wild-type domains, which potentially reduces the immunogenicity risk associated with engineered cytokines. Finally, unlike other intratumoral cytokine-based therapies, CLN-617 does not rely on viral infection or nucleic acid transfection for *in situ* expression.

CLN-617 Design



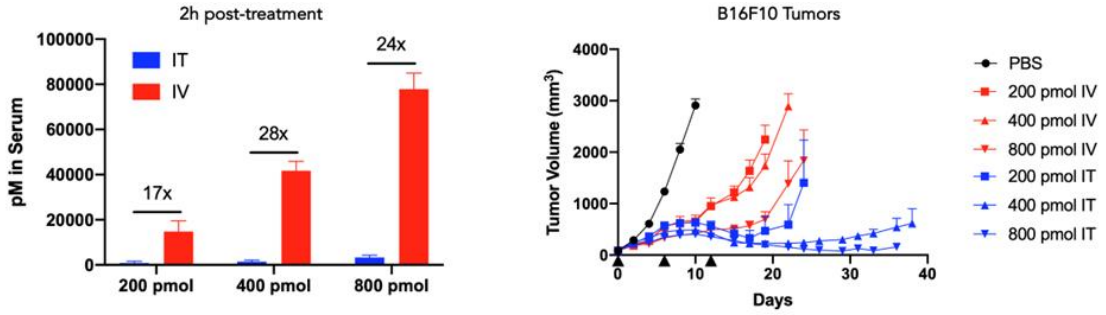
In preclinical studies, a murine surrogate of CLN-617 demonstrated robust single agent antitumor activity in both treated and untreated tumors without inducing systemic toxicity, as measured by reduction in body weight. Given the broad expression of collagen across multiple tumor types and the well-validated anti-tumor activity of cytokine-based therapies, we believe CLN-617 may have utility across a broad range of solid tumors. We believe that CLN-617 is a first-in-class opportunity given it is the only anti-cancer product candidate we are aware of that is designed to co-deliver IL-2 and IL-12 cytokines and retain them in the tumor microenvironment.

The collagen-binding retention technology used in CLN-617 is based on technology that originated in the laboratory of Professor Karl Dane Wittrup at the Massachusetts Institute of Technology ("MIT"). We have further developed and refined this technology to create our Amber platform, which we believe represents a novel platform with the potential to broaden the therapeutic window of cytokines and other immunostimulatory agents with substantially reduced systemic toxicity.

Preclinical Data

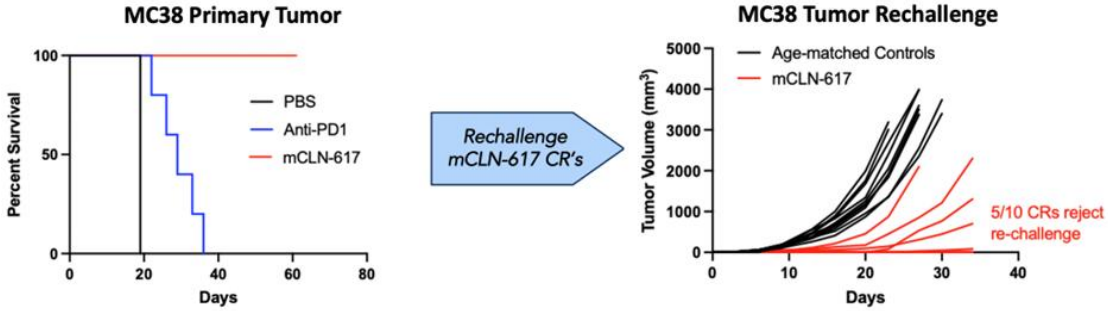
A murine surrogate incorporating the murine homologs of the constituent domains of CLN-617 was generated and named mCLN-617. Retention of mCLN-617 was demonstrated in mice bearing B16F10 tumors which were treated either intratumorally or intravenously with mCLN-617. Two hours after treatment, the concentration of mCLN-617 was assessed in serum, and we found that drug levels following intratumoral injection were on average <5% that of intravenously administered mCLN-617 (left panel below). These results suggest that mCLN-617 is efficiently retained in the tumor, thereby limiting systemic distribution. Intratumoral injection also enhanced the anti-tumor activity of mCLN-617. At each tested dose level, intratumorally administered mCLN-617 outperformed intravenously administered mCLN-617 as measured by tumor growth inhibition (right panel below).

Reduced Systemic Levels of mCLN-617 and Improved Efficacy Following Intratumoral Versus Intravenous Administration



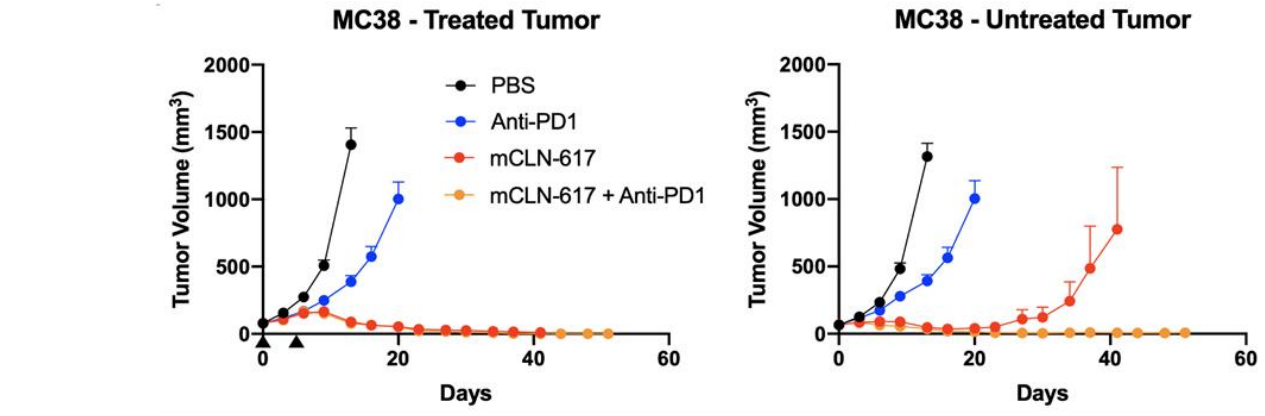
We utilized the MC38 syngeneic tumor model to assess whether mCLN-617 treatment could generate long-term immune memory following primary tumor clearance. As shown in the left panel below, mCLN-617 led to 100% complete responses in treated animals, whereas no complete responses were observed in control or anti-PD1 treated groups. Subsequently, we re-injected tumors into animals that achieved a complete response. As shown in the right panel below, five out of ten mice previously treated with mCLN-617 rejected the newly injected tumors, and all tumors that grew out did so at a slower rate than tumors in age-matched naïve controls. Similar results were achieved in the CT26 syngeneic tumor model.

High Complete Response Rate and Memory Response Following mCLN-617 Treatment



We demonstrated that in addition to mediating long-term memory, mCLN-617 is capable of generating responses against established untreated distal tumors due to the induction of systemic immunity, also known as an abscopal effect. We utilized C57BL/6 mice bearing two MC38 tumors, only one of which was treated with mCLN-617, either alone or in combination with systemically delivered anti-PD1 antibody. mCLN-617 alone mediated significant regression, including complete responses, of both the treated and untreated tumors. The effect was more consistent and durable in the untreated tumor when combined with anti-PD1, despite no significant survival benefit with anti-PD1 treatment alone. These results demonstrate both an abscopal effect and synergy of mCLN-617 with systemically administered anti-PD1 antibody.

Intratumorally delivered mCLN-617 Inhibits Tumor Growth in Both Treated and Untreated Tumors and Synergizes with Systemically Delivered Anti-PD1 Therapy



Through our ongoing studies with mCLN-617, we are seeking to characterize the mechanism of action by which a locally retained cytokine fusion can generate robust systemic anti-tumor immunity. Studies with mCLN-617 in mice bearing two MC38 tumors have thus far demonstrated an improved ratio of effector T cells to immunosuppressive regulatory T cells in both treated and untreated tumors. Furthermore, tumor-specific T cells expanded in peripheral blood, providing evidence of a vaccine-like mechanism of action.

The fully human CLN-617 clinical candidate has been generated, and the bioactivity of both cytokines and the collagen-binding domain has been confirmed *in vitro*. Both a non-GLP pharmacokinetic study and a GLP toxicology study with CLN-617 have been conducted in non-human primates to support an IND filing.

Based on the results of our preclinical studies with mCLN-617, we believe that the inclusion of a collagen-binding domain by our Amber platform has the potential to allow for the safe retention of high levels of cytokines in the tumor microenvironment. While remarkable progress has been made in the treatment of cancer with the adoption of checkpoint inhibitors, including pembrolizumab, ipilimumab, and nivolumab, only a fraction of patients with solid tumors respond to these therapies. We believe a well-tolerated agent that can deliver the functional synergies of IL-2 and IL-12 has the potential to treat a broad range of solid tumors, including those that are not responsive to checkpoint inhibitors.

In February 2023, we filed the IND for CLN-617 and intend to initiate a Phase 1 study by the end of 2023, pending IND clearance.

Our Other Preclinical Programs

In addition to the product candidates described above, we are actively developing several preclinical oncology programs, all in the discovery stage, including our collaboration with Icahn School of Medicine at Mount Sinai for the development of novel hematopoietic progenitor kinase 1 ("HPK1") degraders.

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.

We also face competition more broadly across the oncology market for cost-effective and reimbursable cancer treatments. The most common methods of treating patients with cancer are surgery, radiation and drug therapy, including chemotherapy, hormone therapy, biologic therapy, such as monoclonal and bispecific antibodies, immunotherapy, cell-based therapy and targeted therapy, or a combination of any such methods. There are a variety of available drug therapies marketed for cancer. In many cases, these drugs are administered in combination to enhance efficacy. While our product candidates, if any are approved, may compete with these existing drugs and other therapies, to the extent they are ultimately used in combination with or as an adjunct to these therapies, our product candidates may not be competitive with them. Some of these drugs are branded and subject to patent protection, and others are available on a generic basis. Insurers and other third-party payors may also encourage the use of generic products or specific branded products. As a result, we may face challenges in obtaining market acceptance of, and gaining significant share of the market for, any of our product candidates that we successfully introduce to the market. In addition, many companies are developing new oncology therapeutics, and we cannot predict what the standard of care will be as our product candidates progress through clinical development.

With respect to zipalertinib, which we are co-developing with an affiliate of Taiho, we are aware of other EGFR inhibitors that have accelerated approval or are in clinical development for the treatment of NSCLC patients harboring EGFRex20ins mutations. In May 2021, Rybrevant (amivantimab), an EGFR/cMET bispecific antibody that was developed and is now marketed by Johnson & Johnson obtained accelerated approval from the FDA for adult patients with locally advanced or metastatic NSCLC with EGFRex20ins mutations whose disease has progressed on or after platinum-based chemotherapy. Additionally, in September 2021, Exkivity (mobocertinib), which was developed and is now marketed by Takeda Pharmaceuticals, Inc., obtained accelerated approval from the FDA for adult patients with locally advanced or metastatic NSCLC with EGFRex20ins mutations whose disease has progressed on or after platinum-based chemotherapy. We believe that the most advanced clinical-stage programs for EGFRex20ins patients are sunvozertinib from Dizal Pharmaceutical Co., Ltd and and furmonertinib from ArriVent BioPharma, Inc. and Allist Pharmaceuticals, Inc. Other clinical-stage EGFR ex20ins TKI programs include Oric Pharmaceuticals, Inc.'s ORIC-114 (Voronoi, Inc., in mainland China, Hong Kong, Macau and Taiwan) and Blueprint Medicine Corporation's LNG-451.

With respect to CLN-049, we are aware of several companies that are developing bispecifics for the treatment of AML, including those targeting CD3 and CD33 (Amgen Inc. ("Amgen") and Amphivena Therapeutics, Inc.), CD123 (Macrogenics, Inc. and Xencor, Inc.), and CCL1/CLEC12A (Merus N.V. and Genentech, Inc.). Amgen is developing a bispecific T cell engager targeting FLT3 for AML. There are also several targeted small-molecule therapies approved for the treatment of r/r or first-line AML, including for AML with FLT3 mutations, such as Astellas Pharma Inc.'s XOSPATA (gilteritinib) and Novartis International AG's ("Novartis") RYDAPT (midostaurin). We are also aware of other small molecules that are approved or in development for AML patients with FLT3 mutations, including IDH inhibitors, such as TIBSOVO (ivosidenib) by Servier Pharmaceuticals LLC and IDHIFA (enasidenib) by Agios Pharmaceuticals, Inc., BCL2 inhibitors, such as VENCLEXTA (ventoclax) by AbbVie Inc., and hedgehog pathway inhibitors, such as DAURISMO (glasdegib) by Pfizer, Inc. ("Pfizer").

With respect to CLN-619, we are aware of several companies that are developing cancer therapies targeting MICA/B as a monotherapy and/or in combination with other agents, including: CanCure LLC, Genentech Inc., Novartis, and Bristol-Myers Squibb Company ("Bristol-Myers Squibb"). To our knowledge, none of them has entered clinical development.

With respect to CLN-418, we are unaware of any other candidates in development that combine 4-1BB and B7H4 in a single bispecific molecule. However, there are several candidates that target one or the other of these molecules. For example, urelumab by Bristol Meyers Squibb Company is a monoclonal antibody targeting 4-1BB. Several companies are developing monoclonal antibodies, antibody-drug conjugates, or (CD3) T-cell engagers directed towards B7H4. These companies include Amgen, Nextcure, Inc., Genmab A/S ("Genmab"), Pfizer, AstraZeneca plc ("AstraZeneca"), Seagen Inc., Mersana Therapeutics Inc., and Jiangsu Hansoh Pharmaceutical Group Co., Ltd. Several companies are also developing 4-1BB agonists that target other tumor associated antigens rather than B7H4 (e.g. PD-L1, FAP, CD40, etc.) including Genmab, Inhibrx, Inc., Eli Lilly and Company, Boehringer Ingelheim Pharma GmbH, and Roche AG ("Roche").

With respect to our CLN-978 program, we are aware of a number of companies developing product candidates that target CD19 or other tumor antigens relevant to B-cell ALL and B-NHL using immune cells or other cytotoxic modalities. These mainly include immune cell redirecting therapeutics (e.g., T cell engagers), adoptive cellular therapies (e.g., CAR-Ts) and antibody drug conjugates. Companies developing cell therapies or antibodies targeting CD19 include, but are not limited to, AstraZeneca, Morphosys AG, Novartis, Gilead Sciences Inc., Bristol-Myers Squibb, Allogene Therapeutics Inc., Century Therapeutics, Inc., Nkarta Inc., Autolus Therapeutics plc, ADC Therapeutics, and Amgen.

With respect to CLN-617, we are not aware of any other drug candidates currently under development that integrate both IL-2 and IL-12 into a single multi-functional construct and stimulate the immune system in a tumor-specific manner. We are aware of several companies actively developing clinical-stage programs as either individual IL-2 or IL-12 therapies, including: Alkermes plc, Sanofi S.A., Philogen S.p.A., Roche, Apeiron Biologics AG, Werewolf Therapeutics, Inc., Xilio Therapeutics, Inc., and Dragonfly Therapeutics Inc.

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 have a more favorable label than our product candidates, we could see a reduction or elimination in our commercial opportunity. Our competitors also may obtain FDA or other regulatory approval for their drugs 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. 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.

License Agreements

DKFZ/Tübingen

Our partially-owned subsidiary Cullinan Florentine is party to an exclusive license agreement (the "DKFZ/Tübingen License Agreement"), 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 to 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, 2022, Cullinan Florentine has met the first performance benchmark to create a master cell bank.

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 milestones have been achieved to date under the DKFZ/Tübingen License Agreement.

Furthermore, Cullinan Florentine 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, 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 IND or clinical trial agreement, by providing prior written notice. Licensor may terminate the agreement by providing prior written notice, if Cullinan Florentine or any of its affiliates challenges the validity of certain patent rights. Unless earlier terminated, the DKFZ/Tübingen License Agreement continues on a perpetual basis. Refer to Note 7, *License and Collaboration Agreements*, of our consolidated financial statements included in this Annual Report on Form 10-K for further detail regarding the DKFZ/Tübingen License Agreement.

MIT

Our partially-owned subsidiary Cullinan Amber is party to an exclusive patent license agreement (the "MIT License Agreement") with MIT. Pursuant to the MIT License Agreement, MIT granted to Cullinan Amber an exclusive, worldwide, milestone-, equity- and royalty-bearing license under certain licensed patent rights and applications, with the right to grant sublicenses through three tiers (so long as Cullinan Amber remains an exclusive licensee of the patent rights in the field worldwide) to develop, make, have made, use, sell, have sold, offer to sell, lease, and import licensed products containing specific fusion proteins in the field of diagnosis, prognosis, prophylaxis or treatment of cancer in humans or other animals. MIT shall prepare, file, prosecute and maintain all of the patent rights, and Cullinan Amber shall cooperate with the prosecution, provide comments on patent prosecution documents, and pay all fees and costs relating to such prosecution and maintenance.

Cullinan Amber shall reimburse MIT for certain documented, out-of-pocket expenses incurred by MIT in connection with the preparation, filing, prosecution, maintenance and defense of the patent rights. The MIT License Agreement also provides for anti-dilution adjustments, requiring Cullinan Amber to issue MIT additional shares to ensure the shares issued to MIT do not equal less than the mid-single digit percentage amount until a financing threshold representing the aggregate investment in Cullinan Amber is reached. MIT was also granted participation rights, up to a low double-digit percentage of the securities issued, in any proposed financings of Cullinan Amber. Cullinan Amber is also responsible for paying non-refundable, creditable annual license maintenance fees in an increasing amount over a certain number of years of the license and a fixed amount subsequent to this period of time. In addition, MIT granted to Cullinan Amber an exclusive option to amend the definition of field to include expansion fields, and each such amendment would trigger the payment to MIT of an amendment fee and cause an amendment, to be negotiated upon exercise of the option, to Cullinan Amber's financial obligations with respect to the licensed products to reflect the additional rights and value being added.

Additionally, Cullinan Amber shall pay certain non-refundable, non-creditable milestone payments to MIT upon the achievement by itself or its sublicensees of certain clinical and regulatory milestones in an aggregate amount up to $7.0 million for each distinct licensed product. Each milestone payment is paid one time only up to a certain payment amount, except there are separate milestone payments payable for a second and third indication of a licensed product in an aggregate amount up to $5.5 million per product. Cullinan Amber shall also pay to MIT certain one-time milestone payments for the achievement of certain commercial milestones based on the calculation of net sales across all licensed products in all indications in an aggregate amount up to $12.5 million. As of December, 31, 2022, no milestones have been achieved under the MIT License Agreement.

Under certain conditions upon a change in control, Cullinan Amber is required to pay a specified change in control fee and Cullinan Amber's clinical and regulatory milestone payments shall be increased by a certain low three-digit percentage amount.

Furthermore, Cullinan Amber is required to pay a running mid-single digit royalty percentage on net sales of all licensed products for each reporting period, subject to certain offsets or reductions. The royalties due to MIT for net sales of all licensed products shall not be reduced by more than 50%. Cullinan Amber is also required to share any income from sublicensing the licensed products, with the percentage to be determined by the clinical phase of the licensed product, no greater than low-to-mid double-digit percentages. Such royalty obligations will expire on a country-by-country and product-by-product basis upon the expiration or abandonment of all issued patents and filed patent applications within the patent rights.

Under the MIT License Agreement, MIT must notify Cullinan Amber of certain patentable inventions conceived and reduced to practice during a certain period of time ("Improvements") and Cullinan Amber has the option to acquire rights to those Improvements upon MIT's approval of a business and development plan, not to be unreasonably withheld, for a specified fee. In addition to this specified fee, Cullinan Amber's financial obligations with respect to the Improvements may be amended to reflect the value being added, such as by adding an upfront fee, maintenance fees, and milestone payments.

Cullinan Amber may voluntarily terminate the MIT License Agreement for any reason after providing written notice within a specified period of time in advance, provided that all amounts due to MIT have been paid. MIT has the right to terminate the MIT License Agreement upon written notice to Cullinan Amber if Cullinan Amber ceases to carry out its business related to the MIT License Agreement. Either party may terminate the MIT License Agreement upon a material breach by the other party. Unless earlier terminated, the MIT License Agreement shall remain in effect until the expiration or abandonment of all issued patents and the filed patent application within the patent rights. Refer to Note 7, *License and Collaboration Agreements*, of our consolidated financial statements included in this Annual Report on Form 10-K for further detail regarding the MIT License Agreement.

Adimab

We have a collaboration agreement (the "Adimab Collaboration Agreement"), with 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 based upon mutually agreed upon research plans. Under the Adimab Collaboration Agreement, we have the ability to select a specified low single-digit number of additional biological targets against which Adimab will provide additional antibody discovery and optimization services.

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 its 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 in connection with Adimab's full-time employees' compensation for performance of Adimab's 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.

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 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. Refer to Note 7, *License and Collaboration Agreements*, of our consolidated financial statements included in this Annual Report on Form 10-K for further detail regarding the Adimab Collaboration Agreement.

Harbour

In February 2023, we entered into a License and Collaboration Agreement (the "Harbour License Agreement") with Harbour BioMed US Inc. ("Harbour"), pursuant to which Harbour granted us an exclusive license for the development, manufacturing and commercialization of HBM7008, which we now refer to as CLN-418, in the U.S.

Under the terms of the Harbour License Agreement, we paid Harbour an upfront license fee of $25 million upon entry into the agreement. Additionally, pursuant to the agreement, Harbour will be eligible to receive (i) up to $148 million in milestone payments based on the achievement of pre-specified development and regulatory milestones and (ii) up to an additional $415 million in sales-based milestones as well as tiered royalties up to high teens on a licensed product-by-licensed product basis, as a percentage of U.S. commercial sales. Harbour will grant us certain intellectual property rights to enable us to perform our obligations and exercise our rights under the Harbour License Agreement.

Unless earlier terminated, the Harbour License Agreement will continue in effect until the expiration of our royalty obligations. The Harbour 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. We may terminate the Harbour License Agreement for convenience by providing 90 days' written notice 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 16, 2023, our patent portfolio includes 9 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 31 patent applications pending worldwide. Patents that may issue from our pending patent applications, are expected to expire between 2039 and 2043, 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, through our subsidiary Cullinan MICA, own two patent families related to our CLN-619 product candidate, including patent families directed to compositions, and methods of using such compositions therapeutically. The family of patent applications with claims directed to CLN-619 compositions, if issued, are expected to expire in 2039, excluding any patent term adjustments or extensions, if applicable. For the first of these patent families, patent applications have so far been filed in Australia, Brazil, Canada, mainland China, the European Patent Office (the "EPO"), India, Indonesia, Israel, Japan, Korea, Malaysia, Mexico, New Zealand, the Philippines, Russia, Singapore, South Africa, Thailand, the U.S., and Vietnam. A patent family with claims directed to additional anti-MICA antibody compositions and methods of use, if issued, is expected to expire in 2043, excluding any patent term adjustments or extensions, if applicable. A U.S. provisional application has been filed under this family.

Our portfolio related to our CLN-049 product candidate includes one patent family, in-licensed from the University of Tubingen, directed to compositions, and methods of using such compositions therapeutically. This 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. Patent applications have so far been filed for this family in Australia, Brazil, Canada, mainland China, the EPO, Hong Kong, India, Indonesia, Israel, Japan, Korea, Malaysia, Mexico, New Zealand, the Philippines, Singapore, South Africa, Thailand, the U.S. and Vietnam.

Our portfolio related to our CLN-617 product candidate and Cullinan Amber program includes two patent families. The first family was in-licensed from MIT, directed to compositions, and methods of using such compositions therapeutically. This family of patent applications contain claims covering Cullinan Amber related compositions, which, if issued, are expected to expire in 2039, excluding any patent term adjustments or extensions, if applicable. Patent applications have so far been filed for this family in Australia, Brazil, Canada, mainland China, the EPO, Israel, Japan, Korea, Singapore, and the U.S. The second family is a PCT application owned by Cullinan Amber, which is directed to certain compositions, and methods of using such compositions therapeutically. This family contains claims covering additional Cullinan Amber related compositions, which, if issued, are expected to expire in 2041, excluding any patent term adjustments or extensions, if applicable.

Our portfolio related to our CLN-978 product candidate includes three 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 EPO, 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.

Our portfolio related to compositions comprising compounds which degrade HPK1 and methods of using such compounds therapeutically, includes one patent family that is jointly owned with Icahn School of Medicine at Mount Sinai. This patent family contains claims directed to compositions comprising HPK1 degraders and methods of using such compounds. A PCT application has been filed for this patent family. Applications claiming priority to the PCT application, if issued, are expected to expire in 2042, 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, and currently have no plans to establish, any good manufacturing practice ("GMP"), 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 receive material from our contract manufacturing organizations ("CMOs") for preclinical testing. We receive clinical supply material manufactured in compliance with current GMP requirements ("cGMPs"), and we conduct audits before and during the trial, in cooperation with a CMO, to ensure compliance with the mutually agreed-upon process descriptions and cGMP regulations.

Zipalertinib, which we are co-developing with an affiliate of Taiho, is a small molecule that is manufactured in synthetic processes from available starting materials. The chemistry appears amenable to scale-up and does not currently require unusual equipment in the manufacturing process. We generally expect to rely on third parties for the manufacture of companion diagnostics, which are assays or tests that identify an appropriate patient population for zipalertinib. Depending on the technology solutions we choose, we may rely on multiple third parties to manufacture and sell a single test.

To date, we have obtained drug substance and drug product from single-source third-party contract manufacturers, which is typical for this stage of development. We utilize a global network of manufacturers for our programs in development, with vendors located in the U.S., Europe, and Asia. Any reduction or halt in supply of drug substance or drug product from these contract manufacturers could limit our ability to develop our product candidates until we find a qualified replacement contract manufacturer. However, 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.

CLN-049, CLN-619, CLN-418, CLN-978 and CLN-617 are manufactured from a vial of a master cell bank ("MCB"), from the respective production cell lines. We have one MCB for each program that was produced and tested in accordance with cGMPs and applicable regulations. We either already have in place or intend to produce working cell banks for each product candidate later in product development. It is possible that we could lose multiple cell banks from multiple locations and have our manufacturing severely impacted by the need to replace the cell banks. However, we believe we have adequate backup should any particular cell bank be lost in a catastrophic event.

Governmental Regulation

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. Our product candidates are early-stage and have not 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 drug product candidates regulated under the FDCA, such as zipalertinib, the FDA must approve a New Drug Application ("NDA"). For our biologic product candidates regulated under the FDCA and PHSA, such as CLN-049, CLN-619, CLN-418, and CLN-978, the FDA must approve a Biologics License Application ("BLA"). The process is similar and generally involves 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 at each clinical trial site before each 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.

Preclinical and Clinical Trials

Before testing any drug or biologic in humans, the product candidate must undergo rigorous preclinical testing. Preclinical studies include laboratory evaluations of chemistry, formulation and stability, as well as *in vitro* and animal studies to assess 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. In the U.S., the IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks and imposes a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Some long-term preclinical testing may continue after the IND is submitted. Accordingly, submission of an IND may or may not result in FDA authorization to begin a trial.

The clinical stage of development involves the administration of the product candidate to healthy volunteers or patients 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, 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 specific timeframes 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. The FDA will accept a well-designed and well-conducted foreign clinical study not conducted under an IND if the study was conducted in accordance with GCP requirements, and the FDA is able to validate the data through an onsite inspection if deemed necessary.

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 trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These 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. Failure to exhibit due diligence with regard to conducting required Phase 4 clinical trials could result in withdrawal of approval for products.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical study investigators. Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators fifteen days after the trial sponsor determines the information qualifies for reporting for serious and unexpected suspected adverse events, findings from other studies or animal or *in vitro* testing that suggest a significant risk for human participants exposed to the drug or biologic and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must also notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible but in no case later than seven calendar days after the sponsor's initial receipt of the information.

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 candidate.

Expanded Access

Expanded access, sometimes called 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 under an IND by us or the treating physician for treatment purposes 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.

There is no requirement for a company to provide expanded access to its investigational product. However, if a company decides to make its investigational product available for expanded access, the FDA reviews each request for expanded access and determines if treatment may proceed. Expanded access may be appropriate when all of the following criteria apply: the patient has a serious or immediately life-threatening disease or condition, and there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition; the potential benefit justifies the potential risks of the treatment and the potential risks are not unreasonable in the context of the disease or condition to be treated; and providing the investigational product for the requested use will not interfere with the initiation, conduct, or completion of clinical investigations that could support marketing approval of the expanded access use or otherwise compromise the potential development of the expanded access use.

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.

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 study, or 15 days after the investigational drug or biologic receives designation as a Breakthrough Therapy, Fast Track product, or regenerative medicine advanced therapy. 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

Assuming successful completion of the required clinical testing, 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, 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 NDA or BLA for filing. The FDA makes a decision on accepting an NDA or BLA for filing within 60 days of receipt, and such decision could include a refusal to file by the FDA. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the application. The FDA reviews an NDA or BLA to determine, among other things, whether the product is safe and effective and whether the facility in which it is manufactured, processed, packaged or held meets standards, including cGMP requirements, designed to assure and preserve the product's identity, strength, quality and purity. Under the goals and polices agreed to by the FDA under the Prescription Drug User Fee Act ("PDUFA"), the FDA targets ten months from the filing date in which to complete its initial review of an original NDA or BLA and respond to the applicant, and six months from the filing date of an original NDA or BLA filed for priority review. The FDA does not always meet its PDUFA goal dates for standard or priority NDAs or BLAs, and the review process is often extended by FDA requests for additional information or clarification.

Further, under PDUFA, as amended, each NDA or BLA must be accompanied by a user fee, and the sponsor of an approved NDA or BLA is also subject to an annual program fee. The FDA adjusts the PDUFA user fees on an annual basis. Fee waivers or reductions may be available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs or BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA may refer an application for a drug or biologic to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, which reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

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.

After evaluating the application and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a complete response letter. A complete response letter indicates that the review cycle of the application is complete and the application is not ready for approval. A complete response letter will usually describe all of the deficiencies that the FDA has identified in the NDA or BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the complete response letter without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the complete response letter, the FDA may recommend actions that the applicant might take to place the NDA or BLA in condition for approval, including requests for additional information or clarification. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications.

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, and it remains to be seen how this decision affects orphan drug exclusivity going forward.

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.

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.

In addition, drug and biologics manufacturers and their subcontractors involved in the manufacture and distribution of approved products are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMP, which impose certain procedural and documentation requirements upon us and our CMOs. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory 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 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 an NDA or BLA plus the time between the submission date of an NDA or BLA 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 NDA or BLA.

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 runs from 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, 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., healthcare providers, physicians, and third-party payors will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our business operations and any current or future arrangements with third-party payors, healthcare providers and physicians may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we develop, market, sell and distribute any drugs for which we obtain marketing approval. In the U.S., these laws include, without limitation, state and federal anti-kickback, false claims, physician transparency, and patient data privacy and security laws and regulations, including but not limited to those described below.

- The federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, paying, receiving or providing any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid; a person or entity need not have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. In December 2020, the HHS Office of Inspector General ("OIG") published further modifications to the federal Anti-Kickback Statute. Under the final rules, OIG added safe harbor protections under the Anti-Kickback Statute for certain coordinated care and value-based arrangements among clinicians, providers, and others, although the portion of the rule eliminating safe harbor protection for certain rebates related to the sale or purchase of a pharmaceutical product from a manufacturer to a plan sponsor under Medicare Part D was delayed to January 2026 under the Infrastructure Investment and Jobs Act. Implementation of this change and new safe harbors for point-of-sale reductions in price for prescription pharmaceutical products and pharmacy benefit manager service fees are currently under review by the Biden administration and may be amended or repealed. We continue to evaluate what effect, if any, these rules will have on our business;
- The federal civil and criminal false claims laws, including the civil False Claims Act (the "FCA"), which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false, fictitious or fraudulent; knowingly making, using, or causing to be made or used, a false statement or record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government;
- Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. In addition, the government may assert that a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;
- The federal civil monetary penalties laws, which impose civil fines for, among other things, the offering or transfer or remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state health care program, unless an exception applies;
- The Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), imposes criminal and civil liability for knowingly and willfully executing a scheme, or attempting to execute a scheme, to defraud any healthcare benefit program, including private payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, or falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity need not have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), and their respective implementing regulations, imposes, among other things, specified requirements on covered entities and their business associates relating to the privacy and security of individually identifiable health information including mandatory contractual terms and required implementation of technical safeguards of such information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates in some cases, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;

- The Physician Payments Sunshine Act, enacted as part of the ACA, imposed new annual reporting requirements for certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, for certain payments and "transfers of value" provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. In addition, many states also require reporting of payments or other transfers of value, many of which differ from each other in significant ways, are often not pre-empted, and may have a more prohibitive effect than the Sunshine Act, thus further complicating compliance efforts; and
- Analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and may be broader in scope than their federal equivalents; state and foreign laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, and restrict marketing practices or require disclosure of marketing expenditures and pricing information; state and local laws that require the registration of pharmaceutical sales representatives; state and foreign laws that govern the privacy and security of health information in some circumstances. These data privacy and security laws may differ from each other in significant ways and often are not pre-empted by HIPAA, which may complicate compliance efforts.

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 that potentially harm consumers.

The distribution of drugs and biological 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.

The full scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. 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. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other related governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, disgorgement, exclusion from government funded healthcare programs, such as Medicare and Medicaid, reputational harm, additional oversight and reporting obligations if we become subject to a corporate integrity agreement or similar settlement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to similar actions, penalties and sanctions. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from its business.

U.S. Coverage and Reimbursement

In the U.S. and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Thus, even if a product candidate is approved, sales of the product will depend, in part, on the extent to which third-party payors, including government health programs in the U.S. such as Medicare and Medicaid, commercial health insurers and managed care organizations, provide coverage, and establish adequate reimbursement levels for, the product. In the U.S., no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, 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. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the approved products for a particular indication.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. Factors payors consider in determining reimbursement are based on whether the product is a covered benefit under its health plan; safe, effective and medically necessary; appropriate for the specific patient; cost-effective; and neither experimental nor investigational. Additionally, companies may also need to provide discounts to purchasers, private health plans or government healthcare programs. Nonetheless, product candidates may not be considered medically necessary or cost effective. A decision by a third-party payor not to cover a product could reduce physician utilization once the product is approved and have a material adverse effect on sales, our operations and financial condition. Additionally, a third-party payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor.

The containment of healthcare costs has become a priority of federal, state and foreign 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 of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and 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; created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; and provided incentives to programs that increase the federal government's comparative effectiveness research.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. Various portions of the ACA are currently undergoing legal and constitutional challenges in the U.S. Supreme Court, and members of Congress have introduced several pieces of legislation aimed at significantly revising or repealing the ACA. A case that challenges the constitutionality of the ACA, *California v. Texas*, was argued before the U.S Supreme Court in November 2020. In June 2021, the Supreme Court held that the plaintiffs lacked standing to challenge the ACA. Notwithstanding the Supreme Court's ruling, we cannot say for certain whether there will be future challenges to the ACA or what impact, if any, such challenges may have on our business. The implementation of the ACA is ongoing, the law appears likely to continue the downward pressure on pharmaceutical pricing, especially under the Medicare Drug Rebate Program, and may also increase our regulatory burdens and operating costs. Litigation and legislation related to the ACA are likely to continue, with unpredictable and uncertain results.

Other legislative changes have been proposed and adopted in the U.S. since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030 unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, in the U.S., CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their commercial products, which has resulted in several Congressional inquiries and proposed and enacted state and federal legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for pharmaceutical products. On March 10, 2020, the Trump administration sent “principles” for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Further, the Trump administration previously released a “Blueprint” to lower drug prices and reduce out-of-pocket costs of drugs that contained proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out-of-pocket costs of drug products paid by consumers. HHS has already implemented certain measures. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020. This final rule codified CMS’s policy change that was effective January 1, 2019. However, it is unclear whether the Biden administration will challenge, reverse, revoke or otherwise modify these executive and administrative actions. In addition, individual states in the U.S. have also increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, it is possible that additional governmental action is taken to address the COVID-19 pandemic.

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. EU member states 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.

Compliance with Other Federal and State Laws or Requirements; Changing Legal Requirements

If any products that we may develop are made available in the U.S. to authorized users of the Federal Supply Schedule of the U.S. General Services Administration, additional laws and requirements apply. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, labeling, packaging, distribution, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws, among other requirements to we may be subject.

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.

The failure to comply with any of these laws or regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, exclusion from federal healthcare programs, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals, relabeling or repackaging, or refusal to allow a firm to enter into supply contracts, including government contracts. Any claim or 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. Prohibitions or restrictions on marketing, sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

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 or packaging; (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.

European Drug Development

In the EU, our future products also may be subject to extensive regulatory requirements. As in the U.S., medicinal products can be marketed only if a marketing authorization from the competent regulatory agencies has been obtained.

Similar to the U.S., the various phases of preclinical and clinical research in the EU are subject to significant regulatory controls. Although the EU Clinical Trials Directive 2001/20/EC (the "Clinical Trials Directive") sought to harmonize the EU clinical trials regulatory framework, setting out common rules for the control and authorization of clinical trials in the EU, the EU member states interpreted and applied the provisions of the Clinical Trials Directive differently. This led to significant variations in the EU member state regimes. Under the regime provided by the Clinical Trials Directive, before a clinical trial could be initiated it had to be approved in each of the EU member states where the trial was to be conducted by two distinct bodies: the National Competent Authority (the "NCA"), and one or more Ethics Committees (the "ECs"). All suspected unexpected serious adverse reactions to the investigated drug that occurred during the clinical trial had to be reported to the NCA and ECs of the EU member state where they occurred.

The EU clinical trials legislation currently is undergoing a transition process mainly aimed at harmonizing and streamlining clinical-trial authorization ("CTA"), simplifying adverse-event reporting procedures, improving the supervision of clinical trials and increasing their transparency. In January 2022, the Clinical Trials Regulation EU No 536/2014 (the "Clinical Trials Regulation") entered into application and repealed the Clinical Trials Directive. The Clinical Trials Regulation is directly applicable in all EU member states (and so did not require national implementing legislation in each EU member state), and simplifies and streamlines the approval of clinical studies in the EU, for instance by providing for a streamlined application procedure for CTAs via a single point known as the Clinical Trials Information System ("CTIS"). The Clinical Trials Regulation foresees a three-year transition period. As of January 31, 2023, all new CTA applications must use CTIS and be made pursuant to the Clinical Trials Regulation. From January 31, 2025 and onwards, any trials approved under the Clinical Trial Directive which are still ongoing will need to comply with the Clinical Trials Regulation and be recorded in CTIS.

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 has been transposed into the UK Human Medicines Regulations 2012 and so remains applicable in the UK despite its departure from the EU.

In the EU and UK, the statutory regimes applicable to the advertising of medicinal products are supplemented by the self-regulatory regime governed by the industry's codes of practice developed by trade organizations. Such codes of practice 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"). There are two types of marketing authorizations.

- The centralized MA is issued by the European Commission through the centralized procedure, based on the opinion of the Committee for Medicinal Products for Human Use (the "CHMP"), of the EMA, and is valid throughout the entire territory of the EEA. The centralized procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, advanced-therapy medicinal products (gene-therapy, somatic cell-therapy or tissue-engineered medicines) and medicinal products containing a new active substance indicated for the treatment of human immunodeficiency virus, acquired immunodeficiency syndrome, cancer, neurodegenerative disorders, diabetes, auto-immune and other immune dysfunctions and viral diseases. The centralized procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU. Under the centralized procedure, the maximum timeframe for the evaluation of a MA application by the EMA is 210 days, excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP. Clock stops may extend the timeframe of evaluation of a MA application considerably beyond 210 days. Where the CHMP gives a positive opinion, the EMA provides the opinion together with supporting documentation to the European Commission, who makes the final decision to grant a MA, which is ordinarily issued within 67 days of receipt of the EMA's recommendation. Accelerated assessment might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, particularly from the point of view of therapeutic innovation. The timeframe for the evaluation of a MA application under the accelerated assessment procedure is 150 days, excluding clock stops, but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that the application is no longer appropriate to conduct an accelerated assessment.
- 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 decentralized procedure, an identical dossier is submitted to the NCAs of each of the EEA member states in which the MA is sought, one of which is selected by the applicant as the Reference Member State (the "RMS"). The competent authority of the RMS prepares a draft assessment report, a draft summary of the product characteristics ("SmPC"), and a draft of the labeling and package leaflet, which are sent to the other EEA member states, referred to as the Concerned Member States, for their approval. If the Concerned Member States raise no objections, based on a potential serious risk to public health, to the assessment, SmPC, labeling, or packaging proposed by the RMS, the product is subsequently granted a national MA in all EEA member states to which an application was submitted.

Under the procedures described above, before granting the MA, the EMA or the NCAs of the EEA member states make an assessment of 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 will continue to be recognized in Northern Ireland). All medicinal products with a current centralized MA were automatically converted to Great Britain MAs on January 1, 2021. For a period of three years from January 1, 2021, the Medicines and Healthcare products Regulatory Agency (the "MHRA"), the UK medicines and medical devices regulator, may rely on a decision taken by the European Commission on the approval of a new MA in the centralized procedure, in order to more quickly grant a new Great Britain MA. A separate application will, however, still be required.

European Data and Marketing Exclusivity

In the EEA, innovative medicinal products (including both small molecules and biological medicinal products) benefit from eight years of data exclusivity 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.

European Orphan Designation and Exclusivity

In the EEA, the EMA's Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions which either affect not more than 5 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 EEA, orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity is granted 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 must be requested before submitting an application for marketing approval. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The UK domestic law has adopted the same system for granting orphan exclusivity. However, there is no pre-marketing authorization orphan designation in the UK.

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.

Brexit and the Regulatory Framework in the United Kingdom

In June 2016, the electorate in the UK voted in favor of leaving the EU (commonly referred to as "Brexit"). Thereafter, in March 2017, the country formally notified the EU of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty, and the UK formally left the EU on January 31, 2020. A transition period began on February 1, 2020, during which EU pharmaceutical legislation remained applicable to the UK. When the transition period expired on December 31, 2020, the UK became a "third country" for the purposes of EU law. Since the UK had already implemented the EU pharmaceutical legislation into its domestic legislation through the Human Medicines Regulations 2012 (as amended), immediate changes were made to this legislation to reflect the UK's new status. Article 5(4) of Annex 2 to the Northern Ireland Protocol contained in the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community requires certain aspects of EU pharmaceutical law to be applied in Northern Ireland following the UK's withdrawal from the EU.

On May 1, 2021, the EU and UK trade and cooperation agreement ("TCA") entered into application. The TCA includes specific provisions concerning pharmaceuticals, which include the mutual recognition of the outcomes of GMP inspections. Applicants and MA holders may submit GMP certificates issued by the MHRA for sites located outside the EU/EEA as supporting information for EU regulatory submissions. However, the TCA does not foresee wholesale mutual recognition of UK and EU pharmaceutical regulations. The regulatory regime in Great Britain currently broadly aligns with EU regulations. However, it is possible that these regimes may diverge in the future.

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 EU or the monitoring of the behavior of data subjects in the EU. 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.

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.

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.

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012. We will remain an emerging growth company until the earlier of: (i) the last day of the fiscal year (a) following the fifth anniversary of the completion of the IPO, (b) in which we have total annual gross revenue of at least $1.235 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (ii) the date on which we have issued more than $1 billion in non-convertible debt during the prior three-year period.

Human Capital Resources

As of December 31, 2022, we had 62 full-time employees and two consultants. Nineteen of our employees have M.D. or Ph.D. degrees. Within our workforce, 35 employees are engaged in research and development and 27 are engaged in business development, finance, legal, and general management and administration. Four of the ten members of our management executive team are women. Across our broader population, approximately 60% of full-time employees are women. Our management executive team places significant focus and attention on matters concerning our human capital assets - particularly the diversity of our workforce and their capability development.

Our office space is in Greater Boston, which we believe provides access to a vibrant biotech and pharmaceutical talent pool. We believe that employee compensation should be both competitive and equitable. We have programs in place to attract and retain talent, including stock-based compensation and cash performance awards. We also 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. 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.

Available Information

Our corporate website address is https://www.cullinanoncology.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 product candidates, including zipalertinib (CLN-081/TAS6417), CLN-049, CLN-619, and CLN-418, 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 trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants.

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 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.

Our approach to the identification, discovery, and development of targeted oncology product candidates may never lead to marketable products.

The scientific evidence to support the feasibility of developing product candidates based on our discoveries to date is both preliminary and limited. The patient populations for certain of our product candidates are limited to those with specific target mutations, and we will need to screen and identify these patients with the targeted mutations. Successful identification of patients is dependent on several factors, including achieving certainty as to how specific genetic alterations and larger classes of mutations, such as epidermal growth factor receptor ("EGFR") exon 20 insertion mutations, respond to our product candidates, and developing companion diagnostics to identify such genetic alterations. Furthermore, even if we are successful in identifying patients, we cannot be certain that the resulting patient populations for each mutation or class of mutations will be large enough to allow us to successfully obtain indications for each mutation type and to commercialize our products and achieve profitability. The FDA and other regulatory authorities may not agree with our approach to seek labeling for groups of related mutations, rather than individual mutations, and may require us to conduct additional trials and obtain separate approvals for each individual mutation, which may further affect our ability to successfully commercialize our products, if approved. In addition, even if our approach is successful in showing clinical benefit for tumors harboring certain targeted mutations, we may never successfully identify additional oncogenic mutations. Therefore, we do not know if our approach of treating patients with targeted oncology therapies will be successful, and if our approach is unsuccessful, our business will suffer.

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 may be open-label in study 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 patients in open-label clinical trials are aware when they 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. Given that our Phase 1/2a and pivotal Phase 2b clinical trials of zipalertinib in collaboration with our partners at Taiho Pharmaceutical, Co., Ltd. (“Taiho”) include an open-label dosing 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 and clinical trials, or may not be able to conduct or complete preclinical 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 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 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 independent ethics committee 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 tumor types or indications;
- 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 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 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 approving our product candidates, or such requirements may not be as we anticipate; and
- future 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 ethics committees 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 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 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 and are substantially dependent on our lead product candidates, zipalertinib, CLN-049, CLN-619, and CLN-418. If we are unable to advance these or any of our other 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 will be materially harmed.

We are early in our development efforts. Our lead program, zipalertinib, is in a pivotal Phase 2b clinical trial in collaboration with our partners at Taiho. Additionally, our product candidates CLN-049, CLN-619, and CLN-418 each are in Phase 1 clinical trials. Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful clinical development and eventual commercialization of zipalertinib, CLN-049, CLN-619, and CLN-418 and our other product candidates, if approved. The success of our 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 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 cancer therapies;
- obtaining and maintaining third-party coverage and adequate reimbursement; 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 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 product candidates, obtain regulatory approval, and ultimately commercialize our product candidates, our business will be materially harmed.

There is no guarantee that the results obtained in current preclinical studies or our ongoing clinical trials of zipalertinib in EGFR exon 20 insertion mutation non-small-cell lung carcinoma ("NSCLC"), patients, CLN-049 in patients with relapsed or refractory acute myeloid leukemia ("r/r AML"), CLN-619 in patients with solid tumors, or CLN-418 in patients with advanced solid tumors will be sufficient to obtain regulatory approval or marketing authorization for such product candidates. For example, the FDA may require us to complete trials in addition to our ongoing Phase 1/2a clinical trial and pivotal Phase 2b trial for zipalertinib in collaboration with our partners at Taiho prior to granting regulatory approval. 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. For each of our product candidates, antitumor activity may be different in each of the different tumor types 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 to agree on the optimal patient population, study design, and size for each 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 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 may experience delays 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 a sufficient number of eligible patients to participate in these 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 trial. In particular, because we are focused on patients with specific genetic mutations for the development of zipalertinib, our ability to enroll eligible patients may be limited or enrollment may be slower than we anticipate due to the small eligible patient population. For our Phase 1 trial evaluating CLN-049 in r/r AML patients, our ability to enroll eligible patients may be limited or enrollment may be slower than we anticipate due to enrollment criteria and the single ascending dose design.

In addition to the potentially small populations, the eligibility criteria of our planned clinical trials will further limit the pool of available study participants as we require that patients have specific characteristics, such as a certain severity or stage of disease progression, to include them in a study. 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 study, the availability and efficacy of competing therapies and clinical trials, the proximity and availability of clinical study sites for prospective patients, the availability of genetic sequencing information for patient tumors so that we can identify patients with the targeted genetic mutations, 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;
- 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 current or potential pandemics that may limit patients, principal investigators or staff or clinical site availability (e.g., the COVID-19 pandemic).

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 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 chemotherapy, 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 is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the 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. 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 or IND amendments 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.

We have submitted INDs for zipalertinib, CLN-049, CLN-619 and CLN-978, which are all currently in effect. In addition, we submitted an IND for CLN-617 in February 2023. However, we may not be able to file future INDs 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 regulatory authorities may require additional preclinical studies that we did not anticipate. Moreover, we cannot be sure that submission of an IND will result in the FDA 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 regulatory authorities to suspend or terminate clinical trials, including as a result of a clinical hold. Additionally, even if the FDA or other regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND, 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 on the timelines we expect or to obtain regulatory approvals for our trials may prevent us from completing our clinical trials or commercializing our products on a timely basis, if at all.

We intend to develop CLN-619 and potentially other product candidates in combination with other therapies, which exposes us to additional risks.

We intend to develop CLN-619 and potentially other 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 European Manufacturing Agency (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 cancer 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 cancer 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 develop, 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 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 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 therapeutic 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.

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 trials may cause us, or cause the FDA, the EMA or other regulatory authorities, or IRBs to order us to halt, delay or amend preclinical development or clinical development of our product candidates and could result in more restrictive labelling 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 trial. In addition, if any of our product candidates are tested or used in combination with other drugs, such as our plans to potentially use CLN-619 in combination with other agents, 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 drug. For example, while we believe that zipalertinib has demonstrated a manageable tolerability profile thus far, there can be no assurance that it 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;
- 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;
- we could be sued and held liable for injury caused to individuals exposed 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 regulatory authorities may require us to conduct additional and larger trials than we may plan to support applications for marketing authorization. If we conduct any future clinical trials of zipalertinib, CLN-049, CLN-619, or CLN-418 or of our other 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 evaluating zipalertinib in a Phase 1/2a trial and a pivotal Phase 2b trial in collaboration with our partners at Taiho, CLN-619 in a Phase 1 clinical trial, and CLN-418 in a Phase 1 clinical trial that include centers located inside and outside of the U.S. We may also in the future choose to conduct one or more additional clinical trials outside the U.S., including in Europe and Australia. 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 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 trials are subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. We would need to conduct additional trials if the FDA or any comparable foreign regulatory authority does not accept data from 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.

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 been limited to organizing and staffing our company, business planning, raising capital for us and our subsidiaries, filing patent applications, identifying and 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, complete any 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. We are still in the early stages of development of our product candidates. 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 incurred significant net losses in each period since we began substantive operations. For 2022 and 2021, we reported net income of $109.2 million and a net loss of $67.5 million, respectively. As of December 31, 2022, we had an accumulated deficit of $47.7 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 for our 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 successful 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 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 our previous licensing agreement with Zai Lab, 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 zipalertinib (pursuant to the co-development agreement with Taiho), CLN-049, CLN-619, and CLN-418 in clinical development, in addition to our other product candidates 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 product candidates or any future product candidates;
- our ability to timely seek and obtain regulatory and marketing approvals for any of our product candidates or any future product candidates for which we complete clinical trials;
- the prevalence, duration, and severity of potential side effects or other safety issues experienced by patients receiving our product candidates or future product candidates;
- the willingness of physicians, operators of clinics, and patients to utilize or adopt any of our product candidates or future product candidates over alternative or more conventional therapies, such as chemotherapy;
- the actual and perceived availability, cost, risk profile, and side effects, and efficacy of our product candidates, if approved, relative to existing and future alternative cancer 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 future U.S. sales of zipalertinib, each pursuant to the co-development agreement with Taiho;
- our ability and the ability of third parties with whom we contract to manufacture adequate clinical and commercial supplies of our product candidates or any 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 product candidates or any 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 product candidates and any future product candidates, if approved; and
- our ability to establish and enforce intellectual property rights in and for our product candidates or any 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 product candidates. Even if we are able to commercialize our 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 product candidates or any 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 product candidates and identify and invest in new 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 zipalertinib (pursuant to the co-development agreement with Taiho), CLN-049, CLN-619, and CLN-418 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." Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations, which may include raising funding by one or more of our subsidiaries that could dilute our equity interest in the subsidiary. 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, either by us or by one or more of our subsidiaries. If we or our subsidiaries are unable to raise capital when needed or on attractive terms, we or the applicable subsidiary would be forced to delay, reduce, or eliminate our identification, discovery, and preclinical or clinical development programs, or any future commercialization efforts.

We had cash and cash equivalents and short-term investments of $467.3 million and long-term investments and interest receivable of $82.8 million as of December 31, 2022. We believe that, based upon our current operating plan, our existing capital resources will be sufficient to fund our anticipated operations into 2026. 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 future U.S. sales of zipalertinib, each pursuant to the co-development agreement with 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 or our subsidiaries engage in acquisitions or strategic partnerships, this may increase our or their capital requirements, dilute our or their stockholders, cause us or them to incur debt or assume contingent liabilities, and subject us or them to other risks.

In June 2022, we sold our equity interest in Cullinan Pearl Corp. ("Cullinan Pearl"), formerly a partially-owned subsidiary of the Company, to Taiho and we entered into a co-development agreement with an affiliate of Taiho to co-develop and, at our option, co-commercialize zipalertinib in the U.S. Pursuant to the terms of the co-development agreement with Taiho, development costs for zipalertinib incurred after the sale of our equity interest in Cullinan Pearl will be shared equally between us and Taiho, with each party receiving 50% of any future pre-tax profits from potential U.S. sales of zipalertinib. In addition, in October and November 2022, we purchased equity interests from Cullinan MICA Corp. ("Cullinan MICA") stockholders and acquired additional shares in a private placement. We currently hold 95% of Cullinan MICA's outstanding equity. Cullinan MICA owns the intellectual property related to CLN-619.

We intend to engage in various acquisitions and strategic partnerships in the future, including licensing or acquiring products, intellectual property rights, technologies, or businesses, carried out either by us or by one or more of our wholly- or partially-owned subsidiaries, including a newly-formed subsidiary formed for the purpose of such transaction. Any acquisition or strategic partnership, including the co-development agreement with Taiho, may entail numerous risks to us or the applicable subsidiary, 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 employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and 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.

Risks Related to Our Corporate Structure

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

A key 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. We may not be successful in our efforts in building a pipeline of product candidates for the treatment of various 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, 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.

Additionally, we are pursuing additional in-licenses or acquisitions of development-stage assets or programs, which entails additional risk to us. 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.

Our subsidiaries are party to certain agreements that provide our licensors, collaborators, or other shareholders in our subsidiaries with rights that could delay or impact the potential sale of our subsidiaries or could impact the ability of our subsidiaries to sell assets, or enter into strategic alliances, collaborations, or licensing arrangements with other third parties.

Each of our subsidiaries licenses intellectual property from third parties and several have raised capital from third-party investors. 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, our partially-owned subsidiaries Cullinan Florentine Corp. ("Cullinan Florentine"), and Cullinan Amber Corp. ("Cullinan Amber"), will also owe licensors a success fee in the event of a sale or other disposition of the majority of its assets. These fees 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 partially-owned subsidiaries. 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 our subsidiaries and us less attractive to third parties.

We may form additional subsidiaries and enter into similar agreements with future partners or investors, or our subsidiaries may enter into further agreements, that in each case may contain similar provisions or other terms that are not favorable to us.

Our ability to realize value from our subsidiaries may be impacted if we reduce our ownership to a minority interest or otherwise cede control to other investors through contractual agreements or otherwise.

In the event that any of our subsidiaries require additional capital and its respective board of directors authorizes the transaction, our equity interest in our subsidiaries may be further reduced to the extent such additional capital is obtained from third-party investors rather than from us. However, such transactions would still need to be approved by the board of directors of our respective subsidiary over which we maintain full control.

However, if we do not wish to or cannot provide additional capital to any of our subsidiaries, we may approve of an issuance of equity by a subsidiary that dilutes our ownership and may lose control over the subsidiary.

In June 2022, we completed the sale of our equity interest in Cullinan Pearl, formerly a partially-owned subsidiary of the Company, to Taiho for an upfront payment of $275.0 million. We may receive up to an additional $130.0 million upon the achievement of certain regulatory milestones related to zipalertinib. There is no guarantee that these milestones will be achieved or that we will receive any of the additional $130.0 million. In connection with the sale of our equity interest in Cullinan Pearl, we entered into a co-development agreement with Taiho, pursuant to which we and Taiho will co-develop and, at our option, co-commercialize zipalertinib in the U.S. Taiho and us will share the future clinical development costs of zipalertinib equally, and each will receive 50% of any future pre-tax profits from potential U.S. sales of zipalertinib. There is no guarantee that the co-development and co-commercialization will be successful or that we will receive any net profits and we could lose money.

A single or limited number of subsidiaries may comprise a large proportion of our value.

A large proportion of our value may at any time reside in one or two of our subsidiaries, including intellectual property rights and the value ascribed to the product candidate or program that it is developing. Our consolidated financial condition and prospects may be materially diminished if the clinical development or potential commercialization prospects of a subsidiary's product candidate or program or one or more of the intellectual property rights held by a specific subsidiary becomes impaired. Furthermore, a large proportion of our consolidated revenue may at any time be derived from one, or a small number of, licensed technologies, and termination or expiration of licenses to these technologies would likely have a material adverse effect on our consolidated revenue. Any material adverse impact on the value of a particular subsidiary, including its intellectual property rights or the clinical development of its product candidate or program, could have a material adverse effect on our consolidated business, financial condition, results of operations or prospects.

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 must focus on a limited number of research programs and product candidates and on 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 or fail to recognize or acquire assets that may be more promising than those we acquire. 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 identification, discovery, and preclinical development programs and product candidates for specific indications may not yield any commercially viable products.

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

As of December 31, 2022, we had 62 full-time employees upon which we rely for various administrative, research and development, and other support services shared among our other operating subsidiaries. We also have two consultants who we rely on for research and development, business development, and other services. While we believe this structure enables us to reduce certain infrastructure costs, the small size of our centralized team may limit our ability to devote adequate personnel, time, and resources to support the operations of all of our subsidiaries, including their research and development activities, and the management of financial, accounting, and reporting matters. Given that our employees and management are primarily incentivized at the parent company level, these employees and management team members may not be sufficiently incentivized to maximize the overall value of our entire organization. If our centralized team fails to provide adequate administrative, research and development, or other services across our entire organization, our business, financial condition, and results of operations could be harmed.

Some of our officers and directors currently serve, and in the future may serve, as directors or officers of our subsidiaries, and, as a result, have and may continue to have, fiduciary and other duties to our subsidiaries causing conflicts of interest with respect to their duties to us and their duties to our subsidiaries and in determining how to devote themselves to our affairs and the affairs of our subsidiaries. Our subsidiaries' partners may also disagree with the sufficiency of resources that we provide to each subsidiary.

Certain of our officers are also directors and/or officers of one or more of our subsidiaries and, as a result, have fiduciary or other duties both to us and our subsidiaries. The conflicts of interest that arise from such duties could interfere with the management of our subsidiaries and their programs and product candidates, or result in disagreements with our subsidiaries' partners. For example, an individual who is both a director of one of our subsidiaries and a director of Cullinan owes fiduciary duties to the subsidiary and to the Company as a whole, and such individual may encounter circumstances in which his or her decision or action may benefit the subsidiary while having a detrimental impact on the Company, or vice versa, or on another subsidiary, including one for which he or she also serves as a director. Further, our officers and directors who are also officers and directors of our subsidiaries will need to allocate his or her time to responsibilities owed to Cullinan and each of the subsidiaries for which he or she serves as an officer or director, and will make decisions on behalf of one entity that may negatively impact others. In addition, while most of our subsidiaries have waived any interest or expectation of corporate opportunities that is presented to, or acquired, created or developed by, or which otherwise comes into possession of any director or officer who is also a director or officer of Cullinan disputes could arise between us and our subsidiary's partners regarding a conflict of interest. These partners also may disagree with the amount and quality of resources that our officers and employees devote to the subsidiary they are invested in. Any such disputes or disagreements could distract our management, interfere with our relations with our partners, and take significant time to resolve, which could disrupt the development of our product candidates, delay our potential commercialization efforts, result in increased costs or make it less likely that other third parties will choose to partner with us in the future.

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, cancer treatment centers, and others in the medical community.

The use of targeted oncology medicines as a potential cancer treatment is a recent development and may not become broadly accepted by physicians, patients, hospitals, cancer 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, cancer 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 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, cancer 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. We expect that zipalertinib will compete against small-molecule EGFR inhibitor Exkivity (TAK-788) from Takeda Pharmaceuticals, Inc. and EGFR/cMET bispecific antibody Rybrevant from Johnson & Johnson. Zipalertinib may also compete against EGFR inhibitors sunvozertinib from Dizal Pharmaceutical Co., Ltd., furmonertinib from ArriVent BioPharma, Inc. and Allist Pharmaceuticals, Inc, ORIC-114 from Oric Pharmaceutical, Inc. (Voronoi, Inc. in mainland China, Hong Kong, Macau and Taiwan), and LNG-451 from Blueprint Medicine Corporation, as well as other molecules in preclinical development. We expect that CLN-049 will compete against bispecifics for the treatment of AML, including those targeting CD3 and CD33 (Amgen Inc. and Amphivena Therapeutics, Inc.), CD123 (Macrogenics, Inc. and Xencor, Inc.), FLT3, and CCL1/CLEC12A (Merus N.V. and Genentech, Inc.). We expect that CLN-619 will compete against cancer therapies targeting MICA/B as a monotherapy and/or in combination with other agents, including: CanCure LLC, Genentech Inc., Novartis International AG and Bristol Myers Squibb Company.

If our product candidates, including zipalertinib, CLN-049, and CLN-619, are approved for their currently proposed target indication, they will likely compete with the competitor products mentioned above and with other products that are currently in development. 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 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. In the U.S., recently enacted legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it 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 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 healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Our ability to successfully commercialize our product candidates will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. The availability of coverage and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford treatments such as gene therapy products. Sales of these or other product candidates that we may identify will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If coverage and adequate reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, the third-party payor's determination that use of a product is:

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

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Governmental authorities and other third-party payors have 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.

There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. In the U.S., the principal decisions about reimbursement for new medicines are typically made by Centers for Medicare & Medicaid Services ("CMS"), an agency within the U.S. Department of Health and Human Services ("HHS"). CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. No uniform policy of coverage and reimbursement for products exists among third-party payors and coverage and reimbursement levels for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time consuming and costly process that may require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. It is difficult to predict what CMS will decide with respect to reimbursement for fundamentally novel products such as ours. Reimbursement agencies in Europe may be more conservative than CMS. For example, a number of cancer drugs have been approved for reimbursement in the U.S. and have not been approved for reimbursement in certain European countries. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. 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.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the U.S. Our inability to promptly obtain coverage and profitable reimbursement rates third-party payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. In order to obtain reimbursement, physicians may need to show that patients have superior treatment outcomes with our products compared to standard of care drugs, including lower-priced generic versions of standard of care drugs. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

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. Medicare reimbursement methodologies, whether under Part A, Part B, or clinical laboratory fee schedule may be amended from time to time, and we cannot predict what effect any change to these methodologies would have on any product candidate or companion diagnostic for which we receive approval. 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.

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.

In the U.S., there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Affordable Care Act (the "ACA"), was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the U.S. pharmaceutical industry. The ACA, among other things, subjects biological products to potential competition by lower-cost biosimilars, addresses 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, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of certain branded prescription drugs, and creates a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (increased to 70% pursuant to the Bipartisan Budget Act of 2018, effective as of 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. Various portions of the ACA are currently undergoing legal and constitutional challenges in the U.S. Supreme Court and members of Congress have introduced several pieces of legislation aimed at significantly revising or repealing the ACA. The implementation of the ACA is ongoing, the law appears likely to continue the downward pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs. Litigation and legislation related to the ACA are likely to continue, with unpredictable and uncertain results.

U.S. federal government agencies currently face potentially significant spending reductions. The Budget Control Act of 2011 (the "BCA") established a Joint Select Committee on Deficit Reduction, which was tasked with achieving a reduction in the federal debt level of at least $1.2 trillion. That committee did not draft a proposal by the BCA's deadline. As a result, automatic cuts, referred to as sequestration, in various federal programs were scheduled to take place, beginning in January 2013, although the American Taxpayer Relief Act of 2012 delayed the BCA's automatic cuts until March 1, 2013. While the Medicare program's eligibility and scope of benefits are generally exempt from these cuts, Medicare payments to providers and Part D health plans are not exempt. The BCA did, however, provide that the Medicare cuts to providers and Part D health plans would not exceed two percent unless additional Congressional action is taken. President Obama issued the sequestration order on March 1, 2013, and cuts went into effect on April 1, 2013. Pursuant to the Coronavirus Aid, Relief, and Economic Security Act, also known as the CARES Act, and subsequent legislation, these reductions were suspended from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic and the reduction will be one percent from April 1, 2022 through June 30, 2022.

There has been increasing legislative and enforcement interest in the U.S. with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. The former Trump administration's budget proposal for fiscal year 2021 included a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the former Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Additionally, the former Trump administration released a "Blueprint" to lower drug prices and reduce out-of-pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out-of-pocket costs of drug products paid by consumers. HHS has already implemented certain measures. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. However, it is unclear whether the Biden administration will challenge, reverse, revoke or otherwise modify these executive and administrative actions.

In 2020, former President Trump signed four Executive Orders aimed at lowering drug prices. In response, the FDA released a final rule on September 24, 2020, which went into effect on November 30, 2020, providing guidance for states to build and submit for approval importation plans for certain prescription drugs from Canada. Further, on November 20, 2020 CMS issued an Interim Final Rule implementing the Most Favored Nation ("MFN") Model under which Medicare Part B reimbursement rates will be calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. The MFN Model regulations mandate participation by identified Part B providers and would have applied to all U.S. and territories for a seven-year period beginning January 1, 2021, and ending December 31, 2027. However, in response to a lawsuit filed by several industry groups, on December 28, the U.S. District Court for the Northern District of California issued a nationwide preliminary injunction enjoining government defendants from implementing the MFN Rule pending completion of notice-and-comment procedures under the Administrative Procedure Act. On January 13, 2021, in a separate lawsuit brought by industry groups in the U.S. District of Maryland, the government defendants entered a joint motion to stay litigation on the condition that the government would not appeal the preliminary injunction granted in the U.S. District Court for the Northern District of California and that performance for any final regulation stemming from the MFN Interim Final Rule shall not commence earlier than 60 days after publication of that regulation in the Federal Register. Further, authorities in Canada have passed rules designed to safeguard the Canadian drug supply from shortages. If implemented, importation of drugs from Canada and the MFN Model may materially and adversely affect the price we receive for any of our product candidates. Additionally, on December 2, 2020, HHS published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Pursuant to an order entered by the U.S. District Court for the District of Columbia, the portion of the rule eliminating safe harbor protection for certain rebates related to the sale or purchase of a pharmaceutical product from a manufacturer to a plan sponsor under Medicare Part D has been delayed to January 1, 2023. Further, implementation of this change and new safe harbors for point-of-sale reductions in price for prescription pharmaceutical products and pharmacy benefit manager service fees are currently under review by the Biden administration and may be amended or repealed.

Further, on May 30, 2018, the Right to Try Act was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

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

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

Our revenue prospects could be affected by changes in healthcare spending and policy in the U.S. and abroad. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could negatively impact our business, operations and financial condition.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future, including repeal, replacement or significant revisions to the ACA. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to 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.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

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 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 successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, 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 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 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 may be relatively small since the patients who may potentially be treated with our product candidates are those who are ineligible for or have failed prior treatments, and our estimates of the prevalence of our target patient populations may be inaccurate.

Cancer therapies are sometimes characterized by line of therapy (first line, second line, third line, fourth line, etc.), and the FDA often approves new therapies initially only for a particular line or lines of use. When cancer is detected early enough, first line therapy is sometimes adequate to cure the cancer or prolong life without a cure. Whenever first line therapy, usually chemotherapy, antibody drugs, tumor-targeted small molecules, hormone therapy, radiation therapy, surgery, or a combination of these, proves unsuccessful, second line therapy may be administered. Second line therapies often consist of more chemotherapy, radiation, antibody drugs, tumor-targeted small molecules, or a combination of these. Third line therapies can include chemotherapy, antibody drugs and small-molecule tumor-targeted therapies, more invasive forms of surgery, and new technologies. There is no guarantee that our product candidates, even if approved as a second or third or subsequent line of therapy, would be approved for an earlier line of therapy, and, prior to any such approvals, we may have to conduct additional clinical trials.

Our projections of both the number of people who have the cancers we are targeting, who may have their tumors genetically sequenced, as well as the subset of people with these cancers in a position to receive a particular line of therapy and 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 scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Further, new therapies may change the estimated incidence or prevalence of the cancers that we are targeting. Consequently, even if our product candidates are approved for a second or third line of therapy, the number of patients that may be eligible for treatment with our product candidates may turn out to be much lower than expected. In addition, we have not yet conducted market research to determine how treating physicians would expect to prescribe a product that is approved for multiple tumor types if there are different lines of approved therapies for each such tumor type.

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 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 does grant approval for one or more of our product candidates, it may be for a more narrow indication than we seek. For example, we intend to develop our product candidates and seek approval for a tumor-agnostic indication based on a biomarker. The FDA has approved only a small number of oncology products with tumor-agnostic indications, and there is a risk that the FDA may disagree with or strategy or data and approve only a more narrow indication. 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 regulatory authorities in Spain, Italy, Netherlands, Poland, mainland China, Hong Kong, Singapore, South Korea, and Taiwan, for our zipalertinib, CLN-049, CLN-619, CLN-978 and CLN-617 programs. There is limited experience of regulatory authorities outside of the U.S. with the approval of tumor-agnostic precision cancer medicines.

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, Biologics License Application ("BLA"), New Drug Application ("NDA"), or equivalent application types, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries 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 tumor-agnostic 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 approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

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.

We may in the future seek orphan drug status for zipalertinib, CLN-049, and some of our other future product candidates, but we may be unable to obtain such designations 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. It remains to be seen how this decision affects orphan drug exclusivity going forward.

We may seek orphan drug designation for zipalertinib, CLN-049, and some or all of our other future product candidates in additional orphan indications in which there is a medically plausible basis for the use of these products. Even when 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 zipalertinib, CLN-049, and CLN-619, or any other 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. We may seek Fast Track designation for zipalertinib, CLN-049, and CLN-619, and certain of our future product candidates, but there is no assurance that the FDA will grant this status to any of our 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. Even if we do receive Fast Track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures, and receiving a Fast Track designation 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, if granted for any of our 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 CLN-049 and CLN-619, and some or all of our 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 CLN-049, and CLN-619, and some or all of our future product candidates for the treatment of various cancers, there can be no assurance that we will receive Breakthrough Therapy designation for such product candidates.

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

We may seek approval of zipalertinib, and 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 development or regulatory review or approval process, and receiving accelerated approval does not provide assurance of ultimate full FDA approval. 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 pipeline products, 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.

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.

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 labelling 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 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 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 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. 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.

Separately, the FDA generally is continuing to ensure timely reviews of applications for medical products during the ongoing COVID-19 pandemic in line with its user fee performance goals. However, the FDA may not be able to maintain this pace and review timelines could be extended. In addition, where a pre-approval inspection or an inspection of clinical sites is required and, due to ongoing COVID-19 pandemic and travel restrictions, the FDA is unable to complete such required inspections during the review period, action on such applications may be delayed or prevented. Additionally, regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

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 with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution;
- federal civil and criminal false claims laws and civil monetary penalty laws, including the FCA which impose criminal and civil penalties, including through civil “qui tam” or “whistleblower” actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other federal health care programs that are false or fraudulent; knowingly making or causing a false statement material to a false or fraudulent claim or an obligation to pay money to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing such an obligation. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. The FCA also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. When an entity is determined to have violated the federal civil FCA, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;
- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;
- the federal Physician Payment Sunshine Act, created under the ACA and its implementing regulations, which require manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to HHS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and teaching hospitals, 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; and
- analogous state and foreign laws and regulations, such as state and foreign anti-kickback, false claims, consumer protection and unfair competition laws which may apply to pharmaceutical business practices, including but not limited to, research, distribution, sales and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities; state and local laws requiring the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

We adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant criminal, civil and administrative sanctions including monetary penalties, damages, fines, disgorgement, individual imprisonment, and exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, and we may be required to curtail or restructure our operations, any of which could adversely affect our ability to operate our business and our results of operations.

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. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

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.

In the event we decide to conduct clinical trials or continue to enroll subjects in our ongoing or future clinical trials, we may be subject to additional privacy restrictions. 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.

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 December 13, 2022, the European Commission published a draft EU-U.S. data adequacy decision which sets out a new framework for transatlantic data flows, but there remains uncertainty as to when the proposed framework will become operational. It is also likely that the proposed framework will be subject to legal challenge. 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.

In addition, several U.S. states have recently enacted or are considering enacting comprehensive privacy legislation. Most notably, California recently enacted the California Consumer Privacy Act (the "CCPA"), which creates new GDPR-like individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on covered businesses handling personal data of California consumers or households. The CCPA requires covered businesses to provide new disclosures to consumers about such businesses' data collection, use and sharing practices, provide such consumers new ways to opt-out of certain sales or sharing of personal information, and provide consumers with additional causes of action in the event of a data security breach. The CCPA went into effect on January 1, 2020, and the California Attorney General commenced enforcement actions for violations on July 1, 2020. Further, the California Privacy Rights Act (the "CPRA"), was passed by California voters on November 3, 2020. The CPRA, which amends the CCPA, creates additional obligations with respect to processing and storing personal information that took effect on January 1, 2023 (with certain provisions having retroactive effect to January 1, 2022). 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 continue to monitor the impact the CCPA may have on our business activities. New data privacy laws have been proposed in more than half of the states in the U.S. and in the U.S. Congress, reflecting a trend toward more stringent privacy legislation in the U.S., which trend may accelerate under the current U.S. presidential administration. The effects of this legislation are potentially far-reaching and may require us to modify our data processing practices and policies and to incur substantial costs and expenses in an effort to comply.

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.

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 zipalertinib, CLN-049, CLN-619, and CLN-418 or any other 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, including zipalertinib, CLN-049, CLN-619, and CLN-418, 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 zipalertinib, CLN-049, CLN-619, and CLN-418 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 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 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 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, Cullinan Florentine and Cullinan Amber will each owe licensors a success fee in the event of a sale or other disposition of the majority of its assets. 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, including our differentiated hub-and-spoke business model 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 product candidates, including zipalertinib, CLN-049, CLN-619, and CLN-418, 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 our product candidates may infringe. 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 product candidates or other technologies, could be found 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 have in-licensed one patent family related to CLN-049. We own three patent families related to CLN-619. We own two patent families related to CLN-617. We own three patent families related to CLN-978. 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 that event, 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 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 and could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. 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 the prevailing party 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 may not be effective or sufficient to prevent them from competing. Our patent portfolio is at the very early stage. We will need to decide whether and in which jurisdictions to pursue protection for the various inventions in our portfolio prior to applicable deadlines.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biopharmaceutical products, which could make it difficult for us to stop the infringement of 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 patent. 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 not effectively assign intellectual property rights to us. Moreover, there may be some circumstances where we are unable to negotiate for such ownership rights. Disputes regarding ownership or inventorship of intellectual property can also arise in other contexts, such as collaborations and sponsored research. If we are subject to a dispute challenging our rights in or to patents or other intellectual property, such a dispute could be expensive and time consuming. 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, 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 trial sponsors, principal investigators and 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 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 ongoing, clinical and preclinical product candidates. 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 and do not employ any manufacturing personnel. We cannot assure you 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 changes 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 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 will also 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 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 the conduct of 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, in June 2022, we completed the sale of our equity interest in Cullinan Pearl, formerly a partially-owned subsidiary of the Company, to Taiho, and we entered into a co-development agreement with a subsidiary of Taiho to co-develop and, at our option, co-commercialize zipalertinib in the U.S. Pursuant to the terms of the co-development agreement with Taiho, we will each equally contribute to the future clinical development of zipalertinib in the U.S., and will each receive 50% of any future pre-tax profits from potential U.S. sales of zipalertinib.

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 the use of manufacturing suites in third-party facilities or third parties to manufacture our product candidates. Our business could be harmed if we are unable to use third-party manufacturing suites or if the third-party manufacturers fail to provide us with sufficient quantities of our product candidates or fail to do so 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 our product candidates 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 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 product candidates;
- our third-party manufacturers might be unable to timely manufacture our 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 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 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 product candidates by the FDA, result in higher costs or adversely impact commercialization of our 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 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.

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 product candidates or any future product candidates for clinical trials or our products for patients, 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, potency and stability. 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 and testing, may result in lot failures, product recalls or spoilage. When changes are made to the manufacturing process, we may be required to provide 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 product candidates or any 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

COVID-19 has and may continue to adversely impact our business.

The COVID-19 pandemic and government measures taken in response have had a significant impact, both direct and indirect, on businesses and commerce, including ongoing worker shortages and supply chain disruption. As a result of the COVID-19 pandemic, we also experienced delays in our clinical trial and preclinical development activities, including our ability to enroll and retain patients in our ongoing clinical trials. The extent to which the pandemic impacts our business, preclinical studies and clinical trials in the future will depend on developments that are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the U.S. and other countries, business closures or business disruptions and the effectiveness of actions taken in the U.S. and other countries to contain and treat the disease.

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, 2022, we had 62 full-time employees and two consultants. 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 any 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 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 of the development programs of our 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. 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, 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. Although we devote resources to protect our information systems, we realize that cyberattacks are a threat, and 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 prevent or mitigate security breaches or improper access to, use of, or disclosure of 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) and may cause a material adverse impact to our reputation, affect our ability to conduct new studies and potentially disrupt our business.

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, 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 security or data privacy breaches, we could be exposed to litigation and governmental investigations, which could lead to a potential disruption to our business.

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

Our operations, and those of our CROs, 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, for which we are predominantly self-insured. 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 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 product candidates or any future clinical trials we may conduct, 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 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 product candidates;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our 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 cancer target markets;
- our ability to successfully treat additional types of 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 will be able to exert significant influence over matters subject to stockholder approval.

Our executive officers, directors, and 5% stockholders beneficially owned approximately 63% of our voting stock, based on 45,796,449 shares of our common stock deemed to be outstanding as of December 31, 2022. These stockholders have the ability to influence us through their ownership position. Accordingly, these stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control 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.

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

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act (the "JOBS Act"), enacted in April 2012. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 (as amended, the "Sarbanes-Oxley Act"), reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of our initial public offering, (b) in which we have total annual gross revenue of at least $1.235 billion or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed $700 million as of the last business day of the most recently completed second fiscal quarter, and (2) the date on which we have issued more than $1 billion in non-convertible debt during the prior three-year period.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to not "opt out" of this exemption from complying with new or revised accounting standards and, therefore, we will adopt new or revised accounting standards at the time private companies adopt the new or revised accounting standard and will do so until such time that we either (i) irrevocably elect to "opt out" of such extended transition period or (ii) no longer qualify as an emerging growth company.

Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to continue to take advantage of many of the same exemptions from disclosure requirements, 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 nonvoting 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 nonvoting 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.

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

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. As a result of our most recent private placements and other transactions that have occurred over the past three years, we may have experienced, and may experience, an "ownership change." We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As of December 31, 2022, we had U.S. federal and state NOL carryforwards of $42.6 million and $27.1 million, respectively. The Company generated federal NOLs of $5.8 million prior to 2018, which begin to expire in 2036. State losses also begin to expire in 2036. The Company generated federal NOLs of $36.8 million, which can be carried forward indefinitely. As of December 31, 2022, the Company had federal and state research and development tax credit carryforwards of $0.9 million and $0.3 million, respectively, each of which will begin to expire at various dates through 2037 and 2033, respectively, and which could be limited if we experience an "ownership change." The reduction of the corporate tax rate under the Tax Cuts and Jobs Act of 2017 (the "TCJA"), may cause a reduction in the economic benefit of our NOL carryforwards and other deferred tax assets available to us. Under the TCJA, federal NOLs generated after December 31, 2017 will not be subject to expiration but will not be permitted to be carried back. In addition, under the TCJA, the amount of post 2017 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. As of December 31, 2021, we had U.S. federal and state NOL carryforwards of $117.4 million and $119.0 million, respectively, which will begin to expire at various dates through 2036 and which could be limited if we experience an "ownership change."

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 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 antitakeover provisions and other provisions in our second amended and restated certificate of incorporation and 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 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 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 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 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 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.

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 and make it more difficult for us to effectively market and sell our service to new and existing customers.

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 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 July 2026. We also lease approximately 8,000 square feet of office space in a multi-tenant building in Cambridge, Massachusetts that we have subleased to another tenant through substantially all of our remaining lease term for that office space. 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, 2022, there were 17 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 is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10-K.

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.

Use of Proceeds from our Public Offering of Common Stock

On January 7, 2021, our Registration Statement on Form S-1, as amended (Registration No. 333-251512) was declared effective by the SEC for our initial public offering. At the closing of the offering on January 12, 2021, we sold 13,685,000 shares of common stock, including the exercise in full by the underwriters of their option to purchase up to 1,785,000 additional shares of common stock, at a public offering price of $21.00 per share. The aggregate net proceeds to us from the public offering, inclusive of the over-allotment exercise and after underwriting discounts and offering expenses, were approximately $264.5 million.

As of December 31, 2022, we had not used any of the net proceeds from the IPO. We have invested the net proceeds from the IPO into money market funds and marketable securities. Information related to use of proceeds from registered securities is incorporated herein by reference to the "Use of Proceeds" section of our initial public offering as described in our final prospectus dated January 7, 2021 and filed with the SEC on January 11, 2021 pursuant to Rule 424(b)(4) of the Securities Act. There has been no material change in the planned use of proceeds as described in our final prospectus.

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 clinical-stage biopharmaceutical company focused on modality-agnostic targeted oncology. Our strategy is to identify high-impact cancer targets and then select what we believe is the optimal therapeutic modality for those targets. We source innovation both internally and externally, focusing on focusing on product candidates with novel technology platforms or differentiated mechanisms. Before we advance a product candidate into clinical development, we evaluate its potential for anti-tumor activity as a single agent as well as its ability to generate an immune response or to inhibit oncogenic processes. Using this strategy, we have built a broad and deep pipeline of targeted oncology programs that includes six distinct product candidates, of which five are clinical-stage, as well as multiple research and discovery programs.

Zipalertinib (CLN-081/TAS6417), which we are co-developing 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 ("EGFRex20ins") mutations with relative sparing of cells expressing wild-type EGFR. The U.S. Food and Drug Administration (the "FDA") has granted Breakthrough Therapy designation to zipalertinib. In the fourth quarter of 2022, in collaboration with our partners at Taiho, we initiated a pivotal Phase 2b study in patients with EGFR exon 20 non-small-cell lung cancer ("NSCLC") who progressed after prior systemic therapy. In June 2022, Taiho acquired our equity interest in our partially-owned subsidiary, Cullinan Pearl Corp. ("Cullinan Pearl"), which provided Taiho with worldwide rights to zipalertinib outside of Japan and Greater China, for an upfront payment of $275.0 million. As part of the sale, we are also eligible to receive up to an additional $130.0 million tied to EGFR exon 20 NSCLC regulatory milestones. Concurrently with the closing of the sale of our equity interest in Cullinan Pearl, we entered into a co-development and co-commercialization agreement for zipalertinib with an affiliate of Taiho, pursuant to which we will collaborate to develop zipalertinib and will retain the option to co-commercialize zipalertinib in the United Sates ("U.S."). Development costs, and any future pre-tax profits from potential U.S. sales of, zipalertinib shall be shared equally between us and Taiho.

In addition to zipalertinib, our portfolio includes four other clinical-stage product candidates and one product candidate that is pending FDA clearance for its investigational new drug application ("IND"):

- CLN-049 is a FLT3/CD3 T cell engaging bispecific antibody being investigated in patients with relapsed/refractory acute myeloid leukemia ("AML") or myelodysplastic syndrome ("MDS"). CLN-049 is currently in an ongoing Phase 1 study with initial clinical data expected in mid-2023.
- CLN-619 is a monoclonal antibody that stabilizes expression of MICA/B on the tumor cell surface to promote tumor cell lysis mediated by both cytotoxic innate and adaptive immune cells. CLN-619 has broad therapeutic potential and is being investigated as both monotherapy and in combination with checkpoint inhibitor therapy in an ongoing Phase 1 study in patients with advanced solid tumors with initial clinical data expected in mid-2023.
- CLN-418 is a B7H4/4-1BB bispecific antibody that induces tumor-specific immune activation and is being investigated in an ongoing Phase 1 study in patients with advanced solid tumors with initial clinical data expected in 2024.
- CLN-978 is a CD19/CD3 T cell engaging antibody construct with a human serum albumin ("HSA") binding domain to increase serum half-life. In January 2023, the FDA cleared our IND for CLN-978. We will initially evaluate CLN-978 in a Phase 1 study for the treatment of relapsed/refractory B-cell non-Hodgkin lymphoma ("B-NHL").
- CLN-617 is a fusion protein combining two potent antitumor cytokines, interleukin-2 ("IL-2") and interleukin-12 ("IL-12") with tumor retention domains for the treatment of solid tumors. In February 2023, we filed the IND for CLN-617 and intend to initiate a Phase 1 study by the end of 2023, pending IND clearance.

In addition to the product candidates described above, we are actively developing several preclinical oncology programs, all in the discovery stage, including our collaboration with Icahn School of Medicine at Mount Sinai for the development of novel hematopoietic progenitor kinase 1 degraders.

We hold worldwide development and commercialization rights to CLN-049, CLN-619, CLN-617 and CLN-978, and we hold U.S. development and commercialization rights to CLN-418.We hold intellectual property rights and exclusive options for worldwide intellectual property for our earlier-stage programs.

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, 2022, we have received net proceeds of $541.2 million from equity financings, inclusive of our net proceeds of $264.5 million from our initial public offering ("IPO"). We have received $18.9 million in revenue from our previous license agreement ("Zai License Agreement") with Zai Lab Shanghai Company, Limited ("Zai Lab") and cash proceeds of $275.0 million from the sale of our equity interest in Cullinan Pearl.

As of December 31, 2022, we had cash, cash equivalents and short-term investments of $467.3 million and long-term investments and interest receivable of $82.8 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. With the exception of 2022, we have incurred operating losses and have had negative cash flows from operations since our inception. As of December 31, 2022, we had an accumulated deficit of $47.7 million. Other than the one-time gain from the sale of our equity interest in Cullinan Pearl, 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 therapeutic programs 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.

Impact of COVID-19 Pandemic

The duration and scope of the COVID-19 pandemic continues to be uncertain. The virulence and spread of different strains of the virus remains high in many parts of the world. The extent and duration of the impact of COVID-19 on our operations and financial performance is currently unknown and will depend on future developments that are uncertain and unpredictable. We implemented remote working and other protective measures, but thus far, have not experienced a significant disruption or delay in our operations as it relates to the clinical development or drug production of our product candidates. However, COVID-19 has at times impacted the pace of our enrollment in our clinical trials and the conduct of our preclinical studies. In the future, COVID-19-related restrictions may adversely impact our operations. Such events may result in a period of business, supply and drug product manufacturing disruption, and in reduced operations, any of which could materially affect our business, financial condition and results of operations.

To date, COVID-19 has not had a financial impact on us. The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. A continuation or worsening of the levels of market disruption and volatility seen in the recent past could have an adverse effect on our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business.

Basis of Presentation and Consolidation

Since our inception, we have created wholly-owned subsidiaries or made investments in certain controlled entities. Losses attributed to noncontrolling interests are reported separately in our consolidated statements of operations and comprehensive income (loss).

When we were a private company, we established development subsidiaries when we licensed or acquired exclusive worldwide rights to intellectual property for several of our drug candidates, including Cullinan Florentine Corp. (“Cullinan Florentine”) for CLN-049, Cullinan MICA Corp. (“Cullinan MICA”) for CLN-619, and Cullinan Amber Corp. (“Cullinan Amber”) for CLN-617. Our equity interest in our former development subsidiary, Cullinan Pearl, which had worldwide rights

to zipalertinib outside of Japan and Greater China, was divested in the second quarter of 2022. As a publicly held company, we do not intend to create new development subsidiaries in the future.

The following partially-owned subsidiaries are consolidated into our financial statements in 2022 and 2021:

Consolidated Entities	Current Relationship	Date Control First Acquired	Ownership as of December 31, 2022
Cullinan Pearl Corp.	Divested	November 2018	—
Cullinan Amber Corp.	Partially-owned Subsidiary	December 2019	94%
Cullinan Florentine Corp.	Partially-owned Subsidiary	December 2019	96%
Cullinan MICA Corp.	Partially-owned Subsidiary	May 2020	95%

Cullinan Pearl

We sold our equity interest in our partially-owned subsidiary, Cullinan Pearl, to Taiho in June 2022. Refer to Note 3 of our notes to the consolidated financial statements included in this Annual Report on Form 10-K for additional details relating to the transaction.

Cullinan Amber

Cullinan Amber is our partially-owned operating subsidiary that has a license agreement with the Massachusetts Institute of Technology ("MIT") that provides exclusive worldwide rights to the patents related to technology that originated in the laboratory of Dr. Karl Dane Wittrup to develop novel multifunctional constructs for delivery of immunostimulatory agents such as cytokines that are retained in the tumor microenvironment (the "MIT License Agreement").

In June 2021, we purchased 3.0 million shares of Series A preferred stock from Cullinan Amber, and MIT received 0.2 million shares of common stock from Cullinan Amber pursuant to the MIT License Agreement.

In June 2022, we purchased 6.0 million shares of Series A preferred stock from Cullinan Amber, and MIT received 0.3 million shares of common stock from Cullinan Amber pursuant to the MIT License Agreement.

In November 2022, we purchased 10.0 million shares of Series A preferred stock from Cullinan Amber, MIT received 0.5 million shares of common stock from Cullinan Amber pursuant to the MIT License Agreement, and Dr. Wittrup received 0.2 million shares of common stock from Cullinan Amber pursuant to an equity-based compensation agreement.

As of December 31, 2022, we held common shares and Series A preferred stock that represented 94% of Cullinan Amber's outstanding equity. As of December 31, 2022, noncontrolling interests collectively held common shares that represented 6% of Cullinan Amber's outstanding equity.

Cullinan Florentine

Cullinan Florentine is our partially-owned operating subsidiary that has exclusive worldwide rights to CLN-049, our bispecific antibody targeting FLT3 and CD3, pursuant to an exclusive license agreement with Deutsches Krebsforschungszentrum ("DKFZ"), Eberhard Karls University of Tübingen, Faculty of Medicine, and Universitätsmedizin Gesellschaft für Forschung und Entwicklung mbH, Tübingen ("UFE").

In July 2021, we purchased 7.5 million shares of Series B preferred stock from Cullinan Florentine.

In July 2022, we purchased 3.75 million shares of Series B preferred stock from Cullinan Florentine.

As of December 31, 2022, we held common shares, Series A preferred stock and Series B preferred stock that represented 96% of Cullinan Florentine's outstanding equity. As of December 31, 2022, noncontrolling interests collectively held common shares that represented 4% of Cullinan Florentine's outstanding equity.

Cullinan MICA

Cullinan MICA, formerly known as PDI Therapeutics, Inc., is our partially-owned operating subsidiary that owns intellectual property related to CLN-619, our MICA/B-targeted humanized IgG1 monoclonal antibody.

In June 2021, we purchased 5.4 million shares of Series A senior preferred stock from Cullinan MICA, and certain other existing investors purchased 0.7 million shares of Series A senior preferred stock from Cullinan MICA for $0.9 million.

In March 2022, we purchased 6.7 million shares of Series A senior preferred stock from Cullinan MICA, and certain other existing investors purchased 0.9 million shares of Series A senior preferred stock from Cullinan MICA for $1.2 million.

In October 2022, we purchased convertible notes for Series A senior preferred stock from Cullinan MICA, and certain other existing investors purchased convertible notes for Series A senior preferred stock from Cullinan MICA for $0.2 million.

In October 2022, we purchased 1.5 million shares Cullinan MICA's Series A senior preferred stock, 2.0 million shares of Cullinan MICA's Series A junior preferred stock, and 11.5 million shares of Cullinan MICA's Series A-2 junior preferred stock of Cullinan MICA from two of Cullinan MICA's other stockholders for $30.7 million.

In November 2022, we purchased 0.4 million shares of Cullinan MICA's common stock and 0.9 million of options for Cullinan MICA's common stock from five of Cullinan MICA’s other stockholders for $2.6 million. We also exercised our options to purchase 0.9 million shares of common stock from Cullinan MICA.

As of December 31, 2022, we held 95% of the fully-diluted shares outstanding of Cullinan MICA, including 96% of its Series A preferred stock. As of December 31, 2022, noncontrolling interests collectively owned 5% of the fully-diluted shares outstanding of Cullinan MICA, including 4% of its Series A preferred stock.

Components of Our Results of Operations

License Revenue

We have not generated any revenue from the sale of products since our inception and do not expect to generate any revenue from the sale of products in the near future, if at all. For 2021, we recognized $18.9 million of revenue, relating to the upfront fee earned from the Zai License Agreement.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred in connection with the research and development of our wholly-owned and jointly-developed 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.

General and Administrative Expenses

General and administrative expenses consist primarily of compensation costs for personnel in executive management, finance, 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.

Our general and administrative expenses will continue to increase as we continue to increase our headcount to support development of our product candidates and programs and our continued research activities.

Gain on Sale of Cullinan Pearl

Gain on sale of Cullinan Pearl represents the excess of the consideration received over the carrying value of the non-financial assets sold. Refer to Note 3 of our notes to the consolidated financial statements included in this Annual Report on Form 10-K for additional details relating to the transaction.

Other Income

Other income consists primarily of interest income earned on our cash, cash equivalents, short-term investments and long-term investments.

Income Taxes

Income taxes consist primarily of federal and state income taxes.

Results of Operations

Comparison of 2022 and 2021

The following table presents our results of operations for 2022 and 2021:

	Year Ended December 31,	
(in thousands)	**2022**	**2021**
License revenue	$ —	$ 18,943
Operating expenses:		
Research and development	91,948	57,751
General and administrative	40,189	29,146
Total operating expenses	132,137	86,897
Gain on sale of Cullinan Pearl	276,785	—
Income (loss) from operations	144,648	(67,954)
Other income (expense):		
Interest income	6,611	477
Other income (expense), net	57	(8)
Net income (loss) before income taxes	151,316	(67,485)
Income tax expense	42,121	—
Net income (loss)	109,195	(67,485)
Net loss attributable to noncontrolling interest	(2,019)	(1,915)
Net income (loss) attributable to common stockholders of Cullinan	$ 111,214	$ (65,570)

License Revenue

In 2021, we recognized $18.9 million of revenue relating to the upfront fee earned from the Zai License Agreement.

Research and Development Expenses

	Year Ended December 31,	
(in thousands)	**2022**	**2021**
Zipalertinib	$ 16,889	$ 22,723
CLN-049	6,605	6,442
CLN-619	16,815	8,797
CLN-978	10,822	2,805
CLN-617	12,110	2,231
Early-stage research	6,894	2,073
Other personnel and unallocated	10,795	3,802
Equity-based compensation	11,018	8,878
Total research and development expenses	$ 91,948	$ 57,751

Following the sale of our equity interest in Cullinan Pearl in the second quarter of 2022, development costs and any future potential pre-tax profits from U.S. sales of zipalertinib are shared equally between us and Taiho. The $5.8 million decrease in zipalertinib research and development expenses in 2022 compared to 2021 was primarily related to a one-time sublicense fee in 2021 that did not recur in 2022 ($3.0 million), a decrease in chemistry, manufacturing and controls ("CMC") costs ($2.7 million), and a benefit of from our co-development agreement with Taiho ($0.9 million), partially offset by an increase in preclinical costs ($0.7 million).

The $8.0 million increase in CLN-619 research and development expenses in 2022 compared to 2021 was primarily attributable to increased CRO costs following further enrollment in our ongoing Phase 1 dose-escalation study ($5.2 million) and higher CMC costs to obtain sufficient supply of CLN-619 to support current and future clinical trial activities ($2.6 million).

The $8.0 million increase in CLN-978 research and development expenses in 2022 compared to 2021 was primarily due to higher CMC costs to obtain sufficient supply of CLN-978 to support future clinical trial activities ($3.5 million), an increase in preclinical activities to support IND-enabling activities ($3.3 million), and one-time payments due to a contract research organization for achieving certain regulatory milestones ($0.8 million).

The $9.9 million increase in CLN-617 research and development expenses in 2022 compared to 2021 was primarily related to higher CMC costs to obtain sufficient supply of CLN-617 to support current and future clinical trial activities ($5.5 million) an increase in preclinical activities to support IND-enabling activities ($3.2 million), and higher personnel-related costs to support these increased activities ($1.0 million).

The remaining $14.0 million increase in research and development expenses in 2022 compared to 2021 was primarily related to an increase in early-stage research activities ($4.8 million), increased headcount and expansion of operations to support our research and development activities ($7.0 million), and higher equity-based compensation due to our increased headcount ($2.1 million).

General and Administrative Expenses

The increase of $11.0 million in general and administrative expenses in 2022 compared to 2021 was primarily due to an increase in personnel costs relating to increased headcount ($3.5 million), an increase in professional service fees to support our expanded operations ($3.0 million), non-recurring costs related to the Cullinan Pearl sale ($2.0 million), an increase in equity-based compensation expense due to our increased headcount ($1.5 million), and higher facilities costs ($0.8 million).

Gain on Sale of Cullinan Pearl

The $276.8 million gain on sale of Cullinan Pearl represents the excess of the consideration received over the carrying value of the non-financial assets sold. Refer to Note 3 of our notes to the consolidated financial statements included in this Annual Report on Form 10-K for additional details relating to the transaction.

Other Income

The increase in other income in 2022 compared to 2021 of $6.2 million was primarily related to higher interest income earned.

Income Tax Expense

The income tax expense was $42.1 million in 2022. The net income tax expense recognized for 2022 represents the tax from the gain on sale of Cullinan Pearl, including the utilization of current year and certain historical tax attributes.

We did not record a provision for income taxes in 2021.

Net Loss Attributable to Noncontrolling Interest

Net loss attributable to noncontrolling interests was $2.0 million and $1.9 million in 2022 and 2021, respectively. Net loss attributable to noncontrolling interests 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 partially-owned subsidiaries and the third parties. Refer to Note 8 of our notes to the consolidated financial statements included in this Annual Report on Form 10-K for additional details of capital transactions between the partially-owned subsidiaries and third parties.

Liquidity and Capital Resources

Overview

We have incurred significant operating losses, with the exception of the one-time gain on the sale of our equity interest in Cullinan Pearl in 2022, and 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, 2022, we had cash, cash equivalents, and short-term investments of $467.3 million and long-term investments and interest receivable of $82.8 million.

Based on our current operational plans and assumptions, we expect that our current cash, cash equivalents, short-term investments and long-term investments, will be sufficient to fund operations into 2026. 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 2022, we sold our equity interest in our partially-owned subsidiary, Cullinan Pearl, to Taiho for an upfront payment of $275.0 million.

In October and November 2022, we purchased equity interests in Cullinan MICA from other Cullinan MICA stockholders for $33.3 million which increased our ownership of Cullinan MICA to 95%.

In February 2023, we entered into a license and collaboration agreement (the "Harbour License Agreement") with Harbour BioMed US Inc. ("Harbour"), pursuant to which Harbour granted us an exclusive license for the development, manufacturing and commercialization of CLN-418 in the U.S. Under the terms of the Harbour License Agreement, we paid Harbour an upfront license fee of $25 million at signing.

Cash Flows

Comparison of 2022 and 2021

The following table summarizes our sources and uses of cash for each of the periods presented:

	Year Ended December 31,	
(in thousands)	**2022**	**2021**
Net cash used in operating activities	$ (126,664)	$ (43,433)
Net cash provided by (used in) investing activities	248,975	(333,775)
Net cash provided by (used in) financing activities	(25,933)	268,784
Net increase (decrease) in cash and cash equivalents	$ 96,378	$ (108,424)

Cash Flow from Operating Activities

During 2022, we used $126.7 million of cash for operating activities, primarily consisting of our operating expenses of $132.1 million and $37.8 million in payments for our estimated tax liability from the gain on sale of Cullinan Pearl, partially offset by non-cash charges of $29.8 million and a benefit of $11.2 million from the net change in our operating assets and liabilities. The non-cash charges primarily consisted of equity-based compensation expense and amortization and accretion on our marketable securities.

During 2021, we used $43.4 million of cash for operating activities, primarily consisting of our operating expenses of $86.9 million and the net change in our operating assets and liabilities of $3.5 million, partially offset by non-cash charges of $27.6 million and the $18.9 million upfront payment received pursuant to our license agreement with Zai Lab. The non-cash charges primarily consisted of equity-based compensation expense and amortization and accretion on our marketable securities.

Cash Flow from Investing Activities

During 2022, our investing activities provided $249.0 million of cash, which primarily consisted of proceeds of $352.9 million from the sales and maturities of marketable securities and proceeds of $275.0 million from the sale of our equity interest in Cullinan Pearl, partially offset by $377.9 million used for the purchase of marketable securities and $1.1 million used for the purchase of property and equipment to improve and furnish our leased office space.

During 2021, our investing activities used $333.8 million of cash, which primarily consisted of $525.8 million used for the purchases of marketable securities, partially offset by proceeds of $192.0 million from the sales and maturities of marketable securities.

Cash Flow from Financing Activities

During 2022, our financing activities used $25.9 million of cash, which primarily consisted of $33.3 million paid to acquire shares of Cullinan MICA held by noncontrolling interests, partially offset by proceeds of $6.0 million from stock option exercises and proceeds of $1.2 million from the issuance of noncontrolling interests.

During 2021, our financing activities provided $268.8 million of cash, which primarily consisted of net proceeds of $267.3 million from our initial public offering and proceeds of $3.3 million from stock option exercises, partially offset by payment of deferred offering costs of $2.7 million.

Future Funding Requirements

We expect our expenses to continue to increase in connection with our ongoing activities, particularly as we advance the preclinical activities, manufacturing and clinical trials of our product candidates. In addition, we have and will continue to incur

additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company. Our expenses will also increase as we:

- continue our research and development efforts and submit INDs for our 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, 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;
- develop and implement plans to establish and operate in-house manufacturing operations and facilities, if deemed appropriate;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- 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; 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, and short-term and long-term investments, will be sufficient to fund operations into 2026. 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 commercialization 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 product candidates or 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 product candidates or any 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 payment obligations under various license and collaboration agreements. Under these agreements, we are required to make milestone payments upon successful completion and achievement of certain intellectual property, clinical, regulatory, and sales milestones. The payment obligations under the license and collaboration agreements are contingent upon future events, such as our achievement of specified development, clinical, regulatory, and commercial milestones, and we will be required to make milestone and royalty payments in connection with the sale of products developed under these agreements. As the achievement and timing of these future milestone payments are not probable or estimable, such amounts have not been included in our consolidated balance sheet as of December 31, 2022 and 2021.

As of December 31, 2022, total future minimum lease payments were $6.0 million with $1.9 million payable within 12 months. See Note 13 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.

Revenue Recognition

We recognize revenue when a customer obtains control of promised goods or services. The amount of revenue recognized reflects the consideration to which we expect to be entitled in exchange for these goods and services. To achieve this core principle, we apply 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.

The transaction price is determined based on the consideration to which we will be entitled. The transaction price may include fixed amounts, variable amounts, or both. We allocate the transaction price based on the estimated standalone selling price of the underlying performance obligations. We utilize 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. We also utilize judgement 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. For performance obligations consisting of licenses and other promises, we utilize 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. Upon satisfaction of our performance obligation to Zai Lab in the first quarter of 2021, we recognized revenue of $18.9 million from our license agreement with Zai Lab. The amount recognized represented the upfront fee less foreign tax withholdings as such amounts were not expected to be recovered.

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 measure the fair value of market-based RSUs on the grant date using a Monte Carlo simulation model. We estimate the fair value of the 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 fair value of our common stock prior to the time of the initial public offering and stock price volatility, represent management's estimates and involve inherent uncertainties and the application of management's judgment and selection of comparable companies. 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. For such reporting periods, we estimated expected volatility based the common stock of a selected peer group of similar publicly traded companies for which sufficient historical volatility data was available. As a result, if factors change and management uses different assumptions, equity-based compensation expense could be materially different for future awards.

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. Judgement 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 judgement. We recorded income tax expense for 2022 due to the expected tax from the gain on sale of Cullinan Pearl, partially offset by the release of valuation allowance for expected utilization of current year and certain historical tax attributes against the gain on from the sale. Due to our lack of earnings history previous to the current fiscal year, management determined that a full valuation allowance was required to offset the net deferred tax assets at December 31, 2022.

Emerging Growth Company and Smaller Reporting Status

In April 2012, the JOBS Act was enacted. Section 107 of the JOBS Act provides that an "emerging growth company," or an EGC, can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Thus, an EGC can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to use the extended transition period for new or revised accounting standards during the period in which we remain an emerging growth company; however, we may adopt certain new or revised accounting standards early.

We will remain an emerging growth company until the earliest to occur of (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of our initial public offering, (b) in which we have total annual gross revenue of at least $1.235 billion or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1 billion in non-convertible debt during the prior three-year period.

We are also a "smaller reporting company" meaning that the market value of our stock held by non-affiliates is less than $700 million and our annual revenue was less than $100 million during the most recently completed fiscal year or that the market value of our stock held by non-affiliates is less than $250 million. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than $250 million or (ii) our annual revenue was less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million. If we are a smaller reporting company at the time, we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Recently Issued and Adopted Accounting Pronouncements

A description of recently issued 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

The Company has established 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"), designed to ensure that information required to be disclosed in the reports that the Company files or submits under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and is accumulated and communicated to management, including the principal executive officer (our Chief Executive Officer) and principal financial officer (our Chief Financial Officer), to allow timely decisions regarding required disclosure. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated, as of December 31, 2022, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our disclosure controls and procedures have been designed to provide reasonable assurance of achieving their objectives. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) were effective at the reasonable assurance level as of December 31, 2022.

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. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act as the process designed by, or under the supervision of, our Chief Executive Officer and our Chief Financial Officer, and effected by our board of directors, management, and other personnel, to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of our financial statements for external purposes in accordance with GAAP, and includes those policies and procedures that:

1. Pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of assets;
2. 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
3. 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.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of the effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with policies or procedures may deteriorate.

Our management assessed 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 this evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2022.

As an emerging growth company as defined in the JOBS Act, our independent registered accounting firm is not required to issue an attestation report on the internal control over financial reporting.

Changes in Internal Control over Financial Reporting

There was no change 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, 2022 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

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

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Information About Our Executive Officers

The following table sets forth the name, age as of February 15, 2023, and position of each of our executive officers.

Name	Position at Cullinan Oncology	Officer Since	Age
Nadim Ahmed	President, Chief Executive Officer and Director	2021	55
Patrick Baeuerle, Ph.D.	Chief Scientific Officer	2016	65
Jeffrey Jones, M.D.	Chief Medical Officer	2022	52
Jennifer Michaelson, Ph.D.	Chief Development Officer	2018	56
Corinne Savill, Ph.D.	Chief Business Officer	2017	63
Jacquelyn Sumer, Esq.	Chief Legal Officer, Chief Compliance Officer and Secretary	2022	45
Jeffrey Trigilio	Chief Financial Officer and Treasurer	2020	39

Nadim Ahmed Mr. Ahmed has served as our President and Chief Executive Officer and member of our board of directors since October 2021. Before joining the Company, Mr. Ahmed served as President, Hematology at Bristol Myers Squibb ("BMS"), from November 2019 through January 2021. Prior to this, he served in increasing roles of responsibility at Celgene Corporation ("Celgene") from March 2010 to November 2019, most recently as the President, Global Hematology & Oncology. Prior to his tenure at Celgene, Mr. Ahmed served in increasing roles of responsibility at GlaxoSmithKline plc ("GlaxoSmithKline") from June 1998 through March 2010, most recently as the Senior Marketing Director, Hematologic Oncology Franchise. Mr. Ahmed holds a Master of Science degree from Loughborough University and a Bachelor of Science degree from University College London. We believe that Mr. Ahmed is qualified to serve as a member of our board of directors due to his extensive leadership experience in the biopharmaceutical industry.

Patrick Baeuerle, Ph.D. Dr. Baeuerle co-founded the Company and has served as our Chief Scientific Officer since April 2022. Previously, he was Acting Chief Scientific Officer, Biologics of the Company from September 2016 to April 2022. Dr. Baeuerle also currently serves as an Executive Partner at MPM Capital, a healthcare investment firm ("MPM"), Acting Chief Scientific Officer of Crossbow Therapeutics, Inc., and scientific advisor to Aktis Oncology, Inc. Before joining the Company, Dr. Baeuerle served as Vice President, Research, and General Manager of Amgen Research Munich GmbH from March 2012 through March 2015. Prior to this, he was Chief Scientific Officer at Micromet, Inc. from October 1998 through March 2012, and earlier headed small molecule drug discovery at Tularik Inc., a publicly traded biotechnology company acquired by Amgen Inc. Dr. Baeuerle served as Professor and Chairman of Biochemistry at the Medical Faculty of Freiburg University from 1994 through 1996, where he did groundbreaking research on transcription factor NF-kappaB. He has co-founded MPM's oncology companies Harpoon Therapeutics, Inc., TCR2 Therapeutics, Inc. ("TCR2"), iOmx Therapeutics AG ("iOmx"), Maverick Therapeutics, Inc. and Werewolf Therapeutics, Inc. He currently serves on the board of directors of TCR2 and iOmx. Dr. Baeuerle holds a B.Sc. and Ph.D. in Biology from the University of Munich and performed post-doctoral research with Dr. David Baltimore at the Whitehead Institute at the Massachusetts Institute of Technology.

Jeffrey Jones, M.D. Dr. Jones has served as our Chief Medical Officer since February 2022. Before joining the Company, Dr. Jones served as Vice President, Global Drug Development, Lymphoma and Myeloid Diseases at BMS from April 2020 to February 2022 and as Executive Medical Director, Global Clinical Research and Development at BMS from August 2017 to April 2020. Prior to this, Dr. Jones served as Associate Professor of Clinical Internal Medicine at The Ohio State University College of Medicine. Prior to that, Dr. Jones served as a Clinical Instructor from 2006 to 2014 at The Ohio State University. Dr. Jones received his M.D. from University of Michigan Medical School in Ann Arbor, Michigan and completed his residency in internal medicine at McGill University Faculty of Medicine in Montreal and a fellowship in hematology and medical oncology at MD Anderson Cancer Center in Houston, Texas. Dr. Jones also holds an M.B.A. from The Ohio State University Fisher College of Business and an M.P.H. from the University of Texas School of Public Health.

Jennifer Michaelson, Ph.D. Dr. Michaelson has served as our Chief Development Officer since February 2022. Previously, she was Chief Development Officer, Biologics of the Company from January 2020 to February 2022 and Vice President, Preclinical Research and Early Development of the Company from January 2018 through December 2019. Before joining the Company, Dr. Michaelson served as the Head of Biologics at Celsius Therapeutics, Inc., a biotechnology company, from July 2017 through December 2017. Prior to this, she served in increasing roles of responsibility at Jounce Therapeutics, Inc., from September 2012 through July 2017, most recently as Senior Director and Executive Program Leader and previously as Director of Tumor Immunology and as a consultant. Previously, during her 10 year tenure at Biogen Idec Inc., Dr. Michaelson served as project leader for several monoclonal antibody and bispecific antibody programs in both the oncology and immunology therapeutic areas. Dr. Michaelson holds a B.A. in Biology from Princeton University and Ph.D. from the Department of Cell Biology at Albert Einstein College of Medicine, and completed a post-doctoral fellowship in Philip Leder's laboratory in the Department of Genetics at Harvard Medical School.

Corinne Savill, Ph.D. Dr. Savill has served as our Chief Business Officer since February 2017. Before joining the Company, Dr. Savill served in increasing roles of responsibility at Novartis Pharma AG ("Novartis"), including Global Head of Business Development and Licensing from June 2013 through February 2017, Global Head of Pricing and Market Access from September 2010 through June 2013, Global Head Search and Evaluation, Business Development and Licensing from January 2005 through August 2010 and Regional Manager Europe, Transplantation and Immunology Business Unit from August 2002 through Jan 2005. Prior to her tenure at Novartis, Dr. Savill was Chief Executive Officer of Imutran, a UK based biotechnology company, which was acquired by Novartis. She also previously worked in research at AstraZeneca. Dr. Savill holds a B.S. in Biochemistry from the University of Manchester and obtained her Ph.D. at University College and Middlesex School of Medicine and the Charing Cross Sunley Research Centre in London.

Jacquelyn Sumer, Esq. Ms. Sumer has served as our Chief Legal Officer since August 2022. Before joining the Company, Ms. Sumer served as Chief Legal and Compliance Officer at Genocea Biosciences, Inc. ("Genocea") from February 2021 to June 2022. Prior to Genocea, Ms. Sumer was Vice President, Assistant General Counsel at BMS from November 2019 to February 2021. Prior to this, she served as head of Celgene's CAR T legal team from July 2018 to November 2019. She previously worked at Kaye Scholer, LLP and clerked for the Honorable Gladys Kessler at the United States District Court in Washington D.C. Ms. Sumer holds a J.D. and a Master of Laws in international and comparative law from Duke University School of Law and a B.A. from Bucknell University.

Jeffrey Trigilio Mr. Trigilio has served as our Chief Financial Officer since September 2020. Before joining the Company, Mr. Trigilio served as the Chief Financial Officer at Amylyx Pharmaceuticals, Inc., a pharmaceutical company, from January 2020 through July 2020. Prior to this, he was Vice President, Corporate Finance at BlueRock Therapeutics, Inc. ("Bluerock"), from August 2018 through January 2020. Prior to his tenure at BlueRock, Mr. Trigilio was a Director, Healthcare Investment Banking at RBC Capital Markets LLC from November 2017 through August 2018. He previously served in increasing roles of responsibility at Alexion Pharmaceuticals, Inc. from April 2013 through November 2017 and at Credit Suisse Securities from July 2008 to March 2013. Mr. Trigilio holds a B.A. in Industrial and Labor Relations from Cornell University and an M.B.A. from Columbia University.

The principal occupation and employment during the past five years of each of our executive officers was carried on, in each case except as specifically identified in this Annual Report on Form 10-K, with a corporation or organization that is not a parent, subsidiary or other affiliate of us. There is no arrangement or understanding between any of our executive officers and any other person or persons pursuant to which he or she was or is to be selected as an executive officer.

There are no material legal proceedings to which any of our executive officers is a party adverse to us or our subsidiaries or in which any such person has a material interest adverse to us or our subsidiaries.

Directors

The following table sets forth the name and age as of February 15, 2023 of each of our non-employee directors.

Name	Director Since	Age
Thomas Ebeling	2017	64
Anne-Marie Martin, Ph.D.	2022	51
Anthony Rosenberg	2017	69
David P. Ryan, M.D.	2022	56
Stephen Webster	2020	61

Thomas Ebeling Mr. Ebeling has served as a member of our board of directors since August 2017. He also serves as an Advisor at MPM. Since 2018, he has served as Chief Executive Officer at TE Convest AG, a consulting and executive coaching company. Prior to that, Mr. Ebeling served as the Chief Executive Officer of ProSieben Media SE, a mass media company, from March 2009 through February 2017. Mr. Ebeling previously served as the Chief Executive Officer of Novartis Consumer Health from September 2007 through September 2008, and as Chief Executive Officer of Novartis Pharmaceuticals Corporation from July 2000 through September 2007. He served in numerous leadership roles at PepsiCo Germany from 1991 through 1996. He is a member of the boards of Qiagen N.V. and Orna Therapeutics. Additionally, he currently serves on the board of several private companies. Previously, Mr. Ebeling served on the board of directors of Bayer AG from April 2012 to September 2019 and on the board of directors of Lonza Group AG from March 2013 to March 2017. Mr. Ebeling holds a B.S. in Psychology from the University of Hamburg. We believe that Mr. Ebeling is qualified to serve as a member of our board of directors due to his extensive leadership experience in the life sciences industry.

Anne-Marie Martin, Ph.D. Dr. Martin has served as a member of our board of directors since March 2022. Dr. Martin currently serves as Senior Vice President, Global Head of the Experimental Medicine Unit at GlaxoSmithKline and has held this position since August 2020. She previously served as Senior Vice President, Global Head of Precision Medicine at Novartis from February 2016 to July 2020. Prior to her position at Novartis, she was Vice President, Head of Biomarker Research & Diagnostic Development at Adaptimmune Therapeutics plc ("Adaptimmune"), from May 2015 to February 2016. Prior to Adaptimmune, Dr. Martin held various roles of increasing responsibility at GlaxoSmithKline between March 2005 and April 2015. Additionally, she served as a board observer for Freenome Holdings, Inc., a private biotechnology company, from August 2019 to July 2020. She received her undergraduate degree in biomedical sciences from Sheffield Hallam University and holds a Ph.D. in Immunogenetics from MCP-Hahnemann University. We believe that Dr. Martin is qualified to serve on our board of directors due to her extensive experience in the biotechnology and pharmaceutical sectors.

Anthony Rosenberg Mr. Rosenberg has served as a member of our board of directors since August 2017 and as the Chairperson of our board of directors since April 2020. Currently, Mr. Rosenberg serves as the Chief Executive Officer of TR Advisory Services GmbH, a consultancy firm advising on business development, licensing, and mergers and acquisitions. From April 2015 to April 2020, Mr. Rosenberg served as a Managing Director of MPM. From January 2012 to February 2015, Mr. Rosenberg served as Corporate Head of M&A and Licensing at Novartis. Mr. Rosenberg currently serves on the board of directors of argenx SE. Previously, Mr. Rosenberg served on the board of directors of Radius Health, Inc. He also serves on the board of two private companies. Mr. Rosenberg holds a B.Sc. from the University of Leicester and a M.Sc. Physiology from the University of London. We believe that Mr. Rosenberg is qualified to serve as a member of our board of directors due to his extensive tenure in biotech operations and strategic management.

David P. Ryan, M.D. Dr. Ryan has served as a member of our board of directors since November 2022. Since 2012, Dr. Ryan has served as Clinical Director and Chief of the Massachusetts General Hospital (“MGH”) Cancer Center. He has held increasing roles of responsibility at MGH since 1998, specializing in the research and treatment of patients with cancer. Additionally, Dr. Ryan is currently a Shelby Memorial Professor of Medicine in the Field of Cancer Therapeutics at Harvard Medical School. Dr. Ryan is also a member of the American Society for Clinical Oncology and serves as an advisor to both MPM and BioImpact Capital, an affiliate manager of MPM. Dr. Ryan holds a M.D. from Columbia College of Physicians and Surgeons and a B.A. from the College of the Holy Cross. We believe that Dr. Ryan is qualified to serve as a member of our board of directors due to his extensive experience in oncology clinical research.

Stephen Webster Mr. Webster has served as a member of our board of directors since September 2020. Mr. Webster served as the Chief Financial Officer of Spark Therapeutics, Inc., a gene therapy company, from July 2014 until its acquisition by Roche Holding AG for $4.8 billion in December 2019. He was previously Senior Vice President and Chief Financial Officer of Optimer Pharmaceuticals Inc. from July 2012 until its acquisition by Cubist Pharmaceuticals Inc. in October 2013. Mr. Webster currently serves on the board of directors of NextCure, Inc., Nabriva Therapeutics AG (formerly Nabriva Therapeutics plc) and TCR2. Mr. Webster received an A.B. in Economics from Dartmouth College and an M.B.A. in Finance from The Wharton School of the University of Pennsylvania. We believe Mr. Webster is qualified to serve as a member of our board of directors due to his extensive experience in the biopharmaceutical industry, including his prior experience as a chief financial officer and in other management positions.

There are no family relationships between or among any of our directors or executive officers. The principal occupation and employment during the past five years of each of our directors was carried on, in each case except as specifically identified in this Annual Report on Form 10-K, with a corporation or organization that is not a parent, subsidiary or other affiliate of us. There is no arrangement or understanding between any of our directors and any other person or persons pursuant to which he or she is to be selected as a director.

There are no material legal proceedings to which any of our directors is a party adverse to us or any of our subsidiaries or in which any such person has a material interest adverse to us or our subsidiaries.

Code of Business Conduct and Ethics

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer, controller, or persons performing similar functions. A current copy of the code is posted on the corporate governance section of our website, which is located at https://investors.cullinanoncology.com/documents-charters. If we make any substantive amendments to, or grant any waivers from, the code of business conduct and ethics for any officer, we will disclose the nature of such amendment or waiver on our website or in a current report on Form 8-K.

Stockholder Nomination Process

There have been no material changes to the previously disclosed procedures by which our stockholders may recommend nominees to our board of directors.

Audit Committee

Our board of directors has established an audit committee. Thomas Ebeling, Anthony Rosenberg and Stephen Webster serve on the audit committee, which is chaired by Stephen Webster. Our board of directors has determined that each member of the audit committee is "independent" for audit committee purposes as that term is defined by the rules of the Securities and Exchange Commission ("SEC"), and Nasdaq Stock Market LLC ("Nasdaq"), and that each has sufficient knowledge in financial and auditing matters to serve on the audit committee. Our board of directors has designated Stephen Webster as an "audit committee financial expert," as defined under the applicable rules of the SEC.

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires our directors, executive officers and beneficial owners of more than 10% of our common stock to file reports of holdings and transactions in securities of the Company with the SEC. The SEC has designated specific deadlines for these reports, and we must identify in this Part III of our Annual Report on Form 10-K those persons who did not file these reports when due.

Based solely on a review of on Forms 3, 4 and 5 and any amendments thereto filed electronically with the SEC with respect to the most recent fiscal year and written representations from the reporting persons, we believe all Section 16(a) filing requirements were satisfied in 2022 with the exception of the Form 4 filed by Corinne Savill on July 21, 2022 reporting the sale of 5,042 shares of common stock on July 18, 2022.

Item 11. Executive Compensation.

The compensation provided to our named executive officers for 2022 and 2021 is detailed in the Summary Compensation Table and accompanying footnotes and narrative that follow this table. Our named executive officers for 2022, which consist of the individual who served as our principal executive officer during 2022 and our next two most highly compensated executive officers who were serving as executive officers at the end of the last completed fiscal year, are:

- Nadim Ahmed, our President and Chief Executive Officer;
- Patrick Baeuerle, Ph.D., our Chief Scientific Officer; and
- Jeffrey Trigilio, our Chief Financial Officer.

Summary Compensation Table

The following table presents total compensation awarded to, earned by or paid to our named executive officers for services rendered to us in all capacities during the years listed below.

Name and Principal Position	Year	Salary	Bonus[1]	Stock Awards[2]	Option Awards[2]	All Other Compensation	Total
Nadim Ahmed[3]	2022	$ 618,000	$ 370,800	$ 2,762,750 [4]	$ —	$ 148,977 [6]	$ 3,900,527
President and Chief Executive Officer	2021	$ 125,000	$ 699,000	$ —	$ 37,723,200	$ —	$ 38,547,200
Patrick Baeuerle, Ph.D.	2022	$ 463,500	$ 266,234	$ 510,000 [5]	$ 686,250	$ 34,000 [7]	$ 1,959,984
Chief Scientific Officer	2021	$ 450,000	$ 218,000	$ —	$ 3,973,177	$ 34,800 [7]	$ 4,675,977
Jeffrey Trigilio	2022	$ 452,000	$ 260,352	$ 510,000 [5]	$ 686,250	$ 15,634 [8]	$ 1,924,236
Chief Financial Officer	2021	$ 400,000	$ 220,000	$ —	$ 2,032,777	$ 14,858 [8]	$ 2,667,635

(1) The amounts reported for 2022 represent discretionary cash bonuses paid by us based on our named executive officers' performance during such fiscal year. Additionally, the amounts reported for 2022 for both Dr. Baeuerle and Mr. Trigilio include a cash retention bonus for their continued service through August 2022 in the amounts of $46,350 and $45,200, respectively. The amounts reported for 2021 represent discretionary cash bonuses paid by us based on our named executive officers' performance during such fiscal year, prorated for Mr. Ahmed to reflect the portion of the year during which he was employed by the Company. In addition, the amount reported for Mr. Ahmed for 2021 reflects a sign-on bonus of $625,000 paid in October 2021.

(2) The amounts reported represent the aggregate grant date fair value of the stock-based compensation awards granted to the named executive officers during 2022 and 2021, respectively, computed in accordance with FASB ASC Topic 718, disregarding the effects of estimated forfeitures. The assumptions used to value the equity awards for this purpose are set forth in Note 9 to our consolidated financial statements included in this Annual Report on Form 10-K.

(3) Mr. Ahmed commenced employment with the Company in October 2021. He also serves as a member of our board of directors but does not receive any additional compensation for his service as a director.
(4) The amount reported represents the grant date fair value of Mr. Ahmed's market-based restricted stock units ("RSUs") based upon the probable achievement level of the corporate stock price metrics associated with the award at the time of grant.
(5) The amounts reported represent the grant date fair value of Dr. Baeuerle's and Mr. Trigilio's service-based RSUs, which were valued based on the closing price of our common stock on the grant date.
(6) The amount reported for Mr. Ahmed for 2022 includes $46,343 of commuting and related travel expenses (the "travel expenses"), a housing allowance of $87,000, and $15,250 of 401(k) matching contributions. The housing allowance reported for 2022 reflects $15,000 in housing expenses for the portion of 2021 that Mr. Ahmed was employed by us but that were not paid to Mr. Ahmed until early 2022.
(7) The amount reported for Dr. Baeuerle for 2022 and 2021 represents the value of the corporate apartment provided by us to Dr. Baeuerle.
(8) The amount reported for Mr. Trigilio for 2022 includes 401(k) matching contributions of $15,250. The amount reported for Mr. Trigilio for 2021 consists of 401(k) match contributions of $14,500.

Narrative to Summary Compensation Table

Overview

Our executive compensation program is designed to attract, retain and reward key employees and to align their interests with the interests of our stockholders. Our Chief Executive Officer makes recommendations to our compensation committee about the compensation of his direct reports (except with respect to his own compensation), and our compensation committee is responsible for determining the compensation of our executive officers.

Until November 2022, our compensation committee had engaged Radford as its independent compensation consultant and has subsequently engaged Compensia in such capacity. Each of Radford and Compensia are independent compensation consulting firms and assist or assisted, as the case may be, the compensation committee in evaluating the Company's executive and director compensation practices, including program design, identification of an appropriate peer group for compensation comparison purposes and providing competitive market pay data. Prior to engaging each of Radford and Compensia, our compensation committee assessed the independence of each of Radford and Compensia from management and, on the basis of that assessment and after taking into consideration the independence factors that are required to be considered under applicable stock exchange listing standards and SEC rules, determined that none of the work performed by either Radford or Compensia gave rise to a conflict of interest or would compromise either Radford or Compensia's independence.

Base Salary

During 2022 and 2021 the annual base salary for Mr. Ahmed was $618,000 and $600,000, respectively. During 2022 and 2021, the annualized base consulting fees for Dr. Baeuerle were $464,000 and $450,000, respectively. During 2022 and 2021, the annual base salary for Mr. Trigilio was $452,000 and $400,000, respectively.

Bonus Arrangements

Pursuant to the terms of Mr. Ahmed's employment agreement, his target incentive bonus was 50% of his base salary in both 2022 and 2021. Based on the compensation committee and board of directors' evaluation of his performance during 2022 and 2021, Mr. Ahmed was awarded a discretionary bonus equal to 60% and 59% of his base salary, respectively. In 2021, his bonus was pro-rated to reflect the portion of the year during which he was employed by the Company. Additionally, in 2021, Mr. Ahmed was granted a one-time sign-on bonus of $625,000, pursuant to the terms of his employment agreement.

Pursuant to the terms of Dr. Baeuerle's consulting agreement, his target incentive bonus was 40% of his annualized base consulting fees in both 2022 and 2021. Based on the compensation committee's evaluation of his performance during 2022 and 2021, Dr. Baeuerle was awarded a discretionary bonus equal to 47% and 48% of his annualized base consulting fees, respectively.

Pursuant to the terms of Mr. Trigilio's employment agreement, his target incentive bonus was 40% of his base salary in both 2022 and 2021. Based on the compensation committee's evaluation of his performance during 2022 and 2021, Mr. Trigilio was awarded a discretionary bonus equal to 48% and 55% of his base salary, respectively.

Additionally, Dr. Baeuerle and Mr. Trigilio received retention bonuses as part of an initiative implemented broadly across the workforce. The purpose of the retention initiative was to ensure workforce stabilization and continuity during a transition period, especially for key roles given the company had 31 full time employees as of December 31, 2021. Pursuant to the supplemental bonus agreements entered into in February 2022, Dr. Baeuerle and Mr. Trigilio are each entitled to cash retention bonuses tied to continued service with the Company through August 2023. The total bonus amount is paid in installments according to the following payout schedule: 20% in August 2022, 40% in February 2023 and the remaining 40% in August 2023. In 2022, Dr. Bauerle and Mr. Trigilio received $46,350 and $45,200, respectively, for their continued service through the August 2022 payout date.

Equity Compensation

Our employees and executive officers are eligible to receive stock options and other stock-based awards pursuant to our 2021 Stock Option and Incentive Plan (the "2021 Stock Plan").

Although we do not have a formal policy with respect to the grant of equity incentive awards to our executive officers, we believe that equity awards provide our executive officers with a strong link to our long-term performance, create an ownership culture and help to align the interests of our executive officers and our stockholders. In addition, we believe that equity awards with multi-year vesting requirements promote executive retention because they incentivize our executive officers to remain in our employment during the vesting period. Our compensation committee periodically reviews the equity incentive compensation of our executive officers, including our named executive officers, and from time to time may grant equity incentive awards to them. We typically grant equity awards in the form of stock options in connection with the commencement of an executive officer's employment and as a combination of both stock options and RSUs on an annual basis thereafter. We set option exercise prices at the closing market price of a share of our common stock on the date of grant (or the immediately preceding date on which a closing market price was reported if there is no closing market price on the date of grant).

On March 5, 2022, pursuant to the terms of his employment agreement, Mr. Ahmed was granted market-based RSUs that represent the right to receive, at settlement, 215,000 shares of our common stock. The number of shares subject to market-based RSUs represents the number of shares issuable upon vesting, assuming the Company achieves its corporate stock price metrics at the target achievement level. The number of shares issuable, if any, when the award vests will depend on the degree of achievement of corporate stock price metrics at the vesting date and ranges between 0% and 200% of the target number of shares. The market-based RSUs will vest and be settled three years from the grant date in an amount to be determined based on the price per share of our common stock at such time. The market-based RSUs is subject to vesting acceleration in the event of a change in control of the Company prior to the vesting date. On October 18, 2021, in connection with the commencement of his employment with us, Mr. Ahmed was granted an option to purchase 2,710,000 shares of our common stock at an exercise price of $21.12 per share with a vesting commencement date of October 18, 2021. One forty-eighth of the shares underlying the option vest monthly subject to continued service through each vesting date. The unvested portion of this option is subject to vesting acceleration in connection with a change in control of the Company, also known as a "sale event", or termination of Mr. Ahmed's employment by us without "cause" (each as defined in the 2021 Stock Plan).

On February 11, 2022, Dr. Baeuerle was granted (i) an option to purchase 75,000 shares of our common stock at an exercise price of $13.60 per share and (ii) RSUs that represent the right to receive, at settlement, 37,500 shares of our common stock (the "2022 Bauerle Equity Awards"). One forty-eighth of the shares underlying the 2022 Baeuerle Equity Awards vest monthly, subject to continued service through each vesting date. On January 7, 2021, in connection with the equity exchange related to our reorganization prior to our initial public offering, Dr. Baeuerle was granted (i) an option to purchase 262,114 shares of our common stock at an exercise price of $4.30 per share with a vesting commencement date of September 1, 2018 and (ii) an option to purchase 407,993 shares of our common stock at an exercise price per share of $4.30 with a vesting commencement date of May 15, 2019, (collectively, the "Baeuerle Equity Exchange Options"). On January 7, 2021, Dr. Baeuerle was also granted an option to purchase 286,665 shares of our common stock at an exercise price of $21.00 per share, reflecting the initial public offering price of our common stock on such date, with a vesting commencement date of January 7, 2021 (the "Baeuerle IPO Option" and, together with the Baeuerle Equity Exchange Options, the "2021 Baeuerle Options"). With respect to each of the 2021 Baeuerle Options, 25% of the shares underlying the option vest on the first anniversary of the vesting commencement date and the remaining shares vest in 36 equal monthly installments thereafter, subject to continued service through each vesting date. The unvested portions of the 2022 Baeuerle Equity Awards and the 2021 Baeuerle Options are subject to vesting acceleration in connection with a change in control of the Company, also known as a "sale event", or termination of Dr. Baeuerle's consulting relationship by us without "cause" (each as defined in the 2021 Stock Plan).

On February 11, 2022, Mr. Trigilio was granted (i) an option to purchase 75,000 shares of our common stock at an exercise price of $13.60 per share and (ii) RSUs that represent the right to receive, at settlement, 37,500 shares of our common stock, (the "2022 Trigilio Equity Awards"). One forty-eighth of the shares underlying the 2022 Trigilio Equity Awards vest monthly, subject to continued service through each vesting date. On January 7, 2021, in connection with the equity exchange related to our reorganization prior to our initial public offering, Mr. Trigilio was granted an option to purchase 252,891 shares of our common stock at an exercise price of $4.30 per share with a vesting commencement date of September 8, 2020 (the "Trigilio Equity Exchange Option"). On January 7, 2021, Mr. Trigilio was also granted an option to purchase 146,665 shares of our common stock at an exercise price of $21.00 per share, reflecting the initial public offering price of our common stock on such date, with a vesting commencement date of January 7, 2021 (the "Trigilio IPO Option" and, together with the Trigilio Equity Exchange Option, the "2021 Trigilio Options"). With respect to each of the 2021 Trigilio Options, 25% of the shares underlying the option vest on the first anniversary of the vesting commencement date and the remaining shares vest in 36 equal monthly installments thereafter, subject to continued service through each vesting date. The unvested portions of the 2022 Trigilio Equity Awards and the 2021 Trigilio Options are subject to vesting acceleration in connection with a change in control of the Company, also known as a "sale event", or termination of Mr. Trigilio's employment by us without "cause" (each as defined in the 2021 Stock Plan).

Employment Agreements and Service Agreements with our Named Executive Officers

We have entered into employment agreements or service agreements with each of our named executive officers. Each agreement sets forth such executive officer's base salary or base consulting fee, as applicable, target bonus percentage, and eligibility to participate in our benefit plans generally. Each of Mr. Ahmed and Mr. Trigilio is also subject to a confidentiality, assignment and non-solicitation agreement, which provides for a perpetual post-termination confidentiality covenant as well as non-solicitation of employees and consultants covenants that apply during employment and for one year following termination. In December 2020, we also entered into a new service agreement with Dr. Baeuerle, which became effective upon our initial public offering. The terms "cause", "good reason" and "change in control" referred to below are defined in each named executive officer's employment agreement or service agreement, as applicable.

Nadim Ahmed

In October 2021, we entered into an employment agreement with Mr. Ahmed, who currently serves as our President and Chief Executive Officer. The employment agreement provides for an annual base salary, subject to periodic review by our board of directors or compensation committee, and an annual target bonus equal to 50% of Mr. Ahmed's annual base salary, with the actual amount of any bonus payable determined in the sole discretion of our board of directors or compensation committee based on milestones to be determined by our board of directors or compensation committee. Pursuant to his employment agreement, Mr. Ahmed received a sign-on bonus of $625,000, which is repayable by him if he resigns other than for good reason or is terminated by us for cause, in either case within 18 months of the commencement of his employment (with any repayment obligation being pro-rated after the first anniversary). Mr. Ahmed is also entitled to a housing allowance of $6,000 per month to secure temporary housing until the earlier of the fourth anniversary of his employment commencement date or the date on which he no longer has a need for temporary housing. The employment agreement also provides for Mr. Ahmed to be nominated for election to our board of directors and to be recommended to our stockholders for election to our board of directors for so long as he remains our Chief Executive Officer.

Under Mr. Ahmed's employment agreement, in the event that Mr. Ahmed's employment is terminated by us without cause or Mr. Ahmed resigns for good reason, subject to the execution and effectiveness of a separation agreement, including a general release of claims in our favor and, in the Company's sole discretion, a one-year post-employment noncompetition agreement, he will be entitled to receive (i) an amount equal to 12 months of his then-current base salary plus a pro-rata portion of his annual bonus, based on actual performance for the year, and (ii) if Mr. Ahmed is participating in our group health plans immediately prior to his termination and elects COBRA health continuation, continuation of such group health coverage at the same rate as if he were an active employee, until the earliest of (A) the 12-month anniversary of his termination, (B) his eligibility for group medical plan benefits under any other employer's group medical plan or (C) the cessation of his continuation rights under COBRA. The employment agreement also provides that, in lieu of the payments and benefits described above, in the event that Mr. Ahmed's employment is terminated by us without cause or Mr. Ahmed resigns for good reason, in either case within 12 months following a change in control of the Company, subject to the execution and effectiveness of a general release of claims in our favor, he will be entitled to receive (i) an amount equal to 24 months of his then-current base salary (or his base salary in effect immediately prior to the change in control, if higher) plus his prorated annual bonus, based on actual performance for the year, and (ii) an amount equal to the premiums the Company would have paid to its group health plan provider or the COBRA provider as a monthly employer contribution if Mr. Ahmed had remained employed by the Company for an additional 24 months. In addition, in the event of a termination of Mr. Ahmed's employment by us without cause or by him for good reason, in either case within 12 months following a change in control of the Company, all outstanding equity awards that vest solely based on time will become fully vested and any performance-based RSUs outstanding will vest pro-rata based on the period of Mr. Ahmed's employment during the applicable performance period.

Patrick Baeuerle, Ph.D.

In connection with our initial public offering in 2021, we entered into a service agreement with Dr. Baeuerle, who currently serves as our Acting Chief Scientific Officer. This service agreement supersedes the prior consulting agreement entered into between Dr. Baeuerle and the Company on January 1, 2019. The service agreement provides for fixed annualized consulting fees, subject to periodic review by our board of directors or compensation committee, and an annual target bonus equal to 40% of Dr. Baeuerle's annualized consulting fees, with the actual amount of any bonus payable determined in the sole discretion of our board of directors or compensation committee, subject to the terms of any applicable incentive compensation plan of the Company.

Under Dr. Baeuerle's service agreement, in the event that Dr. Baeuerle's engagement is terminated by us without cause or Dr. Baeuerle resigns for good reason, subject to the execution and effectiveness of a separation agreement, including a general release of claims in our favor, he will be entitled to receive an amount equal to nine months of his then-current annualized consulting fee plus a pro-rata portion of his annual target bonus. The service agreement also provides that, in lieu of the payments described above, in the event that Dr. Baeuerle's engagement is terminated by us without cause or Dr. Baeuerle resigns for good reason, in either case within 12 months following a change in control of the Company, subject to the execution and effectiveness of a general release of claims in our favor, he will be entitled to receive a lump sum cash payment equal to (i) 12 months of his then-current annualized consulting fee (or his annualized consulting fee in effect immediately prior to the change in control if higher) plus (ii) his annual target bonus for the then-current year (or the annual target bonus in effect immediately prior to the change in control, if higher).

The service agreement also provides that in the event Dr. Baeuerle's engagement ends as a result of his death or disability, unless otherwise set forth in an award agreement evidencing an equity award subject to performance-based vesting, 25% of each then-unvested equity award outstanding, plus an additional 5% for each full year of service to the Company, will immediately accelerate and become fully vested and exercisable or nonforfeitable on the date of termination. The service agreement further provides that in the event Dr. Baeuerle's engagement is terminated by us without cause or Dr. Baeuerle resigns for good reason, in either case within 12 months following a change in control of the Company, each outstanding equity award will immediately accelerate and become fully vested and exercisable or nonforfeitable on the date of termination.

Jeffrey Trigilio

In connection with our initial public offering in 2021, we entered into a new employment agreement with Mr. Triglio who currently serves as our Chief Financial Officer. His employment agreement provides for an annual base salary, subject to periodic review by our board of directors or compensation committee, and an annual target bonus equal to 40% of Mr. Trigilio's annual base salary, with the actual amount of any bonus payable determined in the sole discretion of our board of directors or compensation committee, subject to the terms of any applicable incentive compensation plan of the Company.

Under Mr. Trigilio's employment agreement, in the event that Mr. Trigilio's employment is terminated by us without cause or Mr. Trigilio resigns for good reason, subject to the execution and effectiveness of a separation agreement, including a general release of claims in our favor and, in the Company's sole discretion, a one-year post-employment noncompetition agreement, he will be entitled to receive (i) an amount equal to nine months of his then-current base salary plus a pro-rata portion of his annual target bonus, and (ii) if Mr. Trigilio is participating in our group health plans immediately prior to his termination and elects COBRA health continuation, continuation of such group health coverage at the same rate as if he were an active employee, until the earliest of (A) the nine-month anniversary of his termination, (B) his eligibility for group medical plan benefits under any other employer's group medical plan or (C) the cessation of his continuation rights under COBRA. Mr. Trigilio's employment agreement also provides that, in lieu of the payments and benefits described above, in the event that his employment is terminated by us without cause or he resigns for good reason, in either case within 12 months following a change in control of the Company, subject to the execution and effectiveness of a general release of claims in our favor, he will be entitled to receive (i) a lump sum cash payment equal to 12 months of his then-current base salary (or his base salary in effect immediately prior to the change in control, if higher) plus his annual target bonus for the then-current year (or the annual target bonus in effect immediately prior to the change in control, if higher), and (ii) if Mr. Trigilio is participating in our group health plans immediately prior to his termination and elects COBRA health continuation, continuation of such group health coverage at the same rate as if he were an active employee, until the earliest of (A) the 12-month anniversary of his termination, (B) his eligibility for group medical plan benefits under any other employer's group medical plan or (C) the cessation of his continuation rights under COBRA.

Mr. Trigilio's employment agreement also provides that in the event his employment ends as a result of his death or disability, unless otherwise set forth in an award agreement evidencing an equity award subject to performance-based vesting, 25% of each then-unvested equity award outstanding, plus an additional 5% for each full year of service to the Company, will immediately accelerate and become fully vested and exercisable or nonforfeitable on the date of termination. The employment agreement further provides that in the event Mr. Trigilio's employment is terminated by us without cause or Mr. Trigilio resigns for good reason, in either case within 12 months following a change in control of the Company, unless otherwise set forth in an award agreement evidencing an equity award subject to performance-based vesting, each outstanding equity award will immediately accelerate and become fully vested and exercisable or nonforfeitable on the date of termination.

Outstanding Equity Awards at Fiscal Year End Table

The following table presents the outstanding equity awards held by each of our named executive officers as of December 31, 2022.

	Option Awards				Stock Awards			
Name	Number of securities underlying unexercised options exercisable	Number of securities underlying unexercised options unexercisable	Option exercise price	Option expiration date	Number of shares or units that have not vested	Market value of shares or units that have not vested[1]	Equity incentive plan awards: number of unearned shares, units or other rights that have not vested	Equity incentive plan awards: market or payout value of unearned shares, units or other rights that have not vested[1]
Nadim Ahmed	790,416	1,919,584 [2]	$ 21.12	10/17/2031	—	—	—	—
	—	—	—	—	—	—	53,750 [3]	$ 567,063
Patrick Baeuerle, Ph.D.	240,114	—	$ 4.30	10/28/2030	—	—	—	—
	365,493	42,500 [4]	$ 4.30	10/28/2030	—	—	—	—
	137,360	149,305 [4]	$ 21.00	12/30/2030	—	—	—	—
	15,625	59,375 [4]	$ 13.60	2/11/2032	—	—	—	—
	—	—	—	—	3,903 [5]	$ 41,177	—	—
	—	—	—	—	2,774 [5]	$ 29,266	—	—
	—	—	—	—	29,688 [6]	$ 313,208	—	—
Jeffrey Trigilio	119,250	110,641 [4]	$ 4.30	10/28/2030	—	—	—	—
	70,276	76,389 [4]	$ 21.00	12/30/2030	—	—	—	—
	15,625	59,375 [4]	$ 13.60	2/11/2032	—	—	—	—
	—	—	—	—	29,688 [6]	$ 313,208	—	—

(1) Amounts shown are based on a price of $10.55 per share, which was the closing market price of our common stock as reported on the Nasdaq Global Select Market on the last trading day of the year, December 30, 2022.

(2) Represents an option to purchase shares of our common stock, which vests as follows: 25% of the shares underlying the option vest on the first anniversary of the vesting commencement date and the remaining shares vest in 36 equal monthly installments thereafter, subject to the executive's continued service through each vesting date.

(3) Represents shares of common stock underlying market-based RSUs granted on March 5, 2022, which vests three years from the grant date in an amount to be determined based on the price per share of our common stock at such time, assuming the Company achieves its corporate stock price metrics at the threshold achievement level.

(4) Represents an option to purchase shares of our common stock, which vests in 48 monthly equal installments, subject to the named executive officer's continued service through each vesting date.

(5) Represents shares of restricted stock granted on December 16, 2019, which vest in 48 monthly equal installments, subject to the named executive officer's continued service through each vesting date.

(6) Reflects shares of common stock underlying service-based RSUs granted on February 11, 2022, which vest in 48 monthly equal installments, subject to the named executive officer's continued service through each vesting date.

Compensation Risk Assessment

We do not believe that our executive compensation program encourages excessive or unnecessary risk taking. Our compensation program, including any performance-based compensation, is designed to encourage our named executive officers and other employees to remain focused on both short-term and long-term strategic goals. As a result, we do not believe that our compensation programs are reasonably likely to have a material adverse effect on us.

Employee Benefits

Our eligible U.S. employees participate in a tax-qualified retirement plan that provides an opportunity to save for retirement on a tax-advantaged basis. Plan participants are able to defer eligible compensation subject to applicable annual limits under the Internal Revenue Code of 1986, as amended (the "Code"). We make a safe harbor matching contribution equal to 100% of our employee's deferrals, up to a maximum of 5% of the employee's salary, subject to applicable Code limits.

All of our full-time employees, including our executive officers, are eligible to participate in certain medical, disability and life insurance benefit programs offered by us. We pay the premiums for term life insurance and short and long-term disability for all of our employees, including our executive officers. We also provide all employees, including our executive officers, paid time off benefits including, vacation, sick time and holidays. We do not sponsor any qualified or non-qualified defined benefit plans for any of our employees or executive officers.

In accordance with our insider trading policy, our directors and executive officers may adopt written plans, known as Rule 10b5-1 plans, in which they will contract with a broker to buy or sell shares of our common stock on a periodic basis. Under a Rule 10b5-1 plan, a broker executes trades pursuant to parameters established by the director or officer when entering into the plan, without further direction from the director or officer. In addition, our directors and executive officers may buy or sell additional shares outside of a Rule 10b5-1 plan when they are not in possession of material, nonpublic information.

Director Compensation

Director Compensation Table

The table below shows all compensation earned by or paid to our non-employee directors during 2022. Nadim Ahmed, our Chief Executive Officer, does not receive any compensation for his services as director and, consequently, is not included in this table. The compensation received by Mr. Ahmed during 2022 is set forth in the "Executive Compensation—Summary Compensation Table."

Name	Fees Earned or Paid in Cash	Option Awards[1][2]	Total
Thomas Ebeling	$ 50,500	$ 149,923	$ 200,423
Ansbert Gadicke, M.D.[3]	$ 36,667	$ 149,923	$ 186,590
Anne-Marie Martin, Ph.D.[4]	$ —[5]	$ 349,991	$ 349,991
Anthony Rosenberg	$ 86,500	$ 149,923	$ 236,423
David P. Ryan, M.D.[6]	$ 6,667	$ 249,994	$ 256,661
Stephen Webster	$ 59,000	$ 149,923	$ 208,923

(1) Amounts represent the aggregate grant date fair value of options to purchase shares of our common stock granted to our non-employee directors in 2022, computed in accordance with FASB ASC Topic 718, excluding the effect of estimated forfeitures. The assumptions used to value the options for this purpose are set forth in Note 9 to our consolidated financial statements included in this Annual Report on Form 10-K.

(2) As of December 31, 2022, the aggregate number of shares of our common stock subject to outstanding option awards held by our non-employee directors was as follows: Mr. Ebeling, 108,499 shares; Dr. Gadicke, 7,800 shares; Dr. Martin, 36,880 shares; Mr. Rosenberg, 232,159 shares; Dr. Ryan, 26,150 shares; and Mr. Webster, 49,564 shares.

(3) Dr. Gadicke resigned from our board of directors effective November 1, 2022. His fees were pro-rated to reflect the number of days he served as a member of the board and committees in 2022.

(4) Dr. Martin was appointed to our board of directors on March 1, 2022.

(5) In lieu of the annual cash retainer fees otherwise paid to our non-employee directors, Dr. Martin was granted an option to purchase 36,880 shares of our common stock with a grant date fair value of approximately $350,000 upon her appointment.

(6) Dr. Ryan was appointed to our board of directors on November 1, 2022. His fees were pro-rated to reflect the number of days he has served as a member of the board.

Non-Employee Director Compensation Policy

Under our non-employee director compensation policy, we pay our non-employee directors a cash retainer for service on the board of directors and for service on each committee on which the director is a member. The chairperson of our board of directors receives an additional annual retainer for such service. The fees are designed to enable us to attract and retain, on a long-term basis, highly qualified non-employee directors. A schedule of non-employee director cash retainers is set forth below.

	Annual Retainer	
Board of Directors:		
Members	$	35,000
Additional retainer for non-executive chairperson	$	30,000
Audit Committee:		
Members (other than chairperson)	$	7,500
Chairperson	$	15,000
Compensation Committee:		
Members (other than chairperson)	$	5,000
Chairperson	$	10,000
Nominating and Corporate Governance Committee:		
Members (other than chairperson)	$	4,000
Chairperson	$	8,000

In addition, our non-employee director compensation policy provides that, upon initial election to our board of directors, each non-employee director will be granted an option to purchase shares of our common stock with a grant date fair value of $250,000 (the "Initial Grant"). The Initial Grant vests in equal installments on the first, second and third anniversaries of the grant date, subject to continued service as a director through the applicable vesting date. Furthermore, on the date of each annual meeting of stockholders, each non-employee director who continues as a non-employee director following such meeting will be granted an option to purchase shares of our common stock with a grant date fair value of $150,000 (the "Annual Grant"). The Annual Grant will vest in full on the earlier of (i) the first anniversary of the grant date or (ii) our next annual meeting of stockholders, subject to continued service as a director through the applicable vesting date. Directors are not entitled to the Annual Grant until they have been on the board for a full year. Initial Grants and Annual Grants vest in full upon the sale of the Company.

The initial grant awarded to Dr. Martin was an option to purchase shares of our common stock with a grant date fair value of $350,000 instead of the $250,000 value set out in our director compensation policy due to Dr. Martin not receiving standard board and committee fees. The award vests in equal installments on the first, second and third anniversaries of the grant date, subject to continued service as a director through the applicable vesting date.

We reimburse all reasonable out-of-pocket expenses incurred by non-employee directors in attending meetings of the board of directors and committees.

Under the non-employee director compensation policy, the aggregate amount of compensation, including both equity compensation and cash compensation, paid to a non-employee director in any year for service as a director may not exceed $500,000 ($750,000 for the year in which the non-employee director is initially elected or appointed to our board of directors).

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

The following table sets forth information, to the extent known by us or ascertainable from public filings, with respect to the beneficial ownership of our common stock as of February 15, 2023 by:

- each of our directors;
- each of our named executive officers;
- all of our directors and executive officers as a group; and
- each person, or group of affiliated persons, who is known by us to beneficially owner of 5% or greater of the outstanding shares of our common stock.

The column entitled “Percentage of Shares Beneficially Owned” is based on a total of 39,327,298 shares of our common stock outstanding as of February 15, 2023.

Beneficial ownership is determined in accordance with the rules and regulations of the SEC and includes voting or investment power with respect to our common stock. Shares of our common stock subject to options that are currently exercisable or exercisable within 60 days of February 15, 2023 are considered outstanding and beneficially owned by the person holding the options for the purpose of calculating the percentage ownership of that person but not for the purpose of calculating the percentage ownership of any other person. Except as otherwise noted, the persons and entities in this table have sole voting and investing power with respect to all of the shares of our common stock beneficially owned by them, subject to community property laws, where applicable. Except as otherwise indicated in the table below, addresses of named beneficial owners are in care of Cullinan Oncology, Inc., One Main Street, Suite 1350, Cambridge, MA 02142.

Name of Beneficial Owner	Shares Beneficially Owned	Percentage of Shares Beneficially Owned
5% or Greater Stockholders		
UBS Oncology Impact Fund L.P.[(1)]	7,648,268	19.45 %
Entities affiliated with BVF, Inc.[(2)]	7,509,059	16.39 %
Entities affiliated with F2 Ventures[(3)]	3,783,971	9.62 %
CHI Advisors LLC[(4)]	3,317,544	8.44 %
The Vanguard Group[(5)]	2,812,965	7.15 %
BlackRock, Inc.[(6)]	2,506,215	6.37 %
Named Executive Officers and Directors		
Nadim Ahmed[(7)]	961,411	2.39 %
Patrick Baeuerle, Ph.D.[(8)]	1,175,101	2.93 %
Jeffrey Trigilio[(9)]	254,627	*
Thomas Ebeling[(10)]	159,528	*
Anne-Marie Martin, Ph.D.[(11)]	12,294	*
Anthony Rosenberg[(12)]	260,686	*
David P. Ryan, M.D.	—	*
Stephen Webster[(13)]	23,605	*
All executive officers and directors as a group (12 persons)[(14)]	3,517,920	8.34 %

* Less than one percent

(1) Information herein is solely based on a Form 4 filed with the SEC on September 20, 2021 by (i) OIF, (ii) Oncology Impact Fund (Cayman) Management L.P., or OIF GP, (iii) MPM Oncology Impact Management LP, or MPM LP, and (iv) MPM Oncology Impact Management GP LLC, or MPM GP. The general partner of OIF is OIF GP. The general partner of OIF GP is MPM LP. The general partner of MPM LP is MPM GP. Dr. Ansbert Gadicke was a member of our board of directors and is a managing member and the managing director of MPM GP. Each of the entities and individuals listed above expressly disclaims beneficial ownership of the securities listed above except to the extent of any pecuniary interest therein. The address of these entities 450 Kendall Street, Cambridge, MA 02142.

(2) Information herein is based on a Schedule 13G/A filed with the SEC on February 14, 2023 and information available to us. The number of shares shown includes (i) 1,034,059 shares of common stock and (ii) 6,475,000 shares of common stock issuable upon the conversion of Series A Preferred Stock, par value $0.0001 per share ("Preferred Stock"). Biotechnology Value Fund, L.P., or BVF, is deemed to be the beneficial owner of 4,058,854 shares of common stock, 3,500,000 shares of which are issuable upon the conversion of Preferred Stock, all of which such entity reported having shared voting and dispositive power. BVF I GP LLC, or BVF GP, is deemed to be the beneficial owner of 4,058,854 shares of common stock, 3,500,000 shares of which are issuable upon the conversion of Preferred Stock, all of which such entity reported having shared voting and dispositive power. Biotechnology Value Fund II, L.P., or BVF2, is deemed to be the beneficial owner of 2,992,808 shares of common stock, 2,600,000 shares of which are issuable upon the conversion of Preferred Stock, all of which such entity reported having shared voting and dispositive power. BVF II GP LLC, or BVF2 GP, is deemed to be the beneficial owner of 2,992,808 shares of common stock, 2,600,000 shares of which are issuable upon the conversion of Preferred Stock, all of which such entity reported having shared voting and dispositive power. Biotechnology Value Trading Fund OS LP, or Trading Fund OS, is deemed to be the beneficial owner of 364,161 shares, all of which such entity reported having shared voting and dispositive power. BVF Partners OS Ltd., or Partners OS, is deemed to be the beneficial owner of 364,161 shares, 300,000 shares of which are issuable upon conversion of Preferred Stock, all of which such entity reported having shared voting and dispositive power. A certain Partners' managed account is deemed to be the beneficial owner of 93,236 shares of common stock, 75,000 shares of which are issuable upon the conversion of Preferred Stock, all of which such entity reported having shared voting and dispositive power. BVF GP Holdings LLC, or BVF GPH, is deemed to be the beneficial owner of 7,051,662 shares of common stock, 6,100,000 shares of which are issuable upon conversion of Preferred Stock, all of which such entity reported having shared voting and dispositive power. BVF Partners L.P., or Partners, is deemed to be the beneficial owner of 7,509,059 shares of common stock, 6,475,000 shares of which are issuable upon conversion of Preferred Stock, all of which such entity reported having shared voting and dispositive power. BVF Inc. is deemed to be the beneficial owner of 7,509,059 shares of common stock, 6,475,000 shares of which are issuable upon conversion of Preferred Stock, all of which such entity reported having shared voting and dispositive power. Mark N. Lampert is deemed to be the beneficial owner of 7,509,059 shares of common stock, 6,475,000 shares of which are issuable upon conversion of Preferred Stock, all of which he reported as having shared voting and dispositive power. BVF GP is the general partner of BVF. BVF2 GP is the general partner of BVF2. Partners OS is the general partner of Trading Fund OS. BVF GPH is the sole member of each of BVF GP and BVF2 GP. Partners is the investment manager of BVF, BVF2, Trading Fund OS and the Partners' managed account and is the sole member of Partners OS. BVF Inc. is the general partner of Partners. Mr. Lampert is a director and officer of BVF Inc. The address for correspondence for BVF, BVF GP, BVF2, BVF2 GP, BVF GPH, Partners, BVF Inc. and Mr. Lampert is 44 Montgomery St., 40thFloor, San Francisco, California 94104. The address for correspondence for Trading Fund OS and Partners OS is PO Box 309 Ugland House, Grand Cayman, KY1-1104, Cayman Islands.

(3) Information herein is solely based on a Schedule 13G/A filed with the SEC on February 15, 2023. Globeways Holdings Ltd., or Globeways is deemed to be the beneficial owner of 1,577,440 shares of common stock, all of which such entity reported having shared voting and dispositive power. F2 Bioscience I 2017 Ltd., or F2 Bioscience 2017 is deemed to be the beneficial owner of 537,392 shares of common stock, all of which such entity reported having shared voting and dispositive power. F2 MG Ltd., or F2 MG is deemed to be the beneficial owner of 548,333 shares of common stock, all of which such entity reported having shared voting and dispositive power. Globeways Holdings II Ltd., or Globeways II is deemed to be the beneficial owner of 1,013,334 shares of common stock, all of which such entity reported having shared voting and dispositive. F2-TPO Investments, LLC, or F2 TPO is deemed to be the beneficial owner of 622,175 shares of common stock, all of which such entity reported having shared voting and dispositive power. F2 Bio TD, LLC, or F2 Bio is deemed to be the beneficial owner of 71,599 shares, all of which such entity reported having shared voting and dispositive power. F2 MC, LLC, or F2 MC is deemed to be the beneficial owner of 214,798 shares of common stock, all of which such entity reported having shared voting and dispositive power. F2 GC, LLC, or F2 GC is deemed to be the beneficial owner of 104,762 shares of common stock, all of which such entity reported having shared voting and dispositive power. F2 Vision Management Sarl, or F2 Vision Management is deemed to be the beneficial owner of 985,394 shares of common stock, all of which such entity reported having shared voting and dispositive power. F2 Vision SCS, or F2 Vision is deemed to be the beneficial owner of 985,394 shares of common stock, all of which such entity reported having shared voting and dispositive power. Morana Jovan-Embiricos is deemed to be the beneficial owner of 3,783,971 shares of common stock, with respect to which she reported having sole voting and dispositive power over 207,803 shares and shared voting and dispositive power over 3,576,168 shares. Dr. Morana Jovan-Embiricos was a member of our board of directors and is the founding director and shareholder of Globeways, which is the appointed manager of each of F2 Bioscience 2017 and F2 MG. Dr. Morana Jovan-Embiricos is also the founder of Globeways' wholly-owned subsidiary Globeways II, which is the appointed manager of F2 TPO, F2 MC, F2 GC and F2 Bio. Dr. Morana Jovan-Embiricos is also the founder of Globeways' wholly-owned subsidiary F2 Vision Management, which is the appointed manager of F2 Vision. Dr. Morana Jovan-Embiricos makes investment decisions on behalf of all such entities with respect to shares held by such entities. The address for correspondence of Dr. Morana Jovan-Embiricos, Globeways, F2 Bioscience 2017 and Globeways II is c/o LJ Management (Suisse) SA, 7 Rue da la Confederation, Geneva 1204, Switzerland. The address for correspondence of F2 MG is c/o GISEV (Suisse) SA, Contrada di Sassello 2, 6900 Lugano, Switzerland. The address for correspondence of F2 TPO, F2 Bio, F2 GC and F2 MC is c/o Twin Focus, 75 Park Plaza, Boston, MA 02116 USA. The address for correspondence of F2 Vision and F2 Vision Management is c/o Atalux, 74 Grand-Rue, Luxembourg V8 L-1660.

(4) Information herein is solely based on a Schedule 13G/A filed with the SEC on February 13, 2023. CHI Advisors LLC is deemed to be the beneficial owner of 3,317,544 shares of common stock, all of which such entity reported having sole voting and dispositive power. The address for correspondence of CHI Advisors LLC is 599 Lexington Avenue, 19th Floor, New York, New York 10022.

(5) Information herein is solely based on a Schedule 13G/A filed with the SEC on February 9, 2023. The Vanguard Group is deemed to be the beneficial owner of 2,812,965 shares of common stock, with respect to which such entity reported having sole dispositive power over 2,780,265 shares, shared voting power over 17,057 shares and shared dispositive power over 32,200 shares. The address for correspondence of The Vanguard Group is 100 Vanguard Blvd., Malvern, Pennsylvania 19355.

(6) Information herein is solely based on a Schedule 13G filed with the SEC on February 3, 2023. BlackRock, Inc. is deemed to be the beneficial owner of 2,506,215 shares of common stock, with respect to which such entity reported having sole voting power over 2,434,609 shares and sole dispositive power over 2,506,215 shares. The address for correspondence of BlackRock, Inc. is 55 East 52nd Street, New York, NY 10055.

(7) Consists of (i) 1,620 shares of common stock held by Mr. Ahmed and (ii) 959,791 shares subject to options held by Mr. Ahmed which are vested and exercisable within 60 days of February 15, 2023.
(8) Consists of (i) 281,268 shares of common stock held by an entity of which Dr. Baeuerle is Managing Director and has sole voting and investment power over these shares, (ii) 69,541 shares of common stock held by Dr. Baeuerle, (iii) 1,562 shares underlying RSUs held by Dr. Baeuerle which are vested within 60 days of February 15, 2023 and (iv) 822,730 shares subject to options held by Dr. Baeuerle which are vested and exercisable within 60 days of February 15, 2023.
(9) Consists of (i) 8,367 shares of common stock held by Mr. Trigilio, (ii) 1,562 shares underlying RSUs which are vested within 60 days of February 15, 2023 and (iii) 244,698 shares subject to options held by Mr. Trigilio which are vested and exercisable within 60 days of February 15, 2023.
(10) Consists of (i) 67,504 shares of common stock held by Mr. Ebeling and (ii) 92,024 shares subject to options held by Mr. Ebeling which are vested and exercisable within 60 days of February 15, 2023.
(11) Consists of 12,294 shares subject to options held by Dr. Martin which are vested and exercisable within 60 days of February 15, 2023.
(12) Consists of (i) 45,002 shares of common stock held by Mr. Rosenberg and (ii) 215,684 shares subject to options held by Mr. Rosenberg which are vested and exercisable within 60 days of February 15, 2023.
(13) Consists of 23,605 shares subject to options held by Mr. Webster which are vested and exercisable within 60 days of February 15, 2023.
(14) Consists of (i) 641,232 shares of common stock (ii) 4,998 shares underlying RSUs which are vested within 60 days of February 15, 2023 and (iii) 2,871,690 shares subject to options which are vested and exercisable within 60 days of February 15, 2023.

Securities Authorized for Issuance under Equity Compensation Plans

The following table provides information as of December 31, 2022 with respect to the shares of our common stock that may be issued under our existing equity compensation plans.

	Equity Compensation Plans as of December 31, 2022		
Plan Category	**Number of securities to be issued upon exercise of outstanding options, warrants and rights**	**Weighted-average exercise price of outstanding options, warrants and rights**	**Number of securities remaining available for future issuance under equity compensation plans (excluding securities in first column)**
Equity compensation plans approved by security holders[1][2][3]	7,695,780	$ 18.03	2,980,918
Equity compensation plans not approved by security holders[4]	1,638,500	$ 12.38	—
Total	9,334,280	$ 17.04	2,980,918

(1) Consists of the 2021 Stock Plan and our 2021 Employee Stock Purchase Plan (the "ESPP").
(2) The 2021 Stock Plan provides that the number of shares reserved and available for issuance under the plan will automatically increase each January 1 by (i) 5% of the number of shares of our common stock outstanding on the immediately preceding December 31, or (ii) such lesser number of shares as determined by our compensation committee. On January 1, 2023, 2,289,822 additional shares were reserved for issuance under the 2021 Stock Plan pursuant to this provision.
(3) The ESPP provides that the number of shares reserved and available for issuance under the plan will automatically increase each January 1 by the lesser of (i) 833,330 shares of common stock, (ii) 1% of the number of shares of our common stock outstanding on the immediately preceding December 31, or (iii) such lesser number of shares as determined by our board of directors. On January 1, 2023, 457,964 additional shares were reserved for issuance under the ESPP pursuant to this provision.
(4) Consists of shares of common stock issuable upon exercise of outstanding stock options granted pursuant to the Nasdaq inducement grant exception as a component of employment compensation for employees. The inducement grants were made as an inducement material to employees entering into employment with us in accordance with Nasdaq Listing Rule 5635(c)(4).

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

Other than the compensation agreements and other arrangements described under “Executive Compensation” and “Director Compensation” in this Part III of the Annual Report on Form 10-K and the transactions described below, since January 1, 2021, there has not been and there is not currently proposed, any transaction or series of similar transactions to which we were, or will be, a party in which the amount involved exceeded, or will exceed, $120,000 and in which any director, executive officer, holder of five percent or more of any class of our capital stock or any member of the immediate family of, or entities affiliated with, any of the foregoing persons, had, or will have, a direct or indirect material interest.

Participation in our IPO

Certain of our executive officers and existing stockholders purchased shares of our common stock in our initial public offering ("IPO"), in January 2021 at the initial public offering price. The following table sets forth the number of shares of our common stock purchased by our executive officers and existing stockholders at the initial public offering price of $21.00 per share.

Stockholder	Shares of Common Stock	Aggregate Purchase Price
Owen Hughes[1]	2,500	$ 52,500
Jeffrey Trigilio[2]	2,250	$ 47,250
Entities affiliated with F2 Ventures[3]	200,000	$ 4,200,000
UBS Oncology Impact Fund L.P.[4]	300,000	$ 6,300,000

(1) At the time of the IPO, Owen Hughes was our President and Chief Executive Officer.

(2) Jeffrey Trigilio is our Chief Financial Officer.

(3) Entities affiliated with F2 Ventures, including F2 Bio TD, LLC, F2 MC, LLC, F2 TPO Investments LLC, F2 GC, LLC and F2 MG Limited, collectively, beneficially own more than five percent of our outstanding common stock. Dr. Jovan-Embiricos, a former member of our board of directors, serves as Managing Partner of F2 Ventures.

(4) UBS Oncology Impact Fund L.P., or OIF, beneficially owns more than five percent of our outstanding common stock. Dr. Baeuerle, our Chief Scientific Officer serves as Executive Partner at OIF. Dr. Gadicke, a former member of our board of directors, serves as Managing Director of OIF.

Agreements with Our Stockholders

Preferred Stock Financing Agreements

In connection with our preferred stock financings prior to our IPO, we entered into an investors' rights agreement and stockholders agreement, in each case, with the purchasers of our preferred stock and certain holders of our common stock. All of the material provisions of these agreements terminated immediately prior to the completion of our IPO, other than the provisions relating to registration rights, which continued in effect following the completion of our IPO and entitle the holders of such rights to demand that we file a registration statement, subject to certain limitations, and to request that their shares be covered by a registration statement that we are otherwise filing.

Royalty Transfer Agreements

Cullinan Amber Corp. ("Cullinan Amber"), Cullinan Florentine Corp. ("Cullinan Florentine"), and Cullinan MICA Corp. ("Cullinan MICA") are each party to royalty transfer agreements (the "Royalty Transfer Agreements") with MPM Oncology Charitable Foundation, Inc., and UBS Optimus Foundation (together, the "Foundations"). Under each of these respective agreements, each Foundation is entitled to receive a low single digit royalty percentage of all global net sales of any products developed by the applicable subsidiary, subject to limitations after patent expirations and on intellectual property developed after a change of control.

Unless earlier terminated, each Royalty Transfer Agreement shall terminate on a country-by-country basis upon the later of (i) the date that is the 12th anniversary of the first commercial sale of that subsidiary's product in such country and (ii) the expiration of the last to expire issued patent claim of any pre-acquisition intellectual property covering the composition or use of such that subsidiary's product in such country. The Foundations are affiliated with OIF, which beneficially owns more than five percent of our outstanding common stock, and Dr. Gadicke, a former member of our board of directors.

Simultaneously with the execution of each Royalty Transfer Agreement, Cullinan Amber, Cullinan Florentine, and Cullinan MICA each also entered into a letter agreement (the "Royalty Letter") with the Foundations and the Company. Pursuant to the Royalty Letters, the parties agreed that a portion of the cash consideration paid by the Company to the applicable subsidiary for the purchase of securities was to be treated as consideration for the right to receive a low single digit royalty percentage of all global net sales of any company products received by the applicable subsidiary (the "Royalty Stream"). Further, effective immediately subsequent to the purchase by the Company of the Royalty Stream, the Company transferred its rights under the Royalty Stream to the Foundations by directing the applicable subsidiary to execute, deliver, and perform a Royalty Transfer Agreement. In June 2022, in connection with the sale of our equity interest in Cullinan Pearl Corp. ("Cullinan Pearl") to Taiho Pharmaceutical Co., Ltd. ("Taiho"), we amended the Royalty Transfer Agreement and Royalty Letter applicable to Cullinan Pearl to provide that the applicable Royalty Stream would not include the net sales of products owned or controlled by Taiho that are commercialized by or on behalf of Taiho in Japan. The form of royalty transfer agreement is filed as Exhibit 10.21 to our Registration Statement on Form S-1 filed on December 18, 2020.

Employment and Consulting Arrangements

We have entered into employment or consulting agreements with our executive officers. For more information regarding the agreements with our named executive officers, see "Executive Compensation—Employment Agreements."

Consulting Agreement with Corinne Savill, Ph.D.

Effective as of January 12, 2021, we entered into a Services Agreement with Dr. Savill pursuant to which we agreed to pay Dr. Savill a consulting fee of $380,000 per year and Dr. Savill is eligible to receive a 40% annual performance bonus subject to approval of our board of directors. For 2022, Dr. Savill's base consulting fee was increased to $391,400. The services agreement has a term that expires on the last date on which Dr. Savill provides services to the Company.

Indemnification Agreements

We have entered into agreements to indemnify our directors and executive officers. These agreements will, among other things, require us to indemnify these individuals for certain expenses (including attorneys' fees), judgments, fines and settlement amounts reasonably incurred by such person in any action or proceeding, including any action by or in our right, on account of any services undertaken by such person on behalf of our Company or that person's status as a member of our board of directors to the maximum extent allowed under Delaware law.

Related Person Transaction Policy

Our board of directors reviews and approves transactions with directors, officers and holders of five percent or more of our voting securities and their affiliates, each a related party. Our related party transactions policy provides that such transactions must be approved by our audit committee. Pursuant to this policy, the audit committee has the primary responsibility for reviewing and approving or disapproving "related party transactions," which are transactions between us and related persons in which the aggregate amount involved exceeds or may be expected to exceed $120,000 and in which a related person has or will have a direct or indirect material interest. For purposes of this policy, a related person is defined as a director, executive officer, nominee for director, or greater than 5% beneficial owner of our common stock, in each case since the beginning of the most recently completed year, and their immediate family members.

Director Independence

Applicable Nasdaq rules require a majority of a listed company's board of directors to be comprised of independent directors. In addition, the Nasdaq rules require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and corporate governance committees be independent and that audit committee members also satisfy independence criteria set forth in Rule 10A-3 under the Exchange Act and that compensation committee members satisfy independence criteria set forth in Rule 10C-1 under the Exchange Act. Under applicable Nasdaq rules, a director will only qualify as an "independent director" if, in the opinion of the listed company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee, accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries or otherwise be an affiliated person of the listed company or any of its subsidiaries. In addition, in affirmatively determining the independence of any director who will serve on a company's compensation committee, Rule 10C-1 under the Exchange Act requires that a company's board of directors must consider all factors specifically relevant to determining whether a director has a relationship to such company which is material to that director's ability to be independent from management in connection with the duties of a compensation committee member, including: the source of compensation to the director, including any consulting, advisory or other compensatory fee paid by such company to the director, and whether the director is affiliated with the company or any of its subsidiaries or affiliates.

Our board of directors has determined that all current members of the board of directors, except Nadim Ahmed, are independent directors, including for purposes of the rules of Nasdaq and the SEC. In making such independence determination, our board of directors considered the relationships that each non-employee director has with us and all other facts and circumstances that our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director. In considering the independence of the directors listed above, our board of directors considered the association of our directors with the holders of more than 5% of our common stock. There are no family relationships among any of our directors or executive officers. Mr. Ahmed is not an independent director under these rules because he is our President and Chief Executive Officer.

Item 14. Principal Accountant Fees and Services.

We incurred the following fees from KPMG LLP for the audit of the consolidated financial statements and for other services provided during 2022 and 2021.

Fee Category	2022	2021
Audit fees[1]	$ 702,500	$ 470,000
Audit-related fees[2]	—	—
Tax fees[3]	307,420	104,210
All other fees[4]	—	—
Total Fees	$ 1,009,920	$ 574,210

(1) Audit fees consist of fees for the professional services rendered by KPMG for the audit of our annual financial statements, the financial statements included in our Form 10-Qs, the review of our interim financial statements, comfort letters and consents.

(2) Audit-related fees consist of fees for assurance and related services that are reasonably related to the performance of audits or reviews of our financial statements and were not reported above under "Audit fees".

(3) Tax fees consist of fees for tax compliance, tax advice and tax planning.

(4) There were no other fees for 2022 and 2021.

Audit Committee Pre-approval Policy and Procedures

Our audit committee has adopted policies and procedures relating to the approval of all audit and non-audit services that are to be performed by our independent registered public accounting firm. This policy provides that we will not engage our independent registered public accounting firm to render audit or non-audit services unless the service is specifically approved in advance by our audit committee or the engagement is entered into pursuant to the pre-approval procedure described below.

From time to time, our audit committee may pre-approve specified types of services that are expected to be provided to us by our independent registered public accounting firm during the next 12 months. Any such pre-approval details the particular service or type of services to be provided and is also generally subject to a maximum dollar amount.

During 2022 and 2021, no services were provided to us by KPMG LLP other than in accordance with the pre-approval policies and procedures described above.

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.

(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 ONCOLOGY, INC.

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

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

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Cullinan Oncology, Inc. and subsidiaries (the Company) as of December 31, 2022 and 2021, 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, 2022 and 2021, 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.

/s/ KPMG LLP

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

Boston, Massachusetts

March 9, 2023

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

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 156,152	$ 59,774
Short-term investments	311,140	230,692
Prepaid expenses and other current assets	7,180	6,098
Total current assets	474,472	296,564
Property and equipment, net	1,174	77
Operating lease right-of-use assets	4,130	—
Other assets	459	147
Long-term investments	80,882	140,397
Total assets	$ 561,117	$ 437,185
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,660	$ 3,169
Accrued expenses and other current liabilities	14,135	8,577
Income tax payable	4,282	—
Operating lease liabilities, current	1,421	—
Total current liabilities	22,498	11,746
Long-term liabilities:		
Operating lease liabilities, net of current portion	3,590	—
Deferred rent	—	65
Total liabilities	26,088	11,811
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock, $0.0001 par value, 10,000,000 shares authorized as of December 31, 2022 and 2021; no shares issued and outstanding as of December 31, 2022 and 2021, respectively.	—	—
Common stock, $0.0001 par value, 150,000,000 shares authorized as of December 31, 2022 and 2021; 45,796,449 and 44,292,102 shares issued and outstanding as of December 31, 2022 and 2021, respectively.	5	4
Additional paid-in capital	585,320	584,714
Accumulated other comprehensive loss	(2,601)	(838)
Accumulated deficit	(47,695)	(158,909)
Total Cullinan stockholders' equity	535,029	424,971
Noncontrolling interests	—	403
Total stockholders' equity	535,029	425,374
Total liabilities and stockholders' equity	$ 561,117	$ 437,185

See accompanying notes to the consolidated financial statements.

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

	Year Ended December 31,	
	2022	2021
License revenue	$ —	$ 18,943
Operating expenses:		
Research and development	91,948	57,751
General and administrative	40,189	29,146
Total operating expenses	132,137	86,897
Gain on sale of Cullinan Pearl	276,785	—
Income (loss) from operations	144,648	(67,954)
Other income (expense):		
Interest income	6,611	477
Other income (expense), net	57	(8)
Net income (loss) before income taxes	151,316	(67,485)
Income tax expense	42,121	—
Net income (loss)	109,195	(67,485)
Net loss attributable to noncontrolling interests	(2,019)	(1,915)
Net income (loss) attributable to common stockholders of Cullinan	$ 111,214	$ (65,570)
Comprehensive income (loss):		
Net income (loss)	$ 109,195	$ (67,485)
Unrealized loss on investments	(1,763)	(836)
Comprehensive income (loss)	$ 107,432	$ (68,321)
Comprehensive loss attributable to noncontrolling interest	(2,019)	(1,915)
Comprehensive income (loss) attributable to Cullinan	$ 109,451	$ (66,406)
Earnings (net loss) per share:		
Basic	$ 2.46	$ (1.52)
Diluted	$ 2.38	$ (1.52)
Weighted-average shares used in computing earnings (net loss) per share:		
Basic	45,164	43,077
Diluted	46,640	43,077

See accompanying notes to the consolidated financial statements.

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

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Retained Earnings (Accumulated Deficit)	Noncontrolling Interests in Subsidiaries	Total Stockholders' Equity
	Shares	Amount					
Balances at December 31, 2020	29,831,125	$ 3	$ 292,348	$ (2)	$ (93,339)	$ 1,305	$ 200,315
Initial public offering, net of issuance costs of $22,870	13,685,000	1	264,515	—	—	—	264,516
Issuance of common stock under employee stock purchase plan	12,977	—	218	—	—	—	218
Contributions from noncontrolling interests	—	—	—	—	—	990	990
Net issuance of common stock under equity-based compensation plans	763,000	—	3,281	—	—	—	3,281
Equity-based compensation	—	—	24,352	—	—	23	24,375
Unrealized loss on investments	—	—	—	(836)	—	—	(836)
Net loss	—	—	—	—	(65,570)	(1,915)	(67,485)
Balances at December 31, 2021	44,292,102	4	584,714	(838)	(158,909)	403	425,374
Contributions from noncontrolling interests	—	—	—	—	—	1,527	1,527
Acquisition of noncontrolling interests	—	—	(32,706)	—	—	(575)	(33,281)
Net issuance of common stock under equity-based compensation plans	1,504,347	1	6,019	—	—	—	6,020
Equity-based compensation	—	—	27,293	—	—	664	27,957
Unrealized loss on investments	—	—	—	(1,763)	—	—	(1,763)
Net income (loss)	—	—	—	—	111,214	(2,019)	109,195
Balances at December 31, 2022	45,796,449	$ 5	$ 585,320	$ (2,601)	$ (47,695)	$ —	$ 535,029

See accompanying notes to the consolidated financial statements.

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

	Year Ended December 31,	
	2022	2021
Operating activities:		
Net income (loss)	$ 109,195	$ (67,485)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Gain on sale of Cullinan Pearl	(276,785)	—
Equity-based compensation expense	27,957	24,375
Amortization or accretion on marketable securities	1,294	3,098
Non-cash contributions from noncontrolling interests	374	67
Realized loss on marketable securities	109	—
Depreciation and amortization	93	53
Gain on disposal of fixed assets	(77)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,130)	(3,269)
Accounts payable	(509)	(4,835)
Accrued expenses and other liabilities	8,533	4,563
Income tax payable	4,282	—
Net cash used in operating activities	(126,664)	(43,433)
Investing activities:		
Purchase of marketable securities	(377,916)	(525,813)
Sales and maturities of marketable securities	352,933	192,038
Sale of Cullinan Pearl, net of cash transferred with sale of $2,898	275,000	—
Purchase of property and equipment	(1,133)	—
Proceeds from sale of property and equipment	91	—
Net cash provided by (used in) investing activities	248,975	(333,775)
Financing activities:		
Acquisition of noncontrolling interests	(33,281)	—
Net issuance of common stock under equity-based compensation plans	6,020	3,281
Issuance of convertible notes	2,375	—
Repayment of convertible note	(2,200)	—
Contributions from noncontrolling interests	1,153	923
Proceeds from initial public offering	—	267,268
Payment of deferred offering costs	—	(2,688)
Net cash provided by (used in) financing activities	(25,933)	268,784
Net increase (decrease) in cash and cash equivalents	96,378	(108,424)
Cash and cash equivalents at beginning of period	59,774	168,198
Cash and cash equivalents at end of period	$ 156,152	$ 59,774
SUPPLEMENTAL NONCASH DISCLOSURE		
Non-cash investing and financing activities and supplemental cash flow information		
Purchases of property and equipment included in accounts payable and accrued expenses and other liabilities	$ 71	$ —
Cash paid for income taxes	$ 37,801	$ —
Cash paid for interest	$ 32	$ —
Deferred offering costs paid in the prior year	$ —	$ 65

See accompanying notes to consolidated financial statements.

(1) Nature of Business and Basis of Presentation

Organization

Cullinan Oncology, Inc., together with its consolidated subsidiaries ("Cullinan" or "the Company"), is a clinical-stage biopharmaceutical company focused on modality-agnostic targeted oncology. Cullinan's predecessor company, Cullinan Pharmaceuticals, LLC was formed in September 2016 and was subsequently renamed Cullinan Oncology, LLC ("LLC") in November 2017. The LLC's wholly-owned subsidiary, Cullinan Management, Inc. ("Management"), was formed in September 2016 and became the surviving entity in a reverse merger with the LLC in January 2021. In February 2021, Management changed its name to Cullinan Oncology, Inc.

The Company completed the sale of its entire equity interest in its partially-owned subsidiary, Cullinan Pearl Corp. ("Cullinan Pearl"), to Taiho Pharmaceutical Co., Ltd ("Taiho") in June 2022. Refer to Note 3 for additional details relating to the transaction. The sale of the Company's equity interest in Cullinan Pearl did not meet the criteria to be reported as a discontinued operation under the accounting principles generally accepted in the United States ("U.S. GAAP"). Therefore, prior period consolidated financial statements and disclosures have not been retroactively restated to reflect the impact of the sale of the Company's equity interest in Cullinan Pearl.

Reorganization, Reverse Stock Split and Initial Public Offering

In January 2021, the Company completed its initial public offering ("IPO") in which it issued and sold 13,685,000 shares of its common stock, including 1,785,000 shares sold pursuant to the full exercise of the underwriters' option to purchase additional shares, at a price to the public of $21.00 per share. The shares began trading on the Nasdaq Global Select Market on January 8, 2021 under the symbol "CGEM". The net proceeds received by the Company from the offering were $264.5 million, after deducting underwriting discounts, commissions and other offering expenses.

Immediately prior to the effectiveness of the Company's registration statement, the Company completed its reorganization, whereby the LLC merged with and into Management and Management was the surviving entity (the "Reorganization"). Management was the registrant in the IPO.

Liquidity

The Company has incurred operating losses, with the exception of the one-time gain on the sale of Cullinan Pearl in 2022, and negative cash flows from operations since its inception and expects to continue to generate operating losses for the foreseeable future. The Company's ultimate success depends on the outcome of its research and development activities as well as the ability to commercialize the Company's product candidates. The Company 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 products and development, 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 the Company's expectations for a number of reasons, including reasons beyond the Company's control.

In June 2022, the Company completed the sale of the Company's equity interest in its partially-owned subsidiary, Cullinan Pearl, to Taiho for an upfront payment of $275.0 million. Refer to Note 3 for additional details relating to the transaction.

Since inception, the Company 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 $467.3 million and long-term investments and interest receivable of $82.8 million as of December 31, 2022, 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.

(2) Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements of the Company have been prepared in conformity with U.S. GAAP and in accordance with applicable rules and regulations of the Securities and Exchange Commission ("SEC") for financial reporting and include accounts of the Company and its consolidated subsidiaries. Intercompany balances and transactions have been eliminated in consolidation.

Principles of Consolidation

The Company consolidates entities in which it has a controlling financial interest. The Company evaluates each of its subsidiaries to determine whether the entity represents a variable interest entity ("VIE") for which consolidation should be evaluated under the VIE model, or alternatively, if the entity is a voting interest entity, for which consolidation should be evaluated using the voting interest model ("VOE"). The Company concluded that none of its subsidiaries is a VIE and has consolidated each subsidiary under the VOE. Under the VOE, the Company consolidates the entity if it determines 1) that it directly, or indirectly, has greater than 50% of the voting shares or other equity holders do not have substantive voting, participation, or liquidation rights, or 2) when the company has a controlling financial interest through its control of the board of directors, and the significant decisions of the entity are made at the board level.

The Company had investments in the following partially-owned subsidiaries during 2022 and 2021:

Consolidated Entities	Relationship as of December 31, 2022	Date Control First Acquired
Cullinan Pearl Corp.	Divested	November 2018
Cullinan Amber Corp.	Partially-owned Subsidiary	December 2019
Cullinan Florentine Corp.	Partially-owned Subsidiary	December 2019
Cullinan Mica Corp.	Partially-owned Subsidiary	May 2020

Use of Estimates

The preparation of the Company'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, the Company's management evaluates its estimates, which include, but are not limited to, estimates related to prepaid and accrued research and development expenses 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.

Segments

The Company has determined that its Chief Executive Officer is the Chief Operating Decision Maker ("CODM"). The Company operates and manages the business as one reporting and one operating segment, which is the business of developing early-stage cancer therapeutics. The Company's CODM reviews financial information on an aggregate basis for purposes of allocating resources and evaluating financial performance. All of the Company's assets are located in the U.S.

Concentration of Risk

The Company had no significant concentration of credit risk as of December 31, 2022. Cash and cash equivalents are primarily maintained with two financial institutions in the U.S. as of December 31, 2022. Deposits at banks may exceed the insurance provided on such deposits. These deposits may be redeemed upon demand, and therefore, bear minimal risk. 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.

The Company 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 obtain future financing; regulatory approval and market acceptance of, and reimbursement for, product candidates; performance of third-party clinical research organizations and manufacturers upon which the Company relies; protection of the Company's intellectual property; litigation or claims against the Company based on intellectual property, patent, product, regulatory or other factors; and the Company's ability to attract and retain employees necessary to support its growth.

The Company is dependent on third-party manufacturers to supply products for research and development activities in its programs. In particular, the Company relies and expects to continue to rely on a small number of manufacturers to supply it with its requirements for drug substance and drug products related to these programs. These programs could be adversely affected by a significant interruption in the 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, 2022 and 2021, cash equivalents consist of government-backed money market funds.

Investments

The Company 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 is included in interest income. Interest and 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 the Company's marketable securities. The Company periodically reviews its marketable securities for impairment and adjusts these investments to their fair value when a decline in market value is deemed to be other than temporary. Declines in fair value judged to be other-than-temporary on marketable securities, if any, are included in other income (expense), net.

Fair Value of Financial Instruments

The Company 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 2022 or 2021.

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

As of December 31, 2022 and 2021, 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.

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

The Company 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.

The Company 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, the Company 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 the Company 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.

Deferred Offering Costs

The Company capitalizes costs that are directly associated with in-process equity financings until such financings are consummated at which time such costs are recorded against the gross proceeds of the offering. Should the in-process equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the consolidated statements of operations and comprehensive income (loss). The Company incurred $2.7 million of deferred offering costs in 2020 and recorded such amounts against the gross proceeds of the Company's IPO within the statements of stockholders' equity for 2021.

Noncontrolling Interests

Noncontrolling interests represent third-party interests in the Company's partially-owned subsidiaries. The Company determines the amount of the noncontrolling interests in the net assets of the Company's partially-owned 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 the third parties would hypothetically receive at each balance sheet date under the liquidation provisions of the partially-owned subsidiaries, assuming the net assets of the partially-owned subsidiaries were liquidated at their recorded amounts determined in accordance with U.S. GAAP and distributed to the owners of the partially-owned subsidiaries. Net income (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 partially-owned subsidiaries and the 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 the Company 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 the Company 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. The Company 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. The Company 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. The Company also utilizes judgement 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, the Company 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. At the end of the reporting period, the Company compares payments made to third-party service providers to the estimated progress toward completion of the research or development objectives. Such estimates are subject to change as additional information becomes available. Depending on the timing of payments to the service providers and the progress that the Company estimates has been made as a result of the service provided, the Company may record net prepaid or accrued expense relating to these costs.

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

The Company has entered into various research and development related contracts with parties both inside and outside of the U.S. The payments related to these agreements are recorded as research and development expenses as incurred. The Company records accrued liabilities for estimated ongoing research and development costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies or clinical trials, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates.

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 made to employees and non-employees 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.

The Company grants service-based RSUs, market-based RSUs and stock options to employees and non-employees. 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. The Company estimated the fair value of the stock options using the Black-Scholes option pricing model, which requires the input of objective and subjective assumptions. Certain assumptions used, including the fair value of the Company's common stock prior to the IPO and 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.

The Company 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 are classified or in which the award recipient's service payments are classified.

Income Taxes

The Company 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 reflect in the period in which the change in judgment occurs.

Comprehensive Income (Loss)

Comprehensive income (loss) is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from nonowner sources. The Company's only element of other comprehensive loss is unrealized gains and losses on investments.

Earnings (Net Loss) per Share

Basic earnings (net loss) per share is determined by dividing earnings (net loss) attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period. Diluted earnings (net loss) per share is determined by dividing earnings (net loss) attributable to common stockholders by the weighted-average number of common shares outstanding during the period, adjusted for the dilutive effect of shares of common stock equivalents as determined using the treasury stock method.

Emerging Growth Company Status

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

The JOBS Act does not preclude an emerging growth company from adopting a new or revised accounting standard earlier than the time that such standard applies to private companies. The Company expects to use the extended transition period for any other new or revised accounting standards during the period in which it remains an emerging growth company.

Recently Adopted Accounting Pronouncements

On January 1, 2022, the Company adopted a new standard on leases (as amended, "ASC 842"), which requires lessees to recognize a lease liability and a ROU asset on the balance sheet for all leases, except certain short-term leases. In connection with its implementation of ASC 842, the Company adopted a package of three practical expedients, allowing it to carry forward its previous lease classification and embedded lease evaluations and not to reassess initial direct costs as of the date of adoption. The Company also adopted a practical expedient that allows it to combine lease and non-lease components for its real estate leases.

The Company's existing lease obligations relating to a single corporate location is subject to the new standard and resulted in operating lease liabilities and ROU assets being recorded on the Company's consolidated balance sheets on the implementation date. The existing lease obligation is classified as an operating lease.

The below table details the balance sheet adjustments recorded on January 1, 2022 in connection with the Company's adoption of ASC 842 (in thousands):

	December 31, 2021		January 1, 2022
	As Reported under ASC 840	ASC 842 Adjustments	As Reported Under ASC 842
Assets			
Operating lease right-of-use asset	$ —	$ 1,311	$ 1,311
Liabilities			
Current portion of operating lease liabilities	$ —	$ 505	$ 505
Deferred rent	$ 65	$ (65)	$ —
Noncurrent portion of operating lease liabilities	$ —	$ 871	$ 871

In December 2019, the Financial Accounting Standards Board issued ASU No. 2019-12, which is intended to simplify the accounting for income taxes. The Company adopted this standard on January 1, 2022. The adoption of this standard did not have a material impact on the Company's consolidated financial position and consolidated results of operations.

(3) Sale of Cullinan Pearl and Co-Development Agreement with Taiho

In June 2022, the Company sold its equity interest in its partially-owned subsidiary, Cullinan Pearl, which had worldwide rights to zipalertinib (CLN-081/TAS6417), excluding Japan and mainland China, Hong Kong, Macau and Taiwan ("Greater China"), to Taiho for an upfront payment of $275.0 million, with an increase to the purchase price in the amount of $2.9 million for cash held by Cullinan Pearl that was transferred with the sale. Pursuant to the share purchase agreement with Taiho, the Company is also eligible to receive up to an additional $130.0 million tied to epidermal growth factor receptor exon 20 non-small-cell lung cancer regulatory milestones.

The Company concluded the transaction was a sale of non-financial assets, which comprised mainly of intellectual property rights and related intangible assets, and that it transferred control of the non-financial assets at the closing of the sale. The Company recognized a gain on sale of Cullinan Pearl of $276.8 million within income from operations in its consolidated statements of operations and other comprehensive income (loss) for 2022. The table below sets forth the book value of the Cullinan Pearl assets and liabilities sold along with the calculation of the gain on sale based on the cash consideration received.

	(in thousands)
Book value of assets sold	
Cash	$ 2,898
Prepaid expenses and other current assets	619
Amounts attributable to assets sold	3,517
Book value of liabilities sold	
Accrued expenses and other current liabilities	2,404
Amounts attributable to liabilities sold	2,404
Total identifiable net assets sold	1,113
Upfront consideration, inclusive of cash transferred of $2,898	277,898
Gain on sale of Cullinan Pearl	$ 276,785

During 2022, Cullinan Pearl issued $2.2 million of convertible notes to an affiliate of Taiho. The Company repaid these convertible notes along with the accrued interests at the closing of the Cullinan Pearl sale.

Co-Development Agreement with Taiho

In June 2022, concurrently with the closing of the sale of the Company's equity interest in Cullinan Pearl, the Company entered into a co-development agreement with an affiliate of Taiho, pursuant to which the Company will collaborate to develop zipalertinib and will retain the option to co-commercialize zipalertinib in the U.S. Development costs for zipalertinib incurred after the sale of the Company's equity interest in Cullinan Pearl shall be shared equally between Taiho and the Company with each party receiving 50% of any future pre-tax profits from potential U.S. sales of zipalertinib.

The Company concluded that the co-development agreement with Taiho is a collaborative arrangement because the Company is an active participant in the development of zipalertinib. Payments made to or received from Taiho for zipalertinib development activities after the sale are recorded within research and development expenses. For 2022, costs reimbursable by Taiho and reflected as a reduction to research and development expenses were $3.5 million, which had not been reimbursed by Taiho as of December 31, 2022. The Company also recorded research and development expense of $2.5 million related to its share of costs incurred by Taiho, which the Company had not yet reimbursed as of December 31, 2022. The net amount of $1.0 million due from Taiho was recorded within prepaid expenses and other current assets as of December 31, 2022.

(4) Financial Instruments

Investments

The Company recognized its short-term and long-term investments by security type at December 31, 2022 as follows:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
		(in thousands)		
Short-term investments				
Corporate notes	$ 244,498	$ 11	$ (1,743)	$ 242,766
Asset-backed securities	16,625	—	(15)	16,610
Commercial paper	18,035	3	(13)	18,025
U.S. government notes	34,029	—	(290)	33,739
Total short-term investments	313,187	14	(2,061)	311,140
Long-term investments				
Corporate notes	81,436	18	(572)	80,882
Total long-term investments	81,436	18	(572)	80,882
Total investments	$ 394,623	$ 32	$ (2,633)	$ 392,022

The Company recognized its short-term and long-term investments by security type at December 31, 2021 as follows:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
		(in thousands)		
Short-term investments				
Corporate notes	$ 98,642	$ —	$ (95)	$ 98,547
Commercial paper	114,174	—	(27)	114,147
U.S. government notes	18,033	—	(35)	17,998
Total short-term investments	230,849	—	(157)	230,692
Long-term investments				
Corporate notes	117,868	—	(596)	117,272
Asset-backed securities	3,044	—	(8)	3,036
U.S. government notes	20,166	—	(77)	20,089
Total long-term investments	141,078	—	(681)	140,397
Total investments	$ 371,927	$ —	$ (838)	$ 371,089

Fair Value of Financial Instruments

The following table sets forth the fair value of the Company's financial assets that were measured at fair value on a recurring basis as of December 31, 2022:

	Level 1	Level 2	Level 3	Total
		(in thousands)		
Short-term investments				
Corporate notes	$ —	$ 242,766	$ —	$ 242,766
Asset-backed securities	—	16,610	—	16,610
Commercial paper	—	18,025		18,025
U.S. government notes	—	33,739		33,739
Total short-term investments	—	311,140	—	311,140
Long-term investments				
Corporate notes	—	80,882	—	80,882
Total long-term investments	—	80,882	—	80,882
Total investments	$ —	$ 392,022	$ —	$ 392,022

The following table sets forth the fair value of the Company's financial assets that were measured at fair value on a recurring basis as of December 31, 2021:

	Level 1	Level 2	Level 3	Total
		(in thousands)		
Short-term investments				
Corporate notes	$ —	$ 98,547	$ —	$ 98,547
Commercial paper	—	114,147	—	114,147
U.S. government notes	—	17,998	—	17,998
Total short-term investments	—	230,692	—	230,692
Long-term investments				
Corporate notes	—	117,272	—	117,272
Asset-backed securities	—	3,036	—	3,036
U.S. government notes	—	20,089	—	20,089
Total long-term investments	—	140,397	—	140,397
Total investments	$ —	$ 371,089	$ —	$ 371,089

(5) Property and Equipment, net

Property and equipment, net consisted of the following as of December 31, 2022 and 2021:

	December 31,	
	2022	2021
	(in thousands)	
Computers	$ —	$ 70
Office furniture and equipment	681	134
Leasehold improvements	628	105
Total property and equipment, gross	1,309	309
Less: accumulated depreciation	(135)	(232)
Total property and equipment, net	$ 1,174	$ 77

Depreciation expense was $0.1 million and less than $0.1 million for 2022 and 2021, respectively.

(6) Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following as of December 31, 2022 and 2021:

	December 31,	
	2022	2021
	(in thousands)	
Accrued research and development costs	$ 7,486	$ 5,028
Accrued bonus	4,516	2,576
Other current liabilities	1,955	973
Convertible note and accrued interest	178	—
	$ 14,135	$ 8,577

(7) License and Collaboration Agreements

Adimab

The Company has a collaboration agreement with Adimab, LLC ("Adimab") (the "Adimab Collaboration Agreement"). Pursuant to the Adimab Collaboration Agreement, the Company selected a number of biological targets against which Adimab used its proprietary platform technology to discover and/or optimize antibodies based upon mutually agreed-upon research plans. Under the Adimab Collaboration Agreement, the Company has the ability to select a specified number of additional biological targets against which Adimab will provide additional antibody discovery and optimization services.

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 the Company 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, the Company paid a one-time, non-creditable, non-refundable technology access fee. The Company is also required to pay an annual access fee and research funding fees in connection with Adimab's full-time employees' compensation for performance of Adimab's obligations under the Adimab Collaboration Agreement. The Company is also obligated to make certain research delivery, clinical and sales milestone payments to Adimab on a program-by-program basis, subject to certain reductions and discounts.

The Company 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.

The Company 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 2022 and 2021, the Company recorded $0.5 million and less than $0.1 million, respectively, relating to the Adimab Collaboration Agreement within research and development expenses.

Cullinan Amber—Massachusetts Institute of Technology

Cullinan Amber Corp. ("Cullinan Amber") has an exclusive patent license agreement with Massachusetts Institute of Technology ("MIT") to develop a cancer immunotherapy product worldwide (the "MIT License Agreement"). Cullinan Amber is also responsible for paying non-refundable, creditable annual license maintenance fees in an increasing amount over a certain number of years and a fixed amount subsequent to this period of time. In addition, MIT granted to Cullinan Amber an exclusive option to amend the initially determined field to include expansion fields, and such amendment would trigger the payment to MIT of an amendment fee.

Additionally, Cullinan Amber is obligated to pay certain non-refundable, non-creditable milestone payments up to $7.0 million and up to $5.5 million to MIT upon the occurrence of certain clinical and regulatory events associated with its first and second indications, respectively, by product, and up to an additional $12.5 million upon the occurrence of cumulative net sales targets. Each milestone payment is paid one time only up to a certain payment amount. No milestones have been achieved to date under the MIT License Agreement.

Under certain conditions upon a change in control of Cullinan Amber, Cullinan Amber is required to pay a specified change in control fee and Cullinan Amber's clinical and regulatory milestone payments shall be increased by 100%.

Furthermore, Cullinan Amber is required to pay running low single-digit royalty percentage on net sales of all licensed products for each reporting period, subject to certain offsets or reductions. The royalties due to MIT for net sales of the licensed product shall not be reduced by more than a mid double-digit percentage. Cullinan Amber is also required to share any income from sublicensing the licensed products, with the percentage to be determined by the clinical phase of the licensed product, no greater than low to mid double-digit percentages. Such royalty obligations will expire on a country-by-country and product-by-product basis upon the expiration or abandonment of all issued patents and filed patent applications within the patent rights.

During 2022 and 2021, the Company recorded $0.4 million and $0.1 million, respectively, relating to the MIT License Agreement within research and development expenses.

Cullinan Florentine—Tübingen License Agreement

Cullinan Florentine Corp. ("Cullinan Florentine") has an exclusive license agreement (the Tübingen License Agreement) 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 Tübingen License Agreement, DKFZ and University of Tübingen, collectively referred to as the Licensor, granted to Florentine 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.

Florentine 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 Florentine 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, 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 or clinical trial agreement, or CTA, by providing prior written notice. Licensor may terminate the agreement by providing prior written notice, if Cullinan Florentine or any of its affiliates challenges the validity of certain patent rights. Unless earlier terminated, the Tübingen License Agreement continues perpetually. No milestones have been achieved to date under the Tübingen License Agreement. The Company did not incur license fee expense relating to this agreement during 2022 and 2021.

Cullinan MICA—Steinle Agreement

Cullinan MICA has an agreement with Dr. Alexander Steinle (the "Steinle Agreement"), who provided Cullinan MICA with services for the discovery, design and development of monoclonal antibodies that prevent the proteolytic cleavage of MICA from the surface of a cancer cell and augments killing of these cancer cells by immune cells expressing NKG2D receptors (“MICA antibodies”).

Under this agreement, Cullinan MICA shall pay certain non-refundable, non-creditable milestone payments to Dr. Steinle upon the occurrence of certain clinical and regulatory events related to a MICA antibody. Each milestone payment is paid one time only up to a certain payment amount. Cullinan MICA is also required to pay Dr. Steinle a low single digit royalty percentage on net sales of each MICA antibody on a country-by-country and product-by-product basis during the royalty term, subject to certain offsets or reductions. During 2022, the Company recorded $0.1 million related to milestone payments under the Steinle Agreement within research and development expenses.

Cullinan Pearl—Taiho & Zai Lab License Agreements

In 2020, Cullinan Pearl entered into a license agreement (the “Zai License Agreement”) with Zai Lab Shanghai Company, Ltd. (“Zai Lab”) to grant Zai Lab an exclusive royalty-bearing license to research, develop, commercialize and manufacture CLN-081 and products which contain CLN-081 in Greater China. As partial consideration of the license and rights granted to Zai Lab, Zai Lab paid Cullinan Pearl a one-time, irrevocable, nonrefundable license fee of $20.0 million.

The upfront payment received by Cullinan Pearl was subject to foreign tax withholdings. When the licensed intellectual property and technology know-how was transferred to Zai Lab in 2021, the Company recognized revenue of $18.9 million, which represented the upfront fee less the foreign tax withholdings that it did not expect to recover.

Under a revenue sharing agreement with Taiho, the Company also recorded $3.0 million within research and development expenses in 2021 upon receipt of the upfront payment for licensing the Greater China rights for zipalertinib to Zai Lab.

The Company completed the sale of its entire equity interest in Cullinan Pearl to Taiho in June 2022. Refer to Note 3 for additional details relating to the transaction.

(8) Common Stock and Noncontrolling Interests in Subsidiaries

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, 2022.

Noncontrolling Interests in Subsidiaries

Certain subsidiaries issue common stock in connection with licensing agreements and to employees, directors and consultants pursuant to subsidiary equity incentive plans. The holders of subsidiary common stock are entitled to one vote per share. The holders of subsidiary common stock are entitled to receive dividends when and if declared by the subsidiaries’ board of directors and distributions in either case only after the payment of all preferential amounts required to be paid to the holders of shares of preferred stock of the respective subsidiary.

Cullinan Amber

In June 2021, the Company purchased 3.0 million shares of Series A preferred stock from Cullinan Amber, and MIT received 0.2 million shares of common stock from Cullinan Amber pursuant to the MIT License Agreement.

In June 2022, the Company purchased 6.0 million shares of Series A preferred stock from Cullinan Amber, and MIT received 0.3 million shares of common stock from Cullinan Amber pursuant to the MIT License Agreement.

In November 2022, the Company purchased 10.0 million shares of Series A preferred stock from Cullinan Amber, MIT received 0.5 million shares of common stock from Cullinan Amber pursuant to the MIT License Agreement, and a scientific advisor received 0.2 million shares of common stock from Cullinan Amber pursuant to an equity-based compensation agreement.

As of December 31, 2022, the Company held common shares and Series A preferred stock that represented 94% of Cullinan Amber's outstanding equity. As of December 31, 2022, noncontrolling interests collectively held common shares that represented 6% of Cullinan Amber's outstanding equity.

In 2022 and 2021, $0.4 million and less than $0.1 million of losses, respectively, were attributed to the noncontrolling interests of Cullinan Amber.

Cullinan Florentine

In July 2021, the Company purchased 7.5 million shares of Series B preferred stock from Cullinan Florentine Corp.("Cullinan Florentine").

In July 2022, the Company purchased 3.75 million shares of Series B preferred stock from Cullinan Florentine.

As of December 31, 2022, the Company held common shares, Series A preferred stock and Series B preferred stock that represented 96% of Cullinan Florentine's outstanding equity. As of December 31, 2022, noncontrolling interests collectively held common shares that represented 4% of Cullinan Florentine's outstanding equity.

In each of 2022 and 2021, no losses were attributed to the noncontrolling interests of Cullinan Florentine.

Cullinan MICA

In June 2021, the Company purchased 5.4 million shares of Series A senior preferred stock from Cullinan MICA Corp. ("Cullinan MICA"), and certain other existing investors purchased 0.7 million shares of Series A senior preferred stock from Cullinan MICA for $0.9 million.

In March 2022, the Company purchased 6.7 million shares of Series A senior preferred stock from Cullinan MICA, and certain other existing investors purchased 0.9 million shares of Series A senior preferred stock from Cullinan MICA for $1.2 million.

In October 2022, the Company purchased 1.5 million shares of Cullinan MICA's Series A senior preferred stock, 2.0 million shares of Cullinan MICA's Series A junior preferred stock, and 11.5 million shares of Cullinan MICA's Series A-2 junior preferred stock from two of Cullinan MICA’s other stockholders for $30.7 million.

In November 2022, the Company purchased 0.4 million shares of Cullinan MICA's common stock and 0.9 million of options for Cullinan MICA's common stock from five of Cullinan MICA’s other stockholders for $2.6 million. The Company also exercised its options to purchase 0.9 million shares of common stock from Cullinan MICA.

As of December 31, 2022, the Company held 95% of the fully-diluted shares outstanding of Cullinan MICA, including 96% of its Series A preferred stock. As of December 31, 2022, noncontrolling interests collectively owned 5% of the fully-diluted shares outstanding of Cullinan MICA, including 4% of its Series A preferred stock.

In 2022 and 2021, $1.2 million and $1.1 million of losses, respectively, were attributed to the noncontrolling interests of Cullinan MICA.

Prior to being acquired by the Company, the Cullinan MICA board of directors authorized the grant of stock options to employees, directors of, consultants and other key persons to the entity. In October 2022, the Cullinan MICA board of directors authorized the acceleration of vesting for approximately 0.3 million stock options. The vesting acceleration was determined to be a cancellation of the prior award with a concurrent grant of a replacement award and was accounted for as a modification resulting in $0.6 million in incremental equity-based compensation expense. As of December 31, 2022, Cullinan MICA had approximately 0.2 million stock options held by noncontrolling interests that were outstanding and exercisable with a weighted-average exercise price of $0.22 per share.

Cullinan Pearl

In June 2022, the Company sold its equity interest in its partially-owned subsidiary, Cullinan Pearl, to Taiho. Refer to Note 3 for additional details relating to the transaction.

Prior to the sale, the Company accounted for the noncontrolling interest using the HLBV method. In 2022 and 2021, $0.3 and $0.7 million of losses, respectively, were attributed to the noncontrolling interests of Cullinan Pearl.

(9) 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 2022 and 2021:

	Year ended December 31,	
	2022	2021
	(in thousands)	
Research and development	$ 11,018	$ 8,914
General and administrative	16,939	15,461
Total equity-based compensation	$ 27,957	$ 24,375

2021 Stock Option and Incentive Plan

Cullinan grants equity awards in the form of stock options, restricted stock awards ("RSAs") and RSUs to its employees, directors, consultants and other key persons through the 2021 Stock Option and Incentive Plan (the "2021 Stock Plan"). The Company also grants 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, 2022, there were approximately 2.2 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 the Company's common stock on the immediately preceding December 31 or such lesser number of shares as determined by the Company's board of directors or compensation committee. On January 1, 2023, the total number of shares available for issuance under the 2021 Stock Plan increased by approximately 2.3 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, the Company 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 2022 and 2021 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 the Company'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 is based on historical volatilities of similar entities within the Company'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.
- The Company considered numerous objective and subjective factors in estimating the fair value of its common stock prior to the IPO, including the concluded equity value based on IPO and liquidation scenarios and their related timing and probabilities of occurrence.

For 2022 and 2021, the weighted-average grant date fair value of the options granted were $9.02 and $15.73 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 2022 and 2021:

	Year Ended December 31, 2022	Year Ended December 31, 2021
Risk-free interest rate	2.65%	1.02%
Expected term (in years)	6.0	6.0
Expected volatility	79.81%	76.22%
Expected dividend yield	0.00%	0.00%

Determining fair value of market-based RSUs

The Company measures the fair value of market-based RSUs on the date of grant using a Monte Carlo simulation model. The Monte Carlo simulation requires the input of assumptions, including the Company's stock price, the volatility of its stock price, remaining term in years, expected dividend yield and risk-free rate. The Company used its own trading history to calculate the expected volatility of the market-based RSUs granted. The risk-free interest rate is determined by reference to implied yields available from U.S. Treasury securities with a remaining term equal to the expected term assumed at the grant date.

The following table details the assumptions used in the Monte Carlo simulation model used to estimate the fair value of the market-based RSUs granted during 2022:

	Year Ended December 31, 2022
Stock price	$ 12.98
Volatility	82.5%
Remaining term (years)	2.7
Risk-free rate	2.9%
Expected dividend yield	0.0

Stock options

The following table summarizes 2022 and 2021 stock option activity (shares and aggregate intrinsic value in thousands):

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2020	4,603	$ 4.30		
Granted	5,482	$ 23.82		
Exercised	(763)	$ 4.30		
Forfeited	(63)	$ 17.23		
Outstanding as of December 31, 2021	9,259	$ 15.77		
Granted	2,888	$ 12.96		
Exercised	(1,523)	$ 4.31		
Forfeited	(1,290)	$ 13.80		
Outstanding as of December 31, 2022	9,334	$ 17.04	8.31	$ 11,526
Exercisable as of December 31, 2022	3,706	$ 15.31	7.32	$ 10,060

As of December 31, 2022 and 2021, there were $66.0 million and $75.8 million in unrecognized compensation costs that are expected to be recognized over a remaining weighted-average period of 2.9 and 3.2 years, respectively.

The aggregate intrinsic value of options is calculated as the difference between the exercise price of the options and the fair value of the Company's common stock for those options that had exercise prices lower than the fair value of the Company's common stock. The total intrinsic value of options exercised in 2022 and 2021 was $13.1 million and $10.7 million, respectively.

RSUs

In February 2022, the Company granted service-based RSUs to employees and non-employees. In June 2022, the Company entered into an agreement to grant market-based RSUs to its Chief Executive Officer. The following table summarizes the activity related to RSUs during 2022 (shares in thousands):

	Number of Shares	Weighted-Average Grant Date Fair Value
Outstanding unvested as of December 31, 2021	—	$ —
Granted[(1)]	502	$ 13.28
Vested	(46)	$ 13.60
Forfeited	(87)	$ 13.60
Outstanding unvested as of December 31, 2022	369	$ 13.16

(1) The number granted 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, 2022, there was $4.3 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 2022 was $0.6 million.

RSAs

As part of the Reorganization in January 2021, the Company exchanged equity awards issued by the Company and its partially-owned subsidiaries prior to the Reorganization for RSAs of the Company's common stock. The following table summarizes the activity related to RSAs during 2022 and 2021 (shares in thousands) as if the prior equity awards were converted to RSAs at the earliest period presented:

	Number of Shares	Weighted-Average Grant Date Fair Value
Outstanding unvested as of December 31, 2020	364	$ 2.04
Vested	(275)	$ 1.45
Outstanding unvested as of December 31, 2021	89	$ 3.87
Vested	(46)	$ 3.87
Forfeited	(28)	$ 3.87
Outstanding unvested as of December 31, 2022	15	$ 3.87

As of December 31, 2022 and 2021, there was $0.1 million and $0.3 million in unrecognized compensation cost related to RSAs expected to be recognized over a remaining weighted-average period of 1.0 and 1.5 years, respectively. The total fair value of RSAs that vested during 2022 and 2021 was $0.6 million and $8.5 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, 2022, there were approximately 0.8 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 the Company'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, 2023, the total number of shares available for issuance under the ESPP increased by approximately 0.5 million shares under this provision.

During each of 2022 and 2021, the Company issued less than 0.1 million shares of its common stock pursuant the ESPP.

(10) Related Party Transactions

Cullinan Amber, Cullinan Florentine and Cullinan MICA are each party to royalty transfer agreements with MPM Oncology Charitable Foundation, Inc. and UBS Optimus Foundation (together, the "Foundations"). Under each of these respective agreements, each Foundation is entitled to receive a low single digit royalty percentage of all global net sales of any products developed by the applicable subsidiary, subject to limitations after patent expirations and on intellectual property developed after a change of control. The Company has deemed these royalty transfer agreements to be freestanding financial instruments that should be accounted for at fair value. The Company has concluded that these instruments had no value at the inception of the agreements.

Given the early-stage nature of the underlying technologies and inherent technical, regulatory and competitive risks associated with achieving approval and commercialization, the Company ascribed no value to the royalty transfer agreements as of December 31, 2022 and December 31, 2021. The Company currently does not have 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, 2022. The Company will monitor these instruments for changes in fair value at each reporting date.

(11) Income Taxes

During 2022, the Company recorded a current income tax expense of $42.1 million. The income tax expense recorded for 2022 was driven by the tax from the gain on sale of Cullinan Pearl, partially offset by the release of the valuation allowance for the utilization of current year and certain historical tax attributes against the gain from the sale. Refer to Note 3 for additional details on the sale of Cullinan Pearl. During 2021, the Company did not record a current or deferred income tax expense or benefit due to current and historical losses incurred by the Company. The Company's net income (loss) before income taxes consists solely of domestic income and losses.

A reconciliation of the Company's statutory income tax rate to the Company's effective income tax rate in 2022 and 2021 is as follows:

	Year ended December 31,	
	2022	2021
Federal statutory rate	21.00%	21.00%
State taxes, net of federal benefit	4.71%	9.96%
Valuation allowance	1.13%	(32.12)%
Other	0.97%	1.16%
	27.81%	—%

As of December 31, 2022 and 2021, the net deferred income tax asset balance related to the following:

	December 31,	
	2022	2021
	(in thousands)	
Deferred tax assets:		
Net operating loss	$ 10,531	$ 31,414
Capitalized research and development	18,724	—
Capitalized organizational and start-up expenses	127	140
Licenses	461	1,875
Accrued expenses	1,977	968
Research and development credit	1,110	1,563
Equity-based compensation	12,087	8,584
Basis difference on gain on sale of Cullinan Pearl	1,805	—
Lease liability	1,345	—
Gross deferred tax assets	48,167	44,544
Valuation allowance	(46,766)	(44,552)
Net deferred tax asset	1,401	(8)
Deferred tax liability		
ROU asset	1,108	—
Depreciation and amortization	293	(8)
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, 2022 and 2021, the Company had federal NOL carryforwards, of $42.6 million and $117.4 million, respectively, which may be available to offset future income tax liabilities. As of December 31, 2022, $36.8 million of the Company's federal NOL carryforwards can be carried forward indefinitely, and the remaining $5.8 million begins to expire in 2036. As of December 31, 2022 and 2021, the Company had state NOL carryforwards of $27.1 million and $119.0 million, respectively, which may be available to offset future income tax liabilities. As of December 31, 2022, the Company's state NOL carryforwards begin to expire in 2036.

As of December 31, 2022 and 2021, the Company had federal research and development tax credit carryforwards of $0.9 million and $1.3 million, respectively. As of December 31, 2022, the Company's federal research and development tax credit carryforwards begin to expire in 2036. As of each of December 31, 2022 and 2021, the Company had state research and development tax credit carryforwards of $0.3 million which can be carried forward indefinitely.

The Company 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, with the exception of the one-time gain on the sale of Cullinan Pearl in 2022, estimated future taxable income and prudent and feasible tax planning strategies and has concluded that it is more likely than not that the Company will not realize the benefits of its deferred tax assets. As a result, as of December 31, 2022, the Company has maintained a full valuation allowance against its remaining net deferred tax assets. The Company's valuation allowance increased during 2022 and 2021 due primarily to the generation of NOLs as follows:

	Year ended December 31,	
	2022	2021
	(in thousands)	
Valuation allowance at beginning of year	$ 44,552	$ 22,642
Increases recorded to income tax provision	1,712	21,674
Increases recorded to equity	502	236
Valuation allowance at end of year	$ 46,766	$ 44,552

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 the Company 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. The Company 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, 2022 and 2021, the Company 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, 2022 and 2021, no accrued interest or penalties are included in the consolidated balance sheets.

The Company 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. The Company's federal and state income tax returns are generally subject to tax examinations for tax years 2016 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.

(12) 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, the Company 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 the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. 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, the Company 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, 2022 and 2021.

Legal proceedings

The Company 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. The Company expenses as incurred the costs related to such legal proceedings.

(13) Leases

The Company has an operating lease for approximately 8,000 square feet of office space in a multi-tenant building in Cambridge, Massachusetts, which commenced in February 2018 and goes through June 2024 (the "Suite 520 Lease"). In August 2022, the Company entered into an additional operating lease (the "Suite 1350 Lease") for approximately 14,000 square feet of office space in a multi-tenant building in Cambridge, Massachusetts through July 2026. Lease expense consisted of operating lease costs of $1.1 million for 2022. Rent expense under the prior lease accounting standard was $0.6 million for 2021.

The following table summarizes supplemental cash flow information for 2022 (in thousands):

	Year Ended December 31, 2022
Cash paid for amounts included in measurement of lease liabilities:	
Operating cash flows from operating leases[(1)]	$ 260
ROU asset obtained in exchange for an operating lease liability	$ 4,931

(1) Operating cash flows from operating leases includes cash inflow of $0.3 million reimbursed by the lessor for improvements made to the newly leased office space pursuant to the terms of the Suite 1350 lease.

The following table summarizes the weighted-average lease term and discount rate as of December 31, 2022:

	December 31, 2022
Weighted-average remaining lease term (in years)	3.2
Weighted-average discount rate	10.8%

As the Company'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. The Company'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.

The following table summarizes the Company's future minimum lease payments under the new lease accounting standard as of December 31, 2022 (in thousands):

	December 31, 2022
2023	$ 1,881
2024	1,738
2025	1,461
2026	872
Total future minimum lease payments	5,952
Less: imputed interest	(941)
Total lease liabilities at present value	$ 5,011

The following table summarizes the Company's future minimum lease payments under the prior lease accounting standard as of December 31, 2021 (in thousands):

Years Ending December 31,	(in thousands)
2023	$ 608
2024	618
2025	313
	$ 1,539

Sublease Agreement

In September 2022, the Company entered into a sublease agreement through May 2024 for the Suite 520 Lease. For 2022, the Company recorded sublease income of $0.1 million within other income (expense), net. The Company expects to receive sublease payments of approximately $0.6 million in 2023 and $0.3 million in 2024. These expected sublease payments are equal to the fixed payments that the Company is required to make under its lease.

(14) Earnings (Net Loss) per Share

The following table sets forth the calculation of basic and diluted earnings (net loss) per share for 2022 and 2021:

	Year ended December 31,	
	2022	2021
	(in thousands, except per share data)	
Numerator:		
Net income (loss) attributable to common stockholders of Cullinan	$ 111,214	$ (65,570)
Denominator:		
Weighted-average common stock outstanding - basic	45,164	43,077
Dilutive effect of common stock issuable from assumed exercise of equity awards	1,476	—
Weighted-average common stock outstanding - diluted	46,640	43,077
Earnings (net loss) per share:		
Basic	$ 2.46	$ (1.52)
Diluted	$ 2.38	$ (1.52)

The Company used the treasury stock method to determine the number of dilutive shares. The following table sets forth potential common shares that were excluded from the computation of the diluted earnings (net loss) per share for 2022 and 2021 because their effect would have been anti-dilutive:

	Year ended December 31,	
	2022	2021
Stock options	6,842	9,259
RSAs	—	89
RSUs	25	—
ESPP	7	—
Total	6,874	9,348

(15) Subsequent Events

BVF common stock exchange

In January 2023, the Company entered into an exchange agreement with Biotechnology Value Fund, L.P., Biotechnology Value Fund II, L.P., Biotechnology Value Trading Fund OS LP and MSI BVF SPV, LLC (the "Stockholders"), pursuant to which the Stockholders exchanged 6.5 million shares of the Company's common stock for 0.6 million shares of newly designated Series A convertible preferred stock, a "toothless" preferred stock, par value $0.0001 per share. Following the exchange, the Company had 39.3 million shares of common stock outstanding and 0.6 million shares of Series A preferred stock outstanding, which are convertible into 6.5 million shares of common stock.

Each share of the preferred stock will be convertible into 10 shares of Common Stock at the option of the holder at any time, subject to certain limitations, including that the holder will be 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. Shares of preferred stock will 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-licensing of CLN-418

In February 2023, the Company and Harbour BioMed US Inc. ("Harbour") entered into a license and collaboration agreement (the "Harbour License Agreement"), pursuant to which Harbour granted to the Company an exclusive license for the development, manufacturing and commercialization of HBM7008 (CLN-418) in the U.S.

Under the terms of the Harbour License Agreement, the Company paid Harbour an upfront license fee of $25 million at signing. Harbour will be eligible to receive up to $148 million in milestone payments based on the achievement of pre-specified development and regulatory milestones. Harbour is also eligible to receive up to an additional $415 million in sales-based milestones as well as tiered royalties up to the high teens on a licensed product-by-licensed product basis, as a percentage of U.S. commercial sales. In addition, under the Harbour License Agreement, Harbour will grant the Company certain intellectual property rights to enable the Company to perform its obligations and exercise its rights under the Harbour License Agreement.

Unless earlier terminated, the Harbour License Agreement will continue in effect until the expiration of the Company's royalty obligations. The Harbour 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. The Company may terminate the Harbour License Agreement for convenience by providing 90 days' written notice to Harbour. In the Harbour 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.

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 February 25, 2021 (incorporated by reference to Exhibit 3.1 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).
3.2	Second Amended and Restated Bylaws of the Registrant, effective as of February 25, 2021 (incorporated by reference to Exhibit 3.2 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).
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-1 (File No. 333-251512) filed with the SEC on December 28, 2020).
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).
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†	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).

10.9†	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).
10.10†	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).
10.11#	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).
10.12#	Consulting Agreement, dated January 1, 2019, by and between the Registrant and Corinne Savill (incorporated by reference to Exhibit 10.14 of the Registrant's Registration Statement on Form S-1 (File No. 333-251512) filed with the SEC on December 18, 2020).
10.13	Sublease, effective as of December 14, 2017, by and between Teva Pharmaceuticals USA, Inc. and the Registrant (incorporated by reference to Exhibit 10.17 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 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).
10.15	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).
10.16	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).
10.17	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).
10.18	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).
10.19#	Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.23 of the Registrant's Registration Statement on Form S-1 (File No. 333-251512) filed with the SEC on December 18, 2020).
10.20#	Services Agreement, by and between the Registrant and Patrick Baeuerle (incorporated by reference to Exhibit 10.25 of the Registrant's Registration Statement on Form S-1 (File No. 333-251512) filed with the SEC on January 4, 2021).
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*	Employment Agreement, effective January 7, 2021, between the Registrant and Jeffrey Trigilio
10.24*	Form of Stock Purchase and Transfer Agreement for Institutional Transferors
10.25*	Form of Stock Purchase and Transfer Agreement for Individual Transferors

10.26†*	Second Amendment to Exclusive Patent License Agreement, dated December 20, 2022, by and between the Massachusetts Institute of Technology and Cullinan Amber Corp.
10.27*	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
21.1*	List of Subsidiaries of the Registrant.
23.1*	Consent of KPMG LLP, the Company'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.
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
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* 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 Oncology, Inc.

Date: March 9, 2023

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 Jeffrey Trigilio, 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 **Nadim Ahmed**	President, Chief Executive Officer and Director (Principal Executive Officer)	March 9, 2023
/s/ Jeffrey Trigilio **Jeffrey Trigilio**	Chief Financial Officer (Principal Financial and Accounting Officer)	March 9, 2023
/s/ Thomas Ebeling **Thomas Ebeling**	Director	March 9, 2023
/s/ Anne-Marie Martin **Anne-Marie Martin**	Director	March 9, 2023
/s/ Anthony Rosenberg **Anthony Rosenberg**	Director	March 9, 2023
/s/ David P. Ryan, M.D. **David P. Ryan, M.D.**	Director	March 9, 2023
/s/ Stephen Webster **Stephen Webster**	Director	March 9, 2023

EMPLOYMENT AGREEMENT

This Employment Agreement ("Agreement") is made between Cullinan Management, Inc., a Delaware corporation (the "Company"), and Jeff Trigilio (the "Executive") and is effective as of the closing of the Company's first underwritten public offering of its equity securities pursuant to an effective registration statement under the Securities Act of 1933, as amended (the "Effective Date"). Except with respect to the Equity Documents (as defined below) and subject to Section 10 below, this Agreement supersedes in all respects all prior agreements between the Executive and the Company regarding the subject matter herein, including without limitation (i) the Employment Agreement between the Executive and the Company dated August 25, 2020 (the "Prior Agreement"), and (ii) any offer letter, employment agreement or severance agreement.

WHEREAS, the Company desires to continue to employ the Executive and the Executive desires to continue to be employed by the Company on the new terms and conditions contained herein.

NOW, THEREFORE, in consideration of the mutual covenants and agreements herein contained and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties agree as follows:

1. Employment.

(a) Term. The Company shall employ the Executive and the Executive shall be employed by the Company pursuant to this Agreement commencing as of the Effective Date and continuing until such employment is terminated in accordance with the provisions hereof (the "Term"). The Executive's employment with the Company shall continue to be "at will," meaning that the Executive's employment may be terminated by the Company or the Executive at any time and for any reason subject to the terms of this Agreement.

(b) Position and Duties. The Executive shall serve as the Chief Financial Officer, Secretary and Treasurer of the Company and shall have such powers and duties as may from time to time be prescribed by the Chief Executive Officer (the "CEO") or other duly authorized executive. The Executive shall devote the Executive's full working time and efforts to the business and affairs of the Company. Notwithstanding the foregoing, the Executive may serve on other boards of directors, with the approval of the Board of Directors of the Company (the "Board"), or engage in religious, charitable or other community activities as long as such services and activities do not interfere with the Executive's performance of the Executive's duties to the Company.

2. Compensation and Related Matters.

(a) Base Salary. The Executive's initial base salary shall be paid at the rate of $400,000 per year. The Executive's base salary shall be subject to periodic review by the Board or the Compensation Committee of the Board (the "Compensation Committee"). The base salary in effect at any given time is referred to herein as "Base Salary." The Base Salary shall be payable in a manner that is consistent with the Company's usual payroll practices for executive officers.

(b) Incentive Compensation. The Executive shall be eligible to receive cash incentive compensation as determined by the Board or the Compensation Committee

from time to time. Commencing January 1, 2021, the Executive's initial target annual incentive compensation shall be 40% percent of the Executive's Base Salary. The target annual incentive compensation in effect at any given time is referred to herein as "Target Bonus." The actual amount of the Executive's annual incentive compensation, if any, shall be determined in the sole discretion of the Board or the Compensation Committee, subject to the terms of any applicable incentive compensation plan that may be in effect from time to time. Except as otherwise provided herein, as may be provided by the Board or the Compensation Committee or as may otherwise be set forth in the applicable incentive compensation plan, the Executive must be employed by the Company on the date such incentive compensation is paid in order to earn or receive any annual incentive compensation.

(c) Expenses. The Executive shall be entitled to receive prompt reimbursement for all reasonable expenses incurred by the Executive during the Term in performing services hereunder, in accordance with the policies and procedures then in effect and established by the Company for its executive officers.

(d) Location. It is understood and agreed that the Executive will work remotely, *provided* that the Executive shall be required to travel to the Company's main office, currently located in Cambridge, MA, on a regular basis and as necessary and may also be required to travel for business as necessary.

(e) Other Benefits. The Executive shall be eligible to participate in or receive benefits under the Company's employee benefit plans in effect from time to time, subject to the terms of such plans.

(f) Paid Time Off. The Executive shall be entitled to take paid time off in accordance with the Company's applicable paid time off policy for executives, as may be in effect from time to time.

(g) Equity. The equity awards held by the Executive shall continue to be governed by the terms and conditions of the Company's applicable equity incentive plan(s) and the applicable award agreement(s) (collectively, the "Equity Documents"); *provided, however*, and notwithstanding anything to the contrary in the Equity Documents, (i) in the event that the Date of Termination (as defined below) is a result of the Executive's death pursuant to Section 3(a) or disability pursuant to Section 3(b), 25% of the Executive's then-unvested stock options and other stock-based awards held by the Executive, including, without limitation, any awards that are subject to performance-based vesting, except to the extent otherwise provided in the applicable option agreement that governs such performance-based award (the "Equity Awards"), plus an additional 5% for each full year of the Executive's service to the Company, shall immediately accelerate and become fully vested and exercisable or nonforfeitable on the Date of Termination, and (ii) in the event that the Date of Termination is a result of a termination by the Company without Cause under Section 3(d) or a termination by the Executive for Good Reason under Section 3(e), in each case during the Change in Control Period (as such terms are defined below), then any outstanding Equity Awards shall immediately accelerate and become fully vested and exercisable or nonforfeitable on the Date of Termination.

3. Termination. The Executive's employment hereunder may be terminated without any breach of this Agreement under the following circumstances:

(a) Death. The Executive's employment hereunder shall terminate upon death.

(b) Disability. The Company may terminate the Executive's employment if the Executive is disabled and unable to perform or expected to be unable to perform the essential functions of the Executive's then existing position or positions under this Agreement with or without reasonable accommodation for a period of 180 days (which need not be consecutive) in any 12-month period. If any question shall arise as to whether during any period the Executive is disabled so as to be unable to perform the essential functions of the Executive's then existing position or positions with or without reasonable accommodation, the Executive may, and at the request of the Company shall, submit to the Company a certification in reasonable detail by a physician selected by the Company to whom the Executive or the Executive's guardian has no reasonable objection as to whether the Executive is so disabled or how long such disability is expected to continue, and such certification shall for the purposes of this Agreement be conclusive of the issue. The Executive shall cooperate with any reasonable request of the physician in connection with such certification. If such question shall arise and the Executive shall fail to submit such certification, the Company's determination of such issue shall be binding on the Executive. Nothing in this Section 3(b) shall be construed to waive the Executive's rights, if any, under existing law including, without limitation, the Family and Medical Leave Act of 1993, 29 U.S.C. §2601 *et seq*. and the Americans with Disabilities Act, 42 U.S.C. §12101 *et seq*.

(c) Termination by the Company for Cause. The Company may terminate the Executive's employment hereunder for Cause. For purposes of this Agreement, "Cause" shall mean any of the following:

(i) conduct by the Executive constituting a material act of misconduct in connection with the performance of the Executive's duties, including, without limitation, (A) willful failure or refusal to perform material responsibilities that have been requested by the CEO; (B) dishonesty to the CEO with respect to any material matter; or (C) misappropriation of funds or property of the Company or any of its subsidiaries or affiliates other than the occasional, customary and *de minimis* use of Company property for personal purposes;

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

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

(iv) continued non-performance by the Executive of the Executive's duties hereunder (other than by reason of the Executive's physical or mental illness, incapacity or disability) which has continued for more than 30 days following written notice of such non- performance from the CEO;

(v) a breach by the Executive of any of the provisions contained in Section 8 of this Agreement or the Restrictive Covenants Agreement (as defined below);

(vi) a material violation by the Executive of any of the Company's written employment policies; or

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

(d) Termination by the Company without Cause. The Company may terminate the Executive's employment hereunder at any time without Cause. Any termination by the Company of the Executive's employment under this Agreement which does not constitute a termination for Cause under Section 3(c) and does not result from the death or disability of the Executive under Section 3(a) or (b) shall be deemed a termination without Cause.

(e) Termination by the Executive. The Executive may terminate employment hereunder at any time for any reason, including but not limited to, Good Reason. For purposes of this Agreement, "Good Reason" shall mean that the Executive has completed all steps of the Good Reason Process (hereinafter defined) following the occurrence of any of the following events without the Executive's consent (each, a "Good Reason Condition"):

(i) a material diminution in the Executive's responsibilities, authority or duties;

(ii) a material diminution in the Executive's Base Salary except for across-the-board salary reductions based on the Company's financial performance similarly affecting all or substantially all senior management employees of the Company;

(iii) a material change in the geographic location of the principal office of the Company to which the Executive is assigned, such that there is an increase of at least thirty (30) miles of driving distance to such location from the Executive's principal residence as of such change; or

(iv) a material breach of this Agreement by the Company.

The "Good Reason Process" consists of the following steps:

(i) the Executive reasonably determines in good faith that a Good Reason Condition has occurred;

(ii) the Executive notifies the Company in writing of the first occurrence of the Good Reason Condition within 60 days of the first occurrence of such condition;

(iii) the Executive cooperates in good faith with the Company's efforts, for a period of not less than 30 days following such notice (the "Cure Period"), to remedy the Good Reason Condition;

(iv) notwithstanding such efforts, the Good Reason Condition continues to exist at the end of the Cure Period; and

(v) the Executive terminates employment within 60 days after the end of the Cure Period.

If the Company cures the Good Reason Condition during the Cure Period, Good Reason shall be deemed not to have occurred.

4. Matters related to Termination.

(a) Notice of Termination. Except for termination as specified in Section 3(a), any termination of the Executive's employment by the Company or any such termination by the Executive shall be communicated by written Notice of Termination to the other party hereto. For purposes of this Agreement, a "Notice of Termination" shall mean a notice which shall indicate the specific termination provision in this Agreement relied upon.

(b) Date of Termination. "Date of Termination" shall mean: (i) if the Executive's employment is terminated by death, the date of death; (ii) if the Executive's employment is terminated on account of disability under Section 3(b) or by the Company for Cause under Section 3(c), the date on which Notice of Termination is given; (iii) if the Executive's employment is terminated by the Company without Cause under Section 3(d), the date on which a Notice of Termination is given or the date otherwise specified by the Company in the Notice of Termination; (iv) if the Executive's employment is terminated by the Executive under Section 3(e) other than for Good Reason, 30 days after the date on which a Notice of Termination is given, and (v) if the Executive's employment is terminated by the Executive under Section 3(e) for Good Reason, the date on which a Notice of Termination is given after the end of the Cure Period. Notwithstanding the foregoing, in the event that the Executive gives a Notice of Termination to the Company, the Company may unilaterally accelerate the Date of Termination and such acceleration shall not result in a termination by the Company for purposes of this Agreement.

(c) Accrued Obligations. If the Executive's employment with the Company is terminated for any reason, the Company shall pay or provide to the Executive (or to the Executive's authorized representative or estate) (i) any Base Salary earned through the Date of Termination; (ii) unpaid expense reimbursements (subject to, and in accordance with, Section 2(c) of this Agreement); and (iii) any vested benefits the Executive may have under any employee benefit plan of the Company through the Date of Termination, which vested benefits shall be paid and/or provided in accordance with the terms of such employee benefit plans (collectively, the "Accrued Obligations").

(d) Resignation of All Other Positions. To the extent applicable, the Executive shall be deemed to have resigned from all officer and board member positions that the Executive holds with the Company or any of its respective subsidiaries and affiliates upon the termination of the Executive's employment for any reason. The Executive shall execute any documents in reasonable form as may be requested to confirm or effectuate any such resignations.

5. Severance Pay and Benefits Upon Termination by the Company without Cause or by the Executive for Good Reason Outside the Change in Control Period. If the Executive's employment is terminated by the Company without Cause as provided in Section 3(d), or the Executive terminates employment for Good Reason as provided in Section 3(e), in each case outside of the Change in Control Period, then, in addition to the Accrued Obligations, and subject to (i) the Executive signing a separation agreement and release in a form and manner satisfactory to the Company, which shall include, without limitation, a general release of claims against the Company and all related persons and entities, a reaffirmation of all of the Executive's Continuing Obligations (as defined below), and, in the Company's sole discretion, a one-year post-employment noncompetition agreement, and shall provide that if the Executive breaches any of the Continuing Obligations, all payments of the Severance Amount shall immediately

cease (the "Separation Agreement"), and (ii) the Separation Agreement becoming irrevocable, all within 60 days after the Date of Termination (or such shorter period as set forth in the Separation Agreement):

(a) the Company shall pay the Executive an amount equal to the sum of (A) 9 months of the Executive's Base Salary plus (B) a pro-rata portion of the Target Bonus based on the Date of Termination (the "Severance Amount"); and

(b) subject to the Executive's copayment of premium amounts at the applicable active employees' rate and the Executive's proper election to receive benefits under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA"), the Company shall pay to the group health plan provider or the COBRA provider a monthly payment equal to the monthly employer contribution that the Company would have made to provide health insurance to the Executive if the Executive had remained employed by the Company until the earliest of (A) the 9 month anniversary of the Date of Termination; (B) the date that the Executive becomes eligible for group medical plan benefits under any other employer's group medical plan; or (C) the cessation of the Executive's health continuation rights under COBRA; *provided, however*, that if the Company determines that it cannot pay such amounts to the group health plan provider or the COBRA provider (if applicable) without potentially violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), then the Company shall convert such payments to payroll payments directly to the Executive for the time period specified above. Such payments to the Executive shall be subject to tax-related deductions and withholdings and paid on the Company's regular payroll dates.

The amounts payable under Section 5, to the extent taxable, shall be paid out in substantially equal installments in accordance with the Company's payroll practice over 9 months commencing within 60 days after the Date of Termination; *provided, however*, that if the 60-day period begins in one calendar year and ends in a second calendar year, such payments, to the extent they qualify as "non-qualified deferred compensation" within the meaning of Section 409A of the Internal Revenue Code of 1986, as amended (the "Code"), shall begin to be paid in the second calendar year by the last day of such 60-day period; *provided, further*, that the initial payment shall include a catch-up payment to cover amounts retroactive to the day immediately following the Date of Termination. Each payment pursuant to this Agreement is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A-2(b)(2).

6. Severance Pay and Benefits Upon Termination by the Company without Cause or by the Executive for Good Reason within the Change in Control Period. The provisions of this Section 6 shall apply in lieu of, and expressly supersede, the provisions of Section 5 if (i) the Executive's employment is terminated either (a) by the Company without Cause as provided in Section 3(d), or (b) by the Executive for Good Reason as provided in Section 3(e), and (ii) the Date of Termination is within the Change in Control Period. These provisions shall terminate and be of no further force or effect after the Change in Control Period.

(a) If the Executive's employment is terminated by the Company without Cause as provided in Section 3(d) or the Executive terminates employment for Good Reason as provided in Section 3(e) and in each case the Date of Termination occurs during the Change in Control Period, then, in addition to the Accrued Obligations, and subject to the signing of a general release of claims against the Company and all related persons and entities (the "Release") by the Executive and the Release becoming fully effective, all

within the time frame set forth in the Release but in no event more than 60 days after the Date of Termination:

(i) the Company shall pay the Executive a lump sum in cash in an amount equal to the sum of (A) twelve (12) months of the Executive's then-current Base Salary (or the Executive's Base Salary in effect immediately prior to the Change in Control, if higher) plus (B) 1.0 times the Executive's Target Bonus for the then-current year (or the Executive's Target Bonus in effect immediately prior to the Change in Control, if higher); and

(ii) subject to the Executive's copayment of premium amounts at the applicable active employees' rate and the Executive's proper election to receive benefits under COBRA, the Company shall pay to the group health plan provider or the COBRA provider a monthly payment equal to the monthly employer contribution that the Company would have made to provide health insurance to the Executive if the Executive had remained employed by the Company until the earliest of (A) the twelve (12) month anniversary of the Date of Termination; (B) the date that the Executive becomes eligible for group medical plan benefits under any other employer's group medical plan; or (C) the cessation of the Executive's health continuation rights under COBRA; *provided, however*, that if the Company determines that it cannot pay such amounts to the group health plan provider or the COBRA provider (if applicable) without potentially violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), then the Company shall convert such payments to payroll payments directly to the Executive for the time period specified above. Such payments to the Executive shall be subject to tax-related deductions and withholdings and paid on the Company's regular payroll dates.

The amounts payable under this Section 6(a), to the extent taxable, shall be paid or commence to be paid within 60 days after the Date of Termination; *provided, however*, that if the 60-day period begins in one calendar year and ends in a second calendar year, such payments to the extent they qualify as "non-qualified deferred compensation" within the meaning of Section 409A of the Code, shall be paid or commence to be paid in the second calendar year by the last day of such 60-day period.

(b) Additional Limitation.

(i) Anything in this Agreement to the contrary notwithstanding, in the event that the amount of any compensation, payment or distribution by the Company to or for the benefit of the Executive, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise, calculated in a manner consistent with Section 280G of the Code, and the applicable regulations thereunder (the "Aggregate Payments"), would be subject to the excise tax imposed by Section 4999 of the Code, then the Aggregate Payments shall be reduced (but not below zero) so that the sum of all of the Aggregate Payments shall be $1.00 less than the amount at which the Executive becomes subject to the excise tax imposed by Section 4999 of the Code; *provided* that such reduction shall only occur if it would result in the Executive receiving a higher After Tax Amount (as defined below) than the Executive would receive if the Aggregate Payments were not subject to such reduction. In such event, the Aggregate Payments shall be reduced in the following order, in each case, in

reverse chronological order beginning with the Aggregate Payments that are to be paid the furthest in time from consummation of the transaction that is subject to Section 280G of the Code: (1) cash payments not subject to Section 409A of the Code; (2) cash payments subject to Section 409A of the Code; (3) equity-based payments and acceleration; and (4) non-cash forms of benefits; *provided* that in the case of all the foregoing Aggregate Payments all amounts or payments that are not subject to calculation under Treas. Reg. §1.280G-1, Q&A-24(b) or (c) shall be reduced before any amounts that are subject to calculation under Treas. Reg. §1.280G-1, Q&A-24(b) or (c).

(ii) For purposes of this Section 6(b), the "After Tax Amount" means the amount of the Aggregate Payments less all federal, state, and local income, excise and employment taxes imposed on the Executive as a result of the Executive's receipt of the Aggregate Payments. For purposes of determining the After Tax Amount, the Executive shall be deemed to pay federal income taxes at the highest marginal rate of federal income taxation applicable to individuals for the calendar year in which the determination is to be made, and state and local income taxes at the highest marginal rates of individual taxation in each applicable state and locality, net of the maximum reduction in federal income taxes which could be obtained from deduction of such state and local taxes.

(iii) The determination as to whether a reduction in the Aggregate Payments shall be made pursuant to Section 6(b)(i) shall be made by a nationally recognized accounting firm selected by the Company (the "Accounting Firm"), which shall provide detailed supporting calculations both to the Company and the Executive within 15 business days of the Date of Termination, if applicable, or at such earlier time as is reasonably requested by the Company or the Executive. Any determination by the Accounting Firm shall be binding upon the Company and the Executive.

(c) Definitions. For purposes of this Agreement, the following terms shall have the meanings set forth below:

(i) "Change in Control" shall mean a "Sale Event" as defined in the Company's 2021 Stock Option and Incentive Plan, as amended or restated from time to time.

(ii) "Change in Control Period" shall mean the period commencing on the occurrence of the first event constituting a Change in Control and ending twelve (12) months after the occurrence of the first event constituting a Change in Control.

7. Section 409A.

(a) Anything in this Agreement to the contrary notwithstanding, if at the time of the Executive's separation from service within the meaning of Section 409A of the Code, the Company determines that the Executive is a "specified employee" within the meaning of Section 409A(a)(2)(B)(i) of the Code, then to the extent any payment or benefit that the Executive becomes entitled to under this Agreement or otherwise on account of the Executive's separation from service would be considered deferred compensation otherwise subject to the 20 percent additional tax imposed pursuant to Section 409A(a) of the Code as a result of the application of Section 409A(a)(2)(B)(i) of the Code, such payment shall not be payable and such benefit shall not be provided until the date that is

the earlier of (A) six months and one day after the Executive's separation from service, or (B) the Executive's death. If any such delayed cash payment is otherwise payable on an installment basis, the first payment shall include a catch-up payment covering amounts that would otherwise have been paid during the six-month period but for the application of this provision, and the balance of the installments shall be payable in accordance with their original schedule.

(b) All in-kind benefits provided and expenses eligible for reimbursement under this Agreement shall be provided by the Company or incurred by the Executive during the time periods set forth in this Agreement. All reimbursements shall be paid as soon as administratively practicable, but in no event shall any reimbursement be paid after the last day of the taxable year following the taxable year in which the expense was incurred. The amount of in-kind benefits provided or reimbursable expenses incurred in one taxable year shall not affect the in-kind benefits to be provided or the expenses eligible for reimbursement in any other taxable year (except for any lifetime or other aggregate limitation applicable to medical expenses). Such right to reimbursement or in-kind benefits is not subject to liquidation or exchange for another benefit.

(c) To the extent that any payment or benefit described in this Agreement constitutes "non-qualified deferred compensation" under Section 409A of the Code, and to the extent that such payment or benefit is payable upon the Executive's termination of employment, then such payments or benefits shall be payable only upon the Executive's "separation from service." The determination of whether and when a separation from service has occurred shall be made in accordance with the presumptions set forth in Treasury Regulation Section 1.409A-1(h).

(d) The parties intend that this Agreement will be administered in accordance with Section 409A of the Code. To the extent that any provision of this Agreement is ambiguous as to its compliance with Section 409A of the Code, the provision shall be read in such a manner so that all payments hereunder comply with Section 409A of the Code. Each payment pursuant to this Agreement is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A-2(b)(2). The parties agree that this Agreement may be amended, as reasonably requested by either party, and as may be necessary to fully comply with Section 409A of the Code and all related rules and regulations in order to preserve the payments and benefits provided hereunder without additional cost to either party.

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

8. Continuing Obligations.

(a) Restrictive Covenants Agreement. As a condition of the Executive's continued employment, the Executive is required to enter into the Employee Confidentiality, Assignment and Nonsolicitation Agreement attached hereto as Exhibit A (the "Restrictive Covenants Agreement"). For purposes of this Agreement, the obligations in this Section 8 and those that arise in the Restrictive Covenants Agreement and any other agreement relating to confidentiality, assignment of inventions, or other restrictive covenants shall collectively be referred to as the "Continuing Obligations."

(b) Third-Party Agreements and Rights. The Executive hereby confirms that the Executive is not bound by the terms of any agreement with any previous employer or other party which restricts in any way the Executive's use or disclosure of information, other than confidentiality restrictions (if any), or the Executive's engagement in any business. The Executive represents to the Company that the Executive's execution of this Agreement, the Executive's employment with the Company and the performance of the Executive's proposed duties for the Company will not violate any obligations the Executive may have to any such previous employer or other party. In the Executive's work for the Company, the Executive will not disclose or make use of any information in violation of any agreements with or rights of any such previous employer or other party, and the Executive will not bring to the premises of the Company any copies or other tangible embodiments of non-public information belonging to or obtained from any such previous employment or other party.

(c) Litigation and Regulatory Cooperation. During and after the Executive's employment, the Executive shall cooperate fully with the Company, including in (i) the defense or prosecution of any claims or actions now in existence or which may be brought in the future against or on behalf of the Company which relate to events or occurrences that transpired while the Executive was employed by the Company, and (ii) the investigation, whether internal or external, of any matters about which the Company believes the Executive may have knowledge or information. The Executive's full cooperation in connection with such claims, actions or investigations shall include, but not be limited to, being available to meet with counsel to answer questions or to prepare for discovery or trial and to act as a witness on behalf of the Company at mutually convenient times. During and after the Executive's employment, the Executive also shall cooperate fully with the Company in connection with any investigation or review of any federal, state or local regulatory authority as any such investigation or review relates to events or occurrences that transpired while the Executive was employed by the Company. The Company shall reimburse the Executive for any reasonable out-of-pocket expenses incurred in connection with the Executive's performance of obligations pursuant to this Section 8(c).

(d) Relief. The Executive agrees that it would be difficult to measure any damages caused to the Company which might result from any breach by the Executive of the Continuing Obligations, and that in any event money damages would be an inadequate remedy for any such breach. Accordingly**,** the Executive agrees that if the Executive breaches, or proposes to breach, any portion of the Continuing Obligations, the Company shall be entitled, in addition to all other remedies that it may have, to an injunction or other appropriate equitable relief to restrain any such breach without showing or proving any actual damage to the Company.

9. Consent to Jurisdiction. The parties hereby consent to the jurisdiction of the state and federal courts of the Commonwealth of Massachusetts. Accordingly, with respect to any such court action, the Executive (a) submits to the exclusive personal jurisdiction of such courts; (b) consents to service of process; and (c) waives any other requirement (whether imposed by statute, rule of court, or otherwise) with respect to personal jurisdiction or service of process.

10. Integration. This Agreement constitutes the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior agreements between the parties concerning such subject matter, including the Prior Agreement, *provided* that the Equity

Documents and any obligations regarding confidentiality and invention assignment remain in full force and effect.

11. Withholding; Tax Effect. All payments made by the Company to the Executive under this Agreement shall be net of any tax or other amounts required to be withheld by the Company under applicable law. Nothing in this Agreement shall be construed to require the Company to make any payments to compensate the Executive for any adverse tax effect associated with any payments or benefits or for any deduction or withholding from any payment or benefit.

12. Assignment; Successors and Assigns. Neither the Executive nor the Company may make any assignment of this Agreement or any interest in it, by operation of law or otherwise, without the prior written consent of the other; *provided, however*, that the Company may assign its rights and obligations under this Agreement (including the Restrictive Covenants Agreement) without the Executive's consent to any affiliate or to any person or entity with whom the Company shall hereafter effect a reorganization or consolidation, into which the Company merges or to whom it transfers all or substantially all of its properties or assets; *provided further* that if the Executive remains employed or becomes employed by the Company, the purchaser or any of their affiliates in connection with any such transaction, then the Executive shall not be entitled to any payments, benefits or vesting pursuant to Section 2(g), Section 5 or Section 6 of this Agreement solely as a result of such transaction. This Agreement shall inure to the benefit of and be binding upon the Executive and the Company, and each of the Executive's and the Company's respective successors, executors, administrators, heirs and permitted assigns. In the event of the Executive's death after the Executive's termination of employment but prior to the completion by the Company of all payments due to the Executive under this Agreement, the Company shall continue such payments to the Executive's beneficiary designated in writing to the Company prior to the Executive's death (or to the Executive's estate, if the Executive fails to make such designation).

13. Enforceability. If any portion or provision of this Agreement (including, without limitation, any portion or provision of any section of this Agreement) shall to any extent be declared illegal or unenforceable by a court of competent jurisdiction, then the remainder of this Agreement, or the application of such portion or provision in circumstances other than those as to which it is so declared illegal or unenforceable, shall not be affected thereby, and each portion and provision of this Agreement shall be valid and enforceable to the fullest extent permitted by law.

14. Survival. The provisions of this Agreement shall survive the termination of this Agreement and/or the termination of the Executive's employment to the extent necessary to effectuate the terms contained herein.

15. Waiver. No waiver of any provision hereof shall be effective unless made in writing and signed by the waiving party. The failure of any party to require the performance of any term or obligation of this Agreement, or the waiver by any party of any breach of this Agreement, shall not prevent any subsequent enforcement of such term or obligation or be deemed a waiver of any subsequent breach.

16. Notices. Any notices, requests, demands and other communications provided for by this Agreement shall be sufficient if in writing and delivered in person or sent by a nationally recognized overnight courier service or by registered or certified mail, postage prepaid, return receipt requested, to the Executive at the last address the Executive has filed in writing with the Company or, in the case of the Company, at its main offices, attention of the Board.

17. Amendment. This Agreement may be amended or modified only by a written instrument signed by the Executive and by a duly authorized representative of the Company.

18. Effect on Other Plans and Agreements. An election by the Executive to resign for Good Reason under the provisions of this Agreement shall not be deemed a voluntary termination of employment by the Executive for the purpose of interpreting the provisions of any of the Company's benefit plans, programs or policies. Nothing in this Agreement shall be construed to limit the rights of the Executive under the Company's benefit plans, programs or policies except as otherwise provided in Section 8 hereof, and except that the Executive shall have no rights to any severance benefits under any Company severance pay plan, offer letter or otherwise. In the event that the Executive is party to an agreement with the Company providing for payments or benefits under such plan or agreement and under this Agreement, the terms of this Agreement shall govern and the Executive may receive payment under this Agreement only and not both. Further, Section 5 and Section 6 of this Agreement are mutually exclusive and in no event shall the Executive be entitled to payments or benefits pursuant to both Section 5 and Section 6 of this Agreement.

19. Governing Law. This is a Massachusetts contract and shall be construed under and be governed in all respects by the laws of the Commonwealth of Massachusetts, without giving effect to the conflict of laws principles thereof. With respect to any disputes concerning federal law, such disputes shall be determined in accordance with the law as it would be interpreted and applied by the United States Court of Appeals for the First Circuit.

20. Counterparts. This Agreement may be executed in any number of counterparts, each of which when so executed and delivered shall be taken to be an original; but such counterparts shall together constitute one and the same document.

IN WITNESS WHEREOF, the parties have executed this Agreement effective on the Effective Date.

CULLINAN MANAGEMENT, INC.

By: /s/ Owen Hughes
Name: Owen Hughes
Title: Chief Executive Officer

EXECUTIVE

/s/ Jeffrey Trigilio
Jeffrey Trigilio

STOCK PURCHASE AND TRANSFER AGREEMENT

This Stock Purchase and Transfer Agreement (the "Agreement") is made and entered into as of [●], 2022 (the "Effective Date"), by and among [●] ("Transferor"), Cullinan Oncology, Inc., a Delaware corporation ("Transferee"), and Cullinan MICA Corp., a Delaware corporation (the "Corporation", together with Transferor and Transferee, the "Parties").

RECITALS

A. Transferor holds the number of shares of the Corporation's [●] indicated below the Transferor's signature hereto; [and]

B. Transferor and Transferee desire to undertake a transaction by which the Transferor shall sell directly to Transferee the number and class of shares of the Corporation's capital stock indicated below the Transferor's signature hereto (the ["Shares"]), all in accordance with the terms and provisions of this Agreement[;]

C. [Transferor is the holder of that certain Convertible Promissory Note in the original principal amount of $[●] dated as of [●] and issued to Transferor pursuant to that certain Note Purchase Agreement by and among the Corporation, Transferor, Transferee and the other parties thereto (the "Note" and, together with the Shares, the "Securities"); and

D. Transferor and Transferee desire to undertake a transaction by which the Transferor shall sell, assign and transfer to Transferee all of Transferor's right, title and interest in the Note, all in accordance with the terms and provisions of this Agreement.]

Now, therefore, in consideration of the foregoing premises and for other good and valid consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

AGREEMENT

The Parties hereby agree as follows:

1. Transfer and Sale. Subject to the terms and conditions of this Agreement and the agreements listed on Exhibit A (collectively with this Agreement, the "Related Agreements"), [(i)] Transferor agrees to transfer and sell the Shares to Transferee, and Transferee agrees to purchase and accept the Shares from Transferor, as of the Effective Date, at the aggregate purchase price for such Shares indicated below the Transferor's signature hereto (the "[Share] Purchase Price") [and (ii) Transferor agrees to transfer, sell and assign all of Transferor's right, title and interest in the Note to Transferee, and Transferee agrees to purchase and accept such transfer and assignment from Transferor, as of the Effective Date, at the aggregate purchase price for the Note indicated below the Transferor's signature hereto (the "Note Purchase Price" and, together with the Share Purchase Price, the "Purchase Price")].

2. Closing. The transfer and sale of the Securities pursuant to this Agreement shall occur on the Effective Date.

(a) Obligations of Transferor. On the Effective Date, Transferor shall deliver to Transferee (i) a Stock Power, in the form attached to this Agreement as Exhibit B, executed by Transferor in favor of Transferee, against payment of the Purchase Price, which shall be paid by wire transfer to a bank account designated by Transferor, [and] (ii) [a duly executed amendment to the Voting Agreement (as defined on Exhibit A attached hereto) in the form attached to this Agreement as Exhibit C and (iii)] a duly executed and completed IRS Form W-9 or appropriate IRS Form W-8 (as applicable). Further, Transferor shall, immediately upon receipt of the Purchase Price from Transferee, notify the Corporation in writing (which may be by electronic mail) of the same.

(b) Obligations of Transferee. On the Effective Date, subject to Transferor's performance of the conditions set forth herein, Transferee shall deliver to Transferor a wire transfer of immediately available funds to an account designated by Transferor to Transferee prior to the Effective Date, in the amount equal to the Purchase Price.

3. Representations and Warranties of Transferee. In connection with the transfer and sale of the Securities to Transferee, Transferee represents and warrants to the Transferor and to the Corporation that:

(a) Purchase Entirely for Own Account. Transferee is acquiring the Securities for investment for Transferee's own account only and not with a view to, or for resale in connection with, any "distribution" of such securities within the meaning of the Securities Act of 1933, as amended (the "Securities Act"). The Transferee was not formed for the specific purpose of acquiring the Securities.

(b) Restricted Securities. Transferee understands that neither the Securities nor any shares of the Corporation's capital stock issued directly or indirectly upon conversion of the Securities (the "Conversion Shares") have been registered under the Securities Act by reason of a specific exemption therefrom, which exemption depends upon, among other things, the bona fide nature of Transferee's investment intent as expressed herein. Transferee understands that the Securities are (and, upon issuance, the Conversion Shares will be) "restricted securities" under applicable U.S. federal and state laws and that, pursuant to these laws, Transferee must hold the Securities indefinitely unless they are registered with the Securities and Exchange Commission and qualified by state authorities, or an exemption from such registration and qualification requirements is available. Transferee acknowledges that the Corporation has no obligation (except as may be set forth in the Investors' Rights Agreement), and does not currently intend, to register or qualify the Securities or the Conversion Shares for resale. Transferee further acknowledges that if an exemption from registration or qualification is available, it may be conditioned on various requirements including, but not limited to, the time and manner of sale, the holding period for the Securities or the Conversion Shares (as applicable), and requirements relating to the Corporation which are outside of Transferee's control, and which the Corporation is under no obligation and may not be able to satisfy.

(c) Accredited Investor. Transferee is an accredited investor as defined in Rule 501(a) of Regulation D of the Securities Act.

(d) Access to Information. Transferee has had access to all information regarding the Corporation and its present and prospective business, assets, liabilities and financial condition that Transferee reasonably considers important in making the decision to acquire the Securities, and Transferee has had ample opportunity to ask questions of the Corporation's representatives concerning such matters.

(e) Sophistication. Transferee (i) is a sophisticated individual or entity familiar with transactions similar to those contemplated by this Agreement, (ii) has adequate information concerning the business and financial condition of the Corporation to make an informed decision regarding the acquisition of the Securities, (iii) has negotiated the terms of this Agreement (including the Purchase Price) on an arm's length basis and has had an opportunity to consult with its legal, tax and financial advisors concerning this

agreement and its subject matter, and (iv) has independently and without reliance upon either Transferor or the Corporation for any information or advice regarding the Corporation or the value of the Securities, and based on such information and the advice of such advisors as Transferee has deemed appropriate, made its own analysis and decision to enter into this Agreement.

(f) Due Authority. Transferee has the power and authority to execute, deliver and perform this Agreement. This Agreement is a binding obligation of Transferee, enforceable against Transferee in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization and other similar laws and the application of general equitable principles. Transferee has taken all reasonable steps to obtain any necessary approvals and waivers required pursuant to the Related Agreements in connection with Transferee's acquisition of the Securities.

4. Representations and Warranties of Transferor. In connection with the transfer of the Securities to Transferee, Transferor represents and warrants to Transferee and the Corporation that:

(a) Ownership. Transferor is the sole beneficial owner of the Securities and the Securities are free and clear of any liens or encumbrances (other than restrictions on transfer under applicable state and federal laws and restrictions under the Related Agreements). Transferor further represents that Transferor has good and marketable title to the Securities and the right and authority to transfer, sell and assign the Securities to the Transferee pursuant to this Agreement and without any third-party consent (except any consent required pursuant to the Related Agreements). Other than the Securities, Transferor does not hold or possess, and has no right, title, or interest in, any shares of capital stock of the Corporation or any options, warrants, rights (including conversion or preemptive rights and rights of first refusal or similar rights) or agreements, orally or in writing, to purchase or acquire from the Corporation any shares of capital stock of the Corporation, or any securities convertible into or exchangeable for shares of capital stock of the Corporation.

(b) Authorization. If Transferor is not a natural person, Transferor has been duly organized and is validly existing under the laws or the jurisdiction of its organization. Transferor has all necessary power and authority to execute, deliver and perform Transferor's obligations under this Agreement. All agreements, instruments and documents contemplated hereby and to transfer, sell and deliver the Securities, and this Agreement constitutes a valid and binding obligation of Transferor.

(c) No Conflict; Consent. The execution, delivery and performance of this Agreement and the consummation of the transactions contemplated hereby will not result in any violation or be in conflict with or constitute, with or without the passage of time and giving of notice, either a default under any provision of any instrument, judgment, order, writ, decree or contract (other than any consent required pursuant to the Related Agreements) or an event which results in the creation of any lien, charge or encumbrance upon the Securities. No consent, approval, order or authorization of, or registration, qualification, designation, declaration or filing with, any foreign, federal, state or local governmental authority or other person or entity on the part of Transferor is required in connection with the consummation of the transactions contemplated by this Agreement, except those that have been duly waiver or properly complied with to the extent applicable to the transfer of the Securities to Transferee pursuant hereto.

(d) Validity. This Agreement, when executed and delivered by Transferor, will constitute the valid and legally binding obligation of Transferor, enforceable in accordance with its terms, except as limited by applicable bankruptcy, insolvency, reorganization, moratorium, fraudulent conveyance, and any other laws of general application affecting enforcement of creditors' rights generally, and as limited by laws relating to the availability of a specific performance, injunctive relief, or other equitable remedies.

(e) Sale for Own Account. Transferor is selling the Securities for Transferor's own account only and not with a view to, or for sale in connection with, a distribution of such securities within the meaning of the Securities Act. No portion of the Purchase Price will be received indirectly by the Corporation.

(f) Sophistication. Transferor (i) is a sophisticated individual or entity familiar with transactions similar to those contemplated by this Agreement and has such knowledge and experience in financial and business matters as to be capable of evaluating the merits, risks and suitability of the transactions contemplated by this Agreement, (ii) has adequate information concerning the business and financial condition of the Corporation to make an informed decision regarding the transactions contemplated by this Agreement, (iii) has negotiated the terms of this Agreement (including the Purchase Price) on an arm's-length basis and has had an opportunity to consult with its legal, tax and financial advisors concerning this Agreement and its subject matter, and (iv) has independently and without reliance upon Transferee or the Corporation for any information or advice regarding the Corporation or the value of the Securities, and based on such information and the advice of such advisors as Transferor has deemed appropriate, made its own analysis and decision to enter into this Agreement. Transferor is fully aware of the possibility that the value of the Securities may significantly appreciate or depreciate over time and by agreeing to sell the Securities pursuant to this Agreement, Transferor is giving up the opportunity to sell the Securities at a higher price in the future. Transferor acknowledges that no Transferee Party is acting as a fiduciary or financial or investment advisor to Transferor, and has not given Transferor any investment advice, opinion or other information on whether the sale of the Securities is prudent.

(g) No General Solicitation. At no time has Transferor presented Transferee with or solicited Transferee through any publicly issued or circulated newspaper, mail, radio, television or other form of general advertisement or solicitation in connection with the sale and transfer of the Securities.

(h) No Broker-Dealer. Transferor has not effected the sale and transfer of the Securities by or through a broker-dealer in any public offering.

5. Informed Decision; Investigation; Future Gains; Tax Consequences; Etc.

(a) Each of Transferor and Transferee (collectively, the "Transacting Parties") has entered into this Agreement based on its knowledge, investigation and analysis. Each of the Transacting Parties acknowledges that the Purchase Price being paid by the Transferee was negotiated at arm's-length, may not represent the fair market value of the Securities, and that the Securities may have a current or future value greater or lesser than the amount paid for the Securities under this Agreement. Each of the Transacting Parties understands that the Corporation's plans for the future may result in the Securities becoming significantly more or less valuable, and that the future value of the Securities could be greater or lesser than the Purchase Price. Neither the Corporation nor any of its agents has made any representation to the parties about the advisability of this decision or the potential future value of the Securities. Each of the Transacting Parties has the capacity to protect its own interests in connection with the transactions contemplated by this Agreement by reason of its business or financial experience or the business or financial experience of its professional advisors who are unaffiliated with, and who are not compensated by the Corporation. Each of the Transacting Parties agrees that neither the Corporation, the other Transacting Party, nor any of their respective affiliated parties are under any obligation to disclose to such party any information or opinion they may have about the potential future value of the Corporation's capital stock, even if such information is material, and each of the Transacting Parties has determined to enter into this Agreement notwithstanding such lack of information. Each of the Transacting Parties hereby acknowledges that any future sale of shares of the Corporation's capital stock could be at a premium or a discount to the Purchase Price, and such sale could occur at any time or not at all. Each of the Transacting Parties hereby acknowledges that it has not relied on any representation or statement of the Corporation or its counterparty

in this transaction, other than those set forth in this Agreement, in making its investment decision to enter into this Agreement.

(b) Each of the Transacting Parties further acknowledges that it has received all information it has deemed appropriate or necessary to enable such Transacting Party to evaluate its decision to enter into this Agreement. Without limiting the foregoing, each of the Transacting Parties expressly acknowledges that (i) the other parties to this Agreement currently may have, and later may come into possession of, information with respect to the Corporation that is not known to such Transacting Party and that may be material to a decision to sell the Securities ("Excluded Information"), (ii) each of the Transacting Parties has determined to enter into this Agreement notwithstanding its lack of knowledge of the Excluded Information, and (iii) the parties shall have no liability to one another, and the parties hereto waive and release any claims that it might have against any other party hereto whether under applicable securities laws or otherwise, with respect to the nondisclosure of the Excluded Information in connection with the transactions contemplated by this Agreement.

6. Corporation Consent. The Corporation fully consents to the transfer of the Securities under this Agreement and hereby waives all applicable notice requirements and all applicable transfer restrictions and requirements under the Related Agreements with respect to the transactions contemplated hereunder.

7. Release.

(a) The Transferor and Transferee each, on behalf of itself and on behalf of its predecessors and successors, past and present agents, representatives, partners, directors, officers, attorneys, employees, servants, shareholders, affiliates, subsidiaries, heirs, executors, administrators and assigns, as well as any person acting by, through, under or in concert with any of the foregoing does hereby release and forever discharge the other Transacting Party, the Corporation, and each party's predecessors and successors, past and present agents, representatives, partners, directors, officers, attorneys, employees, servants, shareholders, affiliates, subsidiaries, heirs, executors, administrators and assigns, as well as any person acting by, through, under or in concert with any of the foregoing, from any and all claims, demands, causes of action, obligations, damages, losses, liabilities, contracts, agreements, promises, debts, costs and expenses of any kind whatsoever, whether at law or in equity, asserted or unasserted, known or unknown, suspected or unsuspected, fixed or contingent (collectively, "Claims" and individually, "Claim"), which such party ever had, now has, or may claim to have against the other Transacting Party or the Corporation, relating to or arising from the transfer and sale of the Securities.

(b) The Transferor and Transferee each hereby acknowledge, severally and not jointly, that it has been advised by legal counsel, is familiar with and fully understands the provisions of California Civil Code Section 1542 (or similar provision in the jurisdiction in which such party resides) which provides as follows: "A general release does not extend to claims that the creditor or releasing party does not know or suspect to exist in his or her favor at the time of executing the release, and that, if known by him or her, would have materially affected his or her settlement with the debtor or released party." Having been so advised, each of the Transferor and Transferee nevertheless elects to and does assume all risks for Claims known or unknown, suspected or unsuspected, heretofore arising from the subject of this Section 10, and specifically waives any rights it may have under Section 1542, as well as under any other applicable statute or common-law principle with a similar effect.

8. Miscellaneous.

(a) Governing Law. The validity, interpretation, construction and performance of this Agreement, and all acts and transactions pursuant hereto and the rights and obligations of the parties hereto

shall be governed, construed and interpreted in accordance with the laws of the state of Delaware, without giving effect to principles of conflicts of law.

(b) Entire Agreement; Amendment. The Related Agreements set forth the entire agreement and understanding of the parties relating to the subject matter therein and supersede all prior or contemporaneous discussions, understandings and agreements, whether oral or written, between them relating to the subject matter hereof. No modification of or amendment to this Agreement, nor any waiver of any rights under this Agreement, shall be effective unless in writing signed by the parties to this Agreement.

(c) Notices. Any notice, demand or request required or permitted to be given under this Agreement shall be in writing and shall be deemed sufficient when delivered personally or by overnight courier or sent by email, or 48 hours after being deposited in the U.S. mail as certified or registered mail with postage prepaid, addressed to the party to be notified at such party's address as set forth on the signature page, as subsequently modified by written notice, or if no address is specified on the signature page, at the most recent address set forth in the Corporation's books and records.

(d) Severability. If one or more provisions of this Agreement are held to be unenforceable under applicable law, the parties agree to renegotiate such provision in good faith. In the event that the parties cannot reach a mutually agreeable and enforceable replacement for such provision, then (i) such provision shall be excluded from this Agreement, (ii) the balance of the Agreement shall be interpreted as if such provision were so excluded and (iii) the balance of the Agreement shall be enforceable in accordance with its terms.

(e) Electronic Delivery. The Corporation may, in its sole discretion, decide to deliver any documents or any notices required by applicable law or the Corporation's Certificate of Incorporation or Bylaws by email or any other electronic means. Transferee hereby consents to (i) conduct business electronically (ii) receive such documents and notices by such electronic delivery and (iii) sign documents electronically and agrees to participate through an on-line or electronic system established and maintained by the Corporation or a third party designated by the Corporation.

(f) Counterparts. This Agreement may be executed in any number of counterparts, each of which when so executed and delivered shall be deemed an original, and all of which together shall constitute one and the same agreement. Counterparts may be delivered via electronic mail (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, e.g., www.docusign.com) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

(g) Successors and Assigns. Except as otherwise provided in this Agreement, this Agreement, and the rights and obligations of the parties hereunder, will be binding upon and inure to the benefit of their respective successors, assigns, heirs, executors, administrators and legal representatives. The Corporation may assign any of its rights and obligations under this Agreement.

(h) Shareholder Agreements. Transferor and the Corporation acknowledge and agree that, effective as of immediately following the transfer of the Shares pursuant to Section 1 [and the effectiveness of the amendment to the Voting Agreement in the form attached hereto as Exhibit C], Transferor shall cease to be shareholder of the Corporation and shall cease to be an "Investor" under, or otherwise be a party to, the Voting Agreement, ROFR and Co-Sale Agreement or Investors' Rights Agreement (each as defined on Exhibit A).

[*Signature Page Follows*]

The parties have executed this Stock Purchase and Transfer Agreement as of the date first written above.

TRANSFEROR:

[●]

By:
Name:
Title:

Address:

Securities	
Class and Series	# of Shares
Series A Senior Preferred Stock	[●]
Series A Junior Preferred Stock	[●]
Series A-1 Junior Preferred Stock	[●]
Series A-2 Junior Preferred Stock	[●]
Shares of Common Stock	[●]
TOTAL SHARES	[●]

[Aggregate Share Purchase Price: $[●]

Note Purchase Price: $[●]]

Purchase Price (total): $[●]

The parties have executed this Stock Purchase and Transfer Agreement as of the date first written above.

TRANSFEREE:

CULLINAN ONCOLOGY, INC.

By:_
Name: Nadim Ahmed
Title: President and CEO

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The parties have executed this Stock Purchase and Transfer Agreement as of the date first written above.

CORPORATION:

CULLINAN MICA CORP.

By:_
Name: Nadim Ahmed
Title: President

EXHIBIT A

RELATED AGREEMENTS

1. The Amended and Restated Certificate of Incorporation of the Corporation (the "Charter").

2. The Bylaws of the Corporation (the "Bylaws").

3. The Voting Agreement, dated as of May 28, 2020, by and among the Corporation and the other parties thereto, as amended (the "Voting Agreement").

4. The Right of First Refusal and Co-Sale Agreement, by and among the Corporation and the other parties thereto, dated as of May 28, 2020 (the "ROFR and Co-Sale Agreement").

5. The Investors' Rights Agreement, dated as of May 28, 2020, by and among the Corporation and the other parties thereto (the "Investors' Rights Agreement").

EXHIBIT B

STOCK POWER

FOR VALUE RECEIVED and pursuant to that certain Stock Purchase and Transfer Agreement by and among by and among [●] ("Transferor"), Cullinan Oncology, Inc., a Delaware corporation ("Transferee"), and Cullinan MICA Corp., a Delaware corporation (the "Corporation"), the Transferor, hereby assigns and transfers unto Transferee [●] shares of the Corporation's [●],whether held in certificated or uncertificated form, and does hereby irrevocably constitute and appoint the Corporation as transfer agent with authority to transfer said stock on the books of the Corporation with full power of substitution in the premises.

Date:____

TRANSFEROR:

[●]

By: _____

Name: ___

Title: ____

[EXHIBIT C

FORM OF AMENDMENT TO VOTING AGREEMENT]

AMENDMENT NO. 1 TO

CULLINAN MICA CORP.

SECOND AMENDED AND RESTATED VOTING AGREEMENT

This Amendment No. 1 (this "**Amendment**") is made as of [●], 2022, by and among Cullinan MICA Corp., a Delaware corporation (the "**Company**"), and the Investors set forth on the signature page hereto and amends that certain Voting Agreement, dated as of May 28, 2020 by and among the Company and the Investors and Key Holders set forth therein (the "**Voting Agreement**"). Capitalized terms used herein but not otherwise defined shall have the meanings given to such terms in the Voting Agreement.

WHEREAS, the Company and the undersigned Investors are parties to the Voting Agreement and each desires to amend the Voting Agreement as set forth herein;

WHEREAS, pursuant to Section 7.8 of the Voting Agreement, the Voting Agreement may be amended by a written instrument executed by the Company and the Requisite Investors if such amendment

is not directly applicable to the rights or obligations of the Key Holders under the Voting Agreement or does not adversely affect the rights of the Key Holders in a manner that is different than the effect on the rights of the other parties to the Voting Agreement; and

WHEREAS, the undersigned Investors constitute the Requisite Investors, and the amendments contemplated by this Amendment are not directly applicable to the rights or obligation of the Key Holders and do not adversely affect the rights of the Key Holders in a manner that is different than the effect on the rights of the other parties to the Voting Agreement.

NOW, THEREFORE, in consideration of the mutual covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

1. In Section 1.1 of the Voting Agreement, "five directors" is hereby changed to "no more than five directors."

2. Section 1.2(a) of the Voting Agreement (inclusive of subsections (i) and (ii) of such Section 1.2(a)) is hereby amended and restated in its entirety as follows:

   > "(a) At each annual or special meeting of stockholders at which an election of Series A Junior Directors is held or pursuant to any written consent of the stockholders to elect as the Series A Junior Directors, two persons designated from time to time by the holders of a majority of the outstanding shares of Series A Junior Preferred Stock, which positions, as of [●], 2022, shall initially be vacant."

3. The final two sentences of Section 7.7(a) of the Voting Agreement are hereby amended and restated in its entirety as follows:

   > "If notice is given to the Company, it shall be sent to One Main Street, Suite 1350, Cambridge, MA 02142, Attention: Chief Financial Officer and Chief Legal Officer"

4. Section 7.8(b) of the Voting Agreement is hereby deleted in its entirety and replaced with "[Intentionally omitted.]".

5. This Amendment may be executed in any number of counterparts, each of which shall be enforceable against the parties that execute such counterparts, and all of which together shall constitute one instrument. A facsimile, telecopy or other reproduction of this Amendment may be executed by one or more parties and delivered by such party by facsimile or any similar electronic transmission device pursuant to which the signature of or on behalf of such party can be seen. Such execution and delivery shall be considered valid, binding and effective for all purposes.

6. The Voting Agreement as modified herein shall remain in full force and effect as so modified.

7. This Amendment and any controversy arising out of or relating to this Amendment shall be governed by and construed in accordance with the internal laws of the State of Delaware.

* * *

Exhibit 10.25

[OPTION] PURCHASE AND TRANSFER AGREEMENT

This Option Purchase and Transfer Agreement (the "Agreement") is made and entered into as of _____, 2022 (the "Effective Date"), by and among [●] ("Transferor"), Cullinan Oncology, Inc., a Delaware corporation ("Transferee"), and Cullinan MICA Corp., a Delaware corporation (the "Corporation", together with Transferor and Transferee, the "Parties").

RECITALS

A. [Transferor holds options to purchase [●] shares of the Corporation's Common Stock for an exercise price of $[●] per share (the "Options") pursuant to, and subject to the terms, conditions and restrictions set forth in, the Corporation's 2019 Equity Incentive Plan (the "Plan") and that certain Stock Option Agreement dated [●] by and among Transferor and the Corporation (the "Option Agreement")]; and

B. Transferor and Transferee desire to undertake a transaction by which the Transferor shall sell and transfer directly to Transferee the Options in accordance with the terms and provisions of this Agreement[, the Plan and the Option Agreement].

Now, therefore, in consideration of the foregoing premises and for other good and valid consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

AGREEMENT

The Parties hereby agree as follows:

1. Transfer and Sale. Subject to the terms and conditions of this Agreement[, the Plan, the Option Agreement] and the agreements listed on Exhibit A (collectively with this Agreement, the Plan, the Option Agreement, the "Related Agreements"), Transferor agrees to transfer and sell the Options to Transferee, and Transferee agrees to purchase and accept the Options from Transferor, as of the Effective Date, for an aggregate purchase price for such Options of $[•] (the "Purchase Price").

2. Closing. The transfer and sale of the Options pursuant to this Agreement shall occur on the Effective Date.

(a) Obligations of Transferor. On the Effective Date, Transferor shall deliver to Transferee [(i) a Stock Power, in the form attached to this Agreement as Exhibit B, executed by Transferor in favor of Transferee, against payment of the Purchase Price, which shall be paid by wire transfer to a bank account designated by Transferor, and (ii)] a duly executed and completed IRS Form W-9 or appropriate IRS Form W-8 (as applicable). Further, Transferor shall, immediately upon receipt of the Purchase Price from Transferee, notify the Corporation in writing (which may be by electronic mail) of the same.

(b) Obligations of Transferee. On the Effective Date, subject to Transferor's performance of the conditions set forth herein, Transferee shall deliver to Transferor a wire transfer of immediately available funds to an account designated by Transferor to Transferee prior to the Effective Date, in the amount equal to the Purchase Price.

3. Representations and Warranties of Transferee. In connection with the transfer and sale of the Options to Transferee, Transferee represents and warrants to the Transferor and to the Corporation that:

(a) Purchase Entirely for Own Account. Transferee is acquiring the Options for investment for Transferee's own account only and not with a view to, or for resale in connection with, any "distribution" of such securities within the meaning of the Securities Act of 1933, as amended (the "Securities Act"). The Transferee was not formed for the specific purpose of acquiring the Options.

(b) Restricted Securities. Transferee understands that [neither] the Options [nor any shares of the Corporation's capital stock issued directly or indirectly upon exercise of the Options (the "Exercise Shares")] have not been registered under the Securities Act by reason of a specific exemption therefrom, which exemption depends upon, among other things, the bona fide nature of Transferee's investment intent as expressed herein. Transferee understands that the Options are [(and, upon issuance, the Exercise Shares will be)] "restricted securities" under applicable U.S. federal and state laws and that, pursuant to these laws, Transferee must hold the Options [(and, upon issuance, the Exercise Shares)] indefinitely unless they are registered with the Securities and Exchange Commission and qualified by state authorities, or an exemption from such registration and qualification requirements is available. Transferee acknowledges that the Corporation has no obligation (except as may be set forth in the Investors' Rights Agreement dated as of May 28, 2020, by and among the Corporation and the other parties thereto, as amended), and does not currently intend, to register or qualify the Options [or the Exercise Shares] for resale. Transferee further acknowledges that if an exemption from registration or qualification is available, it may be conditioned on various requirements including, but not limited to, the time and manner of sale, the holding period for the Options [or the Exercise Shares (as applicable)], and requirements relating to the Corporation which are outside of Transferee's control, and which the Corporation is under no obligation and may not be able to satisfy.

(c) Accredited Investor. Transferee is an accredited investor as defined in Rule 501(a) of Regulation D of the Securities Act.

(d) Access to Information. Transferee has had access to all information regarding the Corporation and its present and prospective business, assets, liabilities and financial condition that Transferee reasonably considers important in making the decision to acquire the Options, and Transferee has had ample opportunity to ask questions of the Corporation's representatives concerning such matters.

(e) Sophistication. Transferee (i) is a sophisticated individual or entity familiar with transactions similar to those contemplated by this Agreement, (ii) has adequate information concerning the business and financial condition of the Corporation to make an informed decision regarding the acquisition of the Options, (iii) has negotiated the terms of this Agreement (including the Purchase Price) on an arm's length basis and has had an opportunity to consult with its legal, tax and financial advisors concerning this agreement and its subject matter, and (iv) has independently and without reliance upon either Transferor or the Corporation for any information or advice regarding the Corporation or the value of the Options, and based on such information and the advice of such advisors as Transferee has deemed appropriate, made its own analysis and decision to enter into this Agreement.

(f) Due Authority. Transferee has the power and authority to execute, deliver and perform this Agreement. This Agreement is a binding obligation of Transferee, enforceable against Transferee in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization and other similar laws and the application of general equitable principles. Transferee has taken all reasonable steps to obtain any necessary approvals and waivers required pursuant to the Related Agreements in connection with Transferee's acquisition of the Options.

4. Representations and Warranties of Transferor. In connection with the transfer of the Options to Transferee, Transferor represents and warrants to Transferee and the Corporation that:

(a) Ownership. Transferor is the sole beneficial owner of the Options and the Options are free and clear of any liens or encumbrances (other than restrictions on transfer under applicable state and federal laws and restrictions under the Related Agreements). Transferor further represents that Transferor has good and marketable title to the Options and the right and authority to transfer, sell and assign the Options to the Transferee pursuant to this Agreement and without any third-party consent (except any consent required pursuant to the Related Agreements). Other than the Options, Transferor does not hold or possess, and has no right, title, or interest in, any shares of capital stock of the Corporation or any options, warrants, rights (including conversion or preemptive rights and rights of first refusal or similar rights) or agreements, orally or in writing, to purchase or acquire from the Corporation any shares of capital stock of the Corporation, or any securities convertible into or exchangeable for shares of capital stock of the Corporation.

(b) Authorization. If Transferor is not a natural person, Transferor has been duly organized and is validly existing under the laws or the jurisdiction of its organization. Transferor has all necessary power and authority to execute, deliver and perform Transferor's obligations under this Agreement. All agreements, instruments and documents contemplated hereby and to transfer, sell and deliver the Options, and this Agreement constitutes a valid and binding obligation of Transferor.

(c) No Conflict; Consent. The execution, delivery and performance of this Agreement and the consummation of the transactions contemplated hereby will not result in any violation or be in conflict with or constitute, with or without the passage of time and giving of notice, either a default under any provision of any instrument, judgment, order, writ, decree or contract (other than any consent required pursuant to the Related Agreements) or an event which results in the creation of any lien, charge or encumbrance upon the Options. No consent, approval, order or authorization of, or registration, qualification, designation, declaration or filing with, any foreign, federal, state or local governmental authority or other person or entity on the part of Transferor is required in connection with the consummation of the transactions contemplated by this Agreement, except those that have been duly waiver or properly complied with to the extent applicable to the transfer of the Options to Transferee pursuant hereto.

(d) Validity. This Agreement, when executed and delivered by Transferor, will constitute the valid and legally binding obligation of Transferor, enforceable in accordance with its terms, except as limited by applicable bankruptcy, insolvency, reorganization, moratorium, fraudulent conveyance, and any other laws of general application affecting enforcement of creditors' rights generally, and as limited by laws relating to the availability of a specific performance, injunctive relief, or other equitable remedies.

(e) Sale for Own Account. Transferor is selling the Options for Transferor's own account only and not with a view to, or for sale in connection with, a distribution of such securities within the meaning of the Securities Act. No portion of the Purchase Price will be received indirectly by the Corporation.

(f) Sophistication. Transferor (i) is a sophisticated individual or entity familiar with transactions similar to those contemplated by this Agreement and has such knowledge and experience in financial and business matters as to be capable of evaluating the merits, risks and suitability of the transactions contemplated by this Agreement, (ii) has adequate information concerning the business and financial condition of the Corporation to make an informed decision regarding the transactions contemplated by this Agreement, (iii) has negotiated the terms of this Agreement (including the Purchase Price) on an arm's-length basis and has had an opportunity to consult with its legal, tax and financial

advisors concerning this Agreement and its subject matter, and (iv) has independently and without reliance upon Transferee or the Corporation for any information or advice regarding the Corporation or the value of the Options [or the Exercise Shares], and based on such information and the advice of such advisors as Transferor has deemed appropriate, made its own analysis and decision to enter into this Agreement. Transferor is fully aware of the possibility that the value of the Options [and/or Exercise Shares] may significantly appreciate or depreciate over time and by agreeing to sell the Options pursuant to this Agreement, Transferor is giving up the opportunity to sell the Options [and/or Exercise Shares] at a higher price in the future. Transferor acknowledges that no Transferee Party is acting as a fiduciary or financial or investment advisor to Transferor, and has not given Transferor any investment advice, opinion or other information on whether the sale of the Options is prudent.

(g) No General Solicitation. At no time has Transferor presented Transferee with or solicited Transferee through any publicly issued or circulated newspaper, mail, radio, television or other form of general advertisement or solicitation in connection with the sale and transfer of the Options.

(h) No Broker-Dealer. Transferor has not effected the sale and transfer of the Options by or through a broker-dealer in any public offering.

5. Informed Decision; Investigation; Future Gains; Tax Consequences; Etc.

(a) Each of Transferor and Transferee (collectively, the "Transacting Parties") has entered into this Agreement based on its knowledge, investigation and analysis. Each of the Transacting Parties acknowledges that the Purchase Price being paid by the Transferee was negotiated at arm's-length, may not represent the fair market value of the Options, and that the Options may have a current or future value greater or lesser than the amount paid for the Options under this Agreement. Each of the Transacting Parties understands that the Corporation's plans for the future may result in the Options [and/or Exercise Shares] becoming significantly more or less valuable, and that the future value of the Options could be greater or lesser than the Purchase Price. Neither the Corporation nor any of its agents has made any representation to the parties about the advisability of this decision or the potential future value of the Options [and/or Exercise Shares]. Each of the Transacting Parties has the capacity to protect its own interests in connection with the transactions contemplated by this Agreement by reason of its business or financial experience or the business or financial experience of its professional advisors who are unaffiliated with, and who are not compensated by the Corporation. Each of the Transacting Parties agrees that neither the Corporation, the other Transacting Party, nor any of their respective affiliated parties are under any obligation to disclose to such party any information or opinion they may have about the potential future value of the Corporation's capital stock, even if such information is material, and each of the Transacting Parties has determined to enter into this Agreement notwithstanding such lack of information. Each of the Transacting Parties hereby acknowledges that any future sale of shares of the Corporation's capital stock could be at a premium or a discount to the Purchase Price, and such sale could occur at any time or not at all. Each of the Transacting Parties hereby acknowledges that it has not relied on any representation or statement of the Corporation or its counterparty in this transaction, other than those set forth in this Agreement, in making its investment decision to enter into this Agreement.

(b) Each of the Transacting Parties further acknowledges that it has received all information it has deemed appropriate or necessary to enable such Transacting Party to evaluate its decision to enter into this Agreement. Without limiting the foregoing, each of the Transacting Parties expressly acknowledges that (i) the other parties to this Agreement currently may have, and later may come into possession of, information with respect to the Corporation that is not known to such Transacting Party and that may be material to a decision to sell the Options ("Excluded Information"), (ii) each of the Transacting Parties has determined to enter into this Agreement notwithstanding its lack of knowledge of the Excluded Information, and (iii) the parties shall have no liability to one another, and the parties hereto waive and

release any claims that it might have against any other party hereto whether under applicable securities laws or otherwise, with respect to the nondisclosure of the Excluded Information in connection with the transactions contemplated by this Agreement.

6. Corporation Consent. The Corporation fully consents to the transfer of the Options under this Agreement and hereby waives all applicable notice requirements and all applicable transfer restrictions and requirements under the [Plan and each of the other] Related Agreements with respect to the transactions contemplated hereunder.

7. Release.

(a) The Transferor and Transferee each, on behalf of itself and on behalf of its predecessors and successors, past and present agents, representatives, partners, directors, officers, attorneys, employees, servants, shareholders, affiliates, subsidiaries, heirs, executors, administrators and assigns, as well as any person acting by, through, under or in concert with any of the foregoing does hereby release and forever discharge the other Transacting Party, the Corporation, and each party's predecessors and successors, past and present agents, representatives, partners, directors, officers, attorneys, employees, servants, shareholders, affiliates, subsidiaries, heirs, executors, administrators and assigns, as well as any person acting by, through, under or in concert with any of the foregoing, from any and all claims, demands, causes of action, obligations, damages, losses, liabilities, contracts, agreements, promises, debts, costs and expenses of any kind whatsoever, whether at law or in equity, asserted or unasserted, known or unknown, suspected or unsuspected, fixed or contingent (collectively, "Claims" and individually, "Claim"), which such party ever had, now has, or may claim to have against the other Transacting Party or the Corporation, relating to or arising from the transfer and sale of the Options.

(b) The Transferor and Transferee each hereby acknowledge, severally and not jointly, that it has been advised by legal counsel, is familiar with and fully understands the provisions of California Civil Code Section 1542 (or similar provision in the jurisdiction in which such party resides) which provides as follows: "A general release does not extend to claims that the creditor or releasing party does not know or suspect to exist in his or her favor at the time of executing the release, and that, if known by him or her, would have materially affected his or her settlement with the debtor or released party." Having been so advised, each of the Transferor and Transferee nevertheless elects to and does assume all risks for Claims known or unknown, suspected or unsuspected, heretofore arising from the subject of this Section 7, and specifically waives any rights it may have under Section 1542, as well as under any other applicable statute or common-law principle with a similar effect.

8. Miscellaneous.

(a) Governing Law. The validity, interpretation, construction and performance of this Agreement, and all acts and transactions pursuant hereto and the rights and obligations of the parties hereto shall be governed, construed and interpreted in accordance with the laws of the state of Delaware, without giving effect to principles of conflicts of law.

(b) Entire Agreement; Amendment. The Related Agreements set forth the entire agreement and understanding of the parties relating to the subject matter therein and supersede all prior or contemporaneous discussions, understandings and agreements, whether oral or written, between them relating to the subject matter hereof. No modification of or amendment to this Agreement, nor any waiver of any rights under this Agreement, shall be effective unless in writing signed by the parties to this Agreement.

(c) Notices. Any notice, demand or request required or permitted to be given under this Agreement shall be in writing and shall be deemed sufficient when delivered personally or by overnight courier or sent by email, or 48 hours after being deposited in the U.S. mail as certified or registered mail with postage prepaid, addressed to the party to be notified at such party's address as set forth on the signature page, as subsequently modified by written notice, or if no address is specified on the signature page, at the most recent address set forth in the Corporation's books and records.

(d) Severability. If one or more provisions of this Agreement are held to be unenforceable under applicable law, the parties agree to renegotiate such provision in good faith. In the event that the parties cannot reach a mutually agreeable and enforceable replacement for such provision, then (i) such provision shall be excluded from this Agreement, (ii) the balance of the Agreement shall be interpreted as if such provision were so excluded and (iii) the balance of the Agreement shall be enforceable in accordance with its terms.

(e) Electronic Delivery. The Corporation may, in its sole discretion, decide to deliver any documents or any notices required by applicable law or the Corporation's Certificate of Incorporation or Bylaws by email or any other electronic means. Transferee hereby consents to (i) conduct business electronically (ii) receive such documents and notices by such electronic delivery and (iii) sign documents electronically and agrees to participate through an on-line or electronic system established and maintained by the Corporation or a third party designated by the Corporation.

(f) Counterparts. This Agreement may be executed in any number of counterparts, each of which when so executed and delivered shall be deemed an original, and all of which together shall constitute one and the same agreement. Counterparts may be delivered via electronic mail (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, e.g., www.docusign.com) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

(g) Successors and Assigns. Except as otherwise provided in this Agreement, this Agreement, and the rights and obligations of the parties hereunder, will be binding upon and inure to the benefit of their respective successors, assigns, heirs, executors, administrators and legal representatives. The Corporation may assign any of its rights and obligations under this Agreement.

(h) Shareholder Agreements. Transferor and the Corporation acknowledge and agree that, effective as of immediately following the transfer of the Options pursuant to Section 1, Transferor shall cease to be shareholder of the Corporation and shall cease to be an "Investor" or "Key Holder" (as applicable) under, or otherwise be a party to, the Voting Agreement or ROFR and Co-Sale Agreement (each as defined on Exhibit A).

[*Signature Page Follows*]

The parties have executed this Option Purchase and Transfer Agreement as of the date first written above.

TRANSFEROR:

[●]

_____

Name: [●]

Address:

The parties have executed this Option Purchase and Transfer Agreement as of the date first written above.

TRANSFEREE:

CULLINAN ONCOLOGY, INC.

By:_
Name: Nadim Ahmed
Title: President and CEO

The parties have executed this Option Purchase and Transfer Agreement as of the date first written above.

CORPORATION:

CULLINAN MICA CORP.

By:_
Name:
Title:

EXHIBIT A

RELATED AGREEMENTS

1. The Amended and Restated Certificate of Incorporation of the Corporation (the "Charter").

2. The Bylaws of the Corporation (the "Bylaws").

3. The Voting Agreement, dated as of May 28, 2020, by and among the Corporation and the other parties thereto, as amended (the "Voting Agreement").

4. The Right of First Refusal and Co-Sale Agreement, by and among the Corporation and the other parties thereto, dated as of May 28, 2020 (the "ROFR and Co-Sale Agreement").

EXHIBIT B

STOCK POWER

FOR VALUE RECEIVED and pursuant to that certain Stock Purchase and Transfer Agreement by and among [●] ("Transferor"), Cullinan Oncology, Inc., a Delaware corporation ("Transferee"), and Cullinan MICA Corp., a Delaware corporation (the "Corporation"), the Transferor hereby assigns and transfers unto Transferee [●] shares of the Corporation's Common Stock, whether held in certificated or uncertificated form, and does hereby irrevocably constitute and appoint the Corporation as transfer agent with authority to transfer said stock on the books of the Corporation with full power of substitution in the premises.

Date: ___

TRANSFEROR:

[●]

By:_
Name: [●]

Certain confidential information contained in this document, marked by [***], has been omitted because it is not material and would likely cause competitive harm to Cullinan Oncology, Inc. if publicly disclosed.

Massachusetts Institute of Technology

and

Cullinan Amber Corp.

SECOND AMENDMENT

This Second Amendment, effective as of December 20, 2022 (the "Second Amendment Effective Date") is made by and between the Massachusetts Institute of Technology, a nonprofit research institution having a principal address at 77 Massachusetts Avenue, Cambridge, MA 02139 ("M.I.T.") and Cullinan Amber Corp. ("Company"), a Delaware corporation, with a principal place of business at One Main Street, Cambridge, MA 02142. M.I.T. and Company are parties to that certain Exclusive Patent License Agreement dated December 20, 2019 (the "License Agreement"), and amended by the First Amendment, dated April 3, 2020. M.I.T. and Company may be referred to herein individually as a "Party" or, collectively as the "Parties." All capitalized terms used herein that are not otherwise defined herein shall have their respective meanings as set forth in the License Agreement.

WHEREAS, the License Agreement granted Company a Limited Term Option to Expansion Fields, and:

WHEREAS, Company has requested an extension of said option term with respect to cytokines other than IL2 or IL12 and M.I.T. agrees to grant such extension;

NOW, THEREFORE, the Parties agree to amend the LICENSE AGREEMENT as follows:

1. Sections 1.8 is hereby deleted in its entirety and replaced with the following:
   1.8 "**Expansion Field**" shall mean a protein collagen binding domain fused to [***].
2. Section 2.2 (a) is hereby deleted in its entirety and replaced with the following:
   (a) Limited-Term Option to Expansion Field.
   (i) MIT hereby grants Company an exclusive option to amend the Field to include the Expansion Field (the "Option Right"), provided however, that the Company's exercise of such Option Right is contingent on Company providing MIT with a research and development plan, including specific mutually acceptable diligence requirements, such diligence requirements to be added by amendment to this Agreement for the commercial development of Licensed Products in the Expansion Field.
   (ii) Company may exercise the Option Right upon written notice to MIT on or before the [***] of the Effective Date (the "Option Period"). Company and MIT will enter into a written amendment to this Agreement with respect to any mutually agreed upon change(s) in accordance with this Section 2.2. Company will pay MIT an Amendment Fee of [***] for addition of the Expansion Field so added to this Agreement and, as agreed to by the Parties through good faith negotiations, Company's financial obligations under Sections 4.1(c) and (f) shall be amended with respect to Licensed Products in the Expansion Field to reflect the additional rights and value being added. If Company does not elect to exercise the Option Right or fails to exercise the Option Right during the Option Period with respect to the Expansion Field, or if MIT and Company are

unable to reach agreement on acceptable diligence milestones and/or financials for the Expansion Field within [***] after Company has exercised the Option Right, Company's rights with respect to the Expansion Field under this Section 2.2 shall expire.

3. Except as specifically amended herein, the terms and conditions of the License Agreement shall remain in full force and effect.

IN WITNESS WHEREOF, the parties have caused this Second Amendment to be executed by their duly authorized representatives as of the Second Amendment Effective Date.

MASSACHUSETTS INSTITUTE OF TECHNOLOGY	CULLINAN AMBER CORP.
By: /s/ Lauren Foster	By: /s/ Jennifer Michaelson
Name: Lauren Foster	Name: Jennifer Michaelson
Title: Associate Director, MIT TLO	Title: Chief Development Officer, Biologics

AMENDMENT NUMBER 1

TO

ROYALTY TRANSFER AGREEMENT

This Amendment Number 1 to Royalty Transfer Agreement (this "**Amendment**"), dated as of June 6, 2022, is made by and among Cullinan Pearl Corp., a Delaware corporation (the "**Company**"), MPM Oncology Charitable Foundation, Inc., a Massachusetts charitable foundation ("**MPM Charitable Foundation**") and the UBS Optimus Foundation, a Swiss charitable foundation ("**Optimus**," and together with the MPM Charitable Foundation, each a "**Charitable Foundation**" and together, the "**Charitable Foundations**") and amends that certain Royalty Transfer Agreement, dated as of October 25, 2019, by and among the Company and the Charitable Foundations (the "**Royalty Transfer Agreement**"). All capitalized terms used herein that are not otherwise defined herein shall have their respective meanings as set forth in the Royalty Transfer Agreement.

RECITALS

WHEREAS, the Company and the Charitable Foundations wish to amend the terms of the Royalty Transfer Agreement as set out in this Amendment;

NOW, THEREFORE, in consideration of the promises and mutual covenants hereinafter contained and other valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Company and the Charitable Foundations hereby agree as follows:

1. **Amendment.** The definition of "Company Products" set forth in Section 1 of the Royalty Transfer Agreement shall be deleted in its entirety and replaced with the following:

    ""**Company Products**" shall mean any pharmaceutical product containing that certain chemical compound coded by Company as of the date hereof as TAS6417, also sometimes referred to as CLN-081, *provided, however* that Company Products do not include, and the payment obligations hereunder shall not apply to, any products owned or controlled by Taiho Pharmaceutical Co., Ltd that are commercialized by or on behalf of Taiho Pharmaceutical Co., Ltd in Japan."

2. **Counterparts.** This Amendment may be executed in any number of counterparts, each of which shall be deemed an original and all of which together shall constitute one and the same instrument.

3. **Effect on Agreement.** Except as specifically amended by this Amendment, the Royalty Transfer Agreement will remain in full force and effect and is hereby ratified and confirmed. To the extent a conflict arises between the terms of the Royalty Transfer Agreement and this Amendment, the terms of this Amendment shall prevail but only to the extent necessary to accomplish their intended purpose.

4. **Governing Law.** This Amendment will be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts.

In Witness Whereof, the parties, through their duly authorized representatives, have signed this Amendment on the dates set forth beneath their respective signatures below.

Cullinan Pearl Corp.

By: /s/ Nadim Ahmed

Print Name: Nadim Ahmed

Title: President

MPM Oncology Charitable Foundation, Inc.

By: /s/ Kristen Laguerre

Print Name: Kristen Laguerre

Title: Authorized Signatory

UBS Optimus Foundation

By: /s/ Nina Hoppe

Print Name: Nina Hoppe

Title: Operating Head GSI

And

By: /s/ Haibo Wunderli-Ye

Print Name: Haibo Wunderli-Ye

Title: Head of Business Management

Exhibit 21.1

SUBSIDIARIES

Subsidiary	Jurisdiction of Organization
Cullinan Amber Corp.	Delaware
Cullinan Florentine Corp.	Delaware
Cullinan Mica Corp.	Delaware
Cullinan Securities Corp.	Massachusetts

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the registration statements (No. 333-251943 and 333-263428) on Form S-8 of our report dated March 9, 2023, with respect to the consolidated financial statements of Cullinan Oncology, Inc.

/s/ KPMG LLP

Boston, Massachusetts
March 9, 2023

Exhibit 31.1

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

I, Nadim Ahmed, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2022 of Cullinan Oncology, Inc. (the "registrant");

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

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

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

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

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

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

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

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

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

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

Date: March 9, 2023

By: /s/ Nadim Ahmed

Nadim Ahmed
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, Jeffrey Trigilio, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2022 of Cullinan Oncology, Inc. (the "registrant");

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

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

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

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

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

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

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

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

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

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

Date: March 9, 2023

By: /s/ Jeffrey Trigilio

Jeffrey Trigilio
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATIONS OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Cullinan Oncology, Inc. (the "Company") on Form 10-K for the period ending December 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of their knowledge:

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

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

Date: March 9, 2023

By: /s/ Nadim Ahmed

Nadim Ahmed
President and Chief Executive Officer
(Principal Executive Officer)

Date: March 9, 2023

By: /s/ Jeffrey Trigilio

Jeffrey Trigilio
Chief Financial Officer
(Principal Financial and Accounting Officer)