

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

Amendment No. 3 to

FORM S-1

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

CULLINAN MANAGEMENT, INC.

(Exact name of Registrant as specified in its charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

2836
(Primary Standard Industrial
Classification Code Number)

81-387991
(I.R.S. Employer
Identification Number)

One Main Street
Suite 520
Cambridge, MA 02142
(617) 410-4650

(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

Owen Hughes
President and Chief Executive Officer
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**Approximate date of commencement of the proposed sale to the public:
As soon as practicable after the effective date of this Registration Statement.**

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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 7(a)(2)(B) of the Securities Act.

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered ⁽¹⁾	Proposed Maximum Offering Price Per Share ⁽²⁾	Proposed Maximum Aggregate Offering Price ⁽³⁾	Amount of Registration Fee ⁽⁴⁾
Common Stock, par value \$0.0001 per share	11,500,000	\$20.00	\$230,000,000	\$25,093

- (1) Includes 1,500,000 shares that the underwriters have the option to purchase.
- (2) Estimated solely for the purpose of computing the registration fee in accordance with Rule 457(a) under the Securities Act of 1933, as amended.
- (3) Includes the aggregate offering price of 1,500,000 shares that the underwriters have the option to purchase to cover over-allotments.
- (4) Calculated pursuant to Rule 457(a) under the Securities Act of 1933 as amended. \$19,866 of this registration fee was previously paid by the Registrant in connection with the filing of its Registration Statement on Form S-1 on January 4, 2021.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

EXPLANATORY NOTE

We currently operate as Cullinan Oncology, LLC, or the LLC entity, a Delaware limited liability company. On September 15, 2016, we formed Cullinan Management, Inc., a Delaware corporation, or the Corporation, which is the registrant whose name appears on the cover of this registration statement and is a direct wholly-owned subsidiary of the LLC entity. Prior to the completion of this offering, pursuant to a Contribution Agreement, the LLC entity will contribute all of the stock it owns of each of Cullinan Apollo Corp., Cullinan Florentine Corp., Cullinan Amber Corp., Cullinan Pearl Corp., and Cullinan MICA Corp., or collectively, the Asset Subsidiaries, to the Corporation in exchange for common stock of the Corporation, and as a result, the Asset Subsidiaries will become subsidiaries of the Corporation, or the Contribution. Following the Contribution and prior to the completion of this offering, the LLC entity will merge with and into the Corporation with the Corporation being the surviving entity of such merger, or the LLC Merger. As a result of this merger, the holders of existing units in the LLC entity will exchange those units for corresponding shares of capital stock of the Corporation.

We refer to these transactions throughout the prospectus included in this registration statement collectively as the “Reorganization.” See “Reorganization” for further detail regarding these transactions. On the effective date of the Reorganization, the members of the board of managers of the LLC entity will become the members of the board of directors of the Corporation and the officers of the LLC entity will become the officers of the Corporation.

Shares of the common stock of the Corporation are being offered by the prospectus included in this registration statement.

Except where the context otherwise requires or where otherwise indicated, all share and per share amounts in this registration statement reflect and assume (i) the Reorganization, including the exchange of units of the LLC for corresponding shares of capital stock of the Corporation and (ii) subsequent to the Reorganization, a one-for-7.0390 reverse split of the Corporation’s common stock, which will become effective prior to the completion of this offering.

FINANCIAL STATEMENT PRESENTATION

Except as disclosed in the accompanying prospectus, the audited consolidated financial statements for the years ended December 31, 2018 and 2019 and the notes thereto and the condensed consolidated financial statements as of and for the nine months ended September 30, 2019 and 2020 and the notes thereto and selected historical consolidated financial data and other financial information included in this registration statement are those of the LLC entity and do not give effect to the Reorganization.

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The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities, and we are not soliciting offers to buy these securities in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED JANUARY 6, 2021
Preliminary Prospectus

10,000,000 Shares



Common Stock

We are offering 10,000,000 shares of our common stock. This is our initial public offering and no public market currently exists for our common stock. We expect the initial public offering price to be between \$19.00 and \$20.00 per share. Our common stock has been approved for listing on The Nasdaq Global Select Market under the trading symbol "CGEM".

We are an "emerging growth company" and "smaller reporting company" as defined under the U.S. federal securities laws and will be subject to reduced public company reporting requirements for this prospectus and future filings. See "Prospectus Summary—Implications of Being an Emerging Growth Company and a Smaller Reporting Company."

Investing in our common stock involves a high degree of risk. Please read "[Risk Factors](#)" beginning on page 16 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	<u>PER SHARE</u>	<u>TOTAL</u>
Initial public offering price	\$	\$
Underwriting discounts and commissions ⁽¹⁾	\$	\$
Proceeds, before expenses, to us	\$	\$

(1) See "Underwriting" for a description of all compensation payable to the underwriters.

We have granted the underwriters an option for a period of 30 days from the date of this prospectus to purchase an additional 1,500,000 shares of common stock.

The underwriters expect to deliver the shares of common stock against payment in New York, New York on or about _____, 2021.

Joint Book-Running Managers

MORGAN STANLEY

SVB LEERINK

EVERCORE ISI

Lead Manager

H.C. WAINWRIGHT & CO.

The date of this prospectus is _____, 2021.

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Neither we nor the underwriters have authorized anyone to provide any information other than that contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus is accurate only as of the date on the front cover of this prospectus. Our business, financial condition, results of operations, and prospects may have changed since that date.

Through and including _____, 2021 (the 25th day after the date of this prospectus), all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

For investors outside of the United States: We have not, and the underwriters have not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the United States. Persons outside of the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside of the United States.

Except as disclosed in this prospectus, the audited consolidated financial statements for the years ended December 31, 2018 and 2019 and the notes thereto and the condensed consolidated financial statements as of and for the nine months ended September 30, 2019 and 2020 and the notes thereto, and selected historical consolidated financial data and other financial information included in this registration statement are those of the LLC entity and do not give effect to the Reorganization described below.

Certain numerical figures included in this prospectus have been rounded. Accordingly, numerical figures shown as totals in various tables may not be arithmetic aggregations of the figures that precede them.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before investing in our common stock, you should read the entire prospectus carefully, including the sections entitled “Risk Factors,” “Special Note Regarding Forward-Looking Statements,” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated financial statements and the related notes.

Prior to the completion of this offering, we will complete a series of transactions pursuant to which Cullinan Oncology, LLC will merge with and into its wholly-owned subsidiary, Cullinan Management, Inc., a Delaware corporation, with Cullinan Management, Inc. being the surviving entity of such merger and the entity whose shares are being offered hereby. Prior to the merger, Cullinan Oncology, LLC will contribute all of the stock it owns in each of Cullinan Apollo Corp., Cullinan Florentine Corp., Cullinan Amber Corp., Cullinan Pearl Corp., and Cullinan MICA Corp., to Cullinan Management, Inc., in exchange for common stock of Cullinan Management, Inc. See “Reorganization.” Except where the context otherwise requires or where otherwise indicated, the terms “Cullinan,” “we,” “us,” “our,” “our company,” “the company,” and “our business” refer, prior to the Reorganization discussed below, to Cullinan Oncology, LLC and its consolidated subsidiaries and, after the Reorganization, to Cullinan Management, Inc. and its consolidated subsidiaries.

Overview

We are a biopharmaceutical company focused on developing a diversified pipeline of targeted oncology and immuno-oncology therapies with transformative potential for cancer patients. Our strategy is to build a pipeline of therapeutic candidates that are uncorrelated across multiple dimensions, with a focus on assets that we believe have novel technology, employ differentiated mechanisms, are in a more advanced stage of development than competing candidates, or have a combination of these attributes. In approximately three and a half years, we have efficiently developed or in-licensed a pipeline of seven distinct programs by leveraging our hub-and-spoke business model. We continue to prioritize probability of success and capital efficiency. Specifically, before we advance a therapeutic candidate into clinical development, we evaluate its ability to generate an immune system response or to inhibit oncogenic drivers as a single agent. Importantly, we have terminated programs that do not meet our rigorous criteria for advancement and will continue to do so when we believe we can more efficiently allocate our capital. We currently have one clinical-stage targeted oncology candidate in Phase 1/2a development and six preclinical immuno-oncology therapeutic candidates and programs. We believe our approach will allow us to advance at least one therapeutic candidate into the clinic and one program into IND-enabling studies each year for at least the next several years.

Our lead candidate, CLN-081, is an orally available small molecule designed as a next generation, irreversible epidermal growth factor receptor, or EGFR, inhibitor that is designed to selectively target cells expressing mutant EGFR variants, including EGFR exon 20 insertion, or EGFRex20ins, mutations, with relative sparing of cells expressing wild type EGFR. We are currently evaluating CLN-081 as a treatment for non-small cell lung cancer, or NSCLC, in adult patients with EGFRex20ins mutations in a Phase 1/2a trial. Our most advanced immuno-oncology therapeutic candidates include CLN-049, a bispecific antibody targeting FLT3 and CD3; and CLN-619, a monoclonal antibody designed to stimulate natural killer, or NK, and T cell responses by engaging a unique target, MICA/B. We intend to initially develop CLN-049 for the treatment of acute myeloid leukemia, or AML, and CLN-619 for the treatment of solid tumors. In addition, through our AMBER platform, we are developing CLN-617, a fusion protein uniquely combining, in a single agent, two potent antitumor cytokines, interleukin-2, or IL-2, and interleukin-12, or IL-12, fused with a collagen-binding domain designed to enable tumor retention for the treatment of solid tumors. Our pipeline includes three additional immuno-oncology programs in the lead optimization stage that we believe have compelling mechanisms of action and potential for clinical development. We currently hold worldwide development and commercialization rights to each of our therapeutic candidates, except for CLN-081 in Japan and Greater China (China, Hong Kong, Taiwan and Macau).

The Cullinan Approach

Our mission is to advance and grow a portfolio of innovative, early-stage oncology assets based on the latest scientific breakthroughs. Given these foundations, we think about capital allocation and risk as much as we think about drug development. By focusing our efforts on translational medicine and portfolio diversification, we seek to mitigate overall exposure to many of the inherent risks of drug development. Fundamental to our success is our ability to apply a disciplined set of criteria for asset evaluation and advancement, as well as sequenced capital allocation that preserves resources for programs with greater potential. Our approach is guided by the following core elements:

- Portfolio diversification to mitigate risk and maximize optionality
- Capital allocation based on risk-adjusted potential, including staged funding to pre-specified scientific and clinical results
- Virtual infrastructure and key external relationships to maintain a lean operating base
- Internal development capabilities complemented by external business development
- Focus on translational medicine and therapeutic candidates with *in vivo* single agent activity
- Disciplined asset evaluation and selection

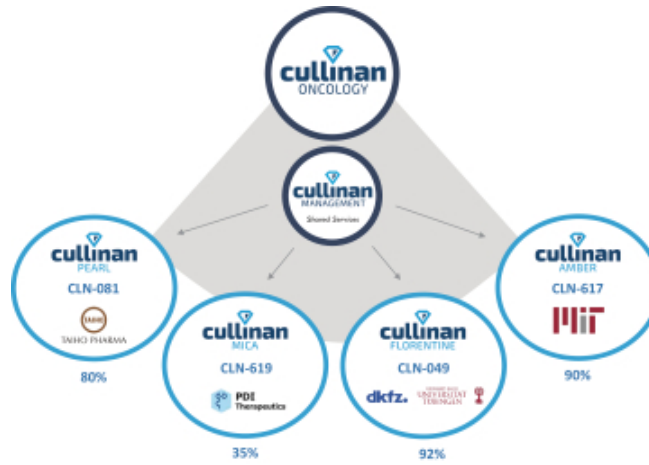
Our Hub-and-Spoke Business Model

We employ a hub-and-spoke business model to execute our strategy of building a diversified oncology company in a capital efficient manner and to provide us with the flexibility to either advance therapeutic candidates ourselves or through transactions with third parties. Our “hub” consists of a holding company, Cullinan Oncology, LLC, or the LLC entity, and an operating company, Cullinan Management, Inc., or Cullinan Management, which, collectively, provide capital, human resources, and other services to each spoke via a shared services agreement. We believe that by centralizing these shared services, including all research and development operations, administrative services, and business development, and allocating employees and resources to each spoke, we can enhance operational efficiency and maintain an optimal cost structure. For example, as of December 31, 2020, we had 20 full time employees and two consultants working on a pipeline of seven active programs. See “Certain Relationships and Related Person Transactions—Agreements with our Subsidiaries—Services Agreements” for more information.

Our hub-and-spoke model also enables us to access both internal and external expertise to build and develop our pipeline. We incubate internal programs, such as NexGem, Opal, and Jade, in our hub, leveraging Cullinan Management’s network of service providers as needed to support our discovery, lead optimization, and IND-enabling efforts. When we decide to license from or collaborate with external parties, we establish distinct subsidiaries, or “spokes”, to hold and advance those programs. This structure enables us to keep licensors economically incentivized at the program level through our ability to offer equity and access to potential cash milestones and royalty payments. Further, because each spoke is a separate legal entity that holds all of the assets related to the development candidate, including the relevant intellectual property, and has no employees, fixed assets, or overhead costs, we have flexibility both to raise capital at either the parent or subsidiary level and to pursue subsidiary-level licenses or stock sales. See “Business—Our Hub-and-Spoke Business Model” for more information.

In the figure below, each “spoke” contains the subsidiary’s therapeutic candidate as well as any relevant licensors or shareholders. The LLC entity’s approximate ownership, as of December 31, 2020, as a percentage of fully-diluted shares outstanding is listed below each circle.

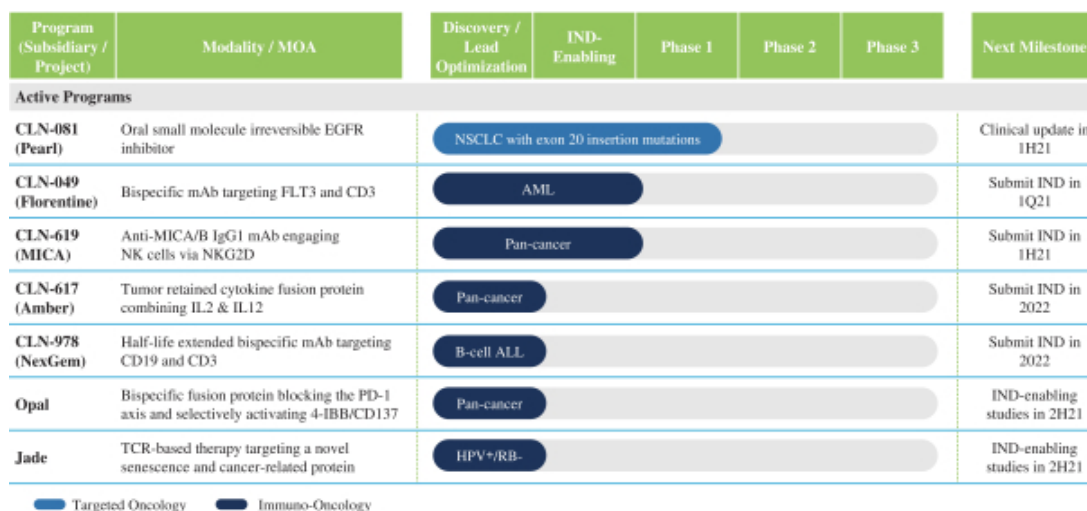
Our Hub-and-Spoke Business Model



The structure of our financing arrangements with each subsidiary enable us to increase our economic ownership when we provide additional capital. Further information about our subsidiaries, including ownership and governance, is included in the “Management’s Discussion and Analysis” section of this prospectus.

Our Pipeline

We have built a pipeline of targeted oncology and immuno-oncology therapeutic candidates and programs that are diversified by mechanism, therapeutic approach, modality, and stage of development. On a quarterly basis, we rigorously assess each of our programs using internally defined success criteria 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. Our current pipeline is summarized in the diagram below:



Our Programs

CLN-081

CLN-081 is an orally available small molecule designed as a next generation, irreversible EGFR inhibitor in development for the treatment of a genetically defined subset of patients with NSCLC. CLN-081 is being developed by our partially-owned subsidiary Cullinan Pearl, and is currently in a Phase 1/2a dose escalation and expansion trial evaluating oral, twice-daily, or BID, administration of various doses in patients with NSCLC harboring EGFRex20ins mutations that have had at least one prior treatment with platinum based chemotherapy or another approved standard therapy. We licensed worldwide rights, excluding Japan, to CLN-081 from Taiho Pharma in 2018, and we recently sublicensed such rights to Zai Lab (Shanghai) Co., Ltd. in Greater China in exchange for an upfront fee, milestones, and royalties. For additional information, see “License Agreements —Zai Lab License Agreement.” In September 2020, at the European Society for Medical Oncology virtual congress, we disclosed preliminary results based on the first 22 patients dosed in this ongoing trial. As of September 1, 2020, amongst 17 evaluable patients across all dose cohorts, we observed a best overall response of partial response in six patients and stable disease in 11 patients. The partial responses included two confirmed and four unconfirmed partial responses, three of whom had not yet reached a confirmatory scan and one who progressed prior to a confirmatory scan. As of the September 1, 2020 data cut-off, no dose limiting toxicities, or DLTs, or Grade 3 treatment-related adverse events, or TRAEs, had been reported. As of the November 10, 2020 data cut-off, amongst 25 evaluable patients across all dose cohorts, we observed a best overall response of partial response in 10 patients, stable disease in 14 patients, and disease progression in one patient. The partial responses included six confirmed and four unconfirmed partial responses, two of whom had not yet reached a confirmatory scan. Regarding the two remaining patients with unconfirmed partial responses, one experienced progressive disease due to a new brain lesion and one died before their second scan after experiencing aspirational pneumonia that was deemed unrelated to study drug by the

investigator. As of the November 10, 2020 data cut-off, we observed one DLT, which was Grade 3 diarrhea TRAE in the 150mg BID dosing cohort, our highest dose evaluated to date, and one other Grade 3 TRAE, which was anemia. We observed no Grade 2 diarrhea TRAEs in the 30, 45, 65, or 100mg BID dose cohorts. We observed one Grade 2 diarrhea TRAE in the 150mg BID dose cohort. As of the November 10, 2020 data cutoff, we observed eight Grade 2 skin rash TRAEs across all dose cohorts. Although these results are preliminary and based on a small number of patients with limited follow-up, we believe that the preclinical and early clinical data as of the data cut-off collectively support the potential of CLN-081 to be a clinically active molecule with a favorable product profile. Given the trial was designed as a dose escalation and expansion study, we anticipate observing additional TRAEs as we enroll more patients and follow them over longer duration periods at higher dose levels. We intend to provide a clinical update in the first half of 2021.

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. Among EGFR mutations, EGFRex20ins mutations account for 7% to 13% of all EGFR mutations in NSCLC patients, with an estimated annual incidence of 2,000 to 5,000 patients in the U.S. and approximately 1,000 to 3,000 patients in France, Germany, Italy, Spain, and the United Kingdom, or EU5. These patients typically have poorer outcomes than those with common types of EGFR mutations, such as exon 19 deletion and exon 21 L858R substitution mutations. Currently, there are no targeted therapies approved for the treatment of NSCLC patients with EGFRex20ins mutations, and approved EGFR inhibitors do not adequately address the needs of this patient population.

CLN-049

CLN-049 is a humanized bispecific antibody that we are developing at our partially-owned subsidiary Cullinan Florentine for the treatment of AML. CLN-049 is designed to simultaneously bind to FLT3 on target leukemic cells and to CD3 on T cells, triggering the T cells to kill the targeted cancer cells via their intrinsic cytolytic mechanisms. FLT3 is expressed frequently on AML cells and leukemic blasts but minimally on healthy blood cells, unlike other tumor surface antigens identified in AML, such as CD33 and CD123. 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. Furthermore, by targeting the extracellular domain of FLT3, we believe CLN-049 has the potential to address a broader patient population than existing small molecule FLT3 kinase inhibitors acting within the intracellular domain, but are limited to a subset of approximately 25% of AML patients with certain mutations. We have observed that CLN-049 led to potent FLT3-dependent killing of leukemic cells *in vitro* at a wide range of FLT3 expression levels on AML cells. In preclinical studies, treatment with CLN-049, even at low doses, led to survival benefit in an AML xenograft model and complete elimination of leukemic blasts in various mouse models implanted with primary patient leukemic cells or AML cell lines. We have completed IND-enabling pharmacology, pharmacokinetic, and safety studies, and we expect to submit our IND for CLN-049 in the first quarter of 2021.

CLN-619

CLN-619, which is being developed by our partially-owned subsidiary Cullinan MICA, is a MICA/B-targeted, humanized IgG1 monoclonal antibody that we are initially developing for the treatment of patients with advanced solid tumors. CLN-619 was designed to promote an antitumor response through multiple mechanisms of action, including engagement of NK and T cells for enhanced lysis of cancer cells. The MICA/B receptor, NKG2D, is expressed in both innate and adaptive effector cell populations. Although several companies have disclosed preclinical programs targeting MICA/B, we are unaware of any clinical-stage programs in development. In preclinical studies, CLN-619 demonstrated antitumor activity as a single agent in multiple *in vivo* models. 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 biologic rationale for combining CLN-619 with other agents. We have completed IND-enabling pharmacology and toxicology studies and are completing good manufacturing practice, or GMP, process work to support an IND submission in the first half of 2021.

CLN-617

We are also developing CLN-617, a fusion protein uniquely combining, in a single agent, two antitumor cytokines, IL-2 and IL-12, with a collagen-binding domain for the treatment of solid tumors. This collagen-binding domain is designed to retain the cytokines in the tumor microenvironment following intratumoral administration, with the goal of minimizing systemic dissemination and associated toxicities of cytokines while prolonging their immunostimulatory antitumor activity. For nearly five decades, clinical researchers have characterized the powerful role cytokines play in stimulating an immune response to cancer. However, despite numerous advancements in protein engineering, delivery and targeting mechanisms, the short serum half-life and severe toxicities associated with systemic cytokine administration have hindered their clinical development and commercial uptake.

We believe that CLN-617, by utilizing a collagen-binding domain, has the potential to address these shortcomings and is the only anti-cancer therapeutic candidate in development that we are aware of that combines IL-2 and IL-12. In preclinical studies, murine surrogates of CLN-617 demonstrated robust single agent antitumor activity in both injected and non-injected contralateral tumors without inducing systemic toxicity, as measured by reduction in body weight. Based on these results, we believe CLN-617 may be capable of generating a systemic immune response that can mediate tumor regression, even in non-injected distal tumors. Given the broad expression of collagens across multiple tumor types and the well-validated antitumor activity of cytokine-based therapies, CLN-617 may have utility across many different types of solid tumors. CLN-617 is being developed by our partially-owned subsidiary Cullinan Amber, and we expect to submit an IND for CLN-617 in 2022. We refer to the collagen-binding technology used in CLN-617 as AMBER, which we believe represents a novel platform with the potential to broaden the therapeutic window of cytokines and other immunostimulatory agents by potentially reducing systemic toxicity.

CLN-978

CLN-978 is a half-life extended, humanized, single-chain T cell engaging antibody construct designed to simultaneously engage CD19 on target cancer cells and CD3 on T cells, triggering redirected T cells to lyse the target cancer cells. In addition to CD19 and CD3 binding domains, CLN-978 has a human serum albumin binding antibody domain, which is designed to prolong its serum half-life. We believe that by potentially extending the serum half-life of CLN-978, we can address limitations related to the dosing regimen of blinatumomab, the only CD19-targeting bispecific T cell engager approved for the treatment of relapsed or refractory B-cell acute lymphoblastic leukemia, or ALL, and potentially offer unique advantages and broader access for patients. CLN-978, referred to as NexGem, mediated highly potent CD19-dependent target cell lysis *in vitro* at various CD19 target expression levels. In preclinical *in vivo* studies, treatment with NexGem, at extremely low doses and with infrequent dosing, led to inhibition of tumor growth and tumor regression in a human CD3e transgenic lymphoma mouse model. CLN-978 is held in our wholly-owned subsidiary Cullinan Management, Inc. We intend to initially evaluate CLN-978 as a novel treatment for B-cell ALL, and expect to submit our IND for CLN-978 in 2022.

Our Other Research Stage Programs

In addition to the therapeutic candidates and programs described above, we are currently evaluating two discovery-stage immuno-oncology programs. Opal is a bispecific fusion protein that is designed to block the PD-1 axis and to selectively activate the 4-1BB/CD137 pathway on T cells in tumors. Jade is a cell therapy that is designed to target a novel senescence and cancer-related protein, and we are collaborating with the Fred Hutchinson Cancer Research Center to identify naturally occurring T cell receptors against this target.

Terminated Programs

Based on early preclinical and clinical results, we have terminated multiple programs in order to allocate resources to what we believe are more promising programs in our portfolio. We believe these decisions

demonstrate our commitment and discipline with respect to our strategy and business model. For example, Apollo, our oral small molecule targeting EBNA1, was terminated due to a lack of translation of the compelling pharmacodynamic effect and antitumor activity seen in preclinical studies into patients. We were able to efficiently evaluate this program with minimal costs, spending approximately \$10 million from initial licensing to date, including the costs related to the sponsored research agreement.

Our Strategy

Our goal is to develop targeted oncology and immuno-oncology therapeutics that will dramatically improve the standard-of-care for patients with cancer. The key elements of our strategy are to:

- Build a pipeline of differentiated oncology therapeutic candidates that are diversified by mechanism, therapeutic approach, modality, and stage of development
- Expand our pipeline through research collaborations, business development, and internally designed programs
- Advance our lead therapeutic candidate, CLN-081, toward potential regulatory approval for the targeted treatment of NSCLC patients with EGFRex20ins mutations
- Establish clinical proof-of-concept for our most advanced immuno-oncology therapeutic candidates, CLN-619 and CLN-049, in patients with solid tumors and hematological malignancies, respectively
- Continue to advance and evolve our pipeline with a goal of advancing one therapeutic candidate into the clinic and one program into IND-enabling studies each year
- Evaluate strategic opportunities to accelerate development timelines and maximize the value of our portfolio

Our History and Team

We began substantive operations in 2017 following Series A funding from F2 Ventures and the UBS Oncology Impact Fund, which is managed by MPM Capital and is one of the largest dedicated pools of capital focused exclusively on oncology investing. Since inception, we have raised approximately \$277.0 million from these investors as well as other institutional investors, including Foresite Capital, Boxer Capital of Tavistock Group, Eventide Asset Management, Nextech Invest, OrbiMed, Venrock Healthcare Capital Partners, Rock Springs Capital, BVF Partners, L.P., and Logos Capital. With less than \$60 million spent as of September 30, 2020, we have prudently built a diverse pipeline of seven uncorrelated targeted oncology and immuno-oncology programs.

Critical to our success has been the ability to assemble an accomplished management team with proven track records in targeted oncology and immuno-oncology. We are led by a senior management team with extensive capabilities in immuno-oncology, biologics and small molecule drug development, as well as business development and portfolio management. Collectively, our team possesses a strong record of success, as demonstrated by 36 accepted INDs and six approved new drug applications, or NDAs, or biologics license applications, or BLAs, and significant previous experiences at leading life sciences companies, including Alexion Pharmaceuticals, Inc., Amgen Inc., Biogen Inc., Bristol Myers Squibb Company, MacroGenics, Inc., Merck & Co., Inc., Novartis International AG, Pfizer Inc., and Sanofi S.A..

Summary of the Material Risks Associated with Our Business

Our business is subject to numerous risks and uncertainties that you should be aware of in evaluating our business. These risks include, but are not limited to, the following:

- 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.
- Following consummation of this offering, we will still need substantial additional funding. 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 use our differentiated hub-and-spoke business model to build a pipeline of product candidates with commercial value.
- 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.
- We are early in our development efforts and are substantially dependent on our lead candidate, CLN-081, and our most advanced immuno-oncology candidates, CLN-049 and CLN-619. If we are unable to advance CLN-081, CLN-049, or CLN-619, or any of our other product candidates through clinical development, or to obtain regulatory approval and ultimately commercialize CLN-081, CLN-049, or CLN-619, or any of our other 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.
- Interim, “topline,” and preliminary data from our clinical trials that we announce or publish from time to time 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 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.
- A single or limited number of subsidiaries may comprise a large proportion of our value.
- Difficulty in enrolling patients could delay or prevent clinical trials of our product candidates, and ultimately delay or prevent regulatory approval.
- 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 product candidates and technology, or any other product candidates or technology we may develop, 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 CLN-081, CLN-049, and CLN-619, 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.
- Our reliance on a central team consisting of a limited number of employees who provide various administrative, research and development, and other services across our organization presents operational challenges that may adversely affect our business.

- The outbreak of the novel coronavirus, COVID-19, may adversely impact our business, including our preclinical studies and clinical trials.
- We are highly dependent on our key personnel and anticipate hiring new key personnel. If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

The summary risk factors described above should be read together with the text of the full risk factors below, in the section entitled “Risk Factors” and the other information set forth in this prospectus, including our consolidated financial statements and the related notes, as well as in other documents that we file with the SEC. The risks summarized above or described in full below are not the only risks that we face. Additional risks and uncertainties not presently known to us, or that we currently deem to be immaterial may also materially adversely affect our business, financial condition, results of operations, and future, growth prospects.

Corporate Information

Cullinan Pharmaceuticals, LLC was formed in September 2016 and was subsequently renamed Cullinan Oncology, LLC in November 2017. Cullinan Oncology, LLC’s, or the LLC entity’s, wholly-owned subsidiary, Cullinan Management, Inc., or the Corporation, was formed in September 2016. Our principal executive offices are located at One Main Street, Suite 520, Cambridge, MA 02142 and our telephone number is (617) 410-4650. Our corporate website address is <https://www.cullinanoncology.com>. Information contained on or accessible through our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is an inactive textual reference only.

Prior to the completion of this offering, pursuant to a Contribution Agreement, or the Contribution Agreement, the LLC Entity will contribute all of the stock it owns of each of Cullinan Apollo Corp., Cullinan Florentine Corp., Cullinan Amber Corp., Cullinan Pearl Corp., and Cullinan MICA Corp., or collectively, the Asset Subsidiaries, to the Corporation in exchange for Common Stock of the Corporation that will result in the Asset Subsidiaries becoming subsidiaries of the Corporation, or the Contribution. Following the Contribution and prior to the completion of this offering, the LLC entity will merge with and into the Corporation, with the Corporation being the surviving entity. As a result of this merger, the holders of existing units in the LLC entity will exchange those units for corresponding shares of capital stock of the Corporation, after which those holders will have received 100% of the outstanding capital stock of the Corporation as of immediately prior to the completion of this offering. See “Reorganization” and “Description of Capital Stock” for additional information, including a description of the terms of our capital stock following the Reorganization and the terms of our second amended and restated certificate of incorporation, effective immediately prior to the closing of the offering, and amended and restated bylaws that will be effective upon the effectiveness of the registration statement of which this prospectus is a part.

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 prospectus are the property of their respective owners. Solely for convenience, the trademarks and trade names in this prospectus 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.

Implications of Being an Emerging Growth Company and a Smaller Reporting Company

We qualify as an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012, or JOBS Act, as amended. As an emerging growth company, we may take advantage of specified reduced

disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

- being permitted to only disclose two years of audited consolidated financial statements in addition to any required unaudited interim financial statements with correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure;
- reduced disclosure about our executive compensation arrangements;
- not being required to hold advisory votes on executive compensation or to obtain stockholder approval of any golden parachute arrangements not previously approved; and
- an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

We may take advantage of these exemptions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of \$1.07 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of this offering; (iii) the date on which we have issued more than \$1.0 billion in nonconvertible debt during the previous three years; or (iv) the last day of the fiscal year in which we are deemed to be a large accelerated filer under the rules of the U.S. Securities and Exchange Commission, or SEC, which means the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the prior June 30th. We may choose to take advantage of some but not all of these exemptions. We have taken advantage of reduced reporting requirements in this prospectus. Accordingly, the information contained herein may be different from the information you receive from other public companies in which you hold stock. In addition, we have elected to avail ourselves of the extended transition period for complying with new or revised accounting standards until the earlier of the date that we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period. As a result, we will be subject to the same new or revised accounting standards as private companies. Accordingly, our consolidated financial statements may not be comparable to the financial statements of public companies that comply with such new or revised accounting standards. We are in the process of evaluating the benefits of relying on other exemptions and reduced reporting requirements under the JOBS Act. Subject to certain conditions, as an emerging growth company, we may rely on certain of these exemptions in future filings, including without limitation, providing an auditor’s attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act.

We are also a “smaller reporting company” as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies until the fiscal year following the determination that either (i) the market value of our common stock held by non-affiliates is greater than \$700 million or (ii) the market value of our common stock held by non-affiliates 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.

THE OFFERING

Common stock offered by us	10,000,000 shares
Option to purchase additional shares	We have granted the underwriters an option, exercisable for 30 days after the date of this prospectus, to purchase up to 1,500,000 additional shares from us at the initial public offering price per share less the underwriting discounts and commissions.
Total common stock to be outstanding immediately after this offering	39,497,847 shares (or 40,997,847 shares if the underwriters exercise their option to purchase additional shares in full)
Use of proceeds	We estimate that we will receive net proceeds from the sale of our common stock in this offering of approximately \$178.5 million, or \$205.6 million if the underwriters fully exercise their option to purchase additional shares, assuming an initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and offering expenses payable by us. We intend to use the net proceeds from this offering, together with our existing cash, cash equivalents, and short term investments for (i) the completion of our Phase 1/2a trial of CLN-081, as well as the initiation of a later stage trial in treatment-experienced NSCLC patients with EGFRex20ins mutations; (ii) the advancement of CLN-049 and CLN-619 into Phase 1/2a clinical trials for patients with r/r AML and advanced solid tumors, respectively; (iii) the advancement of CLN-617 and CLN-978 through IND-enabling studies and, assuming success of those studies and subject to FDA review of an IND submission, the initiation of Phase 1/2a clinical trials; and (iv) the remaining proceeds for the continued advancement of our pipeline, including Jade and Opal, milestones for previously in-licensed programs, the identification and advancement of additional programs and development candidates, hiring of additional personnel, and costs of operating as a public company, and other general corporate purposes. See “Use of Proceeds” for additional information.
Directed share program	At our request, the underwriters have reserved up to 5% of the shares of common stock to be offered by this prospectus for sale, at the initial public offering price, to directors, officers, employees, business

associates and related persons of the Company. Except for any shares acquired by our directors or officers, shares purchased pursuant to the directed share program will not be subject to lock-up agreements with the underwriters. The number of shares of common stock available for sale to the general public will be reduced to the extent these individuals purchase such reserved shares. Any reserved shares that are not so purchased will be offered by the underwriters to the general public on the same basis as the other shares offered by this prospectus. See “Underwriting—Directed Share Program.”

Risk factors

You should read carefully “Risk Factors” beginning on page 16 and other information included in this prospectus for a discussion of factors that you should consider before deciding to invest in our common stock.

Nasdaq Global Select Market symbol

“CGEM”

The number of shares of our common stock to be outstanding after this offering gives effect to the Reorganization and is based on 29,497,847 shares of our common stock (which includes 1,689,949 shares of restricted common stock) outstanding as of September 30, 2020, which assumes the exchange of all outstanding units of Cullinan Oncology, LLC as of September 30, 2020 and 66,599,045 Series C preferred units issued after September 30, 2020 for an aggregate of 29,497,847 shares of common stock of our wholly-owned subsidiary Cullinan Management, (which includes 1,689,949 shares of restricted common stock) prior to the completion of this offering as if such exchange had occurred as of September 30, 2020. See the section of the prospectus titled “Reorganization.”

The number of shares of our common stock to be outstanding immediately following the completion of this offering excludes:

- 12,226,158 shares of our common stock reserved for future issuance under our 2021 Stock Option and Incentive Plan, or the 2021 Plan, which includes currently outstanding equity awards comprised of (i) 4,616,187 shares of common stock issuable upon the exercise of stock options at a weighted average exercise price of \$4.30; and (ii) an aggregate of 1,753,316 shares of our common stock, which will be granted to certain of our executive officers and other employees at the time of effectiveness of the 2021 Plan with an exercise price equal to the initial public offering price per share;
- 320,228 shares of restricted common stock outstanding under our 2021 Plan after September 30, 2020; and
- 416,665 shares of our common stock reserved for future issuance under our 2021 Employee Stock Purchase Plan, or 2021 ESPP, which will become effective in connection with this offering.

Except as otherwise noted, all information in this prospectus assumes or gives effect to:

- the completion of the Reorganization, including the exchange of all outstanding units of Cullinan Oncology, LLC as of September 30, 2020 and 66,599,045 Series C preferred units issued after September 30, 2020 for an aggregate of 29,497,847 shares of common stock of our wholly-owned subsidiary Cullinan Management, (which includes 1,689,949 shares of restricted common stock) prior

to the completion of this offering as if such exchange had occurred as of September 30, 2020, assuming an initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus. See “Reorganization” for further detail;

- immediately following the Reorganization, a one-for-7.0390 reverse split of Cullinan Management’s common stock, which will become effective prior to the completion of this offering;
- no exercise by the underwriters of their option to purchase up to 1,500,000 additional shares of our common stock in this offering; and
- the filing of our second amended and restated certificate of incorporation, effective immediately prior to the closing of the offering, and the adoption of our amended and restated bylaws, effective upon the effectiveness of the registration statement of which this prospectus is a part.

SUMMARY CONSOLIDATED FINANCIAL DATA

The following information is presented for Cullinan Oncology, LLC, which will merge with and into Cullinan Management, Inc., the entity whose shares are being offered hereby. The summary financial information below should be read in conjunction with the information contained in "Selected Financial Information," "Management's Discussion and Analysis of Financial Condition and Results of Operations," our consolidated financial statements and notes thereto, and other financial information included elsewhere in this prospectus. The consolidated statement of operations and comprehensive loss data for the years ended December 31, 2018 and 2019 have been derived from our audited consolidated financial statements. The consolidated statement of operations and comprehensive loss data for the nine months ended September 30, 2019 and 2020 and the summary consolidated balance sheet data as of September 30, 2020 have been derived from our unaudited condensed consolidated financial statements, both of which are included elsewhere in this prospectus. In the opinion of management, the unaudited financial statements include all adjustments, consisting of only normal and recurring adjustments, necessary for a fair presentation of such financial data.

	YEAR ENDED DECEMBER 31,		NINE MONTHS ENDED SEPTEMBER 30,	
	2018	2019	2019	2020
	(unaudited)			
	(in thousands, except share and per share data)			
Consolidated statement of operations data:				
Operating expenses:				
Research and development	\$ 9,584	\$ 16,788	\$ 12,986	\$ 26,582
General and administrative	5,002	5,482	4,305	4,580
Total operating expenses	14,586	22,270	17,291	31,162
Loss from operations	(14,586)	(22,270)	(17,291)	(31,162)
Other income, net:				
Interest income	397	620	368	809
Other (expense) income, net	—	(4)	—	1
Total other income, net	397	616	368	810
Net loss	(14,189)	(21,654)	(16,923)	(30,352)
Net loss attributable to noncontrolling interest	—	(997)	(835)	(6,899)
Net loss attributable to Cullinan	\$ (14,189)	\$ (20,657)	\$ (16,088)	\$ (23,453)
Net loss per unit attributable to common and non-voting incentive unit holders, basic and diluted ⁽¹⁾	\$ (5.56)	\$ (3.23)	\$ (2.67)	\$ (2.62)
Total weighted-average common and non-voting incentive units used in computing net loss per unit, basic and diluted ⁽¹⁾	2,549,865	6,397,443	6,017,973	8,960,373
Comprehensive loss:				
Net loss	\$ (14,189)	\$ (21,654)	\$ (16,923)	\$ (30,352)
Unrealized (loss) gain on investments	—	(4)	—	63
Comprehensive loss	(14,189)	(21,658)	(16,923)	(30,289)
Comprehensive loss attributable to noncontrolling interest	—	(997)	(835)	(6,899)
Comprehensive loss attributable to Cullinan	\$ (14,189)	\$ (20,661)	\$ (16,088)	\$ (23,390)
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited) ⁽¹⁾⁽²⁾		\$ (1.80)		\$ (1.21)
Total weighted-average common stock outstanding used in computing pro forma net loss per unit, basic and diluted (unaudited) ⁽¹⁾⁽²⁾		11,449,625		19,361,467

- (1) See Note 12 to our consolidated financial statements and our condensed consolidated financial statements included elsewhere in this prospectus for a description of how we compute net loss per unit attributable to common and non-voting incentive unit holders, basic and diluted, and the weighted-average common and non-voting incentive units used in computation of per unit amounts.
- (2) Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited) and pro forma weighted average common stock outstanding—basic and diluted (unaudited) gives effect to (i) the completion of the Reorganization—see “Reorganization” for further detail and (ii) subsequent to the Reorganization, the conversion of all outstanding shares of our preferred stock into common stock as if such transactions had occurred on the later of the beginning of the period or the issuance of the redeemable preferred units, but does not reflect the transactions described in “The Reorganization-Reorganization Equity Exchange”, nor does it include units from the Series C offering completed in December 2020.

	AS OF SEPTEMBER 30, 2020		
	ACTUAL	PRO FORMA(1) (unaudited) (in thousands)	PRO FORMA AS ADJUSTED(2)
Consolidated balance sheet data:			
Cash, cash equivalents and short-term investments	\$ 94,892	\$ 219,592	\$ 398,042
Working capital(3)	89,298	213,998	392,448
Total assets	97,317	222,017	400,467
Total liabilities	7,806	7,806	7,806
Redeemable preferred units	151,811	—	—
Common stock	—	3	4
Additional paid-in capital	770	277,279	455,728
Accumulated deficit	(64,993)	(64,993)	(64,993)
Total members’ (deficit), actual; total stockholders’ equity, pro forma and pro forma as adjusted	(62,300)	214,211	392,661

- (1) The consolidated pro forma balance sheet data give effect to the issuance and sale of 66,599,045 Series C preferred units in December 2020 and the completion of the Reorganization and, subsequent to the Reorganization, the conversion of all outstanding preferred stock into common stock, but does not reflect the transactions described in “The Reorganization-Reorganization Equity Exchange.”
- (2) The pro forma as adjusted consolidated balance sheet data give further effect to our issuance and sale of 10,000,000 shares of our common stock offered in this offering at an assumed initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.
- (3) We define working capital as current assets less current liabilities.

A \$1.00 increase (decrease) in the assumed initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash, working capital, total assets, and total stockholders’ equity by \$9.3 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. An increase (decrease) of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash, working capital, total assets, and total stockholders’ equity by \$18.1 million, assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this prospectus, including our consolidated financial statements and related notes appearing elsewhere in this prospectus and the section of this prospectus titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” before you make an investment decision. The risks described below are not the only risks that we face. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and prospects. As a result, the market price of our common stock could decline, and you may lose all or part of your investment in our common stock.

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, and 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.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays, and other known and unknown factors, such as the COVID-19 pandemic. If we decide to commercialize any of our product candidates that may be approved for marketing, we will need to develop commercial infrastructure. We may not be successful in any such transition. 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 therapeutic 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 private placements of Cullinan Oncology, LLC’s preferred units and our subsidiaries’ preferred stock.

We have incurred significant net losses in each period since we began substantive operations in September 2017. For the years ended December 31, 2018 and 2019, we reported net losses of \$14.2 million and \$21.7 million, respectively. For the nine months ended September 30, 2020, we reported a net loss of \$30.4 million. As of September 30, 2020, we had an accumulated deficit of \$65.0 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 investigational new drug applications, or INDs, for our product candidates;

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- conduct preclinical studies and clinical trials for our current and future product candidates, including but not limited to CLN-081, CLN-049, and CLN-619;
- seek marketing approvals for any product candidates that successfully complete clinical trials;
- 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;
- 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;
- obtain, expand, maintain, enforce, and protect our intellectual property portfolio;
- take temporary precautionary measures to help minimize the risk of COVID-19 to our employees;
- hire additional clinical, regulatory, and scientific personnel; and
- operate as a public company.

Because of the numerous risks and uncertainties associated with developing pharmaceutical product candidates, particularly during the COVID-19 pandemic, 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 members' equity and working capital.

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

Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any sales, or collaboration or commercial 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. Most of our product candidates are in the preclinical stages of development and will require additional preclinical studies, and 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. Except for CLN-081, we have not yet administered our product candidates in humans and, as such, we face significant translational risk as our preclinical product candidates advance to the clinical stage, if ever, as promising results in preclinical studies may not be replicated in subsequent clinical trials, and testing on animals may not accurately predict human experience. For example, Apollo, our oral small molecule targeting EBNA1, was terminated due to a lack of translation of compelling preclinical pharmacodynamic effect and antitumor activity into patients. 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, including CLN-049, CLN-619, CLN-617 and CLN-978;

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- whether we are required by the U.S. Food and Drug Administration, or 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, and such regulatory authorities' acceptance of our tumor-agnostic development strategy (i.e., our pursuit of approval based on a biomarker rather than a specific cancer indication);
- 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;
- 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, or cGMP;
- our ability to successfully develop a commercial strategy and thereafter commercialize our product candidates or any future product candidates in the United States 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.

Following consummation of this offering, we will still need substantial additional funding. If we are unable to raise capital when needed, we would be compelled to delay, reduce, or eliminate our product development programs or other operations.

The development of pharmaceutical products is capital intensive. We are currently advancing CLN-081 in clinical development and expect to advance CLN-049 and CLN-619 into clinical development in the near term. We expect our expenses to increase in parallel with our ongoing activities, particularly as we continue our discovery, preclinical, and clinical development activities for our current product candidates, identify and invest in new product candidates, and conduct clinical trials of, and seek marketing approval for, our product candidates. In addition, if we obtain marketing approval for and commercialize any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing, and distribution. Furthermore, upon the closing of this offering, we expect to incur significant additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional

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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. Additionally, 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 Cullinan Oncology, LLC, 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 \$94.9 million as of September 30, 2020. In addition, on December 16, 2020, we received \$124.7 million from the sale of our Series C preferred units. We estimate that our net proceeds from this offering will be \$178.5 million, based on an assumed initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We believe that, based upon our current operating plan, our existing capital resources, together with the net proceeds from this offering will be sufficient to fund our anticipated operations through 2024. Our future capital requirements will depend on many factors, including:

- the scope, progress, results, and costs of discovery, preclinical development, and clinical trials for our 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;
- 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, obtaining, maintaining, enforcing, and protecting our intellectual property rights and defending intellectual property-related claims.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

In addition, if one of our subsidiaries raises funds through the issuance of its equity securities, our equity interest in such subsidiary could be substantially diminished. If one of our subsidiaries raises additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technologies or our product candidates or grant licenses on terms that are not favorable to us.

If you purchase our common stock in this offering, you will incur immediate and substantial dilution in the book value of your shares.

The initial public offering price will be substantially higher than the net tangible book value per share of our common stock. Investors purchasing common stock in this offering will pay a price per share that substantially exceeds the book value of our tangible assets after subtracting our liabilities. As a result, investors purchasing common stock in this offering will incur immediate dilution of \$9.56 per share, based on the assumed initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus. Further, investors purchasing common stock in this offering will contribute approximately 40.7% of the total amount invested by equity holders since our inception, but will own only approximately 25.3% of the total number of shares of our common stock outstanding after this offering.

This dilution is due to our investors who purchased units of Cullinan Oncology, LLC prior to this offering having paid substantially less when they purchased their units than the price offered to the public in this offering, and the grant of restricted units granted to our employees. As a result of the dilution to investors purchasing common stock in this offering, investors may receive significantly less than the purchase price paid in this offering, if anything, in the event of our liquidation. For a further description of the dilution that you will experience immediately after this offering, see the section of this prospectus entitled "Dilution."

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.

We intend to engage in various acquisitions and strategic partnerships in the future, including licensing or acquiring products, intellectual property rights, technologies, or businesses, either by our wholly-owned subsidiary, Cullinan Management, Inc., or Cullinan Management, 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 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;

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- 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 use our differentiated hub-and-spoke business model to build a pipeline of product candidates with commercial value.

A key element of our strategy is to use our differentiated hub-and-spoke business model 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 our research and development efforts to date have resulted in our identification, discovery and preclinical and clinical development of certain of our product candidates, these product candidates may not be safe or effective as cancer treatments, and we may not be able to develop any other product candidates. 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. Our differentiated hub-and-spoke business model is evolving and may not succeed in building a pipeline of product candidates. 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. Even if we are successful in building our pipeline of product candidates, the potential product candidates that we identify may not be suitable for clinical development or generate acceptable clinical data, including as a result of unacceptable toxicity or other characteristics that indicate that they are unlikely to receive marketing approval from the FDA or other regulatory authorities or achieve market acceptance. If we do not successfully develop and commercialize product candidates, we will not be able to generate product revenue in the future, which likely would result in significant harm to our financial position and adversely affect our stock price.

Additionally, we may pursue additional in-licenses or acquisitions of development-stage assets or programs, which entails additional risk to us. While we believe our hub-and-spoke model offers an attractive platform for these transactions and for potential partners, our model is unique and we may not be able to attract or execute transactions with licensors or collaborators who may choose to partner with companies that employ more traditional licensing and collaboration approaches. 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, other than our wholly-owned subsidiary Cullinan Management, has 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.

For example, our partially-owned subsidiary Cullinan Pearl Corp., or Cullinan Pearl, is party to a license agreement, or the Taiho Agreement, with Taiho Pharmaceuticals, Inc., or Taiho, pursuant to which Taiho has a right of negotiation that requires Cullinan Pearl to negotiate in good faith with Taiho prior to proceeding with a transaction to license, sell, assign, transfer or otherwise dispose of a majority of the assets of Cullinan Pearl to a third party, or any transaction with respect to any of the rights licensed from Taiho to Cullinan Pearl. While Cullinan Pearl is not obligated to enter into a transaction with Taiho, the right of negotiation could delay a potential sale or adversely impact our ability to attract a partner or acquirer and could negatively impact prospects for a larger company to acquire Cullinan Pearl or its assets or enter into a collaboration or licensing transaction that would benefit us. Further, Cullinan Pearl must pay Taiho a percentage of the proceeds from the sale, assignment or transfer of less than all or substantially all of Cullinan Pearl's assets. In addition, our partially-owned subsidiaries Cullinan Florentine Corp., or Cullinan Florentine, and Cullinan Amber Corp., or 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. As of December 31, 2020, on a fully-diluted basis, we owned 71% of Cullinan Apollo, 80% of Cullinan Pearl, 90% of Cullinan Amber, 92% of Cullinan Florentine and 35% of Cullinan MICA.

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.

We currently own the majority of the fully-diluted shares outstanding of Cullinan Pearl, Cullinan Florentine, Cullinan Apollo, and Cullinan Amber. Our ownership in Cullinan MICA, which owns intellectual property related to CLN-619, represents 88% of Cullinan MICA's Series A Senior Preferred Stock, but approximately 35% of its fully-diluted common stock equivalent outstanding as of December 31, 2020. However, we currently can designate three of the five directors of the company and have control over certain corporate actions such as the acquisition of Cullinan MICA by any other corporation or entity, through our majority ownership of the Series A Senior Preferred Stock. Further, we will maintain our Series A Senior Preferred Stock ownership percentage by participating in future milestone dependent closings of the Series A financing (for more information please see Note 5 of our condensed consolidated financial statements).

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

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still need to be approved by the board of directors of our respective subsidiary over which we maintain full or, in the case of Cullinan MICA, majority control. For example, in the event Cullinan MICA were to undertake a transaction that could lead to further dilution of our interest, such action would still be subject to protective provisions requiring the consent of a majority in interest of the then-outstanding shares of Series A Senior Preferred Stock, or the Protective Voting Rights, including, among other things, any authorization, designation, recapitalization or issuance of any new class or series of stock or any other securities convertible into equity securities of Cullinan MICA. Cullinan Oncology, LLC currently holds a majority of the Series A Senior Preferred Stock. These Protective Voting Rights give holders of Series A Senior Preferred voting control over any actions that would result in redemptions of equity securities.

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 addition, if the affairs of such minority-owned subsidiaries such as Cullinan MICA were to be conducted in a manner detrimental to the interests or intentions of the Company, our business, reputation, and prospects may be adversely affected. For example, other shareholders of Cullinan MICA could take actions without our consent, including that a majority of shareholders could demand a registration of their shares beginning in April 2025 and such a liquidity event by the other shareholders could have an adverse impact on our investment in the subsidiary.

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 who provide various administrative, research and development, and other services across our organization presents operational challenges that may adversely affect our business.

As of December 31, 2020, we had 20 full-time employees who are employed by our wholly-owned subsidiary, Cullinan Management, 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

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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, including our CEO and director, Owen Hughes, and our Chief Scientific Officer, Leigh Zawel, 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 Oncology, LLC 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 Oncology, LLC, Cullinan Management 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 Oncology, LLC, 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.

We currently outsource, and intend to continue to outsource, nearly all our discovery, clinical development, and manufacturing functions to third-party providers or consultants. Outsourcing these functions has significant risks, and our failure to manage these risks successfully could materially adversely affect our business, results of operations, and financial condition.

Our business model relies upon the use of third parties, such as vendors and consultants, to conduct our drug discovery, preclinical testing, clinical trials, manufacturing, and all other aspects of clinical development. While our reliance on third parties allows us to purposely employ a small number of full-time employees, we may not effectively manage and oversee the third parties that our business depends upon and we have less control over our operations due to our reliance on third parties. While we believe our business model significantly reduces overhead cost, we may not realize the efficiencies of this arrangement if we are unable to effectively manage third parties or if our limited number of employees are unable to manage the operations of each of our subsidiaries, including the development of their programs and product candidates. The failure to successfully and efficiently outsource operational functions or appropriately manage the operations of our subsidiaries could materially adversely affect our business, results of operations, and financial condition.

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 CLN-081, CLN-049, and CLN-619, 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. Failure can occur at any time during the preclinical study and clinical trial processes, and, because our product candidates are in an early stage of development, there is a high risk of failure and we may never succeed in developing marketable products. Any preclinical studies or clinical trials that we may conduct may not demonstrate the safety and efficacy necessary to obtain regulatory approval to market any of our product candidates. 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. While we have not yet initiated clinical trials for certain of our product candidates and are in early stages of clinical trials for CLN-081, it is likely, as is the case with many oncology therapies, that there may be side effects associated with their use. Results of our trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Further, our product candidates could cause undesirable side effects in clinical trials related to on-target toxicity. If on-target toxicity is observed, or if our product candidates have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. In addition, our product candidates could cause undesirable side effects that we have not observed yet to date. Many compounds that initially showed promise in early stage testing for treating cancer have later been found to cause side effects that prevented further development of the compound. In addition to our ongoing clinical trial of CLN-081, patients have been, and will likely continue to be, treated with CLN-081 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 CLN-081, it may negatively affect perceptions of CLN-081, our other product candidates, or our business. In addition, 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 CLN-081 or potentially our other product candidates.

Our discovery, preclinical, and clinical development is focused on the development of targeted oncology and immuno-oncology therapeutic candidates for cancer patients, and our approach to the identification, discovery, and development of product candidates is novel and may never lead to marketable products.

The scientific discoveries that form the basis for our efforts to discover and develop targeted oncology and immuno-oncology therapeutic candidates for cancer patients are relatively new. The scientific evidence to support the feasibility of developing product candidates based on these discoveries 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, or EGFR, Exon 20 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 and immuno-oncology therapies will be successful, and if our approach is unsuccessful, our business will suffer.

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

In connection with the clinical development of our product candidates for certain indications, we may engage third parties 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, European Medicines Agency, or 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 therapeutic 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 therapeutic 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 therapeutic product candidates, or experience delays in doing so, the development of these therapeutic product candidates may be adversely affected or these therapeutic 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 therapeutics 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 therapeutic product candidates.

Preclinical and clinical development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future preclinical studies or clinical trial results. 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. 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.

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. Our preclinical studies and future clinical trials may not be successful.

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 clinical trial of CLN-081 includes an open-label dosing design, the results from this clinical trial 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.

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 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, or 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;

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- we may be unable to add or be delayed in adding a sufficient number of clinical trial sites and obtaining Institutional Review Board, or 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 experiences 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;
- we may experience difficulties in having subjects complete a clinical trial or return for post-treatment follow-up;
- 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

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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.

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 are early in our development efforts and are substantially dependent on our lead targeted oncology product candidate, CLN-081, and our most advanced immuno-oncology product candidates, CLN-049 and CLN-619. If we are unable to advance CLN-081, CLN-049, or CLN-619, or any of our other product candidates through clinical development, or to obtain regulatory approval and ultimately commercialize CLN-081, CLN-049, or CLN-619, or any of our other 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 targeted oncology program, CLN-081 is in a Phase 1/2a clinical trial. Our most advanced immuno-oncology programs, CLN-049 and CLN-619, are currently in preclinical development. 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 CLN-081, CLN-049, and CLN-619, and one or more of 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 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;

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- 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, including CLN-049 and CLN-619, 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, our ongoing and planned clinical trials in EGFR exon 20 insertion mutation non-small-cell lung carcinoma, or NSCLC patients for CLN-081 or, subject to submission to and receipt of authorization from applicable regulatory authorities, our planned dose escalation trials in patients with hematological cancer and solid tumors in CLN-049 and CLN-619, respectively, 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 trial 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 United States, 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 CLN-081, our ability to enroll eligible patients may be limited or enrollment may be slower than we anticipate due to the small eligible patient population. In addition, the target population we are seeking to treat may be smaller than expected, as we cannot be certain how many patients will

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harbor the EGFR exon 20 insertion mutations that CLN-081 is designed to target. In addition, our ability to enroll patients may be significantly delayed by the evolving COVID-19 pandemic and we do not know the extent and scope of such delays at this point.

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 will 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;
- 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 from time to time 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

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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. As a result, topline data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical trials. Interim or preliminary 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. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock after this offering.

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

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

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 submitted our IND for CLN-081 in May 2019, which was allowed to proceed by the FDA in June 2019; however, we may not be able to file future INDs for our product candidates, including CLN-049 and CLN-619, on the timelines we expect. For example, we may experience manufacturing delays or other delays with IND-enabling studies or 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 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 EMA, or

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comparable foreign regulatory authorities outside of the United States 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.

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 CLN-081 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;

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- 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, or 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 Phase 1/2a clinical trial of CLN-081, and that we plan to dose in our future 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, such as our Phase 1/2a clinical trial of CLN-081, 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 CLN-081 or other of our 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 United States, and the FDA and comparable foreign regulatory authorities may not accept data from such trials.

We are evaluating CLN-081 in a global Phase 1/2a trial in patients with NSCLC harboring EGFR exon 20 insertion mutations. We may also in the future choose to conduct one or more additional clinical trials outside the United States, including in Europe. The acceptance of study data from clinical trials conducted outside the United States 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 United States, 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, or 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 United States 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 United States or any such foreign jurisdiction.

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 precision medicines or immuno-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;
- our ability to demonstrate the advantages of our product candidates over other cancer medicines;
- 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.

In addition, although our product candidates differ in certain ways from other precision medicine or immuno-oncology medicine approaches, serious adverse events or deaths in other clinical trials involving precision medicines, even if not ultimately attributable to our product or product candidates, could result in increased government regulation, unfavorable public perception and publicity, potential regulatory delays in the testing or licensing of our product candidates, stricter labeling requirements for those product candidates that are licensed, and a decrease in demand for any such product candidates.

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Even if our products 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 CLN-081 will compete against small molecule EGFR inhibitors poziotinib from Spectrum Pharmaceuticals and mobocertinib (TAK-788) from Takeda Pharmaceuticals. CLN-081 may also compete against Black Diamond's BDTX-189, an EGFR inhibitor. CLN-081 may also compete with amivantamab from Johnson & Johnson, an EGFRxcMET bispecific antibody. We expect that CLN-049 will compete against bi-specifics for the treatment of AML, including those targeting CD3 and CD33 (Amgen, Amphivena), CD123 (Macrogenics, Xencor), FLT3 (Amgen), and CCL1/CLEC12A (Merus, Genentech). We expect that CLN-619 will compete against cancer therapies targeting MICA/B as a monotherapy and/or in combination with other agents, including: Innate Pharma, Inc. (in collaboration with AstraZeneca Inc.), CanCure LLC, Genentech Inc., and Bristol-Myers Squibb.

If our product candidates, including CLN-081, 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 therapeutic 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 therapeutic candidates, we could see a reduction or elimination in our commercial opportunity. For additional information regarding our competition, see "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 United States, 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 United States 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 United States. Other countries allow companies to fix their own prices for medicines, but monitor and control company profits. Additional foreign price controls or other changes

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in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for products may be reduced compared with the United States 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 United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services or 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 United States 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 United States. 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 United States 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 United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, 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 United States Supreme Court, the Trump Administration has issued various Executive Orders which eliminated cost-sharing subsidies and various provisions that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices; and Congress has introduced several pieces of legislation aimed at significantly revising or repealing the ACA. It is unclear whether the ACA will be overturned, repealed, replaced, or further amended. We cannot predict what affect further changes to the ACA would have on our business.

U.S. federal government agencies currently face potentially significant spending reductions. The Budget Control Act of 2011, or 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

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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, these reductions are suspended from May 1, 2020 through December 31, 2020 due to the COVID-19 pandemic. As the legislation currently stands, the reductions will go back into effect January 2021 and will remain in effect through 2030 unless additional Congressional action is taken.

There has been increasing legislative and enforcement interest in the United States 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. At the federal level, the Trump administration's budget for fiscal year 2021 contains a \$135 billion allowance (over a period of time) 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 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 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.

On July 24, 2020, President Trump signed four Executive Orders directing the Secretary of HHS to: (1) eliminate protection under an Anti-Kickback Statute safe harbor for certain retrospective price reductions provided by drug manufacturers to sponsors of Medicare Part D plans or pharmacy benefit managers that are not applied at the point-of-sale; (2) allow the importation of certain drugs from other countries through individual waivers, permit the re-importation of insulin products, and prioritize finalization of FDA's December 2019 proposed rule to permit the importation of drugs from Canada; (3) ensure that payment by the Medicare program for certain Medicare Part B drugs is not higher than the payment by other comparable countries (depending on whether pharmaceutical manufacturers agree to other measures); and (4) allow certain low-income individuals receiving insulin and epinephrine purchased by a Federally Qualified Health Center, or FQHC, as part of the 340B drug program to purchase those drugs at the discounted price paid by the FQHC. On October 1, 2020, the FDA issued its final rule allowing importation of certain prescription drugs from Canada. On September 13, 2020, President Trump signed an Executive Order directing HHS to implement a rulemaking plan to test a payment model, pursuant to which Medicare would pay, for certain high-cost prescription drugs and biological products covered by Medicare Part B, no more than the most-favored-nation price (i.e., the lowest price) after adjustments, for a pharmaceutical product that the drug manufacturer sells in a member country of the Organization for Economic Cooperation and Development that has a comparable per-capita gross domestic product. Although a number of these, and other proposed measures will require authorization through additional legislation to become effective, Congress and the current administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs.

HHS has already started the process of soliciting feedback on some of these measures and, at the same time, is immediately implementing others under its existing authority. 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.

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,

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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 United States 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

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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 products 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 United States or overseas.

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A variety of risks associated with marketing our product candidates internationally could materially adversely affect our business.

We plan to seek regulatory approval of our product candidates outside of the United States and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- differing regulatory requirements in foreign countries, which may result in a longer timeline for obtaining regulatory approvals outside of the United States and be more costly than obtaining approval in the United States;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with international operations may materially adversely affect our ability to attain or maintain profitable operations.

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 United States 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 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

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approval for a tumor-agnostic indication based on a biomarker. FDA has approved only a small number of oncology products with tumor-agnostic indications, and there is a risk that FDA may disagree with our 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 outside of the United States in France, the Netherlands, China, Hong Kong, Singapore, and Taiwan. We intend to engage with EMA regarding regulatory requirements for registration in the European Union, or EU for our CLN-081, CLN-049, and CLN-619 programs. There is limited experience of regulatory authorities outside of the United States 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 United States 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, or BLA, New Drug Application, or 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 United States or elsewhere;

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- 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 therapeutic 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 CLN-081, CLN-049, and CLN-619, 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 United States, or a patient population greater than 200,000 in the United States when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting a BLA or NDA. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and 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.

We may seek orphan drug designation for CLN-081, CLN-049, and CLN-619, 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 United States 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, or 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 3, 2017, the United States Congress passed the FDA Reauthorization Act of 2017, or FDARA. 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. 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 CLN-081, 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 CLN-081, 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.

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

We may seek Breakthrough Therapy designation for CLN-081, 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

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disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy designation for a product candidate may not result in a faster development process, review or approval compared to candidate products developed and considered for approval that have not received Breakthrough Designation and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as Breakthrough Therapies, the FDA may later decide that the product no longer meets the conditions for qualification. Thus, even though we may seek Breakthrough Therapy designation for CLN-081, 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.

Accelerated approval by the FDA, even if granted for CLN-081 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 CLN-081, 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. 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 CLN-081, will be regulated by the FDA as biologics, which must be licensed by FDA prior to marketing under a BLA. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or 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.

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The BPCIA was enacted in March 2010 as an unrelated part of the ACA. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and as a result certain sections of the ACA have not been fully implemented or effectively repealed. In particular, in December of 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year, commonly referred to as the “individual mandate”, was repealed by Congress as part of the Tax Cuts and Jobs Act, effective January 1, 2019. In December 2019, the U.S. Court of Appeals for the Fifth Circuit held that the individual mandate was unconstitutional but remanded part of the case back to the District Court to determine whether other reforms enacted as part of the ACA but not specifically related to the individual mandate or health insurance, including the provisions comprising the BPCIA, could be severed from the rest of the ACA so as not to be declared invalid as well. In March 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case and has allocated one hour and twenty minutes for oral arguments, which are scheduled to occur on November 10, 2020, with a decision likely to follow in 2021. Pending resolution of the litigation, ACA is still operational. It is unclear how such litigation and other efforts to repeal and replace the ACA will impact the ACA and our business. Complying with any new legislation or reversing changes implemented under the ACA could be time-intensive and expensive, resulting in a material adverse effect on our business.

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, or ANDAs, in the United States. 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 United States, 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 United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States 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 practice, or GLP, 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;

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- 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 United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may 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, 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. Average review times at the agency have fluctuated in recent years as a result. 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. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

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

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example, over the last several years the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Separately, in response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most inspections of foreign manufacturing facilities and products while local, national and international conditions warrant. On March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities and provided guidance regarding the conduct of clinical trials, which the FDA continues to update. As of June 23, 2020, the FDA noted it was continuing to ensure timely reviews of applications for medical products during the COVID-19 pandemic in line with its user fee performance goals and conducting mission critical domestic and foreign inspections to ensure compliance of manufacturing facilities with FDA quality standards. As of July 2020, utilizing a rating system to assist in determining when and where it is safest to conduct such inspections based on data about the virus' trajectory in a given state and locality and the rules and guidelines that are put in place by state and local governments, FDA is either continuing to, on a case-by-case basis, conduct only mission critical inspections, or, where possible to do so safely, resuming prioritized domestic inspections, which generally include pre-approval inspections. Foreign pre-approval inspections that are not deemed mission-critical remain postponed, while those deemed mission-critical will be considered for inspection on a case-by-case basis. FDA will use similar data to inform resumption of prioritized operations abroad as it becomes feasible and advisable to do so. The FDA may not be able to maintain this pace and delays or setbacks are possible in the future. Should FDA determine that an inspection is necessary for approval, and an inspection cannot be completed during the review cycle due to restrictions on travel, FDA has stated that it generally intends to issue a complete response letter. Further, if there is inadequate information to make a determination on the acceptability of a facility, FDA may defer action on the application until an inspection can be completed. 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. 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. Future shutdowns or other disruptions could also affect other government agencies such as the SEC, which may also impact our business by delaying review of our public filings, to the extent such review is necessary, and our ability to access the public markets.

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 United States 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 United States, 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

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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 False Claims Act. 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 False Claims Act, or 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 False Claims Act, 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, or 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, or 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

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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 Affordable Care Act 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) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners;
- 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.

Effective upon the closing of this offering, we will adopt 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 physicians is governed by the national anti-bribery laws of EU Member States, such as the U.K. Bribery Act 2010, or the Bribery Act. Infringement of these laws could result in substantial fines and imprisonment. 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 EU, including personal health data, is subject to the EU General Data Protection Regulation, or GDPR, which became effective on May 25, 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including 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 safeguards to protect the security and confidentiality of personal data, providing notification 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 countries outside the EU, including the United States, 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. In addition, the GDPR includes restrictions on cross-border data transfers. The GDPR increased our responsibility and 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. Compliance with the GDPR will 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 activities. Further, the United Kingdom's vote in favor of exiting the EU, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. In particular, it is unclear how data transfers to and from the United Kingdom will be regulated.

In addition, California recently enacted the California Consumer Privacy Act, or CCPA, which creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and

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security obligations on entities handling personal data of consumers or households. The CCPA requires covered companies to provide new disclosure to consumers about such companies' data collection, use and sharing practices, provide such consumers new ways to opt-out of certain sales or transfers of personal information, and provide consumers with additional causes of action. The CCPA went into effect on January 1, 2020, and the California Attorney General commenced enforcement actions for violations on July 1, 2020. While there are currently exceptions for protected health information that is subject to HIPAA and clinical trial regulations, as currently written, the CCPA may impact our business activities. On August 14, 2020, implementing regulations were finalized and became effective as of that date. While clinical trial data and information governed by HIPAA are currently exempt from the current version of the CCPA, other personal information may be applicable and possible changes to the CCPA may broaden its scope. We continue to monitor the impact the CCPA may have on our business activities,

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), private litigation 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 product candidates and technology, or any other product candidates or technology we may develop, 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 CLN-081, CLN-049 and CLN-619 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 United States and other countries with respect to our product candidates, including CLN-081, CLN-049 and CLN-619, 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 United States 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

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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 CLN-081, CLN-049 and CLN-619, 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 United States. 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 United States, 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 United States 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,

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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 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 United States 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 United States 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 United States 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

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our patent applications or the patent rights of others in the U.S. Patent and Trademark Office, or 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. In spite of our best efforts, our licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing 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.

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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, under the Taiho Agreement, while our partially-owned subsidiary Cullinan Pearl is not obligated to enter into a transaction with Taiho, the right of negotiation could delay a potential sale or adversely impact our ability to attract a partner or acquirer and could negatively impact prospects for a larger company to acquire Cullinan Pearl or its assets or enter into a collaboration or licensing transaction that would benefit us. In addition, our partially-owned subsidiaries Cullinan Florentine and 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.

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.

Moreover, any of these parties might breach the agreements and intentionally or inadvertently disclose our trade secret information and we may not be able to obtain adequate remedies for such breaches. In addition, competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights and trade secrets to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, financial condition, results of operations and future prospects.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. If we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful. For example, significant elements of our differentiated hub-and-spoke business model, including aspects of oncogenicity computational algorithms, *in vivo* experiments to validate mechanisms and pharmacology, drug design, and related processes, are based on unpatented trade secrets that are not publicly disclosed. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or

disclose our technology. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us.

Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual or entity during the course of the party's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary technology by third parties. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. Although we require all of our employees to assign their inventions to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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.

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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 CLN-081, CLN-049 and CLN-619, 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 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 United States 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 United States may be maintained in secrecy until the patents are issued, patent applications in the United States 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

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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 four patent families and own a fifth patent family related to CLN-081. We have in-licensed one patent family related to CLN-049. We own three patent families related to CLN-619. 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

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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

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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 European Patent Office, or EPO, or similar proceedings in other foreign patent offices, where either 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 United States.

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.

Any issued patents we may own or in-license covering our product candidates could be narrowed or found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad, including the USPTO.

If we or our licensors or strategic partners initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate, as applicable, is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of patentable subject matter, lack of written description, lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, *inter partes* review, post grant review and equivalent proceedings in foreign jurisdictions (such as opposition proceedings). Such proceedings could result in revocation or amendment to our owned or in-licensed patents or patent applications in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, any rights we may have, allow third parties to commercialize our product candidates or other technologies and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our or priority of invention or other features of patentability with respect to our patents or patent applications. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our product candidates and other technologies. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we or our licensing partners and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, or if we are otherwise unable to adequately protect our rights, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and product candidates.

Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. If we are unsuccessful in any such proceeding or other priority or inventorship dispute, we may be required to obtain and maintain licenses from third parties, including parties involved in any such interference proceedings or other priority or inventorship disputes. Such licenses may not be available on commercially reasonable terms or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture, and commercialization of one or more of the product candidates we may develop. The loss of exclusivity or the narrowing of our patent application claims could limit our ability to stop others from using or commercializing similar or identical technology and products. Any of the foregoing could have a material adverse effect on our business, results of operations, financial condition and prospects.

Changes to patent law in the United States 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 is therefore costly, time-consuming and inherently uncertain. Recent

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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 United States has enacted and implemented wide-ranging patent reform legislation. On September 16, 2011, the Leahy-Smith America Invents Act, or 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. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we were the first to either (i) file any patent application related to our product candidates or other technologies or (ii) invent any of the inventions claimed in our patent applications or any patents we may own or in-license. These changes also allow third party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. An adverse determination in any such proceeding could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in the inability to manufacture or commercialize products without infringing third-party patent rights. Accordingly, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of any of our issued patents, all of which could have a material adverse effect on our business and financial condition.

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 United States. 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 United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories

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where we have patent protection, but where enforcement is not as strong as that in the United States. These products may compete with our product candidates and in jurisdictions where we do not have any issued patents our 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, or 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.

Numerous factors may limit any potential competitive advantage provided by our intellectual property rights.

The degree of future protection afforded by our intellectual property rights, whether owned or in-licensed, is uncertain because intellectual property rights have limitations, and may not adequately protect our business, provide a barrier to entry against our competitors or potential competitors, or permit us to maintain our competitive advantage. Moreover, if a third party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The following examples are illustrative:

- patent applications that we own or in-license may not lead to issued patents;
- patents, should they issue, that we may own or in-license, may not provide us with any competitive advantages, may be narrowed in scope, or may be challenged and held invalid or unenforceable;
- others may be able to develop and/or practice technology, including compounds that are similar to the chemical compositions of our product candidates, that is similar to our technology or aspects of our technology but that is not covered by the claims of any patents we may own or in-license, should any patents issue;
- third parties may compete with us in jurisdictions where we do not pursue and obtain patent protection;
- we, or our licensors or collaborators, might not have been the first to make the inventions covered by a patent application that we own or may in-license in the future;
- we, or our future licensors or collaborators, might not have been the first to file patent applications covering a particular invention;
- others may independently develop similar or alternative technologies without infringing, misappropriating or otherwise violating our intellectual property rights;
- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and may then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not be able to obtain and/or maintain necessary licenses on reasonable terms or at all;
- third parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights, or any rights at all, over that intellectual property;
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such trade secrets or know-how;

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- we may not be able to maintain the confidentiality of our trade secrets or other proprietary information;
- we may not develop or in-license additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

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

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, contract manufacturing organizations, or 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 GCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP 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 GCP regulations. In addition, our clinical trials must be conducted with pharmaceutical product produced under cGMP 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

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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, 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.

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.

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.

In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy and obtain marketing approval.

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 products 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 current 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;
- our contract manufacturers and critical reagent suppliers may be subject to inclement weather, as well as natural or man-made disasters; and
- our contract manufacturers may have unacceptable or inconsistent product quality success rates and yields, and we have no direct control over our contract manufacturers' ability to maintain adequate quality control, quality assurance and qualified personnel.

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.

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 and potency. Manufacturing biologics requires facilities specifically

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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.

Our manufacturing process needs to comply with FDA regulations relating to the quality and reliability of such processes. Any failure to comply with relevant regulations could result in delays in or termination of our clinical programs and suspension or withdrawal of any regulatory approvals.

In order to commercially produce our products at a third party's facility, we will need to ensure compliance with the FDA's cGMP regulations and guidelines. We may encounter difficulties in achieving quality control and quality assurance and may experience shortages in qualified personnel. Our third-party manufacturers are subject to inspections by the FDA and comparable foreign regulatory authorities to confirm compliance with applicable regulatory requirements. Any failure to follow cGMP or other regulatory requirements or delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our precision medicines as a result of a failure of the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our product candidates, including leading to significant delays in the availability of our product candidates for our clinical trials or the termination of or suspension of a clinical trial, or the delay or prevention of a filing or approval of marketing applications for our product candidates. 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.

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 United States 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

The outbreak of the novel coronavirus, COVID-19, may adversely impact our business, including our preclinical studies and clinical trials.

In December 2019, a novel strain of the coronavirus, COVID-19, was identified in Wuhan, China. This virus spread globally, including within the United States and in March 2020 the World Health Organization declared COVID-19 a pandemic. The pandemic and government measures taken in response have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. As a result of the COVID-19 pandemic, we could experience disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- delays or difficulties in enrolling and retaining patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays in receiving authorizations from regulatory authorities to initiate our planned clinical trials;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures (such as endoscopies that are deemed non-essential), which may impact the integrity of subject data and clinical study endpoints;
- risk that participants enrolled in our clinical trials will contract COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events;
- risk that we are unable to enroll participants in our clinical trials in adequate numbers;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- interruptions in preclinical studies due to restricted or limited operations at our laboratory facility;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;
- changes in local regulations as part of a response to the COVID-19 pandemic, which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue such clinical trials altogether;
- limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; and
- interruption or delays to our sourced identification, discovery and clinical activities.

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The COVID-19 pandemic continues to rapidly evolve. The extent to which the pandemic impacts our business, preclinical studies and clinical trials will depend on future developments, which 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 United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

We are highly dependent on our key personnel and anticipate hiring new key personnel. If we are not successful in attracting and 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 attract and 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 other 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, 2020, we had 20 full-time employees and two consultants. As our development and commercialization plans and strategies develop, and as we transition into operating as a public company, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;

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- 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.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including substantially all aspects of legal and compliance, regulatory approval, clinical trial management and manufacturing. There can be no assurance that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and 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.

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.

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

On December 22, 2017, President Trump signed into law the TCJA, which significantly reformed the Internal Revenue Code of 1986, as amended. The TCJA, among other things, contains significant changes to corporate and individual taxation, some of which could adversely impact an investment in our common stock. You are urged to consult your tax adviser regarding the implications of the TCJA on an investment in our common stock.

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 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, upon closing of this offering, 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, 2019, we had U.S. federal net operating loss carryforwards of \$28.5 million and U.S. federal research and development tax credit carryforwards of \$0.6 million, each of which will begin to expire at various dates through 2037 and which could be limited if we experience an “ownership change.” The reduction of the corporate tax rate under the TCJA may cause a reduction in the economic benefit of our net operating loss carryforwards and other deferred tax assets available to us. Under the TCJA, federal net operating losses 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 net operating losses 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 net operating loss deduction itself. As of December 31, 2019, we had a U.S. federal net operating loss carryforward of \$25.5 million, which does not expire but is limited to an annual deduction equal to 80% of annual taxable income.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.

As widely reported, global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive.

Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.

Furthermore, our stock price may decline due in part to the volatility of the stock market and the general economic downturn.

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.

Risks Related to this Offering and Ownership of Our Common Stock

We do not know whether an active, liquid and orderly trading market will develop for our common stock or what the market price of our common stock will be and, as a result, it may be difficult for you to sell your shares of our common stock.

Prior to this offering, there was no public trading market for shares of our common stock. Although we have been approved to list our common stock on The Nasdaq Global Select Market, an active trading market for our shares may never develop or be sustained following this offering. You may not be able to sell your shares quickly or at the market price if trading in shares of our common stock is not active. The initial public offering price for our common stock will be determined through negotiations with the underwriters, and the negotiated price may

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not be indicative of the market price of the common stock after the offering. As a result of these and other factors, you may be unable to resell your shares of our common stock at or above the initial public offering price. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of common stock as consideration.

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 following this offering 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 prospectus, 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;

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- 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.

Further, at our request, the underwriters have reserved up to 5% percent of the shares of common stock to be issued by the Company and offered by this prospectus for sale, at the initial public offering price, to directors, officers, employees, business associates and related persons of the Company. Except for any shares acquired by our directors or officers, shares purchased pursuant to the directed share program will not be subject to lock-up agreements with the underwriters. The number of shares of common stock available for sale to the general public will be reduced to the extent these individuals purchase such reserved shares. Any reserved shares that are not so purchased will be offered by the underwriters to the general public on the same basis as the other shares offered by this prospectus.

In addition, the stock market in general, and the 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. If the market price of our common stock after this offering does not exceed the initial public offering price, you may not realize any return on your investment in us and may lose some or all of your investment. 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.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our 2021 Stock Option and Incentive Plan and 2021 Employee Stock Purchase Plan, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital may be needed in the future to continue our planned operations, including conducting clinical trials, expanded research and development activities, and costs associated with operating as a public company. To raise capital, we may sell common stock, convertible securities, or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities, or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences, and privileges senior to the holders of our common stock, including shares of common stock sold in this offering.

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Pursuant to our 2021 Plan, which will become effective as of the business day immediately prior to the effective date of the registration statement of which this prospectus forms a part, our management is authorized to grant stock options to our employees, directors, and consultants.

Initially, the aggregate number of shares of our common stock that may be issued pursuant to stock awards under the 2021 Plan will be 12,546,386 shares, of which options to purchase 6,369,503 shares and 320,228 shares of restricted common stock will be outstanding as of the consummation of this offering. The number of shares of our common stock reserved for issuance under the 2021 Plan shall be cumulatively increased on January 1, 2022 and each January 1 thereafter by 5% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year or a lesser number of shares determined by our board of directors. Unless our board of directors elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution, which could cause our stock price to fall.

Initially, the aggregate number of shares of our common stock that may be issued pursuant to the ESPP will be 416,665 shares. The number of shares of our common stock reserved for issuance under the ESPP will automatically increase each January 1, beginning on January 1, 2022, by the lesser of 833,330 shares of our common stock, 1% of the outstanding number of shares of our common stock on the immediately preceding December 31, or such lesser number of shares as determined by our compensation committee. Unless our compensation committee elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution, which could cause our stock price to fall.

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

We may seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms unfavorable to us.

We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds from this offering, including for any of the purposes described in the section entitled “Use of Proceeds,” and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. Because of the number and variability of factors that will determine our use of the net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. Our management might not apply our net proceeds in ways that ultimately increase or maintain the value of your investment.

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.

Prior to this offering, our executive officers, directors, and 5% stockholders beneficially owned approximately 76.8% of our voting stock as of December 31, 2020, based on 29,818,075 shares of our common stock (which includes 2,010,177 shares of restricted common stock, including 320,228 shares of restricted common stock granted pursuant to the Restricted Stock Contribution Agreement subsequent to September 30, 2020) deemed to be outstanding as of December 31, 2020 and assuming the sale by us of 10,000,000 shares of common stock in this offering, based on and assumed initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and not accounting for any shares purchased in this offering by certain of our existing stockholders (or their affiliates), we anticipate that same group will hold approximately 57.6% of our outstanding voting stock following this offering (assuming no exercise of the underwriters' option to purchase additional shares), without giving effect to any purchases that certain of these holders may make through our directed share program. Therefore, even after this offering, these stockholders will have the ability to influence us through this ownership position. 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, or 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, or Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in this prospectus and 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 could be an emerging growth company for up to five years following the year in which we complete this offering, although circumstances could cause us to lose that status earlier. 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 this offering, (b) in which we have total annual gross revenue of at least \$1.07 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.

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 this prospectus and our periodic reports and proxy statements. We may take advantage of scaled disclosures

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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.

We will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we will incur significant legal, accounting, and other expenses that we did not incur as a private company. We will be subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which will require, among other things, that we file with the Securities and Exchange Commission, or SEC, annual, quarterly, and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and The Nasdaq Global Select Market to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas, such as “say on pay” and proxy access. Recent legislation permits emerging growth companies to implement many of these requirements over a longer period and up to five years from the pricing of this offering. We intend to take advantage of this new legislation but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment, and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition, and results of operations. The increased costs will decrease our net income or increase our net loss and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees, or as executive officers.

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

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lockup and other legal restrictions on resale discussed in this prospectus lapse, the trading price of our common stock could decline. Upon the closing of this offering, we will have outstanding a total of 39,497,847 shares of common stock. Of these shares, only the shares of common stock sold in this offering by us, plus any shares sold upon exercise of the underwriters’ option to purchase additional shares, will

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be freely tradable without restriction in the public market immediately following this offering. In connection with this offering, our officers, directors and certain other stockholders, representing approximately 95% of our current stockholders, have agreed to be subject to a contractual lock-up with the underwriters, which will expire 180 days after the date of this prospectus.

The lock-up agreements contain important exceptions that govern their applicability. Morgan Stanley & Co. LLC, SVB Leerink LLC, and Evercore Group LLC, however, may, in their sole discretion, permit our officers, directors and other stockholders who are subject to these lock-up agreements to sell shares prior to the expiration of the lock-up agreements.

In addition, shares of common stock that are reserved for future issuance under our 2021 Plan and our 2021 Employee Stock Purchase Plan, each of which became effective upon the effectiveness of the registration statement of which this prospectus forms a part, will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements and Rule 144 and Rule 701 under the Securities Act of 1933, as amended, or the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

After this offering, the holders of 27,807,898 shares of our common stock will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to the 180-day lock-up agreements described above. See “Description of Capital Stock—Registration Rights.” Registration of these shares under the Securities Act would result in such shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

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, which are to become effective upon the closing of this offering, will 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

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- 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 which become effective upon the consummation of this offering designate specific courts in as the exclusive forum for certain litigation that may be initiated by the Company's stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us.

Pursuant to our amended and restated bylaws, which will become effective upon the effectiveness of this registration statement or which this prospectus forms a part, 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 United States 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 United States 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. In connection with this offering, we intend to begin the process of documenting, reviewing, and improving our internal controls and procedures for compliance with Section 404 of the Sarbanes-Oxley Act, which will require annual management assessment of the effectiveness of our internal control over financial reporting. We have begun recruiting additional finance and accounting personnel with certain skill sets that we will need as a public company.

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 will depend in part on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on our company. If no securities or industry analysts commence coverage of our company, the trading price for our stock would likely be negatively impacted. In the event securities or industry analysts initiate coverage, if 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.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the sections entitled “Prospectus Summary,” “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business,” contains forward-looking statements concerning our business, operations and financial performance and condition, as well as our plans, objectives and expectations for our business operations and financial performance and condition that are based on our management’s belief and assumptions and on information currently available to our management. In some cases, you can identify forward-looking statements by terminology such as “may,” “will,” “should,” “expect,” “intend,” “plan,” “anticipate,” “believe,” “estimate,” “target,” “seek,” “predict,” “potential,” “continue” or the negative of these terms or other comparable terminology. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements in this prospectus include, but are not limited to, statements about:

- the success, cost and timing of our clinical development of our product candidates, including CLN-081, CLN-049, and CLN-619;
- 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 for use in our clinical trials;
- the size and growth potential of the markets for oncology and immuno-oncologic 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;
- the expected benefits of our hub-and-spoke business model, including 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;

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- our expected uses of the net proceeds to us from this offering;
- the potential benefits of strategic collaboration agreements, our ability to enter into 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;
- 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; and
- other risks and uncertainties, including those listed under the section titled “Risk Factors.”

You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties and other factors, which are, in some cases, beyond our control and which could materially affect results. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under “Risk Factors” and elsewhere in this prospectus. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those implied or projected by the forward-looking statements. Moreover, we operate in a very competitive and rapidly changing environment and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in or implied by any forward-looking statements we may make. No forward-looking statement is a guarantee of future performance. You should read this prospectus and the documents that we reference in this prospectus and have filed with the SEC as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from any future results expressed or implied by these forward-looking statements.

The forward-looking statements in this prospectus represent our views as of the date of this prospectus. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this prospectus.

This prospectus 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 prospectus, 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 prospectus.

MARKET, INDUSTRY AND OTHER DATA

We obtained the industry, market and competitive position data used throughout this prospectus from our own internal estimates and research, as well as from independent market research, industry and general publications and surveys, governmental agencies and publicly available information in addition to research, surveys and studies conducted by third parties. Internal estimates are derived from publicly available information released by industry analysts and third-party sources, our internal research and our industry experience, and are based on assumptions made by us based on such data and our knowledge of our industry and market, which we believe to be reasonable. In some cases, we do not expressly refer to the sources from which this data is derived. In that regard, when we refer to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph is derived from the same sources, unless otherwise expressly stated or the context otherwise requires. In addition, while we believe the industry, market and competitive position data included in this prospectus is reliable and based on reasonable assumptions, such data involve risks and uncertainties and are subject to change based on various factors, including those discussed in “Risk Factors.” These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties or by us.

USE OF PROCEEDS

We estimate that our net proceeds from the sale of shares of our common stock in this offering will be approximately \$178.5 million, or \$205.7 million if the underwriters exercise in full their option to purchase additional shares, assuming an initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

A \$1.00 increase (decrease) in the assumed initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the net proceeds to us from this offering by \$9.3 million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. An increase (decrease) of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) our net proceeds from this offering by \$18.1 million, assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

As of September 30, 2020, we had cash, cash equivalents and short-term investments of \$94.9 million. In addition, on December 16, 2020, we received \$124.7 million from the sale of our Series C preferred units. We currently intend to use the net proceeds from this offering, together with our existing cash, cash equivalents, and short term investments for the following:

- approximately \$45.0 million to \$55.0 million to complete the Phase 1/2a trial of CLN-081, as well as to fund the initiation of a later stage trial in treatment experienced NSCLC patients with EGFRex20ins mutations;
- approximately \$50.0 million to \$60.0 million to advance CLN-049 and CLN-619 into Phase 1/2a trials for patients with r/r AML and advanced solid tumors, respectively;
- approximately \$40.0 million to \$50.0 million to advance CLN-617 and CLN-978 through IND-enabling studies and, assuming success of those studies and subject to FDA review of an IND submission, to initiate Phase 1/2a trials with those programs; and
- the remaining proceeds for the continued advancement of our pipeline, including Jade and Opal, milestones for previously in-licensed programs, the identification and advancement of additional programs and development candidates, hiring of additional personnel, and costs of operating as a public company, and other general corporate purposes.

We may also use a portion of the net proceeds to make additional investments in our non-wholly-owned subsidiaries, or in-license, acquire, or invest in new businesses, technology, or assets. Although we have no current agreements, commitments, or understandings with respect to any additional investment, in-license, or acquisition, we evaluate such opportunities and engage in related discussions with third parties from time to time.

Based on our current operational plans and assumptions, we expect that the net proceeds from this offering, combined with our current cash, cash equivalents, and short term investments, will be sufficient to fund operations through 2024. 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.

This expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering or the amounts that we will actually spend on the uses set forth above.

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The amounts and timing of our actual expenditures and the extent of our research and development activities may vary significantly depending on numerous factors, including the progress of our development efforts, the status of and results from any preclinical studies or clinical trials we may commence in the future, our ability to take advantage of expedited programs or to obtain regulatory approval for any other therapeutic candidates we may identify and pursue, the timing and costs associated with the manufacture and supply of any other therapeutic candidates we may identify and pursue for clinical development or commercialization, and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering, and investors will be relying on the judgment of our management regarding the application of the net proceeds.

Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation instruments, including short-term and long-term interest-bearing instruments, investment-grade securities, and direct or guaranteed obligations of the U.S. government. We cannot predict whether the proceeds invested will yield a favorable return.

DIVIDEND POLICY

We have never made any cash distributions to our members. Subsequent to our Reorganization, we do not anticipate paying any dividends on our capital stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to fund the development and growth of our business. Any future determination to declare dividends will be subject to the discretion of our board of directors and will depend on various factors, including applicable laws, our results of operations, financial condition, future prospects and any other factors deemed relevant by our board of directors. Investors should not purchase our common stock with the expectation of receiving cash dividends.

REORGANIZATION

LLC Entity (Cullinan Oncology, LLC)

Currently, the capital structure of Cullinan Oncology, LLC, or the LLC entity, consists of six classes of membership units: Non-voting incentive units, common units, Series Seed preferred units, Series A-1 preferred units, Series B preferred units, and Series C preferred units. The LLC entity is the direct parent company of Cullinan Management, Inc., and other operating subsidiaries. The subsidiaries of the LLC entity hold and advance individual therapeutic candidates, with the exception of our wholly-owned subsidiary Cullinan Management, Inc., or the Corporation, which is our shared services provider and program incubator. Each subsidiary's current governance rights will not change as a result of the Reorganization (as defined below). For more information regarding each subsidiary's capitalization and governance rights, see "Management's Discussion and Analysis of Financial Condition and Results of Operations—Basis of Presentation and Consolidation" and for more information on each subsidiary's license agreements, as applicable, see "Business—License Agreements." The subsidiaries of the LLC entity currently consist of the following:

- The Corporation is our wholly-owned operating subsidiary that employs all of our team members and incubates discovery programs until we establish a "spoke" in which to further advance them. We centralize shared services, including all research and development operations, administrative services, and business development at the Corporation, and then allocate employees and resources to the other operating subsidiaries based on the needs and development stage for each therapeutic candidate or program.
- Cullinan Pearl Corp., or Cullinan Pearl, incorporated in November 2018, is our partially-owned operating subsidiary that has exclusive worldwide rights, excluding Japan and Greater China, to CLN-081.
- Cullinan Florentine Corp., or Cullinan Florentine, incorporated in December 2019, is our partially-owned operating subsidiary that has exclusive worldwide rights to CLN-049.
- Cullinan Amber Corp., or Cullinan Amber, incorporated in December 2019, is our partially-owned operating subsidiary that has exclusive worldwide rights to the patents related to the technology that originated from and was developed in the laboratory of Professor Dane Wittrup at the Massachusetts Institute of Technology.
- Cullinan MICA, Corp. (formerly known as PDI Therapeutics, Inc.), or Cullinan MICA, which we assumed operational control of in May 2020, is our partially-owned operating subsidiary that owns intellectual property related to CLN-619.
- Cullinan Apollo Corp, or Cullinan Apollo, incorporated in November 2018, is our partially-owned subsidiary. In May 2020, Cullinan Apollo discontinued development of VK-2019 and terminated its license and collaboration agreements with The Wistar Institute.

Corporate Reorganization

Prior to the completion of this offering, we will complete a series of transactions, which we refer to collectively as the Reorganization. As a result of the Reorganization, we anticipate Cullinan Oncology, LLC will merge with and into the Corporation, with the Corporation being the surviving entity of such merger. The Corporation will become the registrant for purposes of this offering and our consolidated financial statements will be reported by the Corporation.

We believe the steps to the Reorganization will include:

- The LLC entity will contribute all of the stock it owns of each of Cullinan Apollo, Cullinan Florentine, Cullinan Amber, Cullinan Pearl, and Cullinan MICA, or collectively, the Asset Subsidiaries, to the Corporation in exchange for common stock of the Corporation that will result in the Asset Subsidiaries becoming partially-owned subsidiaries of the Corporation;

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- Following this contribution and prior to the completion of this offering, the LLC entity will merge with and into the Corporation with the Corporation being the surviving entity of such merger, or the LLC Merger; and
- Any other steps necessary to effect the Corporation becoming the registrant for this offering and our combined consolidated financial statements being reported from the Corporation going forward after the Reorganization.

As part of the LLC Merger, by operation of law and pursuant to the merger agreement setting forth the terms and conditions of the LLC Merger, the Corporation will acquire all assets of the LLC entity and assume all of its liabilities and obligations. As part of the Reorganization, the existing units of the LLC entity will be cancelled and converted into the corresponding shares of capital stock of the Corporation, after which the holders of such LLC entity units will have received 100% of the outstanding capital stock of the Corporation as of immediately prior to the completion of this offering. As a result of the LLC Merger, the unit holders of the LLC will receive equity in the Corporation as follows:

- Holders of the LLC entity's outstanding Series Seed preferred units shall receive an aggregate of 2,273,050 shares of the Corporation's Series Seed preferred stock;
- Holders of the LLC entity's outstanding Series A-1 preferred units shall receive an aggregate of 7,103,280 shares of the Corporation's Series A preferred stock;
- Holders of the LLC entity's outstanding Series B preferred units shall receive an aggregate of 8,970,154 shares of the Corporation's Series B preferred stock;
- Holders of the LLC entity's outstanding Series C preferred units shall receive an aggregate of 9,461,414 shares of the Corporation's Series C preferred stock; and
- Holders of the LLC entity's outstanding restricted common units shall receive an aggregate of 320,228 shares of the Corporation's restricted common stock.

Following the LLC Merger, and prior to the consummation of this offering, the Corporation will effect a one-for-7.0390 reverse split of its common stock and all outstanding preferred stock of the Corporation will automatically be converted on a 1-for-1 basis into common stock of the Corporation.

Treatment of Outstanding Incentive Equity of Cullinan Oncology, LLC

In connection with the Reorganization, all of the outstanding Non-Voting Incentive Units of the LLC entity will be exchanged for 1,689,949 shares of restricted common stock of the Corporation as provided for in the distribution provisions of the LLC Agreement, and the terms and conditions of the LLC Merger. The portion of the outstanding Non-Voting Incentive Units of the LLC entity that have vested as of the consummation of the Reorganization will be exchanged for shares of common stock of the Corporation, and the remaining portion of unvested outstanding Non-Voting Incentive Units of the LLC entity will be exchanged for restricted common stock of the Corporation. The shares of restricted common stock will be subject to time-based vesting conditions, in accordance with the terms and conditions of the Non-Voting Incentive Units of the LLC entity from which such shares are exchanged. In addition, in connection with the Reorganization, all of the outstanding options to purchase common units of the LLC entity will be exchanged for options to purchase shares of common stock of the Corporation as provided for in the distribution provisions of the LLC Agreement, and the terms and conditions of the LLC Merger. The options to purchase shares of common stock of the Corporation will be subject to time-based vesting conditions, in accordance with the terms and conditions of the options to purchase common units of the LLC entity from which such options are exchanged.

Holding Company Structure

Following the consummation of the Reorganization, the Corporation will be a holding company of the Asset Subsidiaries. As the controlling shareholder of the Asset Subsidiaries, with the exception of Cullinan MICA, and with the right to appoint the majority of members of the board of directors of Cullinan MICA, the Corporation will operate and control the business and affairs of the Asset Subsidiaries. The Corporation will consolidate the financial results of its subsidiaries.

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In connection with the Reorganization, all of the property and assets of the LLC entity, including equity in the Asset Subsidiaries, will become the property and assets of the Corporation, and all of the debts and obligations of the LLC entity will become the debts and obligations of the Corporation by operation of law. The Corporation will be governed by a second amended and restated certificate of incorporation to be filed with the Delaware Secretary of State and amended and restated bylaws, the material portions of each of which are described under the heading “Description of Capital Stock.”

On the effective date of the Reorganization, the members of the board of directors of the LLC entity will become the members of the Corporation’s board of directors and the officers of the LLC entity will become the officers of the Corporation.

The purpose of the Reorganization is to reorganize our corporate structure so that the entity that is offering common stock to the public in this offering is a corporation rather than a limited liability company and so that our existing investors will own our common stock rather than units in a limited liability company. References in this prospectus to our capitalization and other matters pertaining to our equity and shares prior to the Reorganization relate to the capitalization and equity and units of the LLC entity, and after the Reorganization, to the Corporation.

Reorganization Equity Exchange

In October 2020, in connection with the Reorganization, the LLC entity adopted the 2020 Unit Option and Grant Plan, or the 2020 Unit Plan, reserving 36,972,854 million common units for issuance pursuant to the 2020 Unit Plan, and decreased the authorized reserve under the 2016 Equity Incentive Plan such that no more non-voting incentive units could be issued under that plan. Options in respect of 32,493,491 common units were then granted pursuant to the 2020 Unit Plan at an exercise price of \$0.61 per common unit, including the awards to our named executive officers and non-employee directors as described below. The purpose of these option grants was to (a) provide the required equity pursuant to anti-dilution provisions in agreements with certain employees, directors and consultants; (b) grant recently hired individuals equity in accordance with their offer letters and per standard practices; and (c) exchange employees’ shares of restricted stock in Cullinan Amber, Cullinan Pearl, and Cullinan Florentine for restricted common units of the LLC entity as described below, thereby increasing the LLC entity’s ownership in Cullinan Amber, Cullinan Pearl, and Cullinan Florentine.

In addition, in November 2020, the LLC entity entered into a Contribution Agreement, or the Restricted Stock Contribution Agreement, with each holder of restricted stock of Cullinan Amber, Cullinan Pearl, and Cullinan Florentine. Pursuant to the Restricted Stock Contribution Agreement, each holder contributed their respective shares of restricted stock and in exchange received 2,254,231 restricted common units of the LLC entity under the 2020 Unit Plan with an aggregate value equal to the value of the restricted stock contributed to the LLC entity, or the Restricted Stock Contribution.

The board of directors of Cullinan Pearl further authorized the entry into a Common Unit Purchase Agreement with the LLC entity pursuant to which Cullinan Pearl purchased 22,868 common units of the LLC entity for a purchase price of \$0.61 per common unit, for an aggregate of \$13,950, or the Unit Purchase. In addition, the LLC entity entered into subscription agreements with Cullinan Pearl pursuant to which the LLC entity purchased an aggregate of 2,730,225 shares of common stock of Cullinan Pearl.

Simultaneous with the Restricted Stock Contribution, the board of directors of Cullinan Amber, Cullinan Pearl, and Cullinan Florentine determined to accelerate the vesting of the shares of unvested restricted stock immediately prior to the contribution of such stock pursuant to the Restricted Stock Contribution Agreement described above and then terminated their respective stock option and grant plans and the remaining shares reserved for issuance under each respective stock option and grant plan were retired to the status of authorized and unissued shares. The board of directors of Cullinan Pearl also approved the cancellation of all of its outstanding options that were issued pursuant to its stock option and grant plan. In exchange for the cancellation

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of the outstanding options, the holders of such options received a number of restricted common units of the LLC that were acquired in the Unit Purchase for each option's spread value using fair market values prepared by a third party accounting firm. Such restricted common units vest on the same schedule as the options they replaced.

In connection with the equity exchange, each of Mr. Hughes and Drs. Baeuerle and Savill received anti-dilution and make-whole option grants under the 2020 Unit Plan as well as a cash bonus award of \$37,500 each. See "Executive Compensation" for additional information.

CAPITALIZATION

The following table sets forth our cash, cash equivalents, short-term investments and our capitalization as of September 30, 2020:

- on an actual basis;
- on a pro forma basis to give effect to:
 - the issuance and sale of 66,599,045 Series C preferred units in December 2020 for net proceeds of \$124.7 million;
 - the completion of the Reorganization and, subsequent to the Reorganization, the conversion of all outstanding preferred stock into common stock; and
 - the filing and effectiveness of our second amended and restated certificate of incorporation, effective immediately prior to the closing of the offering; and
- on a pro forma as adjusted basis to give further effect to our issuance and sale of shares of our common stock in this offering at an assumed initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma and pro forma as adjusted information below is illustrative only, and our capitalization following the completion of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. You should read this table together with our combined and consolidated financial statements and the related notes appearing at the end of this prospectus and the sections of this prospectus titled “Reorganization,” “Selected Consolidated Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

(In thousands, except share and per share data)	As of September 30, 2020		
	ACTUAL	PRO FORMA	PRO FORMA AS ADJUSTED⁽¹⁾
Cash, cash equivalents and short-term investments	\$ 94,892	\$ 219,592	\$ 398,042
Redeemable preferred units:			
Series Seed redeemable preferred units, \$0.0001 par value; 16,000,000 units authorized issued and outstanding, actual; no units authorized, issued or outstanding, pro forma; no units authorized, issued or outstanding, pro forma as adjusted	3,956	—	—
Series A1 redeemable preferred units, \$0.0001 par value; 50,000,000 units authorized issued and outstanding, actual; no units authorized, issued or outstanding, pro forma; no units authorized, issued or outstanding, pro forma as adjusted	49,946	—	—
Series B redeemable preferred units, \$0.0001 par value; 64,200,000 units authorized, and 63,141,020 units issued and outstanding, actual; no units authorized, issued or outstanding, pro forma; no units authorized, issued or outstanding, pro forma as adjusted	97,909	—	—
Members’ deficit, actual; Stockholders’ equity, pro forma and pro forma as adjusted:			
Non-voting incentive units, \$0.0001 par value; 23,860,000 units authorized, 11,896,500 units issued and outstanding, actual; no units authorized, issued and outstanding, pro forma and pro forma as adjusted	1	—	—

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(In thousands, except share and per share data)	As of September 30, 2020		
	ACTUAL	PRO FORMA	PRO FORMA AS ADJUSTED ⁽¹⁾
Common units, \$0.0001 par value; no units authorized, issued and outstanding, actual; no units authorized, issued and outstanding, pro forma and pro forma as adjusted	—	—	—
Common stock, \$0.0001 par value; no shares authorized, issued and outstanding, actual; 160,000,000 authorized, 29,497,847 shares issued and outstanding, pro forma; 160,000,000 authorized, 39,497,847 issued and outstanding, pro forma as adjusted	—	3	4
Noncontrolling interest in subsidiaries	1,863	1,863	1,863
Additional paid-in capital	770	277,279	455,728
Accumulated other comprehensive income	59	59	59
Accumulated deficit	(64,993)	(64,993)	(64,993)
Total members' deficit, actual; Total stockholders' equity, pro forma and pro forma as adjusted	(62,300)	214,211	392,661
Total capitalization	\$ 89,511	\$ 214,211	\$ 392,661

- (1) A \$1.00 increase (decrease) in the assumed initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash, total stockholders' equity and total capitalization by \$9.3 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. An increase (decrease) of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash, total stockholders' equity and total capitalization by \$18.1 million, assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The number of shares of our common stock to be outstanding after this offering gives effect to the Reorganization and, subsequent to the Reorganization, the conversion of all outstanding preferred stock into common stock, and is based on (i) an assumed initial public offering price of \$19.50 per share, the midpoint of the price range set forth on the cover page of this prospectus, and (ii) 29,497,847 shares of our common stock (which includes 1,689,949 shares of restricted common stock) outstanding as of September 30, 2020, which assumes the exchange of all outstanding units of Cullinan Oncology, LLC as of September 30, 2020 and 66,599,045 Series C preferred units issued after September 30, 2020 for an aggregate of 29,497,847 shares of common stock of Cullinan Management, Inc. (which includes 1,689,949 shares of restricted common stock) prior to the completion of this offering as if such exchange had occurred as of September 30, 2020. See the section of the prospectus titled "Reorganization."

The table above does not include:

- 12,226,158 shares of our common stock reserved for future issuance under our 2021 Stock Option and Incentive Plan, or the 2021 Plan, which includes currently outstanding equity awards comprised of (i) 4,616,187 shares of common stock issuable upon the exercise of stock options at a weighted average exercise price of \$4.30; and (ii) an aggregate of 1,753,316 shares of our common stock, which will be granted to certain of our executive officers and other employees at the time of effectiveness of the 2021 Plan with an exercise price equal to the initial public offering price per share;
- 320,228 shares of restricted common stock outstanding under our 2021 Plan after September 30, 2020; and
- 416,665 shares of our common stock reserved for future issuance under our 2021 ESPP, which will become effective in connection with this offering.

DILUTION

If you invest in our common stock in this offering, your ownership interest will be diluted immediately to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering.

Our historical net tangible book value (deficit) and historical net tangible book value (deficit) per share have not been presented as there were no common shares outstanding as of September 30, 2020.

Our pro forma net tangible book value as of September 30, 2020 was \$214.2 million, or \$7.26 per share of our common stock. Pro forma net tangible book value represents the amount of our total tangible assets less our total liabilities, after giving effect to (i) the issuance of our Series C preferred units and (ii) the Reorganization, including the exchange of all outstanding units of Cullinan Oncology, LLC as of September 30, 2020 and 66,599,045 Series C preferred units issued after September 30, 2020, for an aggregate of 29,497,847 shares of common stock of our wholly-owned subsidiary Cullinan Management (which includes shares of restricted common stock), prior to the completion of this offering, as if such exchange had occurred as of September 30, 2020, assuming an initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and subsequent to the Reorganization, the conversion of all outstanding preferred stock into common stock. Pro forma net tangible book value per share represents pro forma net tangible book value divided by the total number of shares outstanding as of September 30, 2020 after giving effect to the pro forma adjustments described above.

After giving further effect to our issuance and sale of shares of our common stock in this offering at an assumed initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of September 30, 2020 would have been \$392.7 million, or \$9.94 per share. This represents an immediate increase in pro forma as adjusted net tangible book value per share of \$2.68 to existing stockholders and immediate dilution of \$9.56 in pro forma as adjusted net tangible book value per share to new investors purchasing common stock in this offering. Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the assumed initial public offering price per share paid by new investors. The following table illustrates this dilution on a per share basis:

Assumed initial public offering price per share		\$19.50
Pro forma net tangible book value per share as of September 30, 2020	\$7.26	
Increase in pro forma as adjusted net tangible book value per share attributable to new investors purchasing common stock in this offering	<u>2.68</u>	
Pro forma as adjusted net tangible book value per share after this offering		<u>9.94</u>
Dilution per share to new investors purchasing common stock in this offering		<u>\$ 9.56</u>

A \$1.00 increase (decrease) in the assumed initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) our pro forma as adjusted net tangible book value per share after this offering by approximately \$0.24 and dilution per share to new investors purchasing common stock in this offering by approximately \$0.76, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. An increase of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase our pro forma as adjusted net tangible book value per share after this offering by approximately \$0.21 and decrease the dilution per share to new investors purchasing common stock in this offering by approximately \$0.21, assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. A decrease of 1,000,000

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shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would decrease our pro forma as adjusted net tangible book value per share after this offering by approximately \$0.21 and increase the dilution per share to new investors purchasing common stock in this offering by approximately \$0.21, assuming no change in the assumed initial public offering price and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters fully exercise their option to purchase additional shares of common stock in this offering, our pro forma as adjusted net tangible book value per share after this offering would be \$10.24 and the dilution in pro forma as adjusted net tangible book value per share to new investors purchasing common stock in this offering would be \$9.26, assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The following table summarizes, as of September 30, 2020, on the pro forma as adjusted basis described above, the total number of shares of common stock purchased from us, the total consideration paid or to be paid, and the average price per share paid or to be paid by existing stockholders and by new investors in this offering at an assumed initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. As the table shows, new investors purchasing common stock in this offering will pay an average price per share substantially higher than our existing stockholders paid.

	<u>Shares Purchased</u>		<u>Total Consideration</u>		<u>Average Price Per Share</u>
	<u>Number</u>	<u>Percent</u>	<u>Amount</u>	<u>Percent</u>	
Existing stockholders	29,497,847	74.7%	\$283,700,110	59.3%	\$ 9.62
New investors	10,000,000	25.3	195,000,000	40.7	\$ 19.50
Total	<u>39,497,847</u>	<u>100%</u>	<u>\$478,700,110</u>	<u>100%</u>	

A \$1.00 increase (decrease) in the assumed initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the total consideration paid by new investors by \$10.0 million and, in the case of an increase, would increase the percentage of total consideration paid by new investors by 1.2 percentage points and, in the case of a decrease, would decrease the percentage of total consideration paid by new investors by 1.3 percentage points, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same. An increase (decrease) of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the total consideration paid by new investors by \$19.5 million and, in the case of an increase, would increase the percentage of total consideration paid by new investors by 2.3 percentage points and, in the case of a decrease, would decrease the percentage of total consideration paid by new investors by 2.5 percentage points, assuming no change in the assumed initial public offering price per share.

The table above assumes no exercise of the underwriters' option to purchase additional shares in this offering. If the underwriters' option to purchase additional shares is fully exercised, the number of shares of our common stock held by existing stockholders would be reduced to 71.9% of the total number of shares of our common stock outstanding after this offering, and the number of shares of common stock held by new investors purchasing common stock in this offering would be increased to 28.1% of the total number of shares of our common stock outstanding after this offering.

The table above is based on 29,497,847 shares of common stock outstanding as of September 30, 2020 and gives effect to the Reorganization and assumes the exchange of all outstanding units of Cullinan Oncology, LLC as of September 30, 2020 and 66,599,045 Series C preferred units issued after September 30, 2020 for an aggregate of 29,497,847 shares of common stock of our wholly-owned subsidiary Cullinan Management, Inc. (which includes 1,689,949 shares of restricted common stock) prior to the completion of this offering as if such exchange had occurred as of September 30, 2020.

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The table above does not include:

- 12,226,158 shares of our common stock reserved for future issuance under our 2021 Stock Option and Incentive Plan, or the 2021 Plan, which includes currently outstanding equity awards comprised of (i) 4,616,187 shares of common stock issuable upon the exercise of stock options at a weighted average exercise price of \$4.30; and (ii) an aggregate of 1,753,316 shares of our common stock, which will be granted to certain of our executive officers and other employees at the time of effectiveness of the 2021 Plan with an exercise price equal to the initial public offering price per share;
- 320,228 shares of restricted common stock outstanding under our 2021 Plan after September 30, 2020; and
- 416,665 shares of our common stock reserved for issuance under our 2021 Employee Stock Purchase Plan, or 2021 ESPP, which will become effective in connection with this offering.

If common stock options are issued under our equity incentive plan, or if we issue additional shares of common stock in the future, there will be further dilution to investors purchasing common stock in this offering.

SELECTED CONSOLIDATED FINANCIAL DATA

The following information is presented for Cullinan Oncology, LLC, which will merge with and into the Corporation, the entity whose shares are being offered hereby. The consolidated statement of operations and comprehensive loss data for the years ended December 31, 2018 and 2019 and the selected consolidated balance sheet data as of December 31, 2018 and 2019 have been derived from our audited consolidated financial statements. The consolidated statement of operations and comprehensive loss data for the nine months ended September 30, 2019 and 2020 and the selected consolidated balance sheet data as of September 30, 2020 have been derived from our unaudited condensed consolidated financial statements, both of which are included elsewhere in this prospectus. In the opinion of management, the unaudited financial statements include all adjustments, consisting of only normal and recurring adjustments, necessary for a fair presentation of such financial data. You should read this data together with our consolidated financial statements and related notes included elsewhere in this prospectus and the information under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations." Our historical results are not necessarily indicative of the results to be expected in the future for a full year or any interim period.

	YEAR ENDED DECEMBER 31,		NINE MONTHS ENDED SEPTEMBER 30,	
	2018	2019	2019	2020
(unaudited)				
(in thousands, except share and per share data)				
Consolidated statement of operations data:				
Operating expenses:				
Research and development	\$ 9,584	\$ 16,788	\$ 12,986	\$ 26,582
General and administrative	5,002	5,482	4,305	4,580
Total operating expenses	<u>14,586</u>	<u>22,270</u>	<u>17,291</u>	<u>31,162</u>
Loss from operations	(14,586)	(22,270)	(17,291)	(31,162)
Other income, net:				
Interest income	397	620	368	809
Other (expense) income, net	—	(4)	—	1
Total other income, net	<u>397</u>	<u>616</u>	<u>368</u>	<u>810</u>
Net loss	(14,189)	(21,654)	(16,923)	(30,352)
Net loss attributable to noncontrolling interest	—	(997)	(835)	(6,899)
Net loss attributable to Cullinan	<u>\$ (14,189)</u>	<u>\$ (20,657)</u>	<u>\$ (16,088)</u>	<u>\$ (23,453)</u>
Net loss per unit attributable to common and non-voting incentive unit holders, basic and diluted ⁽¹⁾	<u>\$ (5.56)</u>	<u>\$ (3.23)</u>	<u>\$ (2.67)</u>	<u>\$ (2.62)</u>
Total weighted-average common and non-voting incentive units used in computing net loss per unit, basic and diluted ⁽¹⁾	<u>2,549,865</u>	<u>6,397,443</u>	<u>6,017,973</u>	<u>8,960,373</u>
Comprehensive loss:				
Net loss	\$ (14,189)	\$ (21,654)	\$ (16,923)	\$ (30,352)
Unrealized (loss) gain on investments	—	(4)	—	63
Comprehensive loss	(14,189)	(21,658)	(16,923)	(30,289)
Comprehensive loss attributable to noncontrolling interest	—	(997)	(835)	(6,899)
Comprehensive loss attributable to Cullinan	<u>\$ (14,189)</u>	<u>\$ (20,661)</u>	<u>\$ (16,088)</u>	<u>\$ (23,390)</u>
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited) ⁽¹⁾⁽²⁾		<u>\$ (1.80)</u>		<u>\$ (1.21)</u>
Total weighted-average common stock outstanding used in computing pro forma net loss per share, basic and diluted (unaudited) ⁽¹⁾⁽²⁾		<u>11,449,625</u>		<u>19,361,467</u>

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- (1) See Note 12 to our consolidated financial statements and our condensed consolidated financial statements included elsewhere in this prospectus for a description of how we compute net loss per unit attributable to common and non-voting incentive unit holders, basic and diluted, and the weighted-average common and non-voting incentive units used in computation of per unit amounts.
- (2) Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited) and pro forma weighted average common stock outstanding—basic and diluted (unaudited) gives effect to (i) the completion of the Reorganization—see “Reorganization” for further detail—and (ii) subsequent to the Reorganization, the conversion of all outstanding shares of our preferred stock into common stock as if such transactions had occurred on the later of the beginning of the period or the issuance of the redeemable preferred units, but does not reflect the transactions described in “The Reorganization—Reorganization Equity Exchange”, nor does it include units from the Series C offering completed in December 2020.

	<u>As of December 31,</u> <u>2018</u>	<u>As of December 31,</u> <u>2019</u>	<u>As of September 30,</u> <u>2020</u> <u>(unaudited)</u>
	(in thousands)		
Balance Sheet Data:			
Cash, cash equivalents and short-term investments	\$ 33,832	\$ 98,630	\$ 94,892
Working capital ⁽¹⁾	32,895	97,568	89,298
Total assets	34,640	100,461	97,317
Redeemable preferred units	53,902	137,774	151,811
Total members' deficit	(20,650)	(39,909)	(62,300)

- (1) We define working capital as current assets less current liabilities.

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 the "Selected Consolidated Financial Data" section of this prospectus and our consolidated financial statements and the related notes appearing elsewhere in this prospectus. This discussion and other parts of this prospectus 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 prospectus.

Overview

We are a biopharmaceutical company developing a diversified pipeline of targeted oncology and immuno-oncology therapies with transformative potential for cancer patients. In approximately three and a half years, by leveraging our differentiated hub-and-spoke business model, we have efficiently developed or in-licensed a pipeline of seven distinct programs. Our unique business model leverages a central operating company and separate subsidiaries that are established to hold and advance individual therapeutic candidates. Cullinan Management, Inc., or Cullinan Management, our wholly-owned operating subsidiary, employs all of our team members and incubates discovery programs until we establish a "spoke" in which to further advance them. In addition, we centralize shared services, including all research and development operations, administrative services, and business development, in Cullinan Management and allocate employees and resources to each spoke based on the needs and development stage of each therapeutic candidate. As of September 30, 2020, we had five partially-owned development subsidiaries, or spokes, in addition to Cullinan Management: Cullinan Pearl Corp., or Cullinan Pearl, which is advancing CLN-081; Cullinan Apollo Corp., or Cullinan Apollo, which was formed around VK-2019, a drug that we subsequently decided to discontinue development of in May 2020; Cullinan MICA Corp., or Cullinan MICA, which is advancing CLN-619; Cullinan Florentine Corp., or Cullinan Florentine, which is advancing CLN-049; and Cullinan Amber Corp., or Cullinan Amber, which is developing our AMBER platform and advancing CLN-617 as its first therapeutic candidate. Cullinan Management, Cullinan Pearl, Cullinan MICA, Cullinan Florentine and Cullinan Amber are collectively referred to as the Asset Subsidiaries. Our earlier-stage programs, NexGem, Opal and Jade, are currently held in Cullinan Management. At December 31, 2019, we had four partially-owned development subsidiaries in addition to Cullinan Management: Cullinan Amber, Cullinan Apollo, Cullinan Florentine and Cullinan Pearl.

Since our inception in 2016, we have focused substantially 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. To support these activities, we and our wholly-owned subsidiary, Cullinan Management, (i) identify and secure new programs, (ii) set up new subsidiaries to further advance individual programs, (iii) recruit key management team members, (iv) raise and allocate capital across the portfolio, and (v) provide certain shared services, including research and development operations, administrative services, and business development, to our subsidiaries. We do not have any products approved for sale and have not generated any revenue from product sales.

Since inception, we have funded our operations primarily through the sale of redeemable preferred units. In October 2016, we received \$4.0 million from the purchase and sale of our Series Seed preferred units. Subsequently, in April 2017, we received approximately \$50.0 million from the purchase and sale of our Series A preferred units. In October and December 2019, we received a total of approximately \$84.3 million for the purchase and sale of our Series B preferred units. In February and March 2020, we received approximately \$14.3 million for the additional sale of our Series B preferred units. Through December 16, 2020, after giving effect to the issuance of our Series C preferred units, our investors have provided approximately \$277.0 million in cumulative net proceeds.

As of September 30, 2020, we had cash, cash equivalents, and short-term investments of \$94.9 million. Subsequent to September 30, 2020, we have received \$124.7 million of proceeds from sales of our Series C

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preferred units. We have incurred operating losses and have had negative cash flows from operations since our inception. Our net loss was \$14.2 million, \$21.7 million and \$30.4 million, for the years ended December 31, 2018 and 2019 and the nine months ended September 30, 2020, respectively. As of September 30, 2020, we had an accumulated deficit of \$65.0 million. We expect to continue to generate operating losses for the foreseeable future. Our future viability is dependent on the success of our research and development and our ability to access additional capital to fund our operations. There can be no assurance that our current operating plan will be achieved or that additional funding will be available on terms acceptable to us, or at all.

We are subject to risks and uncertainties common to early-stage companies in the biotechnology industry including, but not limited to, new technological innovations, protection of proprietary technology, dependence on key personnel, compliance with government regulations, and the ability to obtain additional capital to fund operations. Our 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. The current outbreak of the novel coronavirus, or COVID-19, could materially and adversely affect our results of operations, financial condition and cash flows. The full extent of the impact due to the COVID-19 pandemic will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and actions taken to contain or treat COVID-19, as well as the economic impact. Given the uncertainty around the extent and timing of the potential future spread or mitigation efforts related to the current outbreak of COVID-19, the financial impact cannot be reasonably estimated at this time.

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 statement of operations and comprehensive loss.

The entities that are consolidated in our consolidated financial statements include the following:

<u>Consolidated Entities</u>	<u>Current Relationship</u>	<u>Date Control First Acquired</u>	<u>Ownership as of Sep 30, 2020 %⁽¹⁾</u>	<u>Ownership as of Dec 31, 2020%⁽¹⁾⁽²⁾</u>
Cullinan Management, Inc.	Wholly-owned Subsidiary	September 2016	100%	100%
Cullinan Apollo Corp.	Partially-owned Subsidiary	November 2018	71%	71%
Cullinan Pearl Corp.	Partially-owned Subsidiary	November 2018	65%	80%
Cullinan Amber Corp.	Partially-owned Subsidiary	December 2019	52%	90%
Cullinan Florentine Corp.	Partially-owned Subsidiary	December 2019	66%	92% ⁽³⁾
Cullinan MICA Corp.	Partially-owned Subsidiary	May 2020	24% ⁽⁴⁾	35% ⁽⁴⁾

- (1) Ownership percentages are reflected on a fully-diluted basis.
- (2) In November 2020, the board of directors of Cullinan Pearl, Cullinan Amber, and Cullinan Florentine terminated their respective stock option and grant plan and the remaining shares reserved for issuance under each respective stock option and grant plan were retired to the status of authorized and unissued shares.
- (3) Reflects the closing of the second tranche of the Series A Preferred Stock financing of Cullinan Florentine, which occurred on December 16, 2020, and the issuance of common stock of Cullinan Florentine to DKFZ and UFE on December 18, 2020.
- (4) In December 2020, the board of directors and stockholders of Cullinan MICA approved an amendment to its equity plan that decreased the authorized amount of shares under its equity plan such that no further grants could be made under its equity plan. Any authorized but unissued shares under the equity plan were returned to the status of authorized, unissued shares of common stock. Pursuant to a subscription agreement, the LLC entity subsequently purchased an aggregate of 3,367,804 shares of common stock of Cullinan MICA. As a

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result of these transactions, Cullinan Oncology, LLC's, or the LLC entity's, ownership will increase to approximately 54%, on a fully-diluted basis, upon completion of the remaining two tranches of Series A financing and are subject to the determination of Cullinan MICA's board. See "—Cullinan MICA" below for additional information.

Cullinan Apollo

Cullinan Apollo, incorporated in November 2018, is our partially-owned operating subsidiary that was formed around VK-2019. In December 2018, Cullinan Apollo licensed the exclusive worldwide rights to VK-2019, an Epstein-Barr Nuclear Antigen 1 (EBNA1) inhibitor, from The Wistar Institute, or Wistar. Cullinan Apollo also entered into a Collaborative Research Agreement with Wistar to continue preclinical research and development of VK-2019. In May 2020, Cullinan Apollo discontinued development of VK-2019 and terminated its license and collaboration agreements with Wistar.

Cullinan Pearl

Cullinan Pearl, incorporated in November 2018, is our partially-owned operating subsidiary that has exclusive worldwide rights, excluding Japan and Greater China, to CLN-081, our orally available small molecule designed as a next generation, irreversible EGFR inhibitor that is in development for the treatment of NSCLC patients with EGFR exon 20 insertion mutations. In February 2019, Cullinan Pearl entered into a licensing and collaboration agreement with Taiho Pharmaceutical, Co., Ltd., or Taiho Pharma, for the worldwide rights to CLN-081 outside of Japan, which Taiho Pharma retained. As of December 31, 2020, the LLC entity and Taiho Ventures, LLC, or Taiho Ventures, have purchased an aggregate of \$23.0 million in Series A preferred stock of Cullinan Pearl. Specifically, in February 2019, Cullinan Pearl issued to Taiho Ventures 1,860,000 shares of Series A Preferred Stock at a price of \$1.00 per share for an aggregate purchase price of \$1,860,000. In August 2020, at the election of the board of directors of Cullinan Pearl, Cullinan Pearl closed its subsequent closing of its Series A Preferred Stock financing and issued to Taiho Ventures an additional 1,206,000 shares of Series A Preferred Stock for an aggregate purchase price of \$1,206,000. As of December 31, 2020, the LLC entity owns 87% and Taiho Ventures owns 13% of the Series A preferred stock. Assuming conversion of the Series A preferred stock, the LLC entity owns 80%, Taiho Ventures owns 10%, and Taiho Pharma owns 10% of the fully diluted common stock outstanding of Cullinan Pearl. Pursuant to a voting agreement, by and among Cullinan Pearl, the LLC entity, Taiho Ventures, and other stockholders of Cullinan Pearl, the Series A Preferred stockholders, acting by majority vote, have the right to appoint two members of the board of directors, Taiho Ventures has the right to appoint one director; the LLC entity's chief executive officer, Mr. Hughes, serves as the fourth board member; and two independent directors are appointed by a majority of the other four Cullinan Pearl board of directors.

Cullinan Amber

Cullinan Amber, incorporated in December 2019, is our partially-owned operating subsidiary that has exclusive worldwide rights to the patents related to the technology that originated in the laboratory of Professor Dane Wittrup at the Massachusetts Institute of Technology, or MIT. In December 2019, Cullinan Amber entered into an Exclusive Patent License Agreement with MIT. The LLC entity currently owns 90% of the issued equity of Cullinan Amber, on a fully-diluted basis, including 100% of the shares of Series A preferred stock. MIT and Dr. Wittrup each own approximately 5% of the issued and outstanding equity of Cullinan Amber on a fully-diluted basis. Pursuant to the Series A Preferred Stock Purchase Agreement, by and among Cullinan Amber and the LLC entity, upon election by the Cullinan Amber board of directors, the LLC entity will purchase up to an additional 9,000,000 Series A Preferred Stock at a purchase price of \$1.00 per share of Series A Preferred Stock in one or more closings. Pursuant to a voting agreement by and among Cullinan Amber, the LLC entity, and other stockholders, of the three person board of directors, the holders of Series A preferred stock, acting by majority vote, have the right to designate two members of the board of directors.

Cullinan Florentine

Cullinan Florentine, incorporated in December 2019, is our partially-owned operating subsidiary that has exclusive worldwide rights to CLN-049, our bispecific antibody targeting FLT3 and CD3, pursuant to an

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Exclusive License Agreement with Deutsches Krebsforschungszentrum, or DKFZ, Eberhard Karls University of Tübingen, Faculty of Medicine, or University of Tübingen, and Universitätsmedizin Gesellschaft für Forschung und Entwicklung mbH, Tübingen, or UFE. Through December 16, 2020, the LLC entity has purchased an aggregate of \$12.0 million of shares of Series A preferred stock of Cullinan Florentine through two closings of a Series A financing. In connection with the issuance of additional shares of Series A Preferred Stock to the LLC entity and pursuant to the license agreement with DKFZ, UFE and the University of Tübingen, Cullinan Florentine issued to each of DKFZ and UFE an additional 261,540 and 120,270 shares of common stock of Cullinan Florentine, respectively. As a result, the LLC entity currently owns 92% of the fully diluted shares outstanding of Cullinan Florentine, including 100% of the shares of Series A preferred stock. DKFZ and University of Tübingen currently own in the aggregate approximately 8% of the equity of Cullinan Florentine on a fully-diluted basis. Pursuant to a voting agreement, in the form filed as Exhibit 10.19 hereto, between Cullinan Florentine, the LLC entity and other stockholders, of the four person board of directors, the holders of Series A preferred stock, acting by majority vote, have the right to designate two members of the board of directors, DKFZ and UFE, acting jointly, have the right to appoint one director, and the CEO of Cullinan Florentine, who is currently our CEO, Mr. Owen Hughes, is the fourth board member.

Cullinan MICA

Cullinan MICA, Corp. (formerly known as PDI Therapeutics, Inc.), or Cullinan MICA, of which we assumed operational control in May 2020, is our partially-owned operating subsidiary that owns intellectual property related to CLN-619, our MICA/B-targeted humanized IgG1 monoclonal antibody. The LLC entity purchased 24% of the issued equity of Cullinan MICA, on a fully-diluted basis, including 89% of the outstanding shares of Series A Senior Preferred Stock. Pursuant to the Series A Senior Preferred Stock Purchase Agreement by and among the LLC entity, Cullinan MICA, and other stockholders of Cullinan MICA, the LLC entity will purchase up to an additional \$16.0 million of the aggregate \$18.0 million Series A Senior Preferred Stock in two milestone-dependent closings. The first closing milestone relates to the establishment of an acceptable preliminary dosing, pharmacokinetic, and safety profile, as well as certain Good Manufacturing Practice and regulatory events, in a monotherapy dose escalation study for CLN-619 in patients with advanced solid tumors. Upon the (i) determination of Cullinan MICA's board of directors that the milestone has been achieved or (ii) the election of Cullinan MICA's board of directors to waive the milestone requirements, the purchasers are required to invest approximately an additional \$8.0 million. The second closing milestone relates to the global expansion cohorts for CLN-619 and will be met upon: confirmation of dosing and pharmacodynamics effects, demonstration of clinical efficacy, and achievement of an acceptable safety profile. Upon the (i) determination of Cullinan MICA's board of directors that the milestone has been achieved or (ii) the election of Cullinan MICA's board of directors to waive the milestone requirements, the purchasers are required to invest approximately an additional \$10.0 million. In December 2020, the stockholders and the board of directors of Cullinan MICA approved an amendment to its equity plan that decreased the authorized amount of shares under its equity plan such that no further grants could be made under its equity plan. Any authorized but unissued shares under the equity plan were returned to the status of authorized, unissued shares of common stock. Pursuant to a subscription agreement, the LLC entity subsequently purchased an aggregate of 3,367,804 shares of common stock of Cullinan MICA. As a result of these transactions, the LLC entity's ownership percentage in Cullinan MICA increased to approximately 35% as of December 31, 2020. Therefore, at the time of the first and second milestone closings, the LLC entity will own approximately 45% and 54%, respectively, of the fully diluted capital stock outstanding. Pursuant to a voting agreement, by and among Cullinan MICA, the LLC entity, and other stockholders of Cullinan MICA, of the five person board of directors, the LLC entity has the right to appoint three members of the board of directors. For additional disclosure on the accounting implications of this transaction, please see Note 5 of our condensed consolidated financial statements.

Components of Our Results of Operations

Revenue

We have not generated any revenue since our inception and do not expect to generate any revenue from the sale of products in the near future, if at all. If our development efforts for our therapeutic candidates are successful and result in regulatory approval or if we enter into collaboration or license agreements with third

parties, we may generate revenue in the future from a combination of product sales or payments from such collaboration or license agreements.

Operating expenses

Research and development expenses

Research and development expenses consist primarily of costs incurred in connection with the research and development of our therapeutic candidates and programs. We expense research and development costs and intangible assets acquired that have no alternative future use as incurred. These expenses include:

- employee-related expenses, including salaries, related benefits and equity-based compensation expense, 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 therapeutic candidates and programs, including under agreements with contract research organizations, or CROs;
- costs related to contract manufacturing organizations, or CMOs, that are primarily engaged to provide drug substance and 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; and
- payments made under third-party licensing agreements.

Advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. Such amounts are recognized as an expense as the goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered or the services rendered.

Therapeutic candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect that our research and development expenses will increase substantially in connection with our planned clinical development activities in the near term and in the future. At this time, we cannot accurately estimate or know the nature, timing and costs of the efforts that will be necessary to complete the clinical development of any current or future therapeutic candidates.

Our clinical development costs may vary significantly based on factors such as:

- per patient trial costs;
- the number of trials required for approval;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the trials;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up periods;

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- the cost and timing of manufacturing our therapeutic candidates;
- the phase of development of our therapeutic candidates;
- the efficacy and safety profile of our therapeutic candidates; and
- the number of therapeutic candidates we are developing.

The successful development and commercialization of therapeutic candidates is highly uncertain. This is due to the numerous risks and uncertainties associated with product development and commercialization, including the following:

- the timing and progress of nonclinical and clinical development activities;
- the number and scope of nonclinical and clinical programs we decide to pursue;
- raising necessary additional funds;
- the progress of the development efforts of parties with whom we may enter into collaboration arrangements;
- our ability to maintain our current development programs and to establish new ones;
- our ability to establish new licensing or collaboration arrangements;
- the successful initiation and completion of clinical trials with safety, tolerability and efficacy profiles that are satisfactory to the FDA or any comparable foreign regulatory authority;
- the receipt and related terms of regulatory approvals from applicable regulatory authorities;
- the availability of drug substance and drug product for use in the production of our therapeutic candidates;
- establishing and maintaining agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing, if our therapeutic candidates are approved;
- our ability to obtain and maintain patents, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- our ability to protect our rights in our intellectual property portfolio;
- the commercialization of our therapeutic candidates, if and when approved;
- obtaining and maintaining third-party insurance coverage and adequate reimbursement;
- the acceptance of our therapeutic candidates, if approved, by patients, the medical community and third-party payors;
- competition with other products; and
- a continued acceptable safety profile of our therapies following approval.

A change in the outcome of any of these variables with respect to the development of our therapeutic candidates could significantly change the costs and timing associated with the development of that therapeutic candidate. We may never succeed in obtaining regulatory approval for any of our therapeutic candidates or programs.

General and administrative expenses

General and administrative expenses consist primarily of salaries and related costs for personnel in executive management, finance, corporate and business development, and 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.

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We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support development of our therapeutic candidates and programs and our continued research activities. We also anticipate that we will incur increased accounting, audit, legal, regulatory, compliance, and director and officer insurance costs as well as investor and public relations expenses associated with being a public company.

Other Income

Interest Income

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

Income Taxes

The LLC entity has elected to be treated under the Partnership provisions of the Internal Revenue Code. Accordingly, the LLC entity is not viewed as a tax-paying entity in any jurisdiction and all income and deductions of the LLC entity are reported on our members' individual income tax returns and no income taxes are recorded by the LLC entity. The LLC entity does not have any operations.

Our Subsidiaries are taxed as corporations for federal and state income tax purposes. Our Subsidiaries account for income taxes using the asset and liability method in accordance with FASB ASC Topic 740, Income Taxes. Current income taxes are based on taxable income for federal and state reporting purposes. Deferred income 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 using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. A valuation allowance is provided when it is more likely than not that some portion, or all of a deferred tax asset will not be realized. Due to our Subsidiaries' lacking earnings history, the net deferred tax assets have been fully offset by a valuation allowance.

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

Results of Operations

Comparison of Years Ended December 31, 2018 and 2019

The following table summarizes our results of operations for the years ended December 31, 2018 and 2019:

<u>(in thousands)</u>	<u>Year Ended December 31,</u>	
	<u>2018</u>	<u>2019</u>
Operating expenses:		
Research and development	\$ 9,584	\$ 16,788
General and administrative	5,002	5,482
Total operating expenses	14,586	22,270
Loss from operations	(14,586)	(22,270)
Other income, net:		
Other income, net	397	616
Total other income, net	397	616
Net loss	\$ (14,189)	\$ (21,654)
Net loss attributable to noncontrolling interest	—	(997)
Net loss attributable to Cullinan	<u>\$ (14,189)</u>	<u>\$ (20,657)</u>

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Research and Development Expenses

<u>(in thousands)</u>	<u>Year Ended December 31,</u>		<u>Change</u>
	<u>2018</u>	<u>2019</u>	
Cullinan Pearl (CLN-081)	\$ 114	\$ 7,002	\$ 6,888
Cullinan Apollo (VK-2019)	3,982	4,133	151
Cullinan Florentine (CLN-049)	—	909	909
Cullinan Amber (CLN-617)	—	281	281
Cullinan Wittelsbach Program	3,036	—	(3,036)
Other terminated programs	621	—	(621)
Other personnel and unallocated	1,831	4,463	2,632
Total research and development expenses	<u>\$ 9,584</u>	<u>\$ 16,788</u>	<u>\$ 7,204</u>

Research and development expenses were \$9.6 million for the year ended December 31, 2018, compared to \$16.8 million for the year ended December 31, 2019. We have separately provided additional detail for the research and development expenses incurred in connection with the research and development activities conducted for the therapeutic candidates and programs being developed by our partially-owned subsidiaries Cullinan Amber, Cullinan Florentine, and Cullinan Pearl, certain of our consolidated entities, as we believe they represent key portfolio value drivers. We have also included research and development expense detail for Cullinan Apollo and Cullinan Wittelsbach, which are subsidiaries that we have dissolved, or plan to dissolve in the case of Cullinan Apollo, in the near future. The increase of \$7.2 million was primarily due to CLN-081 clinical activity following our 2019 IND submission and the upfront fee and fair value of common stock issued to Taiho Pharma in connection with our license of ex-Japan rights to CLN-081, as well as increased external research activity associated with our collaborations with Fred Hutch and Adimab LLC, or Adimab, offset by non-recurring costs from our terminated programs, including from Cullinan Wittelsbach.

We are heavily dependent on the success of our therapeutic candidates, the most advanced of which are in preclinical or the early stages of clinical development, which is a lengthy and expensive process with uncertain outcomes and the potential for substantial delays. We cannot give any assurance that any of our therapeutic candidates will receive regulatory approval or, if approved, achieve commercial success.

General and Administrative Expenses

<u>(in thousands)</u>	<u>Year Ended December 31,</u>		<u>Change</u>
	<u>2018</u>	<u>2019</u>	
Personnel-related	\$ 2,580	\$ 2,657	\$ 77
Professional services fees	1,060	1,199	139
Legal fees	663	826	163
Occupancy and other fees	699	800	101
Total general and administrative expenses	<u>\$ 5,002</u>	<u>\$ 5,482</u>	<u>\$ 480</u>

General and administrative expenses were \$5.0 million for the year ended December 31, 2018 compared to \$5.5 million for the year ended December 31, 2019. The increase of \$0.5 million was primarily due to increased expenditure on outside professional services and diligence regarding the Cullinan Amber and Cullinan Florentine transactions, as well as inflationary impact of personnel- and occupancy-related expenses. These increases were largely due to our operations expanding and an increase in headcount to support the additional operations.

Other Income, Net

Other income, net was \$0.4 million during the year ended December 31, 2018 compared to \$0.6 million during the year ended December 31, 2019. The increase of \$0.2 million was primarily related to an increase in interest income resulting from higher average balances on our cash, cash equivalents, and short-term investments.

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Net Loss Attributable to Noncontrolling Interest

Net losses are attributed to noncontrolling interests under the hypothetical liquidation at book value, or HLBV, method for certain subsidiaries. The HLBV method is a point in time calculation that utilizes inputs to determine the amount that the noncontrolling interest holders would receive upon a hypothetical liquidation at each balance sheet date based on the liquidation provisions of the respective articles of incorporation. Net loss attributable to noncontrolling interest was nil in 2018 compared to \$1.0 million associated with our partially-owned subsidiary Cullinan Pearl in 2019.

Comparison of Periods Ended September 30, 2019 and 2020

The following table summarizes our results of operations for the nine months ended September 30, 2019 and 2020:

<u>(in thousands)</u>	<u>Nine Months Ended September 30,</u>	
	<u>2019</u>	<u>2020</u>
	<u>(unaudited)</u>	
Operating expenses:		
Research and development	\$ 12,986	\$ 26,582
General and administrative	4,305	4,580
Total operating expenses	<u>17,291</u>	<u>31,162</u>
Loss from operations	(17,291)	(31,162)
Other income, net:		
Other income, net	368	810
Total other income, net	<u>368</u>	<u>810</u>
Net loss	(16,923)	(30,352)
Net loss attributable to noncontrolling interest	(835)	(6,899)
Net loss attributable to Cullinan	<u>\$ (16,088)</u>	<u>\$ (23,453)</u>

Research and Development Expenses

<u>(in thousands)</u>	<u>Nine Months Ended September 30,</u>		<u>Change</u>
	<u>2019</u>	<u>2020</u>	
	<u>(unaudited)</u>		
Cullinan MICA (CLN-619)	\$ —	\$ 8,560	\$ 8,560
Cullinan Florentine (CLN-049)	—	7,281	7,281
Cullinan Pearl (CLN-081)	5,948	5,390	(558)
Cullinan Apollo (VK-2019)	3,256	1,841	(1,415)
Cullinan Amber (CLN-617)	—	437	437
Other personnel and unallocated	3,782	3,073	(709)
Total research and development expenses	<u>\$ 12,986</u>	<u>\$ 26,582</u>	<u>\$13,596</u>

Research and development expenses were \$13.0 million for the nine months ended September 30, 2019, compared to \$26.6 million for the nine months ended September 30, 2020. The increase of \$13.6 million was primarily due to the consolidation of Cullinan MICA's research and development expenses following our Series A investment in May 2020 and the CLN-049 IND-enabling studies in our Cullinan Florentine subsidiary in 2020 compared to 2019, partially offset by lower expenses associated with our Cullinan Apollo program, which was terminated in 2020 as well as the upfront license fee related to CLN-081 in our partially-owned Cullinan Pearl subsidiary that was incurred in 2019.

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General and Administrative Expenses

<u>(in thousands)</u>	<u>Nine Months Ended September 30,</u>		<u>Change</u>
	<u>2019</u>	<u>2020</u>	
		<u>(unaudited)</u>	
Personnel-related	\$ 2,226	\$ 1,994	\$ (232)
Professional services fees	897	1,109	212
Legal fees	592	800	208
Occupancy and other fees	590	677	87
Total general and administrative expenses	<u>\$ 4,305</u>	<u>\$ 4,580</u>	<u>\$ 275</u>

General and administrative expenses were \$4.3 million for the nine months ended September 30, 2019 compared to \$4.6 million for the nine months ended September 30, 2020. The increase of \$0.3 million was primarily due increased expenditure on outside professional services firms for diligence and negotiation in connection with the Cullinan MICA transaction as well as accounting and audit fees, partially offset by a reduction in general and administrative personnel compared to 2019.

Other Income, Net

Other income, net was \$0.4 million during the nine months ended September 30, 2019 compared to \$0.8 million during the nine months ended September 30, 2020. The increase of \$0.4 million was primarily related to an increase in interest income resulting from higher average balances on our cash, cash equivalents, and short-term investments.

Net Loss Attributable to Noncontrolling Interest

Net losses are attributed to noncontrolling interests under the HLBV method for certain subsidiaries. Net loss attributable to noncontrolling interest under the HLBV method was \$0.8 million for the nine months ended September 30, 2019, compared to \$6.9 million for the nine months ended September 30, 2020. The increase of \$6.1 million was primarily related to the noncontrolling interest held in our partially-owned subsidiary Cullinan MICA.

Liquidity and Capital Resources

Since our inception, we have incurred significant operating losses. 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 our redeemable preferred units. Through December 16, 2020, after giving effect to the sale of our Series C preferred units and our receipt of the net proceeds therefrom, we have received net proceeds of approximately \$277.0 million from sales of our redeemable preferred units. As of September 30, 2020, we had cash, cash equivalents, and short-term investments of \$94.9 million. Subsequent to September 30, 2020, we have received \$124.7 million of net proceeds from sales of our Series C preferred units. Based on our current operational plans and assumptions, we expect that the net proceeds from this offering, combined with our current cash, cash equivalents, and short-term investments, will be sufficient to fund operations through 2024. 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.

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Cash flows

Comparison of Years Ended December 31, 2018 and 2019

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

(in thousands)	Year Ended December 31,	
	2018	2019
Net cash used in operating activities	\$ (13,549)	\$ (20,897)
Net cash used in investing activities	(261)	(35,400)
Net cash (used in) provided by financing activities	(29)	85,715
Net (decrease) increase in cash and cash equivalents	\$ (13,839)	\$ 29,418

Cash Flow from Operating Activities

During the year ended December 31, 2018, operating activities used \$13.5 million of cash and primarily consisted of our net loss of \$14.2 million, offset by changes in net operating assets and liabilities of \$0.3 million, and non-cash charges of \$0.3 million. Our non-cash charges of \$0.3 million primarily consisted of a \$0.2 million license expense in exchange for subsidiary capital stock.

During the year ended December 31, 2019, operating activities used \$20.9 million of cash and primarily consisted of our net loss of \$21.7 million, offset by changes in net operating assets and liabilities of \$0.1 million and non-cash charges of \$0.6 million. Our non-cash charges of \$0.6 million primarily consisted of a \$0.5 million license expense in exchange for subsidiary capital stock.

Cash Flow From Investing Activities

During the year ended December 31, 2018, investing activities used \$0.3 million of cash for the purchases of property and equipment.

During the year ended December 31, 2019, investing activities used \$35.4 million of cash for the purchases short-term investments and less than \$0.1 million for the purchases of property and equipment.

Cash Flow From Financing Activities

During the year ended December 31, 2018, net cash used in financing activities was less than \$0.1 million, primarily consisting of costs and payments related to the issuance of Series B preferred units and subsidiary preferred equity.

During the year ended December 31, 2019, net cash provided by financing activities was \$85.7 million, which primarily consisted of net proceeds from the issuance of Series B preferred units of \$83.9 million and net proceeds of \$1.8 million related to the issuance of noncontrolling interests.

Comparison of Periods Ended September 30, 2019 and 2020

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

(in thousands)	Nine Months Ended September 30,	
	2019	2020
	(unaudited)	
Net cash used in operating activities	\$ (16,028)	\$ (20,336)
Net cash used in investing activities	(15)	(16,860)
Net cash provided by financing activities	1,801	15,243
Net decrease in cash and cash equivalents	\$ (14,242)	\$ (21,953)

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Cash Flow from Operating Activities

During the nine months ended September 30, 2019, operating activities used \$16.0 million of cash and primarily consisted of our net loss of \$16.9 million and changes in net operating assets and liabilities of \$0.3 million, offset by non-cash charges of \$0.6 million. Our non-cash charges of \$0.6 million primarily consisted of a \$0.5 million license expense in exchange for subsidiary common stock.

During the nine months ended September 30, 2020, operating activities used \$20.3 million of cash and primarily consisted of our net loss of \$30.4 million, offset by changes in net operating assets and liabilities of \$2.4 million and non-cash charges of \$7.7 million. Our non-cash charges of \$7.7 million primarily consisted of a \$1.0 million license expense in exchange for subsidiary common stock and \$6.4 million for acquired in-process research and development assets because they had no alternative future use.

Cash Flow From Investing Activities

During the nine months ended September 30, 2019, investing activities used less than \$0.1 million of cash for the purchases of property and equipment.

During the nine months ended September 30, 2020, investing activities used \$16.9 million of cash and primarily consisted of less than \$0.1 million used for the purchases of property and equipment and \$48.3 million of purchases of short-term investments, offset by \$30.0 million proceeds from sales of short-term investments and \$1.5 million of cash acquired as part of the asset acquisition for our MICA program.

Cash Flow From Financing Activities

During the nine months ended September 30, 2019, net cash provided by financing activities was \$1.8 million, which primarily consisted of proceeds from the issuance of noncontrolling interests.

During the nine months ended September 30, 2020, net cash provided by financing activities was \$15.2 million, which primarily consisted of proceeds from our issuances of Series B preferred units in February and March 2020, net of issuance costs, of \$14.0 million.

Future Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities, manufacturing and clinical trials of our therapeutic candidates. In addition, upon the closing of this offering, we expect 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 investigational new drug applications, or INDs, for our therapeutic candidates and programs;
- conduct preclinical studies and clinical trials for our current and future therapeutic candidates, including but not limited to CLN-081, CLN-049, and CLN-619;
- take temporary precautionary measures to help minimize the risk of COVID-19 to our employees;
- 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 therapeutic candidates and to support manufacturing on a commercial scale;
- develop and implement plans to establish and operate in-house manufacturing operations and facility;

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- seek regulatory approvals for any therapeutic candidates that successfully complete clinical trials, if any;
- hire and retain additional personnel, such as non-clinical, clinical, pharmacovigilance, quality assurance, regulatory affairs, manufacturing, distribution, legal, compliance, medical affairs, finance, general and administrative, commercial, and scientific personnel;
- develop, maintain, expand, and protect our intellectual property portfolio; and
- transition our organization to being a public company.

Following this offering, we will be a publicly-traded company and will incur significant legal, accounting, and other expenses that we were not required to incur as a private company. In addition, the Sarbanes-Oxley Act of 2002, as well as rules adopted by the SEC and Nasdaq, requires public companies to implement specified corporate governance practices that are currently not applicable to us as a private company. Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we will first be required to furnish a report by our management on our internal control over financial reporting for the year ending December 31, 2022. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants, and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting. We expect these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

Based on our current operational plans and assumptions, we expect that the net proceeds from this offering, combined with our current cash, cash equivalents, and short-term investments, will be sufficient to fund operations through 2024. 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 therapeutic 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 therapeutic 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 therapeutic candidates or future therapeutic 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;

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- timing delays with respect to preclinical and clinical development of our current and future therapeutic candidates, including as result of the COVID-19 pandemic;
- 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 therapeutic candidates or any future therapeutic 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, or cGMP;
- 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 therapeutic candidates, if and when approved; and
- the 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 therapeutic 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 therapeutic candidates that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Other Commitments

The following table summarizes our contractual obligations as of December 31, 2019 and the effects that such obligations are expected to have on our liquidity and cash flows in future periods:

<u>(in thousands)</u>	<u>Payments Due by Period</u>				
	<u>Total</u>	<u>Less than 1 Year</u>	<u>1 to 3 Years</u>	<u>3 to 5 Years</u>	<u>More Than 5 Years</u>
Operating lease commitments	\$2,728	\$ 590	\$1,825	\$313	\$ —
Total	\$2,728	\$ 590	\$1,825	\$313	\$ —

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, 2019, our condensed consolidated balance sheet as of September 30, 2020, or in the contractual obligations table above.

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In December 2020, we made a payment of \$1.0 million related to certain options available to us under our collaboration agreement with Adimab, related to CLN-978. We expect to make an additional payment of \$0.5 million in 2021 under the same agreement.

In addition, we enter into agreements in the normal course of business with CROs for clinical trials and with vendors for preclinical studies, manufacturing services, and other services and products for operating purposes, which are generally cancelable upon written notice. These payments are not included in the contractual obligations table above.

Critical Accounting Policies and Estimates

Our consolidated financial statements are prepared in accordance with generally accepted accounting principles, or GAAP, in the United States. 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 to our consolidated financial statements and condensed consolidated financial statements appearing at the end of this prospectus, 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.

Principles of Consolidation

We consolidate entities in which we have a direct or indirect controlling financial interest. We evaluate each of our 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. We have concluded that none of our subsidiaries is a VIE and we have consolidated each subsidiary under the voting interest model. Under the voting interest model, we consolidate the entity if it is determined 1) that we directly, or indirectly, have greater than 50% of the voting shares or other equity holders do not have substantive voting, participation, or liquidation rights, or 2) when we have a controlling financial interest through our control of the board of directors, and the significant decisions of the entity are made at the board level.

Net Loss Attributable to Noncontrolling Interests

Net loss attributable to noncontrolling interests in our consolidated statements of operations is a result of our investments in our consolidated entities, which include Cullinan Pearl and Cullinan MICA, and consists of the portion of the net loss of those consolidated entities that is not allocated to us. Changes in the amount of net loss attributable to noncontrolling interests related to these subsidiaries are directly impacted by changes in the net loss of the consolidated entity. To the extent that ownership interests in the Asset Subsidiaries are held by entities other than the LLC entity, management reports these as noncontrolling interests on the consolidated balance sheets. Earnings or losses are attributed to noncontrolling interests under the hypothetical liquidation at book value, or HLBV, method. The HLBV method is a point in time calculation that utilizes inputs to determine the amount that we and our noncontrolling interest holders would receive upon a hypothetical liquidation at each balance sheet date based on the liquidation provisions of the respective articles of incorporation.

Research and Development Contract Costs and Accruals

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

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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 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. To date, there have been no material differences between our accrued costs and actual costs.

Equity-Based Compensation Expense

Because there is no public market for our non-voting incentive units as we are a private company, our board of directors has determined the fair value of our non-voting incentive units by considering a number of objective and subjective factors, including having contemporaneous and retrospective valuations of our equity performed by a third-party valuation specialist, valuations of comparable peer public companies, sales of our redeemable preferred units, operating and financial performance, the lack of liquidity of our non-voting incentive units, and general and industry-specific economic outlook. The fair value of our non-voting incentive units will be determined by our board of directors until such time as our non-voting incentive units are listed on an established stock exchange. We recognize the compensation cost of equity-based awards using the straight-line method over the requisite service period of the award, which is generally the vesting period of the award. We classify equity-based compensation in our consolidated statements of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified. We have elected to recognize the actual forfeitures by reducing the equity-based compensation in the same period as the forfeitures occur.

Income Taxes

The LLC entity has elected to be treated under the Partnership provisions of the Internal Revenue Code. Accordingly, we are not viewed as a tax-paying entity in any jurisdiction and all income and deductions are reported on the members' individual income tax returns and no income taxes are recorded by the LLC entity. The LLC entity does not have any operations.

Our Subsidiaries are taxed as corporations for federal and state income tax purposes. Our Subsidiaries account for income taxes using the asset and liability method in accordance with FASB ASC Topic 740, Income Taxes. Current income taxes are based on taxable income for federal and state reporting purposes. Deferred income 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 using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. A valuation allowance is provided when it is more likely than not that some portion, or all of a deferred tax asset will not be realized. Due to our Subsidiaries' lack of earnings history, the net deferred tax assets have been fully offset by a valuation allowance.

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

Net Loss per Unit

The holders of our redeemable preferred units are entitled to receive distributions, including cumulative returns on their units outstanding, prior and in preference to any distributions on any of our common units and non-voting incentive units, which are also entitled to cumulative returns. For the years ended December 31, 2018 and 2019 and the nine months ended September 30, 2019 and 2020 we determined that our common stock equivalents are our common units and non-voting incentive units.

The Company follows the two-class method when computing net loss per unit as the Company has issued units that meet the definition of participating securities. The two-class method determines net income (loss) per unit for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common unit holders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed. For the years ended December 31, 2018 and 2019, the Company considers its redeemable preferred units to be participating securities as they are entitled to participate in undistributed earnings along with Common Unit and vested Non-Voting Incentive Unit members. Unvested Non-Voting Incentive Units are not considered participating securities.

Basic net income (loss) per unit attributable to common unit holders is computed by dividing the net income (loss) attributable to common and non-voting incentive unit holders by the weighted average number of common and non-voting incentive units outstanding for the period. Diluted net income (loss) attributable to common and non-voting incentive unit holders is computed by adjusting net income (loss) attributable to common and non-voting incentive unit holders to reallocate undistributed earnings based on the potential impact of dilutive securities. Diluted net income (loss) per unit attributable to common and non-voting incentive unit holders is computed by dividing the diluted net income (loss) attributable to common and non-voting incentive unit holders by the weighted average number of common and non-voting incentive units outstanding for the period, including potential dilutive common and non-voting incentive units. For purpose of this calculation, unvested non-voting incentive units and redeemable preferred units are considered potential dilutive common units.

Our redeemable preferred unit contractually entitles the holders of such units to participate in dividends but does not contractually require the holders of such units to participate in losses of us. Accordingly, in periods in which we report a net loss attributable to common and non-voting incentive unit holders, such losses are not allocated to such participating securities. In periods in which we report a net loss attributable to common unit holders, diluted net loss per unit attributable to common and non-voting incentive unit holders is the same as basic net loss per unit attributable to common unit holders, since dilutive common and non-voting incentive units are not assumed to have been issued if their effect is anti-dilutive.

Emerging Growth Company and Smaller Reporting Status

In April 2012, the Jumpstart Our Business Startups Act of 2012, or 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 of 1933, as amended, or 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.

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We will remain an emerging growth company until the earliest to occur of: (1) the last day of the fiscal year in which we have more than \$1.07 billion in annual revenue; (2) the date we qualify as a “large accelerated filer,” with at least \$700.0 million of equity securities held by non-affiliates; (3) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period; and (4) the last day of the fiscal year ending after the fifth anniversary of our initial public offering.

We are also a “smaller reporting company” meaning that the market value of our stock held by non-affiliates plus the proposed aggregate amount of gross proceeds to us as a result of this offering is less than \$700 million and our annual revenue was less than \$100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company after this offering 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.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the Securities and Exchange Commission.

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 to of our consolidated financial statements appearing at the end of this prospectus.

Quantitative and Qualitative Disclosures About Market Risks

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.

BUSINESS

Overview

We are a biopharmaceutical company focused on developing a diversified pipeline of targeted oncology and immuno-oncology therapies with transformative potential for cancer patients. Our strategy is to build a pipeline of therapeutic candidates that are uncorrelated across multiple dimensions, with a focus on assets that we believe have novel technology, employ differentiated mechanisms, are in a more advanced stage of development than competing candidates, or have a combination of these attributes. In approximately three and a half years, we have efficiently developed or in-licensed a pipeline of seven distinct programs by leveraging our hub-and-spoke business model. We continue to prioritize probability of success and capital efficiency. Specifically, before we advance a therapeutic candidate into clinical development, we evaluate its ability to generate an immune system response or to inhibit oncogenic drivers as a single agent. Importantly, we have terminated programs that do not meet our rigorous criteria for advancement and will continue to do so when we believe we can more efficiently allocate our capital. We currently have one clinical-stage targeted oncology candidate in Phase 1/2a development and six preclinical immuno-oncology candidates and programs. We believe our approach will allow us to advance at least one therapeutic candidate into the clinic and one program into IND-enabling studies each year for at least the next several years.

Our lead candidate, CLN-081, is an orally available small molecule designed as a next generation, irreversible epidermal growth factor receptor, or EGFR, inhibitor that is designed to selectively target cells expressing mutant EGFR variants, including EGFR exon 20 insertion, or EGFRex20ins, mutations, with relative sparing of cells expressing wild type EGFR. We are currently evaluating CLN-081 as a treatment for non-small cell lung cancer, or NSCLC, in adult patients with EGFRex20ins mutations in a Phase 1/2a trial. Our most advanced immuno-oncology therapeutic candidates include CLN-049, a bispecific antibody targeting FLT3 and CD3; and CLN-619, a monoclonal antibody designed to stimulate natural killer, or NK, and T cell responses by engaging a unique target, MICA/B. We intend to initially develop CLN-049 for the treatment of acute myeloid leukemia, or AML, and CLN-619 for the treatment of solid tumors. In addition, through our AMBER platform, we are developing CLN-617, a fusion protein combining, in a single agent, two potent antitumor cytokines, interleukin-2, or IL-2, and interleukin-12, or IL-12, fused with a novel collagen-binding domain designed to enable tumor retention for the treatment of solid tumors. Our pipeline includes three additional immuno-oncology programs in the lead optimization stage that we believe have compelling mechanisms of action and potential for clinical development. We currently hold worldwide development and commercialization rights to each of our therapeutic candidates, except for CLN-081 in Japan and Greater China.

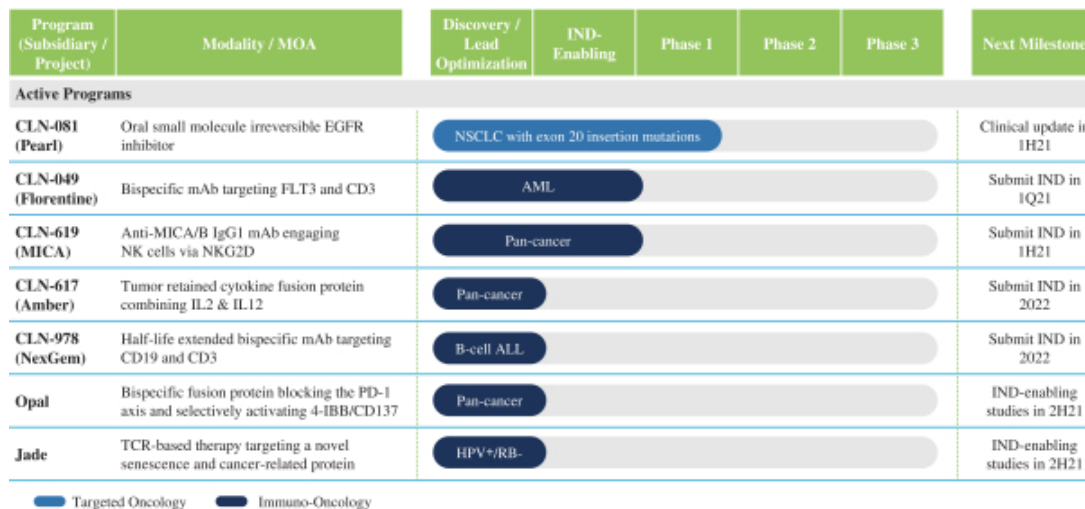
Our unique hub-and-spoke business model leverages a central operating company and separate subsidiaries that are established to hold and advance individual therapeutic candidates. This model enables us to increase operational efficiency, maintain optimal cost structure, attract leading collaborators, and promote asset flexibility. In order to advance and grow our portfolio, we adhere to our Cullinan approach, which is guided by the following core elements:

- Portfolio diversification to mitigate overall risk and maximize optionality
- Capital allocation strategy based on risk-adjusted potential, including staged funding to pre-specified scientific and clinical results
- Virtual infrastructure and key external relationships to maintain a lean operating base
- Internal development capabilities complemented by external business development
- Focus on translational medicine and therapeutic candidates with *in vivo* single agent activity
- Disciplined asset evaluation and selection

Our Pipeline

We have built a pipeline of targeted oncology and immuno-oncology therapeutic candidates and programs that are diversified by mechanism, therapeutic approach, modality, and stage of development. On a quarterly basis, we rigorously assess each of our programs using internally defined success criteria 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. Our current pipeline is summarized in the diagram below:

Our Pipeline



Our lead candidate, CLN-081, is an orally available small molecule, designed as a next generation, irreversible EGFR inhibitor that is designed to selectively target cells expressing mutant EGFR variants. CLN-081 is currently in a Phase 1/2a dose escalation and expansion trial evaluating oral, twice-daily, or BID, administration of various doses in patients with NSCLC harboring EGFRex20ins mutations that have had at least one prior treatment with platinum based chemotherapy or another approved standard therapy. In September 2020, at the European Society for Medical Oncology virtual congress, we disclosed preliminary results based on the first 22 patients dosed in this ongoing trial. As of September 1, 2020, amongst 17 evaluable patients across all dose cohorts, we observed a best overall response of partial response in six patients and stable, disease in 11 patients. The partial responses included two confirmed and four unconfirmed partial responses, three of whom had not yet reached a confirmatory scan and one who progressed prior to a confirmatory scan. As of the September 1, 2020 data cut-off, no DLTs, or Grade 3 treatment-related adverse events, or TRAEs, had been reported. In connection with this offering, we subsequently performed an interim analysis of the ongoing study. As of a November 10, 2020 data cut-off, amongst 25 evaluable patients across all dose cohorts, we observed a best overall response of partial response in 10 patients, stable disease in 14 patients, and disease progression in one patient. The partial responses included six confirmed and four unconfirmed partial responses, two of whom had not yet reached a confirmatory scan. Regarding the two remaining patients with unconfirmed partial responses, one experienced progressive disease due to a new brain lesion growth and one died before their second scan after experiencing aspirational pneumonia that was deemed unrelated to study drug by the investigator. As of the November 10, 2020 data cut-off, we observed one DLT, which was Grade 3 diarrhea TRAE in the 150mg BID dosing cohort, our highest dose evaluated to date, and one other Grade 3 TRAE, which was anemia. We observed no Grade 2 diarrhea TRAEs in the 30, 45, 65, or 100mg BID dose cohorts. We observed one Grade 2 diarrhea TRAE in the 150mg BID dose cohort. As of the November 10, 2020 data cut-off, we observed eight Grade 2 skin rash TRAEs across all dose cohorts. Although these results are preliminary and based on a small number of patients with limited follow-up, we believe that the preclinical and early clinical data

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as of the data cut-off collectively support the potential of CLN-081 to be a clinically active molecule with a favorable product profile. Given the trial was designed as a dose escalation and expansion study, we anticipate observing additional TRAEs as we enroll more patients and follow them over longer duration periods at higher dose levels.

In addition to CLN-081, our pipeline includes six immuno-oncology biologic candidates designed to stimulate one or multiple dimensions of the immune system as a single agent. Our two most advanced immuno-oncology therapeutic candidates are CLN-049, a bi-specific T cell-engaging antibody targeting FLT3 and CD3, and CLN-619, a monoclonal antibody designed to stimulate NK and T cell responses by engaging a unique target, MICA/B. CLN-049 has demonstrated the ability to redirect T cells to lyse FLT3-expressing AML cells *in vitro* and potent antitumor activity *in vivo* in multiple preclinical studies. Based on its hypothesized mechanism of action, we believe CLN-049 has the potential to be employed across the spectrum of molecularly-defined AML subtypes. We intend to initially develop CLN-049 as a novel therapy for the treatment of patients with relapsed or refractory, or *r/r*, AML. In preclinical studies, CLN-619 demonstrated antitumor activity as a single agent in multiple *in vivo* models. 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 intend to initially develop CLN-619 for the treatment of patients with advanced solid tumors.

We are also developing CLN-617, 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 has synergistically enhanced 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. The collagen-binding domain engineered into CLN-617 is designed to retain cytokines in the tumor microenvironment following intratumoral administration, thereby minimizing systemic dissemination and associated toxicities while prolonging immunostimulatory antitumor activity. In preclinical studies, murine surrogates of CLN-617 demonstrated robust single agent antitumor activity in both injected and non-injected contralateral tumors without inducing systemic toxicity, as measured by reduction in body weight. Based on these results, we believe CLN-617 may be capable of generating a systemic immune response that can mediate tumor regression, even in non-injected distal tumors. Given the broad expression of collagen across multiple tumor types and the well-validated antitumor activity of cytokine-based therapies, CLN-617 may have utility across many different types of solid tumors. We refer to the collagen-binding technology used in CLN-617 as AMBER, which we believe represents a novel platform with the potential to broaden the therapeutic window of cytokines and other immuno-stimulatory agents by potentially reducing systemic toxicity.

Our earlier-stage immuno-oncology programs include: CLN-978, a next-generation CD19-targeted, half-life extended T cell engaging antibody; Opal, a bispecific fusion protein that blocks the PD-1 axis and selectively activates the 4-1BB/CD137 pathway on T cells in tumors; and Jade, a cell therapy targeting a novel senescence and cancer-related protein that we are collaborating with the Fred Hutchinson Cancer Research Center to identify naturally occurring T cell receptors, or TCRs, against this target. Depending on the results of our lead optimization efforts, our ongoing preclinical studies, internal portfolio prioritization, and developments in the competitive landscape, we may or may not advance these programs further in development. Furthermore, we are also actively evaluating external collaboration and in-licensing opportunities to continue to expand our pipeline.

Based on early preclinical and clinical results, we have recently terminated multiple programs in order to allocate resources for more promising programs in our portfolio. We believe these decisions demonstrate our commitment and discipline with respect to our strategy and business model. For example, Apollo, an oral small molecule targeting EBNA1, was terminated due to a lack of translation of the compelling pharmacodynamic effect and antitumor activity seen in preclinical studies into patients. We were able to efficiently evaluate this program with minimal costs, spending approximately \$10 million from initial licensing to date, including costs related to the sponsored research agreement.

Our History and Team

We began substantive operations in 2017 following Series A funding from F2 Ventures and the UBS Oncology Impact Fund, which is managed by MPM Capital and is one of the largest dedicated pools of capital

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focused exclusively on oncology investing. Since inception, we have raised approximately \$277.0 million from these investors as well as other institutional investors, including Foresite Capital, Boxer Capital of Tavistock Group, Eventide Asset Management, Nextech Invest, OrbiMed, Venrock Healthcare Capital Partners, Rock Springs Capital, BVF Partners, L.P., and Logos Capital. With less than \$60 million spent as of September 30, 2020, we have prudently built a diverse pipeline of seven uncorrelated targeted oncology and immuno-oncology programs.

Critical to our success has been the ability to assemble an accomplished management team with proven track records in targeted oncology and immuno-oncology. We are led by a senior management team with extensive capabilities in immuno-oncology, biologics and small molecule drug development, as well as business development and portfolio management. Collectively, our team possesses a strong record of success, as demonstrated by 36 accepted INDs and six approved New Drug Applications, or NDAs, or Biologics License Applications, or BLAs, and significant previous experiences at leading life sciences companies, including Alexion Pharmaceuticals, Inc., Amgen Inc., Biogen Inc., Bristol Myers Squibb Company, MacroGenics, Inc., Merck & Co., Inc., Novartis International AG, Pfizer Inc., and Sanofi S.A..

Our Strategy

Our goal is to develop targeted oncology and immuno-oncology therapeutics that will dramatically improve the standard-of-care for patients with cancer. The key elements of our strategy are to:

- **Build a pipeline of differentiated oncology therapeutic candidates that are diversified by mechanism, therapeutic approach, modality, and stage of development.** We seek to mitigate capital risk by accumulating and maintaining a diversified portfolio of uncorrelated therapeutic candidates and programs. We also attempt to mitigate technical risk by intentionally carrying a portfolio mix such that some programs are directed toward novel targets, while others focus on more validated pathways. For the latter programs, we seek to in-license or internally design agents with mechanisms or formats that we believe will be responsible for differentiating tolerability, ease of administration, efficacy, or a combination thereof. Importantly, before we advance a therapeutic candidate into clinical development, we evaluate its ability to generate an immune system response or to inhibit oncogenic drivers as a single agent *in vivo*.
- **Expand our pipeline through research collaborations, business development, and internally designed programs.** Our founders and management team are leaders in oncology drug discovery, clinical development, and business development. Their proven track records and longstanding relationships in the life sciences industry provide us with access to ideas and assets from around the world. In addition, their experiences and deep understanding of molecular and cancer biology also enable us to translate novel concepts into internally designed therapeutic candidates. We are actively evaluating external collaboration and in-licensing opportunities as well as internal development opportunities to continue to expand our pipeline.
- **Advance our lead therapeutic candidate, CLN-081, toward potential regulatory approval for the targeted treatment of NSCLC patients with EGFRex20ins mutations.** Our ongoing Phase 1/2a trial includes a flexible design that enables us to expand dosing cohorts upon demonstration of antitumor responses and adequate tolerability. Based on the preliminary results as of the November 10, 2020 data cutoff, we anticipate accumulating additional safety, tolerability, and efficacy data in expanded 65 mg and 100 mg dose cohorts, with a clinical update expected in the first half of 2021. After determining a recommended Phase 2 dose, or RP2D, we plan to meet with health authorities to discuss the development and regulatory pathways for CLN-081.
- **Establish clinical proof-of-concept for our most advanced immuno-oncology therapeutic candidates, CLN-049 and CLN-619, in patients with hematological malignancies and solid tumors, respectively.** CLN-049's target, FLT3, is expressed frequently on AML cells and leukemic blasts but minimally on healthy blood cells, which differentiates FLT3 from other tumor surface antigens identified in AML, such as CD33 and CD123 that are targeted by antibody-based therapies in development. Furthermore, by targeting extracellular FLT3, we believe CLN-049 has the potential to

reach 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 certain mutations. We intend to submit an IND for a Phase 1/2a trial in adult patients with r/r AML in the first quarter of 2021. Given the mechanistic rationale for both programs and encouraging preclinical results, our goal is to establish clinical proof-of-concept for CLN-049 and CLN-619 through their respective Phase 1/2a trials. CLN-619's target, MICA/B, is expressed by numerous tumor types across both solid tumors and hematological malignancies. Furthermore, the MICA/B receptor, NKG2D, is expressed in both innate and adaptive effector cell populations. We anticipate submitting an IND for a Phase 1/2a trial in the first half of 2021 for the treatment of solid tumors.

- **Continue to advance and evolve our pipeline with a goal of advancing one therapeutic candidate into the clinic and one program into IND-enabling studies each year.** In addition to our three most advanced therapeutic candidates, we have four additional preclinical programs that are designed with the goal of addressing limitations of approved immuno-oncology therapies. For example, we believe 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. Another of our research programs, CLN-978, is half-life extended, humanized, single-chain T cell engaging antibody that we believe has the potential to improve on some of the shortcomings of the approved CD3/CD19 bispecific T cell engager, blinatumomab, and to compete with CD19-targeted CAR-T cell therapies.
- **Evaluate strategic opportunities to accelerate development timelines and maximize the value of our portfolio.** We intend to maximize the value for each of our programs by opportunistically leveraging the existing infrastructure of other companies or internally pursuing later-stages of development and commercialization. Our subsidiaries hold the worldwide rights to our therapeutic candidates, except for CLN-081, for which our licensor, Taiho Pharmaceutical Co., Ltd., or Taiho Pharma, retains rights in Japan and Zai Lab (Shanghai) Co., Ltd., or Zai Lab, has been sublicensed rights by us in Greater China. Our business model provides us with the flexibility to efficiently pursue various types of transactions and collaborations with third parties at the subsidiary level. It also enables us to preserve resources for continued internal investment upon successful achievements of development milestones. We have made and will continue to make decisions regarding each of our subsidiaries and programs with the overarching aim of maximizing both patient benefit and shareholder value.

Our Hub-and-Spoke Business Model

We employ a hub-and-spoke business model to execute our strategy of building a diversified oncology company in a capital efficient manner and to provide us with the flexibility to either advance therapeutic candidates ourselves or through transactions with third parties. Our "hub" consists of a holding company, Cullinan Oncology, LLC, or the LLC entity, and an operating company, Cullinan Management, Inc., or Cullinan Management, which, collectively, provide capital, human resources, and other services to each spoke via a shared services agreement. We believe that by centralizing these shared services, including all research and development operations, administrative services, and business development, and allocating employees and resources to each spoke, we can enhance operational efficiency and maintain an optimal cost structure. For example, as of December 31, 2020, we had 20 full time employees and two consultants working on a pipeline of seven active programs. See "Certain Relationships and Related Person Transactions—Agreements with our Subsidiaries—Services Agreements" for more information.

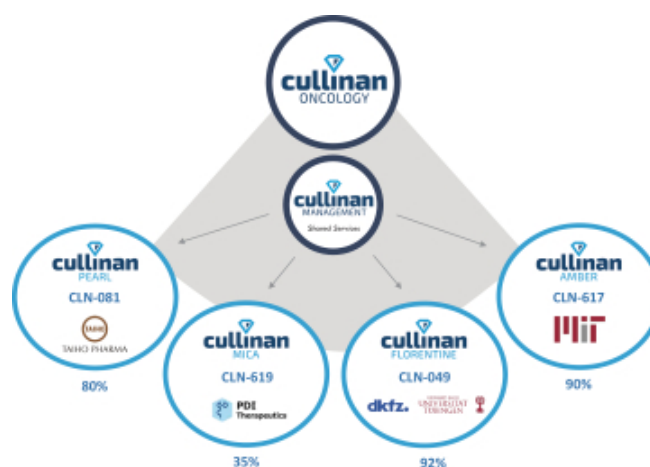
Our hub-and-spoke model also enables us to access both internal and external expertise to build and develop our pipeline. We incubate internal programs, such as NexGem, Opal, and Jade, in our hub, leveraging Cullinan Management's network of service providers as needed to support our discovery, lead optimization, and IND-enabling efforts. When we decide to license from or collaborate with external parties, we establish distinct subsidiaries, or "spokes", to hold and advance those programs. This structure enables us to keep licensors economically incentivized at the program level through our ability to offer equity and access to potential cash milestones and royalty payments. Further, because each spoke is a separate legal entity that holds all of the assets

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related to the development candidate, including the relevant intellectual property, and has no employees, fixed assets, or overhead costs, we have flexibility both to raise capital at either the parent or subsidiary level and to pursue subsidiary-level licenses or stock sales.

In the figure below, each “spoke” contains the subsidiary’s therapeutic candidate as well as any relevant licensors or shareholders. The LLC entity’s ownership, as of December 31, 2020, as a percentage of fully-diluted shares outstanding is listed below each circle.

Our Hub-and-Spoke Business Model



The structure of our financing arrangements with each subsidiary enables us to increase our economic ownership when we provide additional capital. Further information about our subsidiaries, including ownership and governance, is included in the “Management’s Discussion and Analysis” section of this prospectus.

Cullinan Management is our wholly-owned operating subsidiary that employs all of our team members and incubates discovery programs until we establish a “spoke” in which to further advance them. This subsidiary currently holds exclusive rights or options to our three earlier-stage programs, NexGem, Opal, and Jade. We centralize shared services, including all research and development operations, administrative services, and business development at Cullinan Management, and allocate employees and resources to each spoke based on the needs and development stage of each therapeutic candidate.

Our hub-and-spoke business model is designed to (i) enhance operational efficiency, (ii) maintain an optimal cost structure, (iii) attract leading collaborators, and (iv) promote asset flexibility, as further described below.

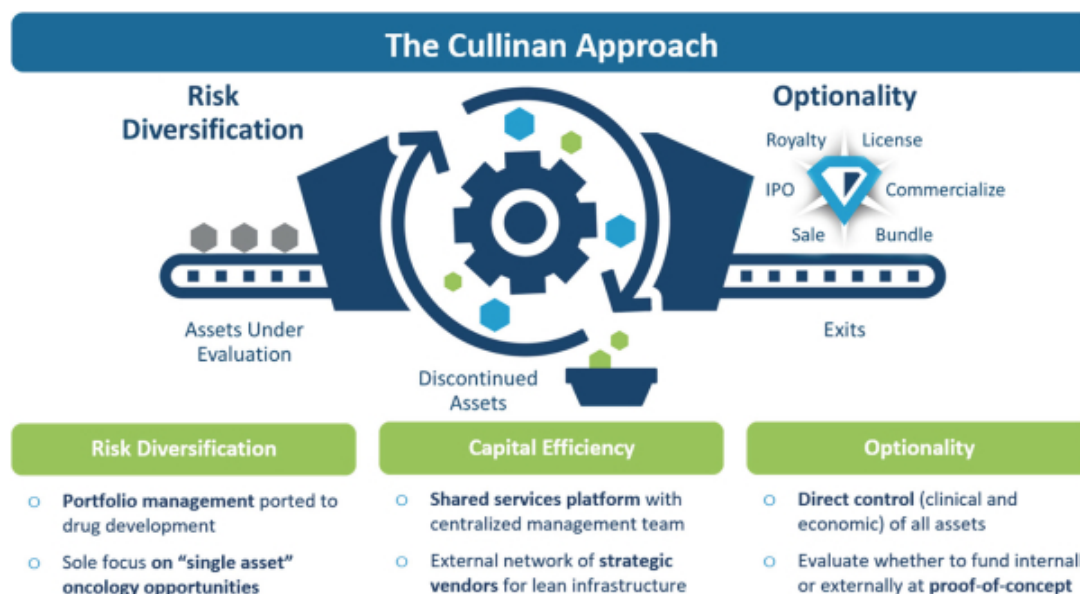
- **Enhance operational efficiency:** We centralize all employees and services at our hub and allocate resources to spokes as needed. We empower managers to access these resources and make program-level decisions in order to increase productivity and speed. We believe this model enables a flexible organizational structure that can achieve scale through the addition of programs without increasing burdensome bureaucracy or redundant infrastructure.
- **Maintain an optimal cost structure:** We have a relatively small number of employees and have built a network of trusted external service providers, choosing to leverage their infrastructure and expertise as needed instead of embarking on capital-intensive lab, manufacturing, and equipment expenditures. As of December 31, 2020, we had 20 full time employees and two consultants working on seven active programs. By reducing overhead costs, we believe we can increase the likelihood that we can generate a return on invested capital.

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- **Attract leading collaborators and licensors:** Each of our subsidiaries has its own capitalization and governance, enabling us to keep licensors economically incentivized at the program level. We believe that the experienced leadership team and shared services at our hub differentiate us from other potential licensees.
- **Promote asset flexibility:** Each spoke is a separate legal entity that holds the relevant intellectual property of its therapeutic candidates or programs and has none of its own employees, fixed assets, or overhead costs. This allows us to efficiently pursue various subsidiary-level transactions, such as stock or asset sales, licensing transactions, strategic partnerships, co-development arrangements, or spin-outs. It also provides us with the flexibility to terminate programs with minimal costs if results do not meet our de-risking criteria for advancement.

The Cullinan Approach

Our mission is to advance and grow a portfolio of innovative, early-stage oncology assets based on the latest scientific breakthroughs. Given these foundations, we think about capital allocation and risk as much as we think about drug development. We believe that by focusing our efforts on translational medicine and portfolio diversification, we can mitigate overall exposure to many of the inherent risks of drug development. The key elements of our approach are illustrated in the figure below.



Fundamental to our success is our ability to apply a disciplined set of criteria for asset evaluation and development advancement, as well as sequenced capital allocation that preserves resources for programs with greater potential. Our approach is guided by the following core elements:

- **Portfolio diversification to mitigate risk and maximize optionality:** We rigorously evaluate which targeted oncology and immunology therapeutic candidates and programs to develop; however, we recognize that failure is inherent in drug development. For that reason, we maintain a portfolio of uncorrelated therapeutic candidates to mitigate overall portfolio risk due to the failure of any single program while also providing exposure to a variety of promising mechanisms and pathways. As of December 31, 2020, our portfolio of seven programs is diversified across stage of development (discovery, IND-enabling, and clinical), therapeutic approach (targeted oncology and immuno-

oncology), modality (small molecule, monoclonal antibodies, bi-specific antibodies, fusion proteins and cell therapy), and tumor indications. We believe that the uncorrelated nature of our programs will ensure that the success or outcome of any individual program is decoupled from the outcome of others in the portfolio, and that this approach, together with our staged funding and disciplined de-risking criteria, provides a fundamentally reduced corporate risk profile.

- **Capital allocation strategy based on risk-adjusted potential, including staged funding to pre-specified scientific and clinical results:** Our initial investments in our subsidiaries are structured to fund programs to key value inflection points, and we seek to commit additional capital to our subsidiaries only when these hurdles are met. We create development plans that tranche funding to clear pre-specified milestones that test hypotheses early in drug development. Our criteria emphasize iterative evaluation of the potential for single agent activity throughout the development of each program. For example, our partially-owned subsidiary Cullinan MICA's \$26 million Series A financing included three tranches. Following the initial close of \$8 million, subsequent funding is contingent upon achieving clinical and regulatory milestones designed to establish clinical proof-of-concept as a monotherapy. These financing structures enable us to minimize spending on programs that do not meet our de-risking criteria for advancement and preserve resources to invest in programs with greater potential.
- **Virtual infrastructure and key external relationships to maintain a lean operating base:** By centralizing shared services, we are able to efficiently allocate employees and resources based on the needs and development stage for each of our therapeutic candidates. Furthermore, we have a relatively small number of employees and have built a network of trusted external service providers and consultants, choosing to leverage their infrastructure and expertise as needed instead of embarking on capital-intensive lab, manufacturing, and equipment expenditures. We believe the combination of our virtual infrastructure and external network enables us to reduce operating costs.
- **Internal development capabilities complemented by external business development:** We believe that simultaneous engagement of multiple mechanistic approaches through a single molecular agent can drive meaningful clinical benefits in oncology care, especially for immuno-oncology approaches. The therapeutic index of such a multi-functional agent is often dictated by the specific design of the molecule, including the structural backbone, the configuration, and assembly of each component, and the desired biological targets. Following our comprehensive review of the oncology landscape, we sometimes conclude that no external assets fully capture the potential therapeutic benefit from these design principles. In these instances, we leverage our team's deep understanding of molecular and cancer biology, together with external sources of expertise, to develop molecules with optimized designs, either through internally sourced ideas or in collaborations with external research centers of excellence.
- **Focus on translational medicine and therapeutic candidates with *in vivo* single agent activity:** Due to the technical risk and significant capital requirements inherent in drug development, we believe the stage of development where drugs transition from preclinical proof-of-mechanism to clinical proof-of-concept is the greatest opportunity for value creation. By focusing our efforts on this stage of drug development, we believe we can advance programs to critical decision and value inflection points quickly and in a capital efficient manner, while preserving resources until clinical proof-of-concept is achieved. In addition, we believe that our focus on robust *in vivo* single agent activity will potentially increase the probability of success in clinical development and reduce the time and capital required to achieve clinical proof-of-concept. Once proof-of-concept is established, we will seek to maximize the value of the program, either through external business development or with continued internal investment.
- **Disciplined asset evaluation and selection:** We systematically map the oncology landscape, canvassing publicly available literature and patent databases as well as our team's longstanding relationships with academic research laboratories, other biotechnology and pharmaceutical companies, and venture capital firms. We apply a set of key criteria to narrow our focus to targets and biological pathways with attractive attributes for drug development. Our team vets potential programs or

therapeutic candidates across multiple parameters, including mechanistic rationale, preclinical and clinical data generated as a single agent, potential commercial and manufacturing viability, fit within our portfolio, intellectual property position, and the potential impact of competition. Before we acquire or license a program, we determine whether it is likely that we could replicate, and ideally extend, scientific results using our network of trusted service providers, additional assay systems and formats, and rigorous *in vivo* disease models. We only commit the resources to establish a subsidiary around a candidate when it has met these criteria and advanced to the lead optimization stage or later.

Our Programs

CLN-081

Our lead therapeutic candidate, CLN-081 (formerly known as TAS6417), is an orally available small molecule designed as a next generation, irreversible EGFR inhibitor in development for the treatment of a genetically defined subset of patients with NSCLC. CLN-081 was designed with a unique chemical scaffold to bind to the active site of exon 20 insertions, inhibiting mutant activity while preserving wild type EGFR activity. In preclinical studies, CLN-081 demonstrated high selectivity for cells expressing EGFR containing activating mutations, including exon 20 insertions, while relatively sparing cells expressing wild type EGFR and displaying antitumor activity in both *in vitro* and *in vivo* models. In our ongoing Phase 1/2a trial, preliminary clinical activity and tolerability data as of November 10, 2020 are encouraging. Amongst 25 evaluable patients across all dose cohorts, we observed a best overall response of partial response in 10 patients, stable disease in 14 patients, and disease progression in one patient as of the data cut-off. The partial responses included six confirmed and four unconfirmed partial responses, two of whom had not yet reached a confirmatory scan. Regarding the other two patients with an unconfirmed partial response, one experienced progressive disease due to a new brain lesion growth and one died before their second scan after experiencing aspirational pneumonia, deemed by the investigator as unrelated to study drug. As of the November 10, 2020 data cut-off, we observed one DLT, which was Grade 3 diarrhea TRAE in the 150mg BID dosing cohort, our highest dose evaluated to date, and one other Grade 3 TRAE, which was anemia.

We licensed worldwide rights, excluding Japan, to CLN-081 from Taiho Pharma in 2018 and initiated a Phase 1/2a dose escalation and expansion trial in previously treated, adult NSCLC patients with EGFRex20ins mutations. We anticipate providing a clinical update from the ongoing Phase 1/2a trial in the first half of 2021. After determining a RP2D, we plan to meet with health authorities to discuss the development and regulatory pathways for CLN-081. We recently sublicensed such rights to Zai Lab in Greater China in exchange for an upfront fee, milestones, and royalties. See “License Agreements — Zai Lab License Agreement” for more information.

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. Each year, more people die of lung cancer than of colon, breast, and prostate cancers combined. The American Cancer Society estimates that, in 2020, there will be approximately 228,820 new cases of lung cancer and approximately 135,720 deaths from lung cancer in the United States. 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, or 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.

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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, or EU5, with EGFRex20ins mutations, as shown in the table below.

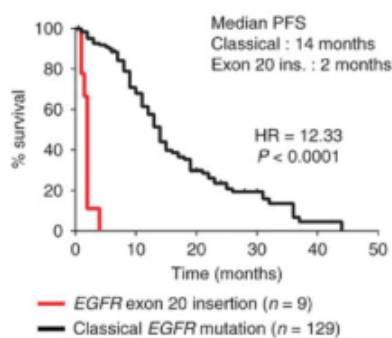
Incidence of Advanced NSCLC Patients with EGFRex20ins Mutations in the U.S. and EU5

	U.S.	EU5
Annual Incidence of NSCLC	160,000	117,000
% of NSCLC Patients with EGFR Mutations	20% to 25%	15% to 20%
% of Patients with EGFR Mutations with EGFRex20ins Mutations	7% to 13%	
Estimated Incidence of Addressable Patient Population	2,000 to 5,000	1,000 to 3,000

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 no targeted therapies approved for NSCLC patients with EGFRex20ins mutations. These patients are typically treated with platinum-based chemotherapy regimens but have poor outcomes. A pooled analysis investigating outcomes in this patient population demonstrated a median overall survival, or OS, of 16.2 months and a median progression-free survival, or PFS, of 4.8 months. Results from a separate publication showed a similar disparity in outcomes between NSCLC patients with EGFRex20ins mutations compared to those with classical mutations following treatment with a single agent EGFR inhibitor. As shown in the figure below, patients with EGFRex20ins mutations demonstrated a median PFS of two months as compared to 14 months for patients with classical EGFR mutations.

NSCLC Patients with Classical Mutations Had Longer Median PFS Than NSCLC Patients with EGFRex20ins Mutations



Numerous other studies investigating approved EGFR inhibitors in patients with EGFRex20ins mutations demonstrated limited efficacy, with response rates ranging from 0% to 28%. These clinical results are supported by preclinical data, which demonstrate that cancer cells bearing EGFRex20ins mutations are not inhibited with clinically-achievable doses of approved EGFR inhibitors. Therefore, we believe there is a high unmet need for NSCLC patients with EGFRex20ins mutations given the limitations of approved EGFR inhibitors and lack of approved targeted therapies for these patients.

The two most advanced EGFR inhibitors in active clinical development for NSCLC patients with EGFRex20ins mutations are poziotinib, from Spectrum Pharmaceuticals, and mobocertinib (TAK-788), from

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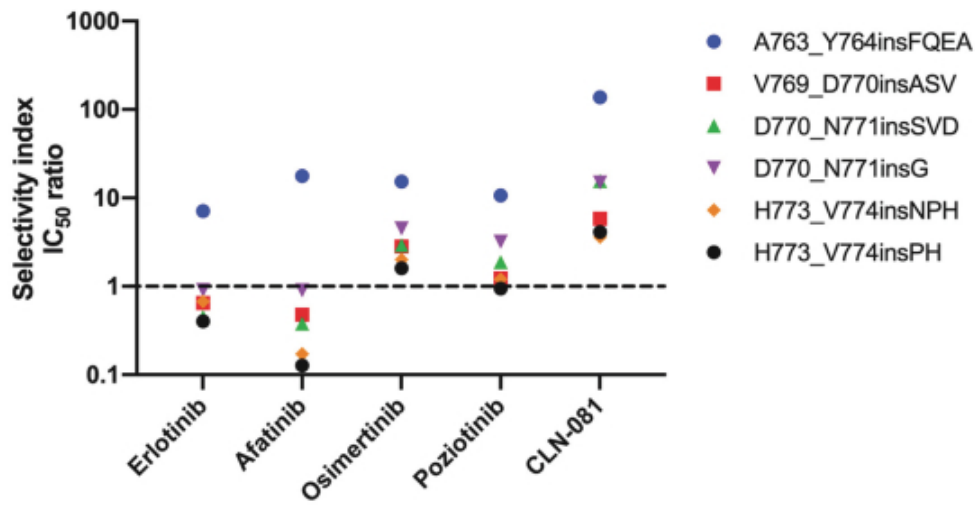
Takeda Pharmaceuticals, Inc., or Takeda. According to data presented at the 2020 American Association for Cancer Research, or AACR, Virtual Annual Meeting, poziotinib dosed at 16mg QD was observed to generate a 14.8% objective response rate, or ORR, in the intent to treat population, or ITT, of 115 patients. Treatment-related adverse events of any grade diarrhea or rash, both classical EGFR-related toxicities, were observed in 79% and 60% of patients, respectively, and Grade 3 or greater events were observed in 25% and 28% patients, respectively. Additionally, 68% of patients experienced dose reductions, 88% experienced drug interruptions, and 10% experienced permanent discontinuation due to TRAEs. Clinical trial results with TAK-788 (mobocertinib) were presented at the European Society of Medical Oncology 2020 Virtual Annual Meeting in September 2020. Among 28 patients treated at the maximum-tolerated dose/RP2D of 160mg QD, the confirmed ORR was 43%. Any grade treatment-related diarrhea and rash were observed in 82% and 46% of patients, respectively, while Grade 3 or greater treatment-related diarrhea were observed in 32% of patients. Takeda reported that approximately 18% of patients experienced dose reductions. In 2019, at the 20th World Conference on Lung Cancer, Takeda reported clinical results from a population of 137 patients treated with TAK-788 across multiple dose levels and 72 patients treated with 160 mg QD TAK-788. Among the 72 patients treated with the RP2D of 160mg QD, any grade treatment-related diarrhea and rash were observed in 85% and 36% of patients, respectively, while Grade 3 or greater treatment-related diarrhea were observed in 18% of patients. We did not conduct head-to-head comparative studies of TAK-788 and CLN-081. As a result, comparative conclusions cannot be drawn between the data presented by Takeda on TAK-788 and the data we have observed for CLN-081.

Our Solution: CLN-081

CLN-081 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. CLN-081 is designed to fit into the ATP-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, CLN-081 demonstrated high selectivity and inhibition of EGFR in cells expressing mutant EGFR proteins, with substantially less inhibition in cells expressing wild type EGFR.

Our licensor evaluated the selectivity index in vitro of CLN-081 versus competing EGFR inhibitors, as measured by the ratio of the half-maximal growth inhibition, or IC50, value of cells expressing wild type EGFR versus cells expressing exon 20 insertion mutant EGFR. As shown below, CLN-081 demonstrated the highest selectivity index, suggesting that CLN-081 may be capable of achieving clinically relevant inhibition of EGFR with exon 20 insertion mutations with relative sparing of wild type EGFR.

CLN-081 Demonstrated Superior Selectivity Across Multiple EGFRex20ins Mutations

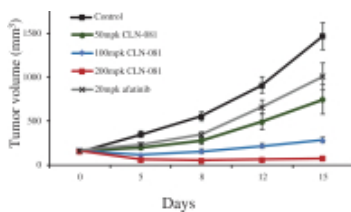


Preclinical Data

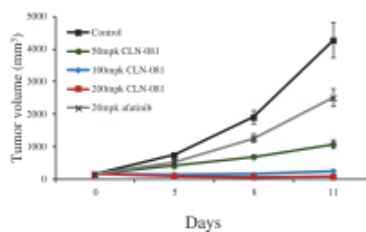
Multiple preclinical studies, including IND-enabling studies, of CLN-081 have been completed, which supported the submission and acceptance of our IND by the FDA in the second quarter of 2019. *In vivo* activity of CLN-081 was evaluated in multiple EGFRex20ins mutation-driven tumor models, including three of the most common insertion mutations: D770_N771insSVD, H773_V774 insNPH, and V769_D770insASV. In all three mouse models, doses of 200 milligrams per kilogram, or mpk, of CLN-081 achieved persistent tumor regression with no body weight loss over five percent. In comparison, 20mpk of afatinib induced only modest tumor growth inhibition in these models. The results of these common insertion mutation models are summarized below.

Tumor Reduction Observed in Mice With CLN-081 Treatment vs. Afatinib or Vehicle in Multiple EGFRex20ins Mutant NSCLC Models

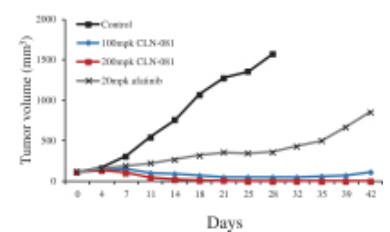
NCI-H1975 xenograft (EGFR D770 N771insSVD)



NIH/3T3 allografts (EGFR H773 V774insNPH)

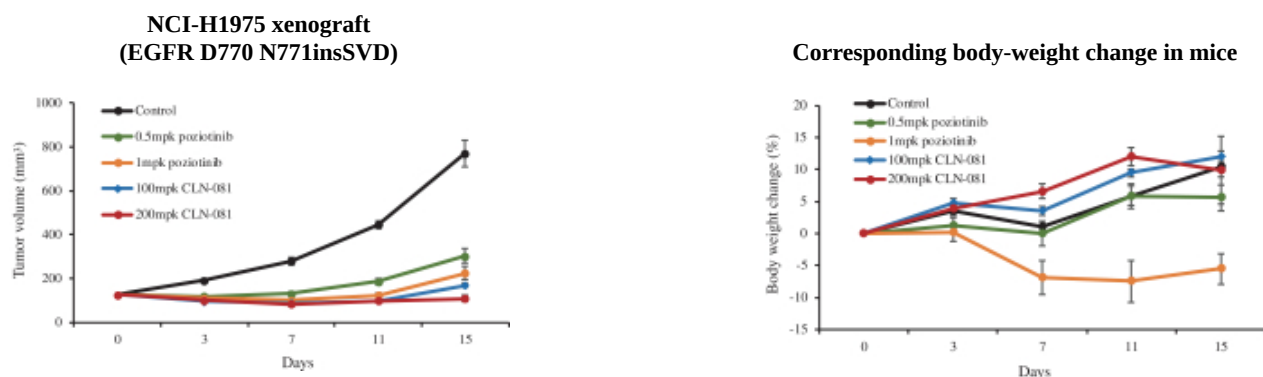


Lung cancer PDX (EGFR V769 D770insASV)



In another preclinical study, the antitumor activity and impact on body weight of CLN-081 was compared to that of poziotinib, which, at the time, was the most advanced EGFRex20ins inhibitor in clinical development. Antitumor activity and body weight change were measured in mice bearing H1975 EGFR D770_N771insSVD xenografts. Comparable tumor growth suppression was observed in the mice treated with 1mpk of poziotinib as those treated with 100mpk of CLN-081. Notably, poziotinib treatment led to body weight loss in all mice. In contrast, mice treated with CLN-081 with doses up to 200mpk showed no significant body weight loss. We believe these results illustrate the potential selectivity and potential therapeutic window for CLN-081. However, preclinical data must be interpreted with caution. We may not observe differentiation in clinical trials that is similar to the results of preclinical comparative studies of CLN-081, and we will not be able to rely upon comparative data from preclinical studies in connection with submissions to the FDA or other regulatory agencies for approval or otherwise.

CLN-081 Inhibited Tumor Growth and Avoided Weight Loss in NSCLC with EGFRex20ins Mutations



Clinical development

We initiated our ongoing Phase 1/2a trial of CLN-081 in the fourth quarter of 2019. This first-in-human, open-label, multi-center trial is designed to evaluate the safety and tolerability, pharmacokinetics, pharmacodynamics, and preliminary efficacy of CLN-081 in adult NSCLC patients with EGFRex20ins mutations.

As of November 10, 2020, 37 patients across five dose escalation cohorts, including cohorts at 30, 45, 65, 100, and 150 mg BID dose levels, received at least one dose of CLN-081. We have further expanded enrollment at the 30, 65, and 100 mg BID dose levels to further characterize the initial antitumor efficacy of CLN-081. We are actively enrolling patients across sites in the U.S., the Netherlands, Singapore, Hong Kong, and Taiwan, and we plan to initiate additional sites, including in China.

The patient population in our trial is heavily pre-treated, with a median of two prior systemic therapies and more than 80% of patients having received two or more prior therapies at study entry (i.e. 3rd line of therapy or greater), as shown in the table below. Further, 40% of patients have received prior treatment with an EGFR inhibitor, including 11% that have received prior treatment with pozoitinib or mobocertinib, and 57% of the patients received prior treatment with a checkpoint inhibitor.

Demographics and Baseline Characteristics for CLN-081 Patient Population

Characteristic	All patients (n=35) ¹	TAK-788 ² (n=28)
Median age, years (range)	64 (44-82)	62 (28-84)
Number of prior systemic anticancer regimens		
1/2	7 (20%) / 14 (40%)	4 (14%) / 9 (32%)
≥3	14 (40%)	15 / 54%
Median (Range)	2 (1-9)	3 (1-7)
Prior EGFR TKI, including pozio / TAK-788 (%)	14 (40%)	6 (21%)
Prior Pozio or TAK-788 (%)	4 (11%)	n/a
Prior checkpoint inhibitor therapy (%)	20 (57%)	17 (61%)
Brain mets at baseline (%)	7 (20%)	12 / (43%)

1) Awaiting baseline demographic data on 2 patients. 2) ASCO 2019 / Analyst Day

These data are derived from two different clinical trials with differences in trial design and patient populations. No head-to-head clinical trials have been conducted.

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Preliminary safety, pharmacokinetic, and efficacy data

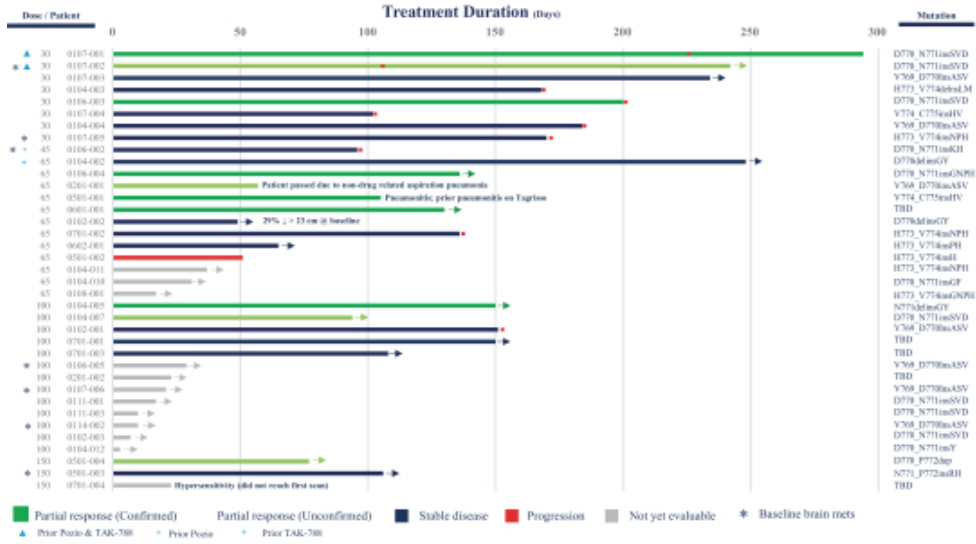
As of November 10, 2020, we observed one DLT, which was Grade 3 diarrhea TRAE in the 150mg BID dosing cohort, our highest dose evaluated to date, and one other Grade 3 TRAE, which was anemia. TRAEs most common to EGFR inhibitors are outlined below. Rash is the most common TRAE observed as of the data cutoff, with 10 patients experiencing Grade 1 rash, eight patients experiencing Grade 2 rash, and no patients experiencing a Grade 3 or greater rash. In addition to rash, diarrhea is another toxicity common to EGFR inhibitors due to inhibition of wild-type EGFR in the GI tract. As of the data cut-off, we observed nine cases of treatment-related diarrhea, of which seven were Grade 1, one was Grade 2, and one was Grade 3 (both the Grade 2 and Grade 3 TRAEs were at the 150mg BID dose).

Dose (BID)	30 mg	45 mg	65 mg	100 mg	150 mg
Safety Population (n)	8	1	12	13	3
DLTs	--	--	--	--	1
Grade 1 TRAEs commonly associated with EGFR TKIs					
Skin Rash (n)	5	--	4	1	--
Diarrhea (n)	3	--	--	3	1
Grade 2 TRAEs commonly associated with EGFR TKIs					
Skin Rash (n)	--	--	5	3	--
Diarrhea (n)	--	--	--	--	1
Grade 3 TRAEs commonly associated with EGFR TKIs					
Skin Rash (n)	--	--	--	--	--
Diarrhea (n)	--	--	--	--	1
Treatment Related Dose Reduction/Interruption (n)	--	--	1/ 1	2/2	1/1

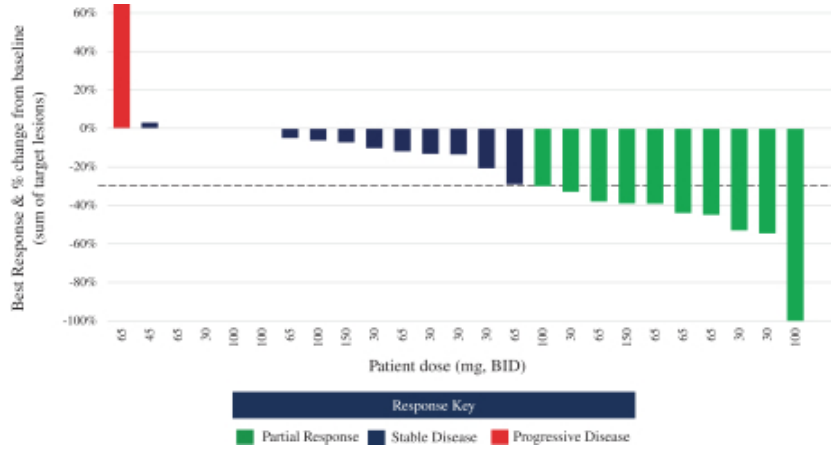
As of the November 10, 2020 data cut-off, preliminary pharmacokinetic data demonstrated a near dose-dependent trend in exposure, as measured by unbound area under the curve, or AUC, and CMAX values. Furthermore, the target unbound AUC required to achieve tumor regression in preclinical studies was reached starting at the initial dose of 30 mg BID.

As of November 10, 2020, among 25 evaluable patients, we observed best responses of partial response in 10 patients, stable disease in 14 patients, and disease progression in one patient, as shown in figure (A) below. Twelve patients were not yet evaluable, meaning that treatment was ongoing, but they had not yet reached their initial on-treatment imaging time point. The partial responses included six confirmed and four unconfirmed partial responses, two of whom had not yet reached a confirmatory scan. Regarding the two remaining patients with unconfirmed partial responses, one experienced progressive disease due to a new brain lesion growth and one died before their second scan after experiencing aspirational pneumonia that was deemed unrelated to study drug by the investigator. One of the two patients that will not confirm was previously treated with mobocertinib, or TAK-788, and initially achieved a partial response, but had brain metastases on a subsequent scan. Per RECIST criteria, the appearance of new lesions was considered progression, resulting in an unconfirmed response despite continued response of the target lesion. Among patients who experienced stable disease, all but one experienced either tumor regression or no tumor growth in their target lesions, as shown in figure (B) below. Furthermore, tumor regression was apparent at the first scan post-baseline in the majority of evaluable patients, as shown in figure (C) below. Responses have been observed across several EFGREx20ins mutation sub-types. Patients in the trial have their initial tumor imaging performed after approximately six weeks of treatment, and then every nine weeks thereafter.

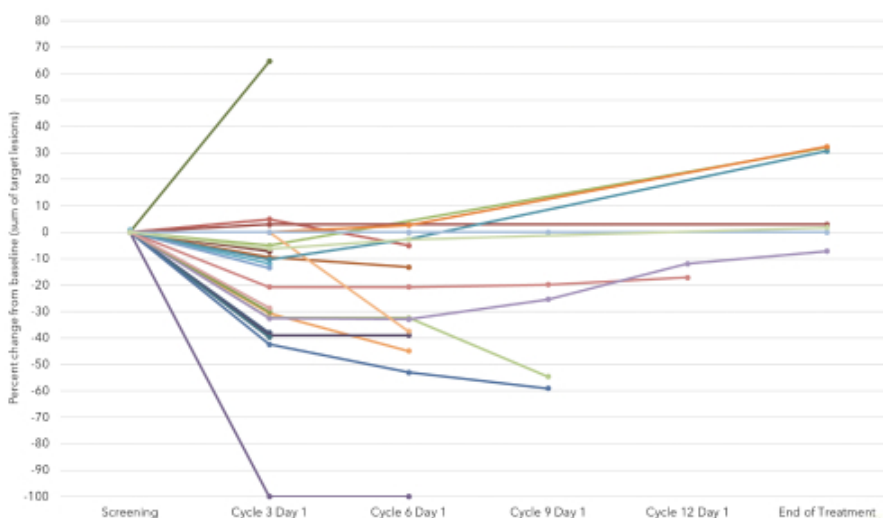
(A) Preliminary Efficacy Results from Ongoing Phase 1/2a Trial of CLN-081



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



(C)—Percentage Change in Sum of Target Lesions from Baseline



Potential Expansion Opportunities for CLN-081

In preclinical studies, CLN-081 has also demonstrated activity against other EGFR mutations beyond exon 20 insertions, including exon 19 deletions, the exon 21 L8585R substitution mutation, T790M resistance mutations, other less prevalent mutations, and select combinations of these mutations. We believe this broad spectrum of activity may offer rationale for future clinical expansion opportunities for CLN-081 into NSCLC patients with other types of EGFR mutations. For example, CLN-081 has demonstrated antitumor activity in preclinical studies in EGFR mutations that emerge in patients that develop acquired resistance to osimertinib.

EGFRex20ins mutations also play a role in other tumor types. For example, approximately 70% of sinonasal squamous cell carcinoma is believed to be driven by exon 20 insertion mutant EGFR. Additionally, EGFRex20ins mutations are believed to drive approximately 1% of various solid tumors, including bladder cancer, liver cancer, endometrial cancer, and others.

CLN-049

Our second most advanced immuno-oncology therapeutic candidate, CLN-049, is a humanized bispecific antibody that we are developing for the treatment of acute myeloid leukemia, or AML. CLN-049 is designed to simultaneously bind to FLT3 on target leukemic cells and to CD3 on T cells, triggering the T cells to kill the target cancer cells. 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. In preclinical studies, treatment with CLN-049, even at low doses, led to survival benefit in an AML xenograft model and complete elimination of leukemic blasts in various mouse models implanted with primary patient leukemic cells or AML cell lines.

Background on Acute Myeloid Leukemia and FLT3

The American Cancer Society estimates that, in 2020, there will be approximately 20,000 newly-diagnosed patients with AML and approximately 11,000 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

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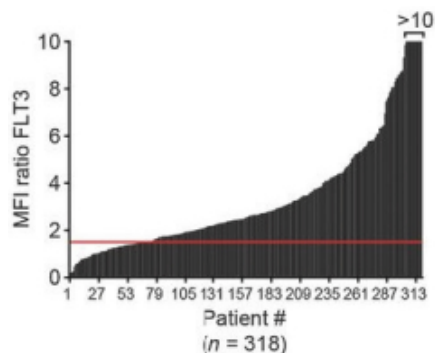
of visceral organs as well as the skin. In addition, patients with AML may be susceptible to bleeding complications due to thrombocytopenia and experience complications from treatment with cytotoxic chemotherapy. These patients may also be severely immuno-compromised secondary to their disease and experience 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, 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, or HSCT. 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.

FLT3, or FMS-like tyrosine kinase 3, 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, or 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 on the surface of cancer cells.

Studies have shown that FLT3 is expressed by FACS staining on AML blasts in at least 75% of AML patients, regardless of an oncogenic driver mutation. 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 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.

Over 75% of AML Patients Show Positive Cell Surface FLT3 Protein Expression



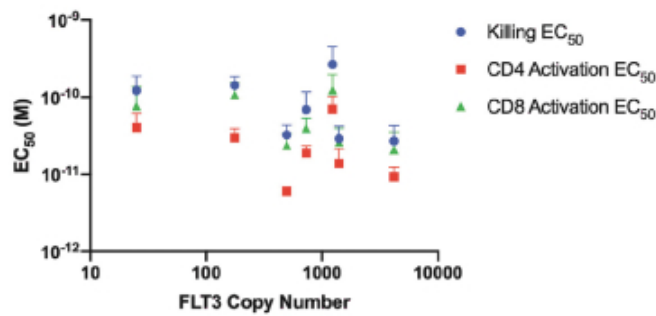
Our Solution: CLN-049

CLN-049 is a humanized bispecific antibody construct comprised of two FLT3-binding domains, an Fc-silenced humanized IgG1 backbone, and CD3-binding single-chain Fv domains, or 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*.

Preclinical data

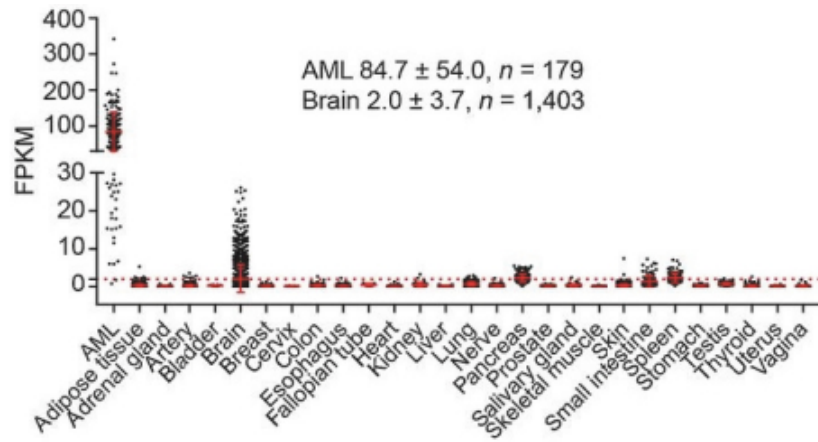
Given the observed variability in FLT3 expression levels among patients, we characterized the killing potential of CLN-049 across multiple cell lines expressing differing levels of FLT3 on the cell surface. As shown in the figures below, CLN-049 was observed to mediate robust target-dependent cell killing *in vitro* across all AML cell lines tested. Importantly, we observed that the EC₅₀ value, i.e. the drug concentration at which 50% of target cells are killed, was in the sub-nM 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. Based on these results, we believe CLN-049 may effectively kill AML target cells with even low levels of FLT3 expression, 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*



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 solid tissues.

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



Importantly, we observed that CLN-049 treatment *in vitro* did not lead to a significant reduction in CD34+ bone marrow cells, as shown in the figure below, supporting our hypothesis that CLN-049 preferentially kills FLT3-expressing leukemic cells while sparing normal cells.

CLN-049 Treatment Did Not Result in Significant Killing of Normal CD34+ Bone Marrow Cells *In Vitro*

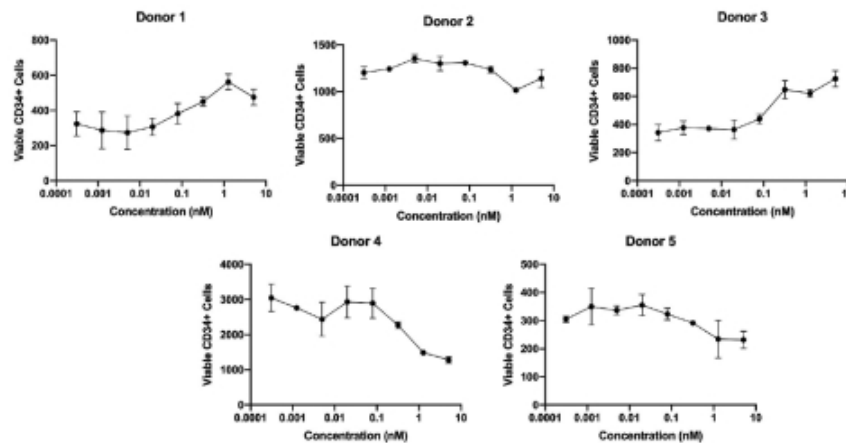
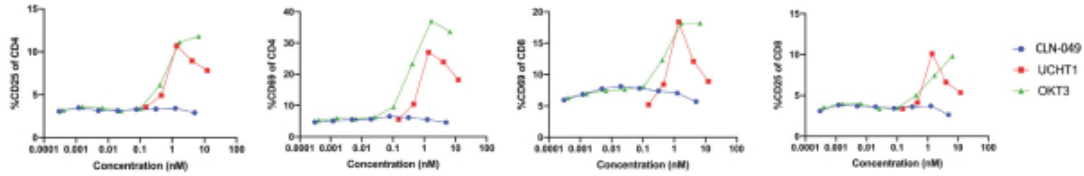


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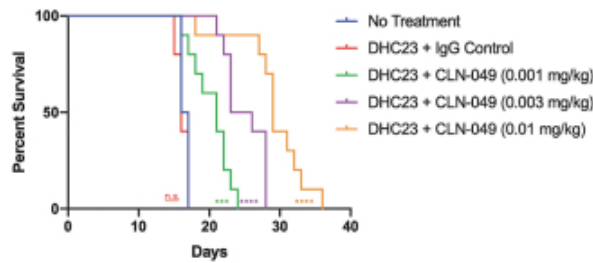
CLN-049 has two CD3-binding arms that can potentially crosslink CD3 on T cells, which may result in target cell-independent T cell activation and systemic cytokine-related toxicities. In preclinical studies, we examined whether CLN-049 can lead to spurious T cell activation in the absence of target cells. 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 CD3 antibody) that induced T cell activation.

CLN-049 Did Not Trigger the Upregulation of Activation Marker CD69 On Purified Human CD4+ or CD8+ T Cells in the Absence of FLT3 Expressing Target Cells



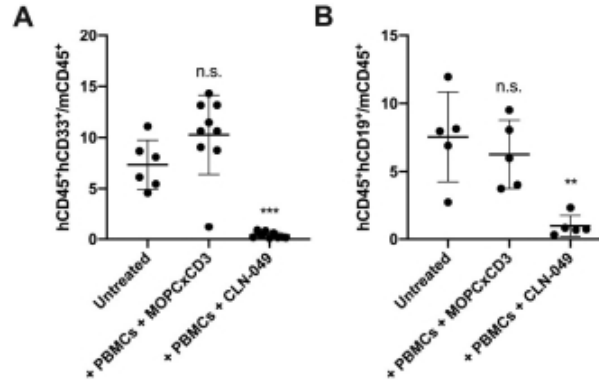
The potential efficacy of CLN-049 was evaluated in a humanized mouse model where a human AML cell line was administered systemically. As shown in the figure below, CLN-049 controlled AML leukemic burden in the engrafted human PBMC (DHC23) mice and led to the extension of the animals' survival in a dose-dependent manner. We believe CLN-049 effected this result by redirecting the T cells in the human PBMC population to kill the target AML cells.

Dose-dependent Effect of CLN-049 on the Survival of Mice with Disseminated Leukemic AML Cells



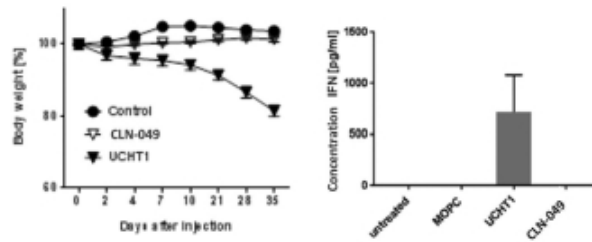
The anti-leukemic activity of CLN-049 was also evaluated using patient-derived AML blasts and PBMCs in a disseminated humanized mouse model. As shown in the figure below, treatment with CLN-049 resulted in a significant reduction in the overall leukemic burden in the bone marrow of both the AML blast (left panel) and ALL cell line model (right panel). 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 Anti-Leukemic Activity in Humanized Mouse Models with Primary AML and ALL Cells



To further evaluate the safety of CLN-049 *in vivo*, CLN-049 was administered in a humanized mouse model inoculated with human PBMC. This study was specifically designed to test possible off-target effects of CLN-049. As shown in the figure below, the administration of CLN-049 did not cause meaningful body weight loss in the treated mice, with the overall body weight profiles being comparable to those of the control group. In contrast, administration of a bivalent cross-linking anti-CD3 antibody, the parental CD3 antibody UCHT1 from which the scFv domains of CLN-049 were derived, led to significant body weight loss (left panel) and the release of the cytokine interferon in serum (right panel), as shown below.

Effect of CLN-049 on Body Weight and Cytokine Release in Humanized Mice



This result further supports our hypothesis that, *in vivo*, the two CD3 binding domains in CLN-049 cannot cross-link CD3 and therefore does not activate T cells in the absence of human FLT3-expressing target cells.

Clinical Development Plan

We intend to initially evaluate CLN-049 as a monotherapy in adult patients with r/r AML in a multi-center, dose escalation and dose expansion trial. We have completed IND-enabling pharmacology, pharmacokinetic, and safety studies, and we expect to submit our IND for CLN-049 in the first quarter of 2021.

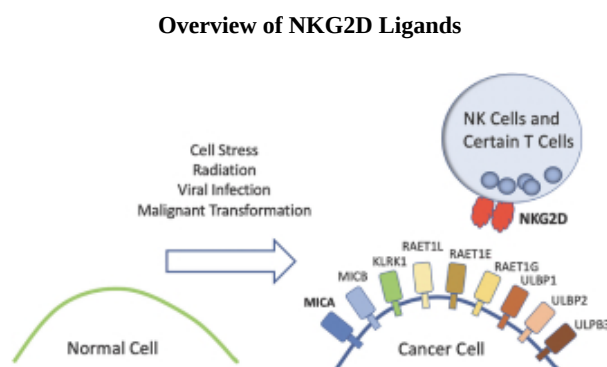
CLN-619

One of our most advanced immuno-oncology therapeutic candidates, 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 engagement of NK and T cells for enhanced lysis of cancer cells. The MICA/B receptor, NKG2D, is expressed in both innate and adaptive immune cell populations. Although several companies have disclosed preclinical MICA/B targeting programs, we are unaware of any clinical stage programs. In preclinical studies, CLN-619 demonstrated antitumor activity as a single agent in multiple *in vivo* tumor models. 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 have completed IND-enabling pharmacology and toxicology studies and are completing good manufacturing practice, or GMP, process work to support an IND submission in the first half of 2021.

Background on NKG2D and MICA/B

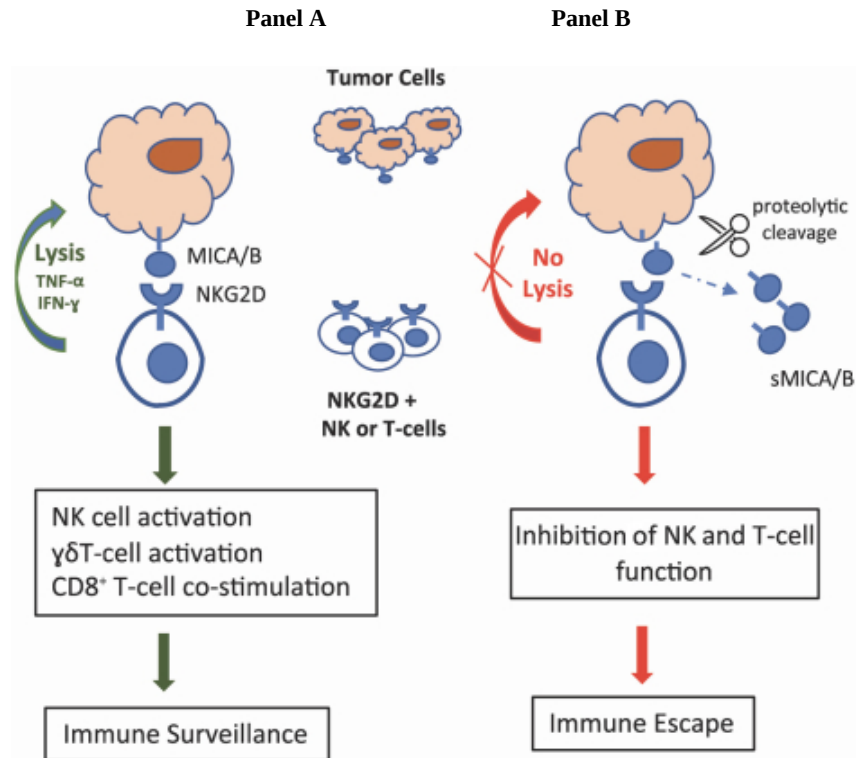
NKG2D is a key activating receptor on NK cells responsible for cytolysis upon binding to ligands expressed on target cells. NKG2D is also expressed on other types of immune cells, including CD8⁺ αβ T cells, natural killer T, or NKT, cells, and gd T cells, and can prime such cells for activation and enhance 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. As illustrated below, there are eight NKG2D ligands in humans: MICA and MICB; UL16 binding protein, or ULBP 1, 2, and 3; and Retinoic Acid Early Transcript, or RAET, 1E, 1G, and 1L (also known as ULBP 4, 5, and 6). All NKG2D ligands comprise an α1a2 extracellular major histocompatibility complex, or MHC, Class I-like superdomain that functionally interacts with the homo-dimeric NKG2D receptor.



MICA/B proteins are broadly recognized by NK cells, gd T cells, and CD8⁺ αβ 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 gd T cells against tumor cells expressing MICA/B. In the case of CD8⁺ αβ T cells, effector responses mediated by the T cell receptor are strongly 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 a3 domain contains a stretch of amino acids that allows for protease cleavage of membrane-bound MICA/B and release from the cell surface, thereby reducing cell surface expression of MICA/B and decreasing NKG2D-mediated killing of tumor cells. This mechanism also concomitantly increases the amount of circulating serum MICA/B, or sMICA/B. Soluble NKG2D ligands have also been shown to contribute to an immunosuppressive microenvironment. The mechanisms underlying this biology are illustrated below. Panel A shows the normal mechanism by which tumor-associated ligands of NKG2D, such as MICA/B, can induce tumor cell killing. Panel B shows how tumor cells, through the proteolytic cleavage of MICA/B, can escape immune surveillance and immune cell-mediated killing.

Role of NKG2D Ligands, MICA/B, in Immune Cell-Mediated Killing of Tumor Cells



Given that proteolytic shedding of NKG2D ligands is an important immune escape mechanism, soluble levels of NKG2D ligands, such as sMICA, in a patient's serum may serve as an important indicator of prognosis. Several studies have shown that cancer patients with high levels of sMICA have a significantly worse prognosis than those patients with low levels of sMICA. The prognostic role of sMICA has been observed across patients with multiple distinct tumor types, including melanoma, NSCLC, pancreatic cancer, colorectal cancer, hepatocellular carcinoma, and multiple myeloma. Across 19 studies that included more than 2,500 patients, a meta-analysis showed that high sMICA levels were associated with poor prognosis of patients with high statistical significance.

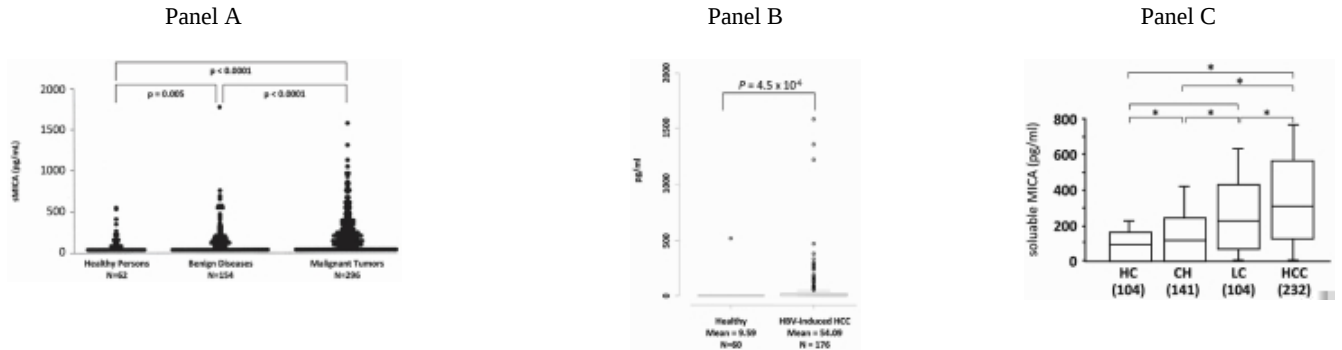
Conversely, multiple studies have shown that the levels of sMICA in healthy individuals are low, usually less than 100 pg/mL, as compared to cancer patients who have high levels of sMICA that can exceed 1,000 pg/mL. However, in the majority of cancer patients, sMICA levels are usually between 100 to 1,000 pg/mL, as

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shown in the figure below. This data suggests that levels of sMICA/B in a patient’s serum may have the potential to be used as a biomarker to evaluate the therapeutic effectiveness of antibodies designed to block proteolytic cleavage of MICA/B from the tumor cell surface.

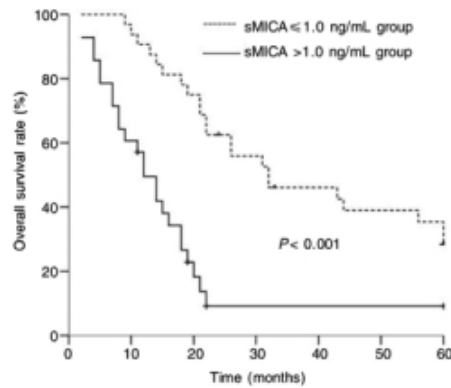
In the figure below, Panel A compares the levels of sMICA in normal healthy individuals to those with benign disease and those with cancer. Panel B shows sMICA levels in patients with hepatocellular carcinoma, or HCC, induced by hepatitis B virus, or HBV, relative to healthy controls and Panel C shows sMICA levels in healthy controls, or HC, compared to patients with chronic hepatitis, or CH, liver cirrhosis, or LC, or HCC.

Three Independent Studies Demonstrate Elevated Levels of sMICA in Cancer Patients



In a study of 60 patients with advanced hepatocellular carcinoma and different serum levels of MICA, patients in the high serum MICA level group (>1 ng/ml) exhibited poorer survival than patients in the low serum MICA group (≤1 ng/ml). The results suggest that higher serum MICA levels relate to poor prognosis in advanced hepatocellular carcinoma.

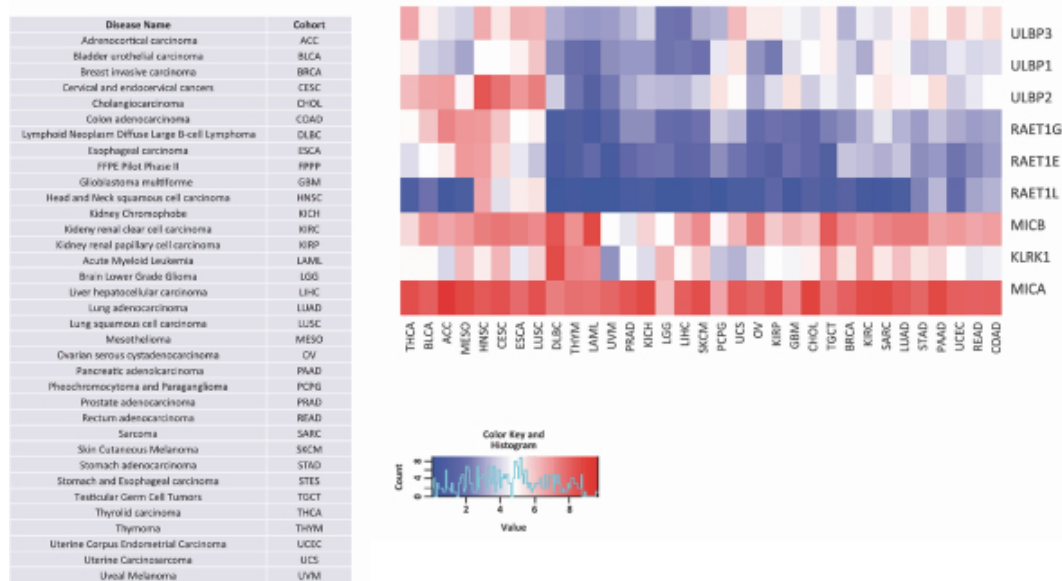
Kaplan Meier Curve of Hepatocellular Carcinoma Patients with Different Serum Levels of MICA



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An analysis of the expression of the NKG2D ligands in The Cancer Genome Atlas, or 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.

Expression of NKG2D Ligands Across Multiple Tumor Types



Data generated via analysis of TCGA database by Monoceros Biosystems.

Our Solution: CLN-619

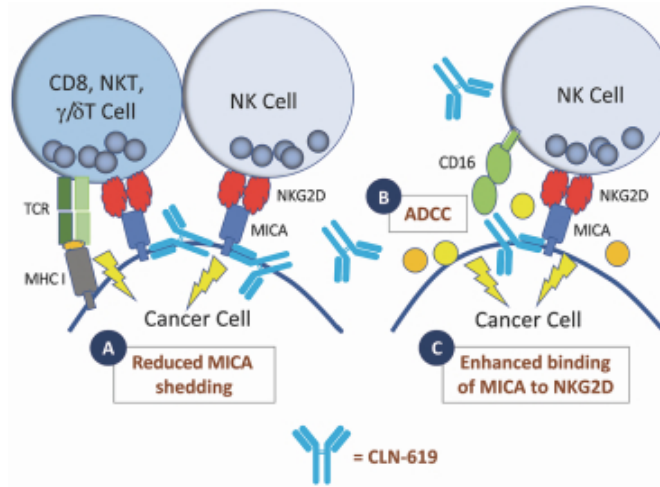
CLN-619 is a MICA/B-targeted humanized IgG1 antibody with an antibody-dependent cell-mediated cytotoxicity-, or ADCC-, competent Fc gamma 1 region capable of mediating effector cell functions through binding to Fc gamma receptors on cytotoxic innate immune cells.

We believe CLN-619 may affect antitumor activity through a multi-pronged mechanism of action. First, we believe that CLN-619 may shield the proteolytic cleavage sites of MICA and MICB on cancer cells from proteases commonly found in the tumor microenvironment. This mechanism would enable the accumulation of MICA/B on the surface of cancer cells and the reduction of shed soluble MICA/B circulating in the serum, as illustrated in figure (A) below. In preclinical studies, treatment with parental CLN-619 clones 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 to MICA/B. MICA/B also interacts with NKG2D expressed on gd, CD8+ αβ, and NKT 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 region, which allows it to engage NK cells by binding to their Fc gamma receptor III/CD16/A, leading to ADCC, as illustrated in figure (B) below. In preclinical studies, treatment with CLN-049 was shown to induce ADCC *in vitro*. Lastly, as illustrated in figure (C) below, our

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preliminary preclinical data suggests that CLN-619 may have the potential to enhance the binding affinity of MICA/B to its NKG2D receptors on NK cells or other immune cells to provide for improved cancer cell lysis. We believe that all of these mechanisms may be acting in a coordinated and unique manner to engage NK cells, which could result in the cancer cell lysis observed in the preclinical studies described below.

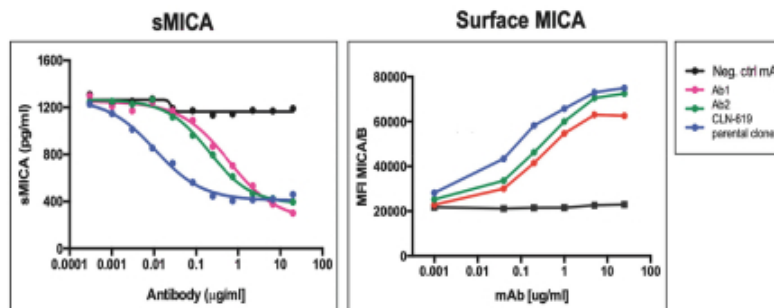
Three Modes of Action of CLN-619



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, and correspondingly, surface MICA levels increased, in a dose-dependent manner, following treatment with CLN-619. CLN-619 was more potent than other antibody candidates (Ab1 and Ab2) in preventing MICA shedding as shown in the figure below.

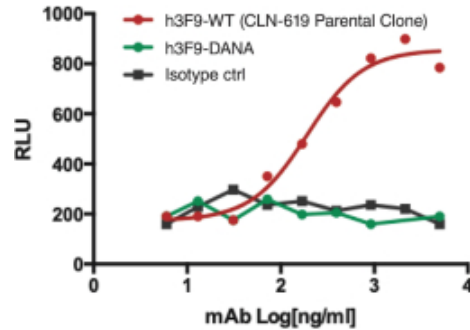
Parental Clone of CLN-619 Reduced Serum MICA and Increased Surface MICA Levels in Hepatoma PLC/PRF/5 Cell Lines



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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, or RLU. Such ADCC activity was abrogated when mutations in the Fc region were introduced into h3F9-DANA, which eliminated the binding to FcγRIIIa 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 Induced ADCC *In Vitro*



In an *in vitro* assay using human NK-92 cells and PLC/PRF/5 cancer cells, the parental clone of CLN-619 enhanced the killing of MICA/B-specific cancer cells by NK cells. As shown in the figure below, the parental clone of CLN-619, at both low and high effector to target, or E:T, ratios, significantly enhanced the extent of target cell killing compared to a control antibody.

In Vitro Assay Using Human NK-92 Cells and PLC/PRF/5 Cancer Cells

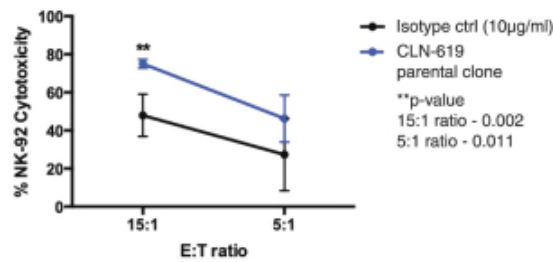
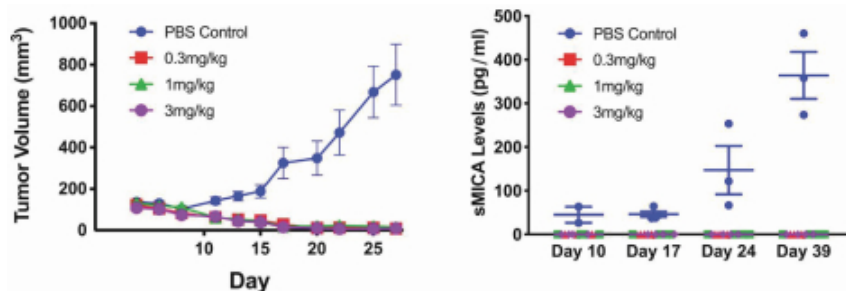


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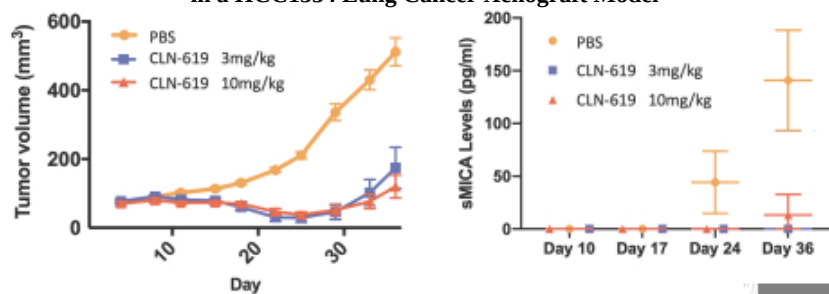
The antitumor activity of CLN-619 was further evaluated in multiple mouse tumor models. In a representative PLC/PRF/5 liver cancer xenograft model, CLN-619 treatment as a single agent resulted in tumor regression at all doses tested, as shown in the left panel of the figure below. In addition, the body weight profiles of treatment groups were comparable to the control group. Importantly, near complete suppression of MICA shedding as measured by soluble MICA levels in the serum was observed, as shown in the right panel of the figure below.

CLN-619 Demonstrated Tumor Regression and Reduced Serum MICA Levels in a PLC/PRF/5 Liver Cancer Xenograft Model



Similarly, 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 left panel of the figure below. We also observed near complete suppression of MICA shedding at all doses tested as measure by soluble MICA serum levels, as shown in the right panel of the figure below.

CLN-619 Demonstrated Tumor Growth Inhibition and Reduced Serum MICA Levels in a HCC1534 Lung Cancer Xenograft Model



Clinical Development Plan

We intend to evaluate CLN-619 as a monotherapy and in combination with pembrolizumab in a multi-center, dose escalation and dose expansion trial. We expect to submit our IND for CLN-619 in the first half of 2021. We are designing our trial to initially evaluate CLN-619 as a monotherapy in patients with advanced solid tumors in dose escalation cohorts. Upon establishing a RP2D, we intend to initiate several expansion cohorts to evaluate the preliminary efficacy of CLN-619 as a monotherapy in patients with selected advanced solid tumors. We also plan to investigate the safety and preliminary efficacy of CLN-619 in combination with pembrolizumab in advanced solid tumors. In addition, candidate biomarkers, including sMICA, will be evaluated in this first-in-human trial to identify patients who may be more likely to respond to CLN-619 and as a means to detect pharmacodynamic activity of CLN-619.

CLN-617

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. For nearly five decades, clinical researchers have studied the powerful role cytokines play in stimulating an immune response to cancer. 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. Severe toxicities associated with systemic cytokine administration and a short serum half-life have hindered their clinical development and broader commercial uptake.

The structure of CLN-617 contains a collagen-binding domain that is designed to enable the retention of fused cytokines in the local tumor microenvironment following intratumoral administration. Collagen binding may help minimize the systemic dissemination and associated toxicities of IL-2 and IL-12 and prolong their immunostimulatory antitumor activity. In preclinical studies, murine surrogates of CLN-617 demonstrated robust single agent antitumor activity in both injected and non-injected contralateral 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 antitumor activity of cytokine-based therapies, we believe CLN-617 may have utility across many different types of solid tumors. Based on publicly available information, we believe that we are the only company that (i) is developing an anti-cancer therapeutic candidate that combines IL-2 and IL-12 within a single therapeutic and (ii) has developed a technology for local retention of cytokines. We expect to submit an IND for CLN-617 in 2022.

The collagen-binding retention technology used in CLN-617 is based on technology that originated in the laboratory of Professor Dane Wittrup at the Massachusetts Institute of Technology, or 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.

Background on Cytokines as Immunotherapies

Cytokines are small proteins that regulate innate and adaptive immunity by mediating cell-to-cell communication. In response to inflammatory conditions, cytokines such as IL-2 and IL-12 are locally synthesized and act in a paracrine fashion at the site of their synthesis. IL-2 and IL-12 are two cytokines that amplify and coordinate immune cell responses for tumor control by inducing the stimulation and proliferation of NK and T cells to mediate antitumor immunity. Furthermore, the two cytokines act synergistically to engage complementary NK and T cell signaling pathways and augment the upregulation of each cytokine's cell surface receptor.

Given their natural occurrence as potent antitumor proteins, clinical researchers have been studying cytokines as immunotherapies for decades. In 1992, the FDA approved aldesleukin, a high-dose IL-2 infusion regimen that demonstrated 15-16% overall response rates in clinical trials, for the treatment of metastatic renal cell carcinoma and metastatic melanoma. Clinical and commercial adoption of aldesleukin has been hindered given its association with frequent grade 3 and 4 severe adverse events, including capillary leak syndrome, sepsis risk associated with impaired neutrophil function, pulmonary edema, hypotension, and acute renal insufficiency.

Clinical researchers have attempted to address the shortcomings of cytokine-based therapies through various engineering strategies in order to enhance their pharmacokinetic, or PK, or specificity profiles. For instance, PEGylation of cytokines is being explored to extend the half-life and enable lower or less frequent dosing, both for purposes of patient convenience and reducing toxicities associated with high serum concentrations of cytokines. Other engineering approaches attempt to reduce the affinity of IL-2 for CD25, the high affinity IL-2 receptor alpha subunit expressed on pro-tumor T regulatory cells, or T_{regs}, and also on activated effector CD8⁺T cells. However, such modified versions of IL-2 may no longer effectively stimulate effector T cells at low IL-2 doses and will retain the poor PK properties of the cytokine after systemic administration.

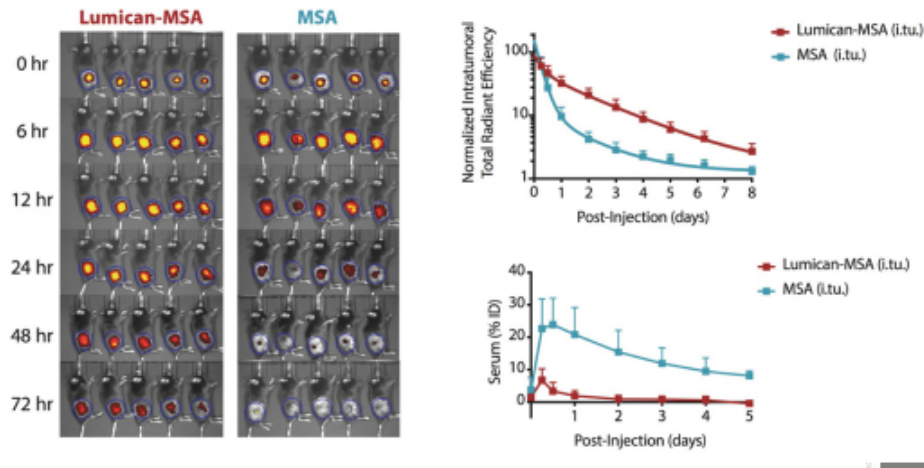
Alternatively, some cytokine-based therapeutic approaches attempt to target the delivery of cytokines to the tumor microenvironment. For example, cytokines have been fused to tumor-targeting antibodies, a format called immunocytokines. These antibodies direct the cytokine to the tumor by targeting cell surface antigens following systemic or local administration. However, this strategy is applicable only to patients that express the specific tumor antigen targeted by the immunocytokine. Furthermore, reduced bioavailability of the cytokine due to antibody internalization and loss of target antigen can limit the efficacy of immunocytokine therapies. Additionally, tumor targeting can be hindered by broad biodistribution due to cytokine affinity for its cognate receptors in blood, limiting bioavailability in the tumor. Another approach being explored to localize cytokine bioactivity to the tumor microenvironment is to obscure the cytokine active site with a tethered blocking domain that is cleaved off by the proteases present in the tumor microenvironment. This approach is still in early preclinical development.

Additionally, delivery of DNA constructs encoding cytokines is another approach to cytokine therapy. Intratumoral administration of plasmid DNA or adenoviruses that induce *in situ* expression of cytokines have also been explored in clinical trials. Likewise, oncolytic viruses, which preferentially replicate in cancer cells and can be administered either intratumorally or systemically, have been designed with genes encoding IL-2 or IL-12. While these approaches ensure that bioactive cytokines are produced in the tumor, they do not prevent systemic leakage of locally produced cytokines from the tumor site. Additionally, *in situ* expression strategies result in the limited ability to control the amount of cytokine expression, which makes pharmacologic dosing challenging.

Our AMBER Platform

With these challenges in mind, Professor Dane Witttrup's team pioneered the research that formed the basis for our AMBER platform. Results from this research, which were published in *Science Translational Medicine* in 2019, showed that intratumorally anchoring the injected IL-2, IL-12, or the combination of both IL-2 and IL-12 to collagen potentiated a systemic antitumor response while retaining the cytokine payload in the tumor microenvironment, thereby avoiding systemic exposure and toxicities. In the figures below, the ability of lumican, a collagen-binding protein, to mediate tumor retention and prevent systemic distribution was measured following administration of fluorescently labeled lumican fused to mouse serum albumin, or MSA, as compared to MSA alone without a collagen-binding domain. Both the images and quantification shown below demonstrate markedly improved retention of the MSA when fused to collagen-binding lumican. Specifically, the figure on the left demonstrates that MSA, when attached to lumican, is retained in the tumor for a longer period of time upon an intratumoral injection as compared to MSA alone without a collagen-binding domain. The figure on the top right illustrates the absolute quantity of lumican-MSA or MSA retained in a tumor over a period of eight days, while the figure on the bottom right demonstrates serum levels of lumican-MSA or MSA leaked out of the tumor, as a percentage of injected dose over time.

Fusion of a Collagen-Binding Protein (Lumican) Improved Tumor Retention of Albumin Following Intratumoral Injection

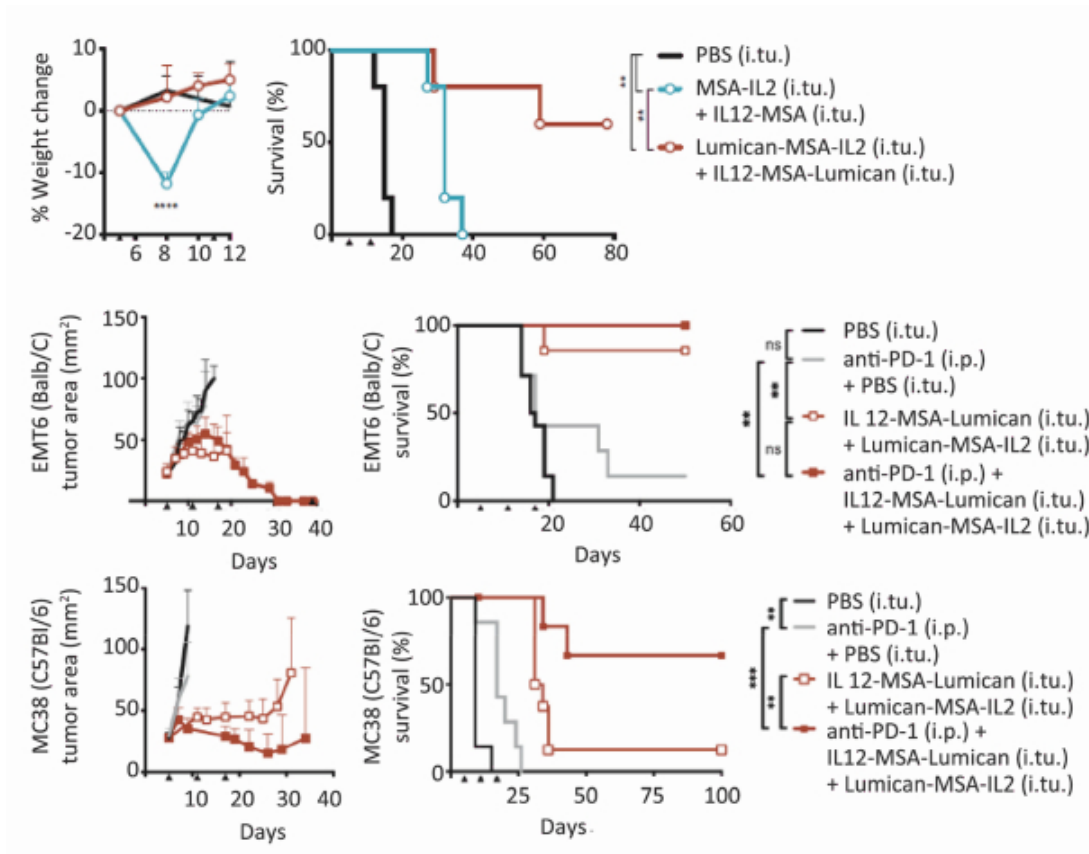


A further study explored the efficacy of lumican-MSA-IL2 and IL12-MSA-lumican fusion proteins each as a monotherapy or in combination in the B16F10 melanoma mouse model. B16F10 melanoma cells grow at highly aggressive rates. They further evade T cell responses via low expression of MHC Class I, making B16F10 tumors one of the most challenging syngeneic models for preclinical immunotherapy studies.

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The combination of lumican-MSA-IL2 and IL12-MSA-lumican showed survival improvement in all tested tumor models, including melanoma (B16F10), breast cancer (EMT6), and colon cancer (MC38), as shown below. Furthermore, the addition of a PD-1 checkpoint inhibitor demonstrated synergistic antitumor activity, with the triplet combination of lumican-MSA-IL2, IL12-MSA-lumican, and a PD-1 checkpoint inhibitor demonstrating improved tumor regression and survival. Neither monotherapy resulted in increased rates of complete responders. Of note, the combination of IL-2 and IL-12 lumican fusion proteins demonstrated significantly improved survival rates without systemic toxicity, as measured by body weight changes. In contrast, injection of cytokines fused to albumin without a collagen-binding domain were not efficacious and caused significant body weight loss.

Impact of Lumican-MSA-IL2 and IL12-MSA-Lumican and Their Combination on Tumor Size, Survival Rates and Body Weight



Our Solution: CLN-617

CLN-617 is a multi-functional cytokine therapeutic candidate designed to exploit the synergistic activities of IL-2 and IL-12 in a single therapeutic agent. We have validated the bioactivity of several murine surrogate designs and demonstrated antitumor activity in *in vivo* animal models. We intend to submit an IND for CLN-617 in 2022.

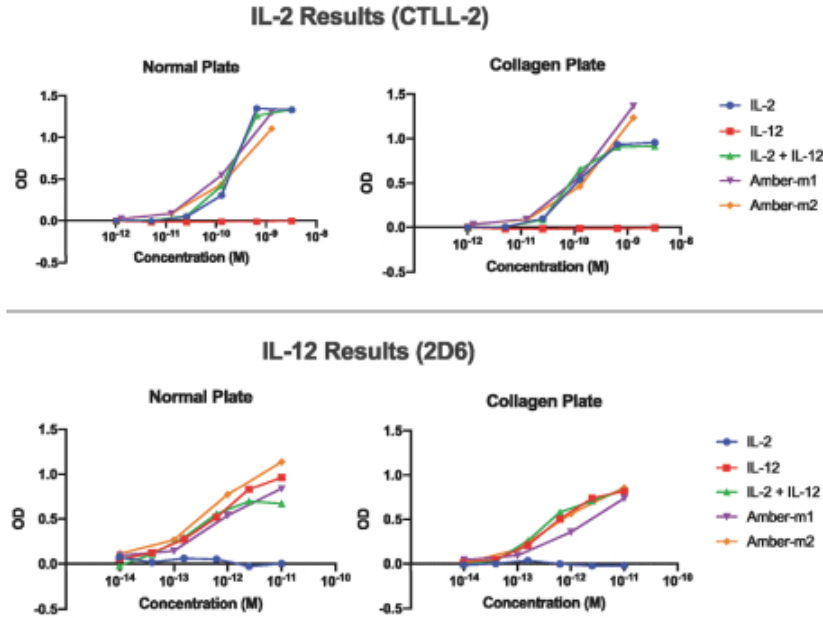
We have generated a variety of multifunctional AMBER-based constructs containing both IL-2 and IL-12 fused to various collagen-binding domains, and we refer to the murine surrogates of these constructs as

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AMBER-m1 and AMBER-m2. While Professor Witttrup’s foundational study focused on lumican, we evaluated collagen-binding domains with different affinities including other proteins that bind to collagen in the tumor microenvironment to enhance retention of the cytokines.

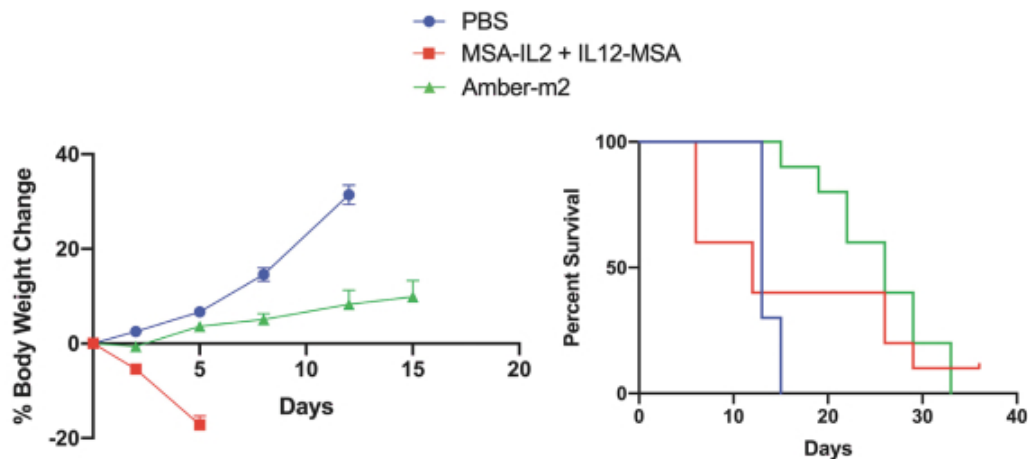
Our murine surrogate AMBER constructs have been assessed for productivity, product quality, and bioactivity. We tested the bioactivity of both IL-2 and IL-12 cytokines by measuring proliferation of respective cell lines in response to IL-2 and IL-12. We compared our constructs with collagen-binding domains to native cytokines in the presence and absence of collagen. As shown below, cytokine activity, measured by optical density, or OD, is maintained in the multifunctional AMBER-m1 and AMBER-m2 constructs and activity is comparable in both the absence and presence of collagen.

In AMBER Constructs, Cytokine Activity Was Fully Retained after Fusion to Collagen-Binding Domain



Based on these results, we further assessed the antitumor activity and tolerability of AMBER-m2 *in vivo* in C57BL/6 mice bearing B16F10 tumors. We compared intratumoral administration of AMBER-m2 to a combination of MSA-IL2 and IL12-MSA, which lack collagen-binding domains. As expected, treatment with MSA-IL2 and IL12-MSA led to systemic toxicity, as measured by reduction in body weight (left panel of figure below). In contrast, AMBER-m2 exhibited single-agent antitumor activity without inducing systemic toxicity, as measured by survival (right panel of figure below). Based on these results, we believe that AMBER-m2, which is presumably retained in the tumor microenvironment, may have the potential to mitigate the systemic toxicity associated with IL-2 and IL-12 therapy, thus potentially improving the therapeutic index while delivering antitumor activity.

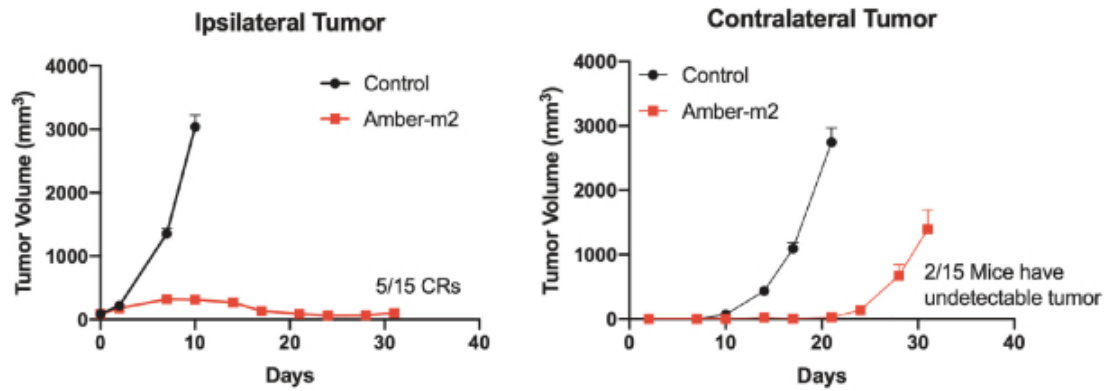
Antitumor Activity and Tolerability of MSA-IL2 + IL12-MSA or AMBER



In the experiments above, body weight changes are no longer recorded following animal death, accounting for the difference in days duration between the left and right figures for the MSA-IL2 + IL12-MSA treated animals.

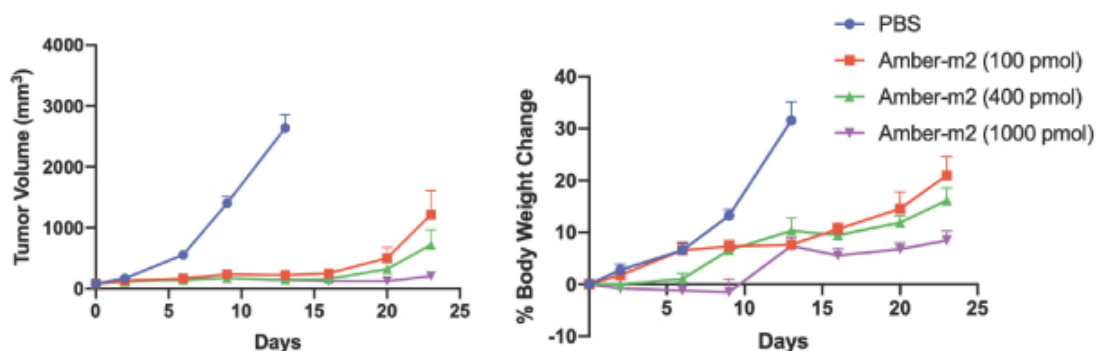
We hypothesized that in addition to mediating local antitumor activity, AMBER-m2 may be capable of generating responses against non-injected contralateral tumors due to the induction of systemic immunity, also known as an abscopal effect. To test our hypothesis, we utilized C57BL/6 mice bearing two B16F10 tumors: an ipsilateral tumor that was directly injected with AMBER-m2 and a contralateral tumor that was implanted 10 days later and never treated with AMBER-m2. Tumor control was observed in both the treated and untreated distal tumors, thus demonstrating an abscopal effect.

AMBER-m2 Inhibits Tumor Growth in Both Injected (Ipsilateral) and Uninjected (Contralateral) B16F10 Tumors, Providing Evidence for an Abscopal Effect



We have also evaluated the dose responsiveness of AMBER-m2 in the B16F10 model. Increasing doses of AMBER-m2 led to increased tumor growth control (left panel of figure below) and all doses did so without inducing significant body weight loss (right panel of figure below). Notably, the highest tested dose of 1,000 pmol is an equivalent dose of 6.4 mpk of body weight, which translates to 0.7 mpk of IL-2 and 2.3 mpk of IL-12. In comparison, only 100 pmol of MSA-IL2 and IL12-MSA led to lethal body weight loss.

Impact of AMBER-m2 on Tumor Growth and Body Weight in the B16F10 Model



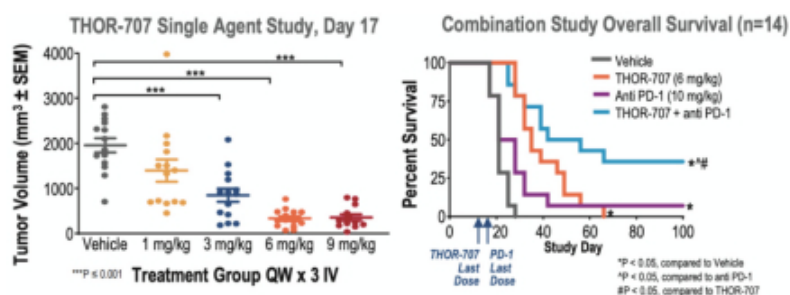
Based on the results of our preclinical studies, we believe that the inclusion of a collagen-binding domain by our AMBER platform has the potential to allow for the safe retention of high levels of cytokines in the tumor microenvironment. While remarkable progress has been made in the treatment of cancer 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 addition, preclinical results show the synergistic effect of adding a checkpoint inhibitor to a IL-2 and IL-12 combination treatment, which we believe may produce deeper responses in patients who respond to checkpoint inhibitors.

We have reviewed the publicly available results of preclinical *in vivo* experiments with other IL-2 and IL-12 based therapeutic candidates. We did not conduct head-to-head comparative studies of the IL-2 and IL-12 based therapeutic candidates described below, and preclinical data may not be similar to clinical results. As a result, comparative conclusions cannot be drawn between these preclinical study data and the preclinical study data we have observed for CLN-617 and AMBER, including due to differences in methodologies, such as dosing and method of administration, and the disease state of the mice.

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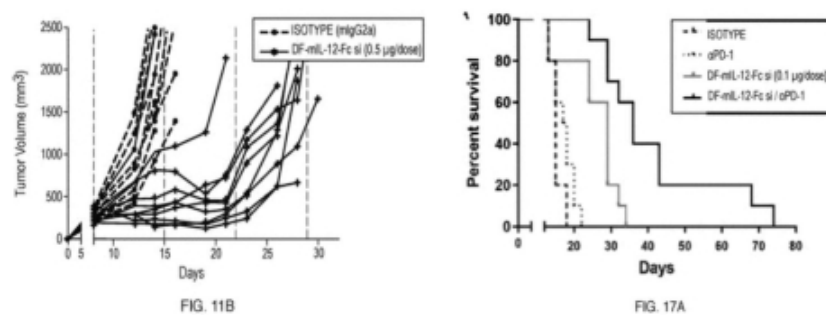
In a study conducted by Synthorx Inc., treatment of syngeneic CT26 tumors with THOR-707, a pegylated IL-2 engineered to have decreased binding to the α chain of the IL-2 receptor subunit, resulted in tumor growth inhibition as shown in the left panel of the figure below. However, no mouse in the THOR-707 mono-therapy treatment group achieved long-term survival as shown in the right panel of the figure below.

An Engineered IL-2, Administered as a Monotherapy, Did Not Induce Any Complete Responses in CT26 Tumors



In a study conducted by Dragonfly Therapeutics, treatment of syngeneic B16F10 tumors with a murine IL-12 fused to an Fc domain via intravenous administration resulted in tumor growth inhibition as shown in left panel of the figure below; however, there was no complete tumor eradication in any of the treated animals. Even with treatment in combination with anti-PD-1 checkpoint inhibitor, no long-term survival was achieved in any of the animals as shown in right panel of the figure below.

An IL-12 Fused to Fc, Administered as a Monotherapy, Did Not Induce Any Complete Responses in B16F10 Tumors



CLN-978

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 a human serum albumin, or HSA, binding domain designed to prolong its serum half-life. CLN-978, referred to as NexGem in the figures below, mediated CD19-dependent target cell lysis *in vitro* on target cell lines with a range of CD19 target expression levels. In preclinical *in vivo* studies, treatment with NexGem, at extremely low and infrequent doses, led to inhibition of tumor growth and tumor regression in a human CD3e transgenic syngeneic lymphoma mouse model. We intend to initially evaluate CLN-978 as a novel treatment for B-cell acute lymphoblastic leukemia, or ALL, and are currently planning IND-enabling pharmacology, pharmacokinetic, and safety studies.

Background on ALL and CD-19

ALL is characterized by the proliferation of immature lymphocytes in the bone marrow. According to the U.S. SEER database, there is estimated to be approximately 6,150 new cases of ALL and 1,520 deaths from ALL in the U.S. in 2020. Overall, approximately 40% of cases of ALL are in adults, and adult patients have a high mortality rate, accounting for approximately 80% of deaths from ALL.

In the pediatric population, ALL is highly curable with the long-term survival rate exceeding 90%. The treatment of children with ALL has benefited from a deeper understanding of the molecular genetics and pathogenesis of the disease as well as advances in the treatment paradigm, including combination chemotherapy. High rates of clinical trial participation in cooperative group studies in children and the development of risk-stratified treatment paradigms has enabled dose improvements in the standard-of-care for children. In contrast, similar treatment strategies have yielded far less favorable outcomes in the adult population, in part due to the higher prevalence of comorbidities and other high-risk features at diagnosis predisposing them to chemotherapy intolerance and resistance.

Approximately 80% of all ALL cases involve lineage lymphocytes in the bone marrow. CD19 is a cell surface antigen expressed on B cells, including cells that have undergone malignant transformation. The persistence of CD19 in cancerous B-cells has made it an attractive target for CD19-directed therapies, including blinatumomab. Blinatumomab belongs to a class of a bispecific T cell engaging antibody construct called BiTE, and is it currently the only CD19-targeting antibody approved for the treatment of r/r B cell ALL as well as for patients with first or second complete remission with minimal residual disease, or MRD.

We believe an opportunity exists to improve on several aspects of blinatumomab, which is made from two tandemly arranged scFv domains binding to CD19 and CD3, respectively. First, blinatumomab's short half-life of 2.1 hours necessitates continuous intravenous infusion to achieve desirable clinical efficacy. Such continuous administration increases the risk of serious catheter-related infections, which occurred in 9.5% of patients in clinical trials and which can be life-threatening or fatal. The dosing regimen and administration requirements, which include extended hospitalization and inpatient care, also present challenges regarding clinical management and monitoring, and may limit patient access to blinatumomab.

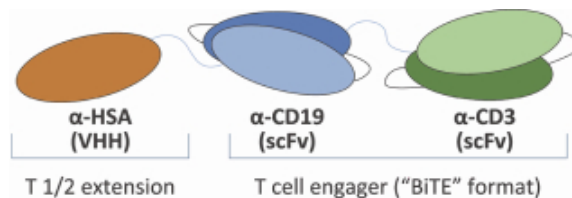
Second, we believe the binding properties of both the CD19 and the CD3 binding domains of blinatumomab may not be optimized to maximize the therapeutic potential of the bispecific T cell engager modality. Specifically, we believe the affinity of each domain to its respective target, on its own and in combination, is a critical determinant for both the efficacy and safety profile of a T cell engager. With regard to safety, main adverse reactions of concern include cytokine release syndrome and neurological toxicities. On the efficacy front, the majority of patients who are refractory to or relapse on blinatumomab treatment still express CD19 on their cancer cells, suggesting a potential benefit from using CD19-specific domains of much higher binding affinity.

A CD19-targeted chimeric antigen receptor T cell, or CAR, therapy, tisagenlecleucel, has also been approved for the treatment of B-cell ALL. Despite its promising clinical antitumor activity, autologous CAR-T cells have significant logistic and clinical limitations. CAR-T cells are produced on an individual-patient basis, which makes their production complex and expensive. In a number of patients in tisagenlecleucel clinical trials, treatment with CAR-T cells was associated with substantial toxicities, including cytokine release syndrome and neurotoxicity, which necessitated treatment in intensive care units. Furthermore, patients need to be at least 3 months post HSCT, and the entire process of autologous CAR-T cell manufacturing generally takes 22 days on average, which may limit the use of these therapies in patients with highly aggressive leukemia and/or active graft versus host disease. We believe a modality with an antibody-like modality such as CLN-978 has the potential to offer unique advantages over CAR-T therapies, particularly with respect to broader and more immediate access for patients as an off-the-shelf therapy.

Our Solution: CLN-978

We designed CLN-978 based on a BiTE-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, or VHH, for binding to HSA. We believe that binding of CLN-978 to albumin has the potential to extend its serum half-life, potentially addressing limitations related to its blinatumomab’s dosing regimen. 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



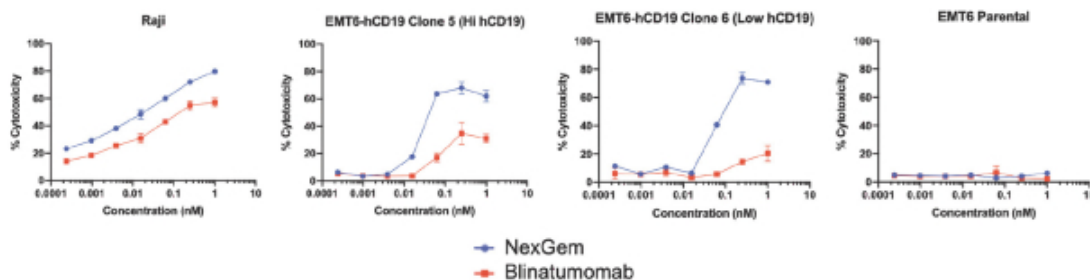
We have collaborated with Adimab LLC to generate antibody-derived binding domains specific for CD19, CD3, and HSA with optimized biophysical and biochemical properties, tailored binding affinities as well as other parameters that are key to developability, manufacturability and preclinical testing of drug candidates. In multiple head-to-head preclinical comparison studies, NexGem has demonstrated improved activity compared to blinatumomab both in terms of redirecting of T cells to lyse CD19-expressing cells *in vitro* and enhanced tumor growth inhibition *in vivo*. Although comparative data from preclinical studies must be interpreted with caution and we may not observe the same differential effect in clinical trials, we believe these preclinical results support further evaluation of CLN-978 for its potential to improve upon the clinical efficacy observed with blinatumomab and for its potential to offer a more convenient dosing profile. In addition to convenience, we believe the ability to target cells with low CD19 expression would potentially enable us to address indications that are not yet addressed by blinatumomab, such as non-Hodgkin’s lymphoma.

We expect the properties of CLN-978 may facilitate our efforts on manufacturing processes and IND-enabling studies, as we believe they will enable us to leverage standard cell line development and purification technologies for GMP manufacturing and conventional non-human primate models for GLP toxicology assessment.

Preclinical Data

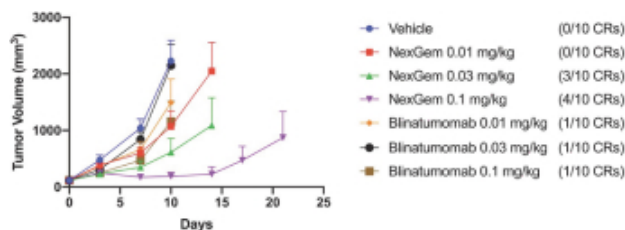
Our NexGem candidates incorporate a CD19 binding domain that was engineered to achieve 100x enhanced binding affinity to CD19 compared to blinatumomab as measured using plasmon resonance, which we believe may contribute to improved cytolytic potency in an *in vitro* model. As shown in the figure below, NexGem outperformed blinatumomab in the cell lines evaluated as measured by both the EC50 value of redirected cell lysis and the maximum percentage of lysis. Notably, the relative improvement in cytolytic potency of CLN-978 as compared to blinatumomab was the highest in target cells expressing relatively low levels of CD19. 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 EMT6 parental cell line, which lacks CD19 expression, was not susceptible to lysis at any of the drug concentrations tested.

Comparison of NexGem Versus Blinatumomab *in vitro* Cytotoxicity Assays



NexGem has also demonstrated antitumor activity *in vivo* compared to blinatumomab in a human CD3e transgenic model, where the mice were implanted with a syngeneic tumor engineered to express human CD19. As shown in the figure below, NexGem outperformed blinatumomab in tumor growth inhibition at every dose level tested. Furthermore, at the 0.1 mg/kg dose level, NexGem treatment resulted in a complete response in 40% of mice compared to only 10% of mice treated with blinatumomab.

Antitumor Activity of NexGem Versus Blinatumomab In a Human CD3 Transgenic Mouse Model Bearing Human CD19 Expressing Syngeneic Tumors



Given the potential contribution of the CD3 binding domain to the cytokine release profile of a T cell engager, we explored multiple variants of the CD3 binding domain of CLN-978. We plan to nominate our final therapeutic candidate based on the totality of evidence, including *in vitro* cell killing, *in vitro* cytokine release, and *in vivo* antitumor activity, to optimize the overall risk-benefit profile of the program.

Our Earlier-Stage Programs

In addition to the programs described above, we are evaluating two discovery-stage immuno-oncology programs, Opal and Jade, both of which are in the lead optimization stage.

For our Opal program, we are exploring a construct that combines checkpoint inhibition and immune co-stimulatory receptor activation in a single protein. We are evaluating various single-chain fusion protein formats using an affinity optimized PD-1 extracellular domain and a single-chain 4-1BBL designed to selectively activate the 4-1BB/CD137 pathway on T cells inside tumors. We believe that the combination of these natural binding elements could potentially drive synergistic antitumor immune mobilization while reducing the systemic toxicity often associated with past co-stimulatory immune agonists. We are designing our lead construct such that the activation of the co-stimulatory receptor is dependent on the binding to immune checkpoint ligands, which have generally higher expression levels in tumor tissues compared to normal tissues. We also believe that our approach has the potential to demonstrate advantages over antibody-based bispecific constructs that typically require selection of format specific epitopes and appropriate affinities for target binding.

We are developing our Jade program as part of an ongoing collaboration with the Fred Hutchinson Cancer Research Center, a world leader in finding self-reactive, human T cells of high affinity. Our goal is to develop a TCR-T cell therapy targeting a novel senescence and cancer-related protein. We are collaborating with Fred Hutchinson Cancer Research Center to search for naturally occurring TCRs against this target.

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 therapeutic 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 therapeutic 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 therapeutic 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 therapeutic candidates progress through clinical development.

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With respect to our lead therapeutic candidate, CLN-081, we are aware of other EGFR inhibitors that are in clinical development for the treatment of NSCLC with EGFRex20ins mutations. We believe that the two most advanced are poziotinib from Spectrum Pharmaceuticals and mobocertinib (TAK-788) from Takeda Pharmaceuticals. Additional EGFR inhibitors in development include Black Diamond's BDTX-189 and Dizal Pharmaceutical's DZD9008. Additionally, Johnson & Johnson is developing amivantamab, an EGFRxcMET bispecific antibody, for the treatment of NSCLC with EGFRex20ins mutations.

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: Innate Pharma, Inc. (in collaboration with AstraZeneca Inc.), CanCure LLC, Genentech Inc., Novartis International AG, and Bristol-Myers Squibb Company. To our knowledge, none of them has entered clinical development.

With respect to CLN-049, we are aware of several companies that are developing bi-specifics for the treatment of AML, including those targeting CD3 and CD33 (Amgen, Amphivena), CD123 (MacroGenics, Xencor), and CCL1/CLEC12A (Merus, Genentech). These agents are limited to a subset of AML blasts that express CD33, CD123, and CCL1, whereas multiple published studies have demonstrated that FLT3 is expressed in at least 70% of AML blasts. 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' XOSPATA (gilteritinib) and 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) and IDHIFA (enasidenib), BCL2 inhibitors, such as VENCLEXTA (venetoclax), and hedgehog pathway inhibitors, such as DAURISMO (glasdegib).

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: Nektar Therapeutics, Inc., Alkermes plc, Sanofi, Philogen S.p.A., Roche AG, Apeiron Biologics, and Dragonfly Therapeutics Inc.

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 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 Morphosys AG, Novartis International AG, Gilead Sciences Inc., Bristol-Myers Squibb Company, Allogene Therapeutics Inc., Nkarta Inc., and Amgen 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 with a more favorable label than our therapeutic 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 therapeutic 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

Taiho License Agreement

In February 2019, our partially-owned subsidiary Cullinan Pearl Corp., or Cullinan Pearl, entered into a License and Collaboration Agreement, or the Taiho License Agreement, with Taiho Pharma. Pursuant to the Taiho License Agreement, Cullinan Pearl obtained an exclusive, royalty-bearing worldwide license (excluding

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Japan) to develop, manufacture, commercialize and, subject to certain limitations, sublicense CLN-081 (formerly known as TAS6417) and products containing CLN-081, for use worldwide outside Japan, under the licensed patent rights and know-how.

Under the Taiho License Agreement, Cullinan Pearl agreed to conduct all development activities in accordance with a target product profile and a development plan intended to generate data to seek regulatory approval of CLN-081 from the FDA and EMA and make such data available to Taiho Pharma for use to seek regulatory approval in Japan. Certain of these development activities require using commercially reasonable efforts. Cullinan Pearl must disclose experimental data, results or similar know-how to Taiho Pharma and grant a non-exclusive, royalty free, worldwide license, with the right to sublicense, to Taiho Pharma to develop, manufacture and commercialize CLN-081 and its products in Japan. Cullinan Pearl, and in certain cases Taiho Pharma, are obligated to provide progress reports to each other on development efforts before and, for so long as such party is developing a licensed product, after the first commercial sale of CLN-081. Taiho Pharma also has right of negotiation with Cullinan Pearl in the event Cullinan Pearl decides to commence negotiations with or if Cullinan Pearl receives a bona fide term sheet from a third-party regarding the license, sale, assignment, transfer or material disposition of rights with respect to the licensed product.

As partial consideration for the license, Cullinan Pearl paid an initial, non-refundable, non-creditable license fee of \$2,500,000 and issued Taiho Pharma 1,860,000 shares of Cullinan Pearl common stock. In addition, Cullinan Pearl is obligated to pay non-refundable, non-creditable research and development, regulatory and sales milestone payments upon the occurrence of certain milestone events in an aggregate amount of up to \$154.5 million for development, regulatory and sales milestones. Each milestone is payable only once. No milestones have been achieved to date under the Taiho License Agreement.

Furthermore, on a country-by-country and product-by-product basis, Cullinan Pearl is required to pay running mid single digit to low tens digits royalty percentages of annual aggregate net sales worldwide outside Japan, during the royalty term (such royalty term determined on a product-by-product and country-by-country basis), subject to certain offsets, deductions or reductions related to loss or impairment of exclusivity in the territory. Such royalty obligations will expire on a country-by-country and product-by-product basis upon the latest of (a) the expiration of the last patent which covers a product in such country, (b) the expiration of the applicable exclusivity granted by a regulatory authority and (c) ten years following the first commercial sale of the product in such country.

In the event (i) Taiho Pharma does not exercise its right of negotiation with respect to a licensed product or (ii) Taiho Pharma does exercise its right of negotiation, but the parties do not consummate a transaction, then at the time Cullinan Pearl enters into a subsequent transaction with a third-party for (a) less than all or less than substantially all of Cullinan Pearl's rights in a licensed product, Cullinan Pearl is obligated to pay Taiho Pharma a mid single digit to mid teens percentage of revenue from such transactions or (b) all or substantially all of Cullinan Pearl's rights in a licensed product, Cullinan Pearl is obligated to pay Taiho Pharma a low single digit to mid single digit percentage of revenue from such transactions, provided, however, that such payment under (b) shall not be required following the consummation of an initial public offering of Cullinan Pearl meeting certain requirements. In December 2020, Cullinan Pearl entered into a license agreement, or the Zai License Agreement, with Zai Lab. Pursuant to the terms of the Taiho License Agreement, we are obligated to pay Taiho a mid teen percentage of the \$20.0 million upfront payment received from Zai Lab, as well as potential future collaboration revenue received from Zai Lab under the Zai License Agreement.

Either party may terminate the agreement upon a material breach by the other party or bankruptcy of the other party. Cullinan Pearl may terminate the Taiho License Agreement at any time and for any commercially reasonable justification. Unless earlier terminated, the Taiho License Agreement continues in effect on a product-by-product basis until it expires upon the expiration of all applicable royalty terms with respect to all products in all countries worldwide.

Zai License Agreement

In December 2020, Cullinan Pearl entered into the Zai License Agreement with Zai Lab. Pursuant to the Zai License Agreement, Cullinan Pearl granted Zai Lab an exclusive, royalty-bearing license to research, develop, commercialize and manufacture CLN-081 and products containing CLN-081 in the field in China, Hong Kong, Macau and Taiwan, or collectively, the Territory. Cullinan Pearl has also granted Zai Lab the right to grant sublicenses in multiple tiers in accordance with the Zai License Agreement, under the licensed technology and any improvements discovered or created during the term, to exploit the products in the field in the Territory.

Cullinan Pearl retained (i) all rights under the licensed technology to fulfill its obligations under the Zai License Agreement, (ii) the exclusive rights to exploit the licensed compound and products outside the Territory, (iii) the non-exclusive rights under the licensed technology to conduct global studies in accordance with the Zai License Agreement and (iv) the non-exclusive rights to manufacture or have manufactured the licensed compound or product in the Territory, solely to support (x) the manufacture, development and commercialization of the licensed compound and products outside of the Territory and (y) the manufacture, development and commercialization of the product by Zai Lab in the Territory.

Pursuant to the terms of the Zai License Agreement, Zai Lab shall use commercially reasonable efforts to develop the products in the field in the Territory, including the conduct of all development activities of the products in the field in the Territory in accordance with the development plan.

As partial consideration for the license and rights, Zai Lab will pay Cullinan Pearl an upfront, one-time, irrevocable, non-refundable, non-creditable license fee of \$20.0 million within 40 days of the execution of the Zai License Agreement. In addition, Zai Lab is obligated to pay Cullinan Pearl non-refundable, non-creditable research and development, regulatory and sales milestone payments upon the occurrence of certain milestone events in an aggregate amount of up to \$211.0 million. Each milestone is payable only once. No milestones have been achieved to date under the Zai License Agreement.

Furthermore, on a region-by-region and product-by-product basis, Zai Lab is required to pay tiered royalties from high single digit to low teen digit royalty percentages on of annual aggregate net sales of all future products in the Territory in a calendar year, during the royalty term (such royalty term determined on a product-by-product and region-by-region basis), subject to certain offsets, deductions or reductions related to the expiration of the last-to-expire valid claim in such region, such time as generic competition with respect to such product occurs in such region or in connection with obtaining a license for any patents owned or controlled by a third-party in order to commercialize the licensed product; provided, however, that the royalties due to Cullinan Pearl shall not be reduced by more than fifty percent (50%). Such royalty obligations will be payable on a region-by-region and product-by-product basis from the first commercial sale of the applicable product in such region until the latest of (a) the date the last-to-expire valid claim in such region expires and (b) the tenth anniversary following the first commercial sale of such product in such region. Upon the expiration of the royalty terms, the licenses granted by Cullinan Pearl to Zai Lab in such region with respect to such product in the field shall become fully paid-up, perpetual, irrevocable and sublicenseable in multiple tiers.

Either party may terminate the agreement on a region-by-region basis or in its entirety upon a material breach by the other party or bankruptcy of the other party. Zai Lab may terminate the Zai License Agreement in its entirety or on a product-by-product basis at any time and for any or no reason, provided, however, that Zai Lab will terminate the Zai License Agreement upon prior written notice to Cullinan Pearl if it determines that it shall discontinue all development and commercialization activities with respect to the products. Furthermore, Cullinan Pearl may terminate the Zai License Agreement in its entirety, if Zai Lab or its affiliates commence a legal, administrative or other action challenging the validity, enforceability or scope of any licensed patent or patent (other than the licensed patent) owned or controlled by Cullinan Pearl and its affiliates. In addition, if no active development activities have been conducted by Zai Lab and its affiliates or a permitted sublicensee within 10 months of the execution of the Zai License Agreement and such inactivity is not caused by a serious adverse event or serious adverse drug reaction, a force majeure event or Cullinan Pearl's failure to supply sufficient

quantities of clinical supply product, then Zai Lab will be deemed to have abandoned development for the product and Cullinan Pearl shall have the right to terminate the Zai License Agreement upon written notice, unless Zai Lab has cured such abandonment within 60 days of such written notice. The agreement may also be terminated by mutual written agreement. Unless earlier terminated, the Zai License Agreement continues in effect on a product-by-product basis until the expiration of all applicable royalty terms with respect to all products in any region in the territory.

DKFZ/Tübingen License Agreement

In August 2020, our partially-owned subsidiary Cullinan Florentine Corp., or Cullinan Florentine, entered into an Exclusive License Agreement, or the DKFZ/Tübingen License Agreement, with Deutsches Krebsforschungszentrum, or DKFZ, Eberhard Karls University of Tübingen, Faculty of Medicine, or University of Tübingen, and Universitätsmedizin Gesellschaft für Forschung und Entwicklung mbH, Tübingen, or 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, or collectively, the Performance Benchmarks, by certain specified dates, or 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, 2020, Cullinan Florentine has met the first performance benchmark to create a master cell bank.

Cullinan Florentine paid to Licensor an upfront non-refundable, non-creditable option exercise fee of \$600,000 and, as partial consideration for the licenses, has issued 758,246 and 348,682 shares of Common Stock to DKFZ and University of Tübingen, respectively, who together own eight percent (8%) of Cullinan Florentine's fully diluted shares outstanding as of December 31, 2020. DKFZ and UFE were also granted the right to appoint one representative to the board of directors of Cullinan Florentine for so long as DFKZ and UFE in aggregate hold a mid-double digit percentage of shares of Cullinan Florentine common stock issued pursuant to the DKFZ/Tübingen License Agreement or until a financing threshold representing the aggregate investment in Cullinan Florentine is reached.

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 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

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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 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 DKFZ/Tübingen License Agreement continues on a perpetual basis.

MIT Exclusive Patent License Agreement

In December 2019, our partially-owned subsidiary Cullinan Amber Corp., or Cullinan Amber, entered into an Exclusive Patent License Agreement, or the MIT License Agreement, with the Massachusetts Institute of Technology, or 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 paid MIT an upfront license issue fee of \$50,000 and 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. As of December 31, 2020 Cullinan Amber has reimbursed MIT for \$48,567 in connection with out-of-pocket expenses incurred by MIT in connection with the preparation, filing, prosecution, maintenance and defense of patent rights. In addition, as partial consideration, Cullinan Amber has issued 200,066 shares of common stock of Cullinan Amber to MIT, which owns five percent (5%) of Cullinan Amber's fully diluted shares outstanding as of December 31, 2020. 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 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

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calculation of net sales across all licensed products in all indications in an aggregate amount up to \$12.5 million. No milestones have been achieved to date 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 fifty percent (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, or 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.

Adimab Collaboration Agreement

In November 2018, our wholly-owned subsidiary Cullinan Management entered into a Collaboration Agreement, or the Adimab Collaboration Agreement, with Adimab, LLC, or Adimab. Pursuant to the Adimab Collaboration Agreement, Cullinan Management 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, Cullinan Management has 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, Cullinan Management has a non-exclusive worldwide license under Adimab's technology to perform certain research activities and to evaluate the program antibodies to determine whether Cullinan Management wants 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. In the event Cullinan Management exercises its option, it will pay an option fee for each target subject to certain adjustments.

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

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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, Cullinan Management 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 as defined in the agreement.

Cullinan Management 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.

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 United States 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 December 31, 2020, our patent portfolio includes 12 patent families, including both patent applications we own, and issued patents and patent applications exclusively in-licensed from external technology originators in a respective field. Specifically, we have exclusively in-licensed at least 2 issued US patents, 29 patents issued in foreign jurisdictions, and 44 patent applications pending worldwide. Our earliest issued patents are expected to expire in 2034. Later patents, that may issue from our pending patent applications, are expected to expire between 2037 and 2041, 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.

Our portfolio related to our CLN-081 product candidate includes five patent families directed to compositions, and methods of using such compositions therapeutically. The first family, which is in-licensed from Taiho Pharmaceuticals, covers compositions with claims directed to our CLN-081 product candidate. This patent family includes issued patents in the U.S., major European countries and China, and such patents are expected to expire in 2034, excluding any patent term adjustments or extensions, if applicable. Within this family, patent application were filed in Australia, Brazil, Canada, China, Hong Kong, Macau, European Patent Office, Austria, Belgium, Switzerland, Czech Republic, Germany, Denmark, Spain, Finland, France, United Kingdom, Greece, Hungary, Ireland, Italy, Netherlands, Norway, Poland, Portugal, Romania, Sweden, Turkey, Indonesia, India, Japan, Korea, Mexico, Malaysia, Philippines, Russian Federation, Singapore, Thailand, Taiwan, United States of America, and Vietnam. Three families, also in-licensed from Taiho Pharmaceuticals, include both issued patents and pending patent applications with claims directed to methods of using the CLN-081 product candidate in treating additional diseases where we believe CLN-081 has potential to be active. The first of these three families, titled "Selective Inhibitor of Exon20 Insertion Mutant EGFR", is expected to expire in 2037, excluding any patent term adjustments or extensions, if applicable, that may be available. Within this family, patent applications have so far been filed in Australia, Brazil, Canada, China, European Patent Office, Indonesia, Israel, Japan, Jordan, Korea, Malaysia,

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Mexico, New Zealand, Philippines, Russian Federation, Singapore, Thailand, United States of America, Vietnam, South Africa, and Taiwan. The second of these three families, titled “Selective Inhibitor of Exon 18 and Exon 21 Mutant EGFR”, is expected to expire in 2038, excluding any patent term adjustments or extensions, if applicable, that may be available. Within this family, patent applications have so far been filed in Australia, Canada, China, European Patent Office, Israel, Korea, Taiwan, Singapore, and United States of America. The third of these three families, titled “L718 and/or L792 mutant type treating resistance EGFR inhibitor”, is expected to expire in 2039, excluding any patent term adjustments or extensions, if applicable, that may be available. An international application has been filed under this family. We own a fifth application, which is directed to certain methods of use and dosing protocols. This family is expected to expire in 2041, excluding any patent term adjustments or extensions, if applicable, that may be available. US provisional applications have been filed under this family.

We, through Cullinan MICA, own three 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. An international application has been filed under this family and country-specific applications have been filed so far in Australia and Canada. We plan to enter into additional jurisdictions prior to the applicable deadlines. The family of patent applications with claims directed to additional anti-MICA antibody compositions, if issued, are expected to expire in 2039, excluding any patent term adjustments or extensions, if applicable. An international application has been filed under this family and country-specific applications have been filed so far in Australia and Canada. We plan to enter into additional jurisdictions prior to the applicable deadlines. The family of patent applications with claims directed to additional anti-MICA antibody compositions and methods of use, if issued, are expected to expire in 2041, excluding any patent term adjustments or extensions, if applicable. A US 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. An international application has been filed under this family.

Our portfolio related to our CLN-617 product candidate and Cullinan Amber program includes three patent families. The first family was in-licensed from the Massachusetts Institute of Technology, 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. An international application has been filed under this family. The second two families are two provisional applications owned by Cullinan Amber Corp., which are directed to certain compositions, and methods of using such compositions therapeutically. These two families of patent applications contain 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.

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 United States 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, or 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 GMP manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for preclinical

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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, or CMOs, for preclinical testing. We receive clinical supply material manufactured in compliance with current Good Manufacturing Practice requirements, or cGMPs, and we conduct audits before and during the trial, in cooperation with a CMO, to ensure compliance with the mutually agreed process descriptions and cGMP regulations.

We generally expect to rely on third parties for the manufacture of companion diagnostics for our products, which are assays or tests that identify an appropriate patient population. 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 (DS) for CLN-049 and CLN-619, our most advanced biologic candidates, from single-source third-party contract manufacturers, Abzena and WuXi, respectively. While any reduction or halt in supply of DS from these contract manufacturers could limit our ability to develop our product candidates until we find a qualified replacement contract manufacturer, we have procured sufficient DS to support our planned clinical studies for both CLN-049 and CLN-619. WuXi has also supplied CLN-049 drug product (DP), and we have procured sufficient CLN-049 DP for our planned clinical studies. We have engaged a separate contract manufacturer to produce CLN-619 DP, which is intended to be sufficient for our planned clinical studies. We intend to put in place agreements under which our third-party contract manufacturers will generally provide us with necessary quantities of DS and DP on a project-by-project basis, based on our projected development and commercial supply needs.

Our CLN-049 and CLN-619 product candidates are manufactured from a vial of a master cell bank, or 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. For CLN-049, the MCB is stored in one location, and we are making plans to store at a second location. The research cell bank (RCB) for CLN-049 is stored at a different location from the MCB. For CLN-619, the MCB is stored at two independent sites, and the RCB is stored at a separate location from the RCB locations. We 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

United States Food and Drug Administration Regulation

The United States Food and Drug Administration, or 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, 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, or 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 United States 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

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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 United States, the FDA regulates drugs under the FDCA, and biologics under the FDCA and the Public Health Service Act, or 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 United States.

Our product candidates must be approved for therapeutic indications by the FDA before they may be marketed in the United States. For our drug product candidates regulated under the FDCA, such as CLN-081, FDA must approve a NDA. For our biologic product candidates regulated under the FDCA and PHSA, such as CLN-049 and CLN-619, FDA must approve a 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, or GLP, requirements;
- submission to the FDA of an IND application 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, or 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, or 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;
- 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 United States.

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 United States, 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*

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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 United States, 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. 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 the company 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 United States, 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 United States 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.

- 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. 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.

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 the company or the treating physician for treatment purposes on a case-by-case basis for the following groups: individual patients (single-patient IND applications 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 application.

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, 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 addition, on May 30, 2018, the Right to Try Act was signed into law. The law, 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 I clinical trial, are the subject of an active IND, and are undergoing investigation for FDA approval. Unlike the expanded access framework described above, Right to Try does not require FDA to review or approve requests for use of the investigational product. There is no obligation for a company to make its investigational products available to eligible patients under the Right to Try Act.

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 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 United States 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 pre-clinical 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 United States.

In addition, under the Pediatric Research Equity Act, or 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 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 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 United States, 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. Once the

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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 policies agreed to by the FDA under the Prescription Drug User Fee Act, or 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. 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.

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, or 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, or 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, or 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 United States, or a patient population greater of than 200,000 individuals in the United States when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States 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.

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 United States 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.

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.

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, or 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. All promotional materials for product candidates approved under accelerated approval are subject to prior review by the FDA unless 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 approval of therapeutic products and *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 United States, 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 pre-market approval, or 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.

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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 510(k) submission. A manufacturer that wishes to conduct a clinical study involving the device is subject to the FDA's investigational device exemption, or IDE, regulation. 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 United States, device manufacturers are also subject to 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 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 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 United States.

Post-Approval Requirements for Drugs and Biologics in the United States

In the United States, 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 changes in indications, 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.

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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 Healthcare 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.

United States Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval of our future product candidates, some of our United States patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, 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 United States 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 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 United States. 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.

United States Biosimilars and Exclusivity

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the ACA, signed into law in 2010, includes a subtitle called the Biologics Price Competition and Innovation Act, or 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 United States. 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

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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 Patient Protection and Affordable Care Act, 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 United States 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 United States in addition to the FDA, which may include the Centers for Medicare & Medicaid Services, or CMS, other divisions of the Department of Health and Human Services, or 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 United States

In the United States, 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 United States, 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;
- The federal civil and criminal false claims laws, including the civil False Claims Act, or 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 civil False Claims Act. 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, or 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, or 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) 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. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made in the previous year to certain non-physician providers such as physician assistants and nurse practitioners; 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 United States 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.

United States Coverage and Reimbursement

In the United States 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 United States such as Medicare and Medicaid, commercial health insurers and managed care organizations, provide coverage, and establish adequate reimbursement levels for, the product. In the United States, 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. 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.

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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 United States 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 March 2010, the United States Congress enacted the ACA, which, among other things, included changes to the coverage and payment for products under government health care programs. The ACA included provisions of importance to our potential product candidate that:

- created an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic products, apportioned among these entities according to their market share in certain government healthcare programs;
- expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs and revising the definition of "average manufacturer price," or AMP, for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices;
- 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;
- expanded the types of entities eligible for the 340B drug discount program;
- established the Medicare Part D coverage gap discount program by requiring manufacturers to provide point-of-sale-discounts off the negotiated price of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D; and
- created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

There remain numerous judicial, administrative, executive, and legislative challenges to certain aspects of the Affordable Care. For example, various portions of the ACA are currently undergoing legal and constitutional challenges in the United States Supreme Court, and the Trump Administration has issued various Executive Orders that eliminated cost sharing subsidies and various provisions that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or biologics. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA such as removing penalties, starting January 1, 2019, for not complying with the ACA's individual mandate to carry health insurance, eliminating the implementation of certain of the ACA's mandated fees, and increasing the point-of-sale discount that is owed by

pharmaceutical manufacturers who participate in Medicare Part D. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, and has allotted one hour for oral arguments, which are expected to occur in the fall.

Other legislative changes have been proposed and adopted in the United States 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. These will be suspended from May 1, 2020 through December 31, 2020 due to the COVID-19 pandemic. 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 United States, 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. For example, at the federal level, the Trump administration’s budget proposal for fiscal year 2021 includes 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 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 solicited feedback on some of these measures and has implemented others under its existing authority. 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. Although a number of these and other measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payers. In addition, individual states in the United States 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. For example, on April 18, 2020, CMS announced that qualified health plan issuers under the ACA may suspend activities related to the collection and reporting of quality data that would have otherwise been reported between May and June 2020 given the challenges healthcare providers are facing responding to the COVID-19 virus.

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Outside the United States, 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, 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 European Union 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. European Union 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 to physicians to limit prescriptions. Recently, many countries in the European Union 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 European Union. 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 European Union 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 United States to authorized users of the Federal Supply Schedule of the 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 Union Drug Development

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

Similar to the United States, the various phases of preclinical and clinical research in the European Union are subject to significant regulatory controls. Although the EU Clinical Trials Directive 2001/20/EC has sought to harmonize the EU clinical trials regulatory framework, setting out common rules for the control and authorization of clinical trials in the European Union, the EU Member States have transposed and applied the provisions of the Directive differently. This has led to significant variations in the member state regimes. Under the current regime, before a clinical trial can be initiated it must be approved in each of the EU countries where the trial is to be conducted by two distinct bodies: the National Competent Authority, or NCA, and one or more Ethics Committees, or ECs. Under the current regime all suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial have to be reported to the NCA and ECs of the 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, simplifying adverse-event reporting procedures, improving the supervision of clinical trials and increasing their transparency. Recently enacted Clinical Trials Regulation EU No 536/2014 ensures that the rules for conducting clinical trials in the European Union will be identical.

We are in the process of applying to renew our status with EMA as a small and medium-sized enterprise, or SME. If we obtain SME status with EMA, it will provide access to administrative, regulatory and financial support, including fee reductions for scientific advice and regulatory procedures.

European Union Drug Marketing

Much like the Anti-Kickback Statute prohibition in the United States, 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 European Union. The provision of benefits or advantages to physicians is governed by the national anti-bribery laws of European Union Member States, such as the UK Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain European Union 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 reputational risk, public reprimands, administrative penalties, fines or imprisonment.

European Union Drug Review and Approval

In the European Economic Area, or EEA, which is comprised of the 27 Member States of the European Union together with Norway, Iceland and Liechtenstein, medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA. There are two types of marketing authorizations.

- The Community MA is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use, or 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 medicines such as gene-therapy, somatic cell-therapy or tissue-engineered medicines and medicinal products containing a new active substance indicated for the treatment of HIV, AIDS, 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 European Union.

- National MAs, which are issued by the competent authorities of the Member States of the EEA 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 another Member States through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure. Under the Decentralized Procedure an identical dossier is submitted to the competent authorities of each of the Member States in which the MA is sought, one of which is selected by the applicant as the Reference Member State, or RMS. The competent authority of the RMS prepares a draft assessment report, a draft summary of the product characteristics, or SPC, and a draft of the labeling and package leaflet, which are sent to the other Member States (referred to as the Member States Concerned) for their approval. If the Member States Concerned raise no objections, based on a potential serious risk to public health, to the assessment, SPC, labeling, or packaging proposed by the RMS, the product is subsequently granted a national MA in all the Member States (i.e., in the RMS and the Member States Concerned).

Under the above described procedures, before granting the MA, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

European Union New Chemical Entity Exclusivity

In the European Union, new chemical entities (including both small molecules and biological medicinal products), sometimes referred to as new active substances, qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. The data exclusivity, if granted, prevents regulatory authorities in the European Union from referencing the innovator's data to assess a generic application for eight years, after which generic marketing authorization can be submitted, and the innovator's data may be referenced, but not approved for two years. 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 marketing authorization 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.

European Union Orphan Designation and Exclusivity

In the European Union, 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 affecting not more than 5 in 10,000 persons in the European Union community (or where it is unlikely that the development of the medicine would generate sufficient return to justify the investment) and for which no satisfactory method of diagnosis, prevention or treatment has been authorized (or, if a method exists, the product would be a significant benefit to those affected).

In the European Union, 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 medicinal product approval. 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. 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.

European Pediatric Investigation Plan

In the EEA, MAAs for new medicinal products not authorized have to include the results of studies conducted in the pediatric population, in compliance with a pediatric investigation plan, or PIP, agreed with the EMA's Pediatric Committee, or PDCO. The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the drug for which marketing authorization 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. Once the marketing authorization is obtained in all Member States of the European Union and trial results are included in the product information, the product is eligible for six months' supplementary protection certificate extension, even when the supplementary protection certificate period would otherwise be negative.

European Data Collection

The collection and use of personal health data in the European Economic Area, or the EEA, governed by 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 European Union. 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 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.

Employees

As of December 31, 2020, we had 20 full-time employees and two consultants. Nine of our employees have M.D. or Ph.D. degrees. Within our workforce, nine employees are engaged in research and development and 11 are engaged in business development, finance, legal, and general management and administration. 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.

Facilities

Our corporate headquarters is located in Cambridge, Massachusetts, where we sublease and occupy approximately 7,531 square feet of office space. The current term of our Cambridge lease expires June 30, 2024. We believe our existing facilities are sufficient for our needs for the foreseeable future. To meet the future needs of our business, we may lease additional or alternate space, and we believe suitable additional or alternative space will be available in the future on commercially reasonable terms.

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.

MANAGEMENT

Executive Officers and Directors

The following table and discussion sets forth the name, age, as of December 31, 2020, and position of the individuals who currently serve as directors and executive officers of Cullinan Oncology, LLC and will begin to serve as the directors and executive officers of our wholly-owned subsidiary Cullinan Management following the completion of the Reorganization. The following also includes certain information regarding our directors' and officers' individual experience, qualifications, attributes and skills and brief statements of those aspects of our directors' backgrounds that led us to conclude that they are qualified to serve as directors.

<u>Name</u>	<u>Age</u>	<u>Position(s)</u>
Executive Officers		
Owen Hughes	46	President, Chief Executive Officer, and Director
Jeffrey Trigilio	36	Chief Financial Officer
Patrick Baeuerle, Ph.D.	63	Acting Chief Scientific Officer, Biologics
Raymond T. Keane, Esq.	62	Chief Legal Officer
Jennifer Michaelson, Ph.D.	53	Chief Development Officer, Biologics
Corinne Savill, Ph.D.	61	Acting Chief Business Officer
Jon Wigginton, M.D.	59	Chief Medical Officer
Leigh Zawel, Ph.D.	55	Chief Scientific Officer, Small Molecules
Non-Employee Directors		
Anthony Rosenberg ⁽¹⁾⁽²⁾⁽³⁾	67	Chairperson, Director
Tim Anderson	31	Director
Thomas Ebeling ⁽¹⁾⁽³⁾	61	Director
Ansbert Gadicke, M.D. ⁽²⁾⁽³⁾	62	Director
Morana Jovan-Embiricos, Ph.D.	53	Director
Stephen Webster ⁽¹⁾⁽²⁾⁽³⁾	59	Director

- (1) Member of the Audit Committee
(2) Member of the Compensation Committee
(3) Member of the Nominating and Corporate Governance Committee

Executive Officers

Owen Hughes Mr. Hughes has served as our Chief Executive Officer and member of our board of directors since September 2017. Before joining the Company, Mr. Hughes served as the Chief Business Officer and Head of Corporate Development at Intarcia Therapeutics, Inc. from February 2013 through August 2017. Prior to this, he was a Director at Brookside Capital Investors, L.P., or Brookside Capital, a hedge fund under the Bain Capital, LP umbrella, from May 2008 through February 2013. Prior to his tenure at Brookside Capital, Mr. Hughes was Senior Portfolio Manager at Pyramis Global Advisors LLC, a Fidelity Investments Company, from May 2006 to May 2008. Mr. Hughes has more than 16 years of Wall Street experience, on both the buy and sell-side. He currently serves as the Chairman of the board of directors of Radius Health, Inc., or Radius (Nasdaq: RDUS), as well as board member at Translate Bio, Inc. (Nasdaq: TBIO), and Wren Therapeutics, Inc., a private company. Mr. Hughes holds a B.A. in history from Dartmouth College. We believe that Mr. Hughes is qualified to serve as a member of our board of directors due to his extensive leadership experience in the biopharmaceutical industry.

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. from January

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2020 through July 2020. Prior to this, he was Vice President, Corporate Finance at BlueRock Therapeutics, Inc. from August 2018 through January 2020. Prior to his tenure at BlueRock Therapeutics, Inc., 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.

Patrick Baeuerle, Ph.D. Dr. Baeuerle co-founded the Company and has served as our Acting Chief Scientific Officer—Biologics since September 2016. Dr. Baeuerle also currently serves as an Executive Partner at MPM Capital. 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. Dr. Baeuerle served as Professor and Chairman of Biochemistry at the Medical Faculty of Freiburg University, Germany 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., (Nasdaq: TCRR), or TCR², iOmx Therapeutics AG, or iOmx, Maverick Therapeutics, Inc. and Werewolf Therapeutics, Inc. He currently serves on the board of directors of TCR² (Nasdaq: TCRR) 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.

Raymond T. Keane, Esq. Mr. Keane has served as our Chief Legal Officer since December 2020. Before joining the Company, Mr. Keane served as Chief Legal Officer, Chief Compliance Officer and Corporate Secretary of Intarcia Therapeutics, Inc. from September 2013 through April 2020. Prior to this, he served at Ariad Pharmaceuticals Inc., or Ariad, from 2008 through 2013 as Senior Vice President, General Counsel, Secretary and Chief Compliance Officer. Prior to his tenure at Ariad, Mr. Keane served in increasing roles of responsibility at Bristol-Myers Squibb from 1988 until 2008, most recently as Chief Counsel, Global Marketing and Strategic Development. Mr. Keane has also served on various private company boards of directors. Mr. Keane holds a B.A. from Fordham University and a J.D. from Fordham University School of Law.

Jennifer Michaelson, Ph.D. Dr. Michaelson has served in increasing roles of responsibility at the Company since January 2018, most recently as Chief Development Officer, Biologics since January 2020 and previously as Vice President, Preclinical Research and Early Development from January 2018 through December 2019. Before joining the Company, Dr. Michaelson served as the Head of Biologics at Celsius Therapeutics, Inc. 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 Acting Chief Business Officer since February 2017. Before joining the Company, Dr. Savill served in increasing roles of responsibility at Novartis Pharma AG, 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 Biotech, which was acquired by Novartis. She also previously worked in research at AstraZeneca. Dr. Savill hold a B.S. in

Biochemistry from the University of Manchester (UK) and conducted her postgraduate research at University College and Middlesex School of Medicine (Ph.D.) and the Charing Cross Sunley Research Centre in London.

Jon Wigginton, M.D. Dr. Wigginton has served as our Chief Medical Officer since April 2020. Dr. Wigginton also serves as an Advisor at MPM Capital since April 2020. Before joining the Company, Dr. Wigginton was the Chief Medical Officer of MacroGenics, Inc. from August 2013 through March 2020, where he led the company's evolution of a fully-integrated, clinical-stage cancer immunotherapy organization. Prior to this, he served as the Therapeutic Area Head, Immuno-Oncology, Early Clinical Research and Executive Director, Discovery Medicine-Clinical Oncology at Bristol Myers Squibb Co., or Bristol Myers from October 2008 to August 2013. While there, he led the early clinical development of the Bristol Myers' Immuno-Oncology portfolio including anti-PD-1 and anti-PD-L1 among others. Prior to joining Bristol Myers, Dr. Wigginton was the Director of Clinical Oncology at Merck Research Laboratories Inc. from May 2006 to October 2008, where he led early- and late-stage clinical development teams for small molecules and biologics. During his academic career, Dr. Wigginton served in the Center for Cancer Research, the intramural division of the National Cancer Institute, from July 1992 through May 2007, where he was Head of the Investigational Biologics Section, NCI-CCR, and led an integrated basic, translational and clinical research program focused on combination immunotherapy for cancer, with an emphasis on cytokine-based combinations. Dr. Wigginton holds a B.S. in Biology and an M.D. from the University of Michigan.

Leigh Zawel, Ph.D. Dr. Zawel has served as our Chief Scientific Officer, Small Molecules since August 2017. Dr. Zawel also currently serves as an Executive Partner at MPM Capital since August 2017. Before joining the Company, Dr. Zawel led Pfizer Inc.'s Center for Therapeutic Innovation and worked as the site head for Pfizer's New York and Boston offices from October 2013 through July 2017. Prior to this, he was the oncology site lead at Merck Research Laboratories Inc. Boston from June 2010 through October 2013, where he was responsible for drug discovery efforts focused on the identification of development candidates for programs in the oncology franchise. Dr. Zawel previously worked at Sanofi-Aventis S.A., where he was Director of Cancer Biology, and Novartis Institutes for Biomedical Research/Oncology from 1999 through 2010, where he served in increasing roles of responsibility, most recently as an Oncology Group Leader. Dr. Zawel holds a M.S. in Bacteriology from the University of Wisconsin, a B.S. in Biology from Rutgers University, a Ph.D. in Biochemistry from the University of Medicine and Dentistry of New Jersey and completed his postdoctoral training at Johns Hopkins University School of Medicine.

Non-Employee Directors

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 Capital. 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 (Nasdaq: ARGX) and Radius (Nasdaq: RDUS). 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.

Timothy Anderson Mr. Anderson has served on our Board of Directors since December 2019. Since July 2014, Mr. Anderson serves as a Partner, Head of Research and a co-founding member of Cowen Healthcare Investments. Mr. Anderson focuses on investments in life science and digital medicine companies that have the potential to meaningfully address serious medical conditions. Prior to his role at Cowen Healthcare Investments LP, Mr. Anderson was a biotechnology investment banker on Cowen and Company LLC's healthcare investment banking team. Mr. Anderson is currently a member of the board of directors of several private companies, including Cadent Therapeutics, Inc., VectivBio Holding AG, F2G Ltd., and Autobahn Therapeutics Inc. Mr. Anderson holds a B.A. in economics from Bowdoin College. We believe Mr. Anderson is qualified to serve as a member of our Board of Directors because of his extensive experience in the life sciences industry and in

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investment management. Mr. Anderson has notified us that he will resign from our board of directors immediately prior to the effectiveness of the registration statement of which this prospectus forms a part. Mr. Anderson's resignation is not due to any disagreement with the Company or any matters relating to our operations, policies or practices.

Thomas Ebeling Mr. Ebeling has served as a member of our board of directors since August 2017. Most recently, Mr. Ebeling served as the Chief Executive Officer of ProSiebenSat.1 Media SE from March 2009 through February 2018. Mr. Ebeling previously served as the Chief Executive Officer of Novartis Consumer Health from October 2007 through October 2008, and as Chief Executive Officer of Novartis Pharmaceuticals Corporation from July 2000 through September 2007. He served in numerous leadership roles at the PepsiCo Germany from 1991 through 1996 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.

Ansbert Gadicke, M.D. Dr. Gadicke has served as a member of our board of directors since our inception. Dr. Gadicke co-founded MPM Capital in 1997 and has since served as a Managing Director. Dr. Gadicke has been the driving force at MPM Capital behind building leading biopharmaceutical companies such as BioMarin Pharmaceuticals, Idenix Pharmaceuticals (acquired by Merck & Co.), Mitobridge (acquired by Astellas), and Pharmasset (acquired by Gilead Sciences) and, more recently, iTeos Therapeutics (Nasdaq: ITOS) and AlloVir, Inc., or AlloVir (Nasdaq: ALVR), both of which completed IPOs in 2020. Prior to that, Dr. Gadicke led MPM Capital's Advisory and Investment Banking business from 1992 to 1996 and was in Boston Consulting Group's Health Care Group from 1989 to 1992. He currently serves as a member of the board of directors of TCR² (Nasdaq: TCRR), iTeos Therapeutics SA (Nasdaq: ITOS) and AlloVir, (Nasdaq: ALVR). Previously, Dr. Gadicke also served on the board of directors of publicly traded biopharmaceutical companies Radius (Nasdaq: RDUS) and Chiasma, Inc. (Nasdaq: CHMA). Dr. Gadicke is also a member of the Harvard Medical School Board of Fellows and the Research Advisory Council of Massachusetts General Hospital. Dr. Gadicke received his M.D. from J.W. Goethe University and has held research positions at the Whitehead Institute and Harvard University. While at the German Cancer Research Center, Dr. Gadicke focused on HPV16 and 18 in Professor Harald zur Hausen's group (Nobel Laureate in Physiology or Medicine, 2008). We believe Dr. Gadicke is qualified to serve as a member of our Board of Directors because of his extensive experience in the life sciences industry and his experience working in the venture capital industry.

Morana Jovan-Embiricos, Ph.D. Dr. Jovan-Embiricos has served as a member of our board of directors since March 2017. In 2003, Dr. Jovan co-founded F2 Ventures Ltd., or F2 Ventures, a biotech venture capital platform and has since served as its Managing Partner. Prior to joining F2 Ventures, Dr. Jovan was a partner at MPM Capital from July 2000 to July 2005, where she worked both on the investment side and directly with portfolio companies to help attain critical business development milestones. Dr. Jovan-Embiricos currently serves on the board of directors of and AlloVir (Nasdaq: ALVR) and previously served on the board of directors of TCR² (Nasdaq: TCRR) and Radius Health Inc. (Nasdaq: RDUS). Dr. Jovan-Embiricos currently serves on the board of directors of several private companies, including ElevateBio LLC and Damon Runyon Cancer Institute. Dr. Jovan-Embiricos received her Ph.D. in biophysical chemistry from the University of Cambridge and was a post-doctoral fellow at Harvard University. We believe Dr. Jovan-Embiricos is qualified to serve as a member of our Board of Directors because of her scientific background and experience in the venture capital industry.

Stephen Webster Mr. Webster has served on our board of directors since September 2020. Mr. Webster served as the Chief Financial Officer of Spark Therapeutics, Inc. 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. (Nasdaq: NXTC), Nabriva Therapeutics AG (formerly Nabriva Therapeutics plc) (Nasdaq: NBRV) and TCR² (Nasdaq: TCRR). Mr. Webster received an A.B. in Economics from Dartmouth College and an M.B.A. in Finance from The

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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.

Composition of our Board of Directors

Our board of directors consists of seven members, each of whom are members pursuant to the board composition provisions of our third amended and restated limited liability company agreement and agreements with our stockholders. These board composition provisions will terminate at the time of the Reorganization. Upon the termination of these provisions, there will be no further contractual obligations regarding the election of our directors. Our nominating and corporate governance committee and our board of directors may therefore consider a broad range of factors relating to the qualifications and background of nominees. Our nominating and corporate governance committee's and our board of directors' priority in selecting board members is identification of persons who will further the interests of our stockholders through their established record of professional accomplishment, the ability to contribute positively to the collaborative culture among board members, knowledge of our business, understanding of the competitive landscape, professional and personal experiences, and expertise relevant to our growth strategy. Our directors hold office until their successors have been elected and qualified or until the earlier of their resignation or removal. Our second amended and restated certificate of incorporation that will become effective immediately prior to the closing of this offering will provide that our directors may be removed only for cause by the affirmative vote of the holders of at least two-thirds of the votes that all our stockholders would be entitled to cast in an annual election of directors, and our amended and restated bylaws that will become effective upon the effectiveness of the registration statement of which this prospectus is a part will provide that any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office.

Director Independence

We have been approved to list our common stock on The Nasdaq Global Select Market, or Nasdaq. Under the Nasdaq listing rules, independent directors must comprise a majority of a listed company's board of directors within twelve months from the date of listing. In addition, the Nasdaq listing rules require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and governance committees be independent within twelve months from the date of listing. Audit committee members must also satisfy additional independence criteria, including those set forth in Rule 10A-3 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and compensation committee members must also satisfy the independence criteria set forth in Rule 10C-1 under the Exchange Act. Under Nasdaq listing rules, a director will only qualify as an "independent director" if, in the opinion of that 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 under the Exchange Act, 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: (1) accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries, other than compensation for board service; or (2) be an affiliated person of the listed company or any of its subsidiaries. In order to be considered independent for purposes of Rule 10C-1, the board of directors must consider, for each member of a compensation committee of a listed company, 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, but not limited to: the source of compensation of 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 members of the board of directors, except Owen Hughes and Morana Jovan-Embiricos are independent directors, including for purposes of the rules of Nasdaq and the SEC.

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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. Upon the completion of this offering, we expect that the composition and functioning of our board of directors and each of our committees will comply with all applicable requirements of Nasdaq and the rules and regulations of the SEC. There are no family relationships among any of our directors or executive officers. Mr. Hughes is not an independent director under these rules because he is an executive officer of the Company. Ms. Jovan-Embiricos is not an independent director under these rules because she receives compensation as a consultant to the Company.

Staggered board. In accordance with the terms of our second amended and restated certificate of incorporation that will become effective upon the closing of this offering and amended and restated bylaws that will become effective upon the effectiveness of the registration statement of which this prospectus is a part, our board of directors will be divided into three staggered classes of directors and each will be assigned to one of the three classes. At each annual meeting of the stockholders, a class of directors will be elected for a three-year term to succeed the directors of the same class whose terms are then expiring. The terms of the directors will expire upon the election and qualification of successor directors at the annual meeting of stockholders to be held during the years 2021 for Class I directors, 2022 for Class II directors and 2023 for Class III directors.

- Our Class I directors will be Thomas Ebeling and Morana Jovan-Embiricos;
- Our Class II directors will be Ansbert Gadicke and Anthony Rosenberg; and
- Our Class III directors will be Owen Hughes and Stephen Webster.

Our second amended and restated certificate of incorporation that will become effective upon the closing of this offering and amended and restated bylaws that will become effective upon the effectiveness of the registration statement of which this prospectus is a part provide that the number of our directors shall be fixed from time to time by a resolution of the majority of our board of directors.

The division of our board of directors into three classes with staggered three-year terms may delay or prevent stockholder efforts to effect a change of our management or a change of control.

Committees of our Board of Directors

Our board of directors has established an audit committee and a compensation committee, and plans on establishing a nominating and corporate governance committee, each of which will operate pursuant to a charter to be adopted by our board of directors and which will be effective upon the effectiveness of the registration statement of which this prospectus is a part. The board of directors may also establish other committees from time to time to assist the Company and the board of directors. Upon the effectiveness of the registration statement of which this prospectus is a part, the composition and functioning of all of our committees will comply with all applicable requirements of the Sarbanes-Oxley Act of 2002, Nasdaq and SEC rules and regulations, if applicable. Upon our listing on Nasdaq, each committee's charter will be available on our website at www.cullinanoncology.com. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be part of this prospectus.

Audit committee

Effective upon completion of this offering, Thomas Ebeling, Anthony Rosenberg and Stephen Webster will serve on the audit committee, which will be chaired by Mr. Webster. Our board of directors has determined that

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each are “independent” for audit committee purposes as that term is defined in the rules of the SEC and the applicable Nasdaq rules, and has sufficient knowledge in financial and auditing matters to serve on the audit committee. Our board of directors has designated Mr. Webster as an “audit committee financial expert,” as defined under the applicable rules of the SEC. The audit committee’s responsibilities include:

- appointing, approving the compensation of, and assessing the independence of our independent registered public accounting firm;
- pre-approving auditing and permissible non-audit services, and the terms of such services, to be provided by our independent registered public accounting firm;
- reviewing the overall audit plan with our independent registered public accounting firm and members of management responsible for preparing our financial statements;
- reviewing and discussing with management and our independent registered public accounting firm our annual and quarterly financial statements and related disclosures as well as critical accounting policies and practices used by us;
- coordinating the oversight and reviewing the adequacy of our internal control over financial reporting;
- establishing policies and procedures for the receipt and retention of accounting-related complaints and concerns;
- recommending based upon the audit committee’s review and discussions with management and our independent registered public accounting firm whether our audited financial statements shall be included in our Annual Report on Form 10-K;
- monitoring the integrity of our financial statements and our compliance with legal and regulatory requirements as they relate to our financial statements and accounting matters;
- preparing the audit committee report required by SEC rules to be included in our annual proxy statement;
- reviewing all related person transactions for potential conflict of interest situations and approving all such transactions; and
- reviewing quarterly earnings releases.

Compensation committee

Effective upon completion of this offering, Ansbert Gadicke, Anthony Rosenberg and Stephen Webster will serve on the compensation committee, which will be chaired by Mr. Rosenberg. Our board of directors has determined that each is “independent” under the applicable rules and regulations of Nasdaq, and is a “non-employee director” as defined in Rule 16b-3 promulgated under the Exchange Act. We intend to rely on the Nasdaq transition rules applicable to companies completing an initial public offering, and we plan to have a compensation committee comprised solely of directors that are independent for purposes of serving on a compensation committee within one year after our listing. The compensation committee’s responsibilities include:

- annually reviewing and approving corporate goals and objectives relevant to the compensation of our Chief Executive Officer;
- evaluating the performance of our Chief Executive Officer in light of such corporate goals and objectives and making recommendations to the board of directors with respect to the compensation of our Chief Executive Officer;
- reviewing and approving the compensation of our other executive officers;
- reviewing and establishing our overall management compensation, philosophy and policy;

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- overseeing and administering our compensation and similar plans;
- evaluating and assessing potential and current compensation advisors in accordance with the independence standards identified in the applicable Nasdaq rules;
- retaining and approving the compensation of any compensation advisors;
- reviewing and approving our policies and procedures for the grant of equity-based awards;
- reviewing and making recommendations to the board of directors with respect to director compensation;
- reviewing and discussing with management the compensation disclosure to be included in our annual proxy statement or Annual Report on Form 10-K; and
- reviewing and discussing with the board of directors the corporate succession plans for the Chief Executive Officer and other key officers.

Nominating and corporate governance committee

Effective upon completion of this offering Thomas Ebeling, Ansbert Gadicke, Anthony Rosenberg, and Stephen Webster will serve on the nominating and corporate governance committee, which will be chaired by Mr. Ebeling. Our board of directors has determined that each is “independent” as defined in the applicable Nasdaq rules. The nominating and corporate governance committee’s responsibilities include:

- developing and recommending to the board of directors criteria for board and committee membership;
- establishing procedures for identifying and evaluating board of director candidates, including nominees recommended by stockholders;
- reviewing the size and composition of the board of directors to ensure that it is composed of members containing the appropriate skills and expertise to advise us;
- identifying individuals qualified to become members of the board of directors;
- recommending to the board of directors the persons to be nominated for election as directors and to each of the board’s committees;
- developing and determining a code of business conduct and ethics and a set of corporate governance guidelines;
- developing a mechanism by which violations of the code of business conduct and ethics can be reported in a confidential manner; and
- overseeing the evaluation of the board of directors and management.

Our board of directors may from time to time establish other committees.

Compensation Committee Interlocks and Insider Participation

None of the members of our compensation committee has at any time during the prior three years been one of our officers or employees. None of our executive officers currently serves, or in the past fiscal year has served, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving on our board of directors or compensation committee.

Code of Business Conduct and Ethics

We plan to adopt a code of business conduct and ethics that applies to all of our employees, officers and directors, including those officers responsible for financial reporting, which will be effective upon completion of

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this offering. Upon the completion of this offering, our code of business conduct and ethics will be available on our website at <https://cullinanoncology.com>. We intend to disclose any substantive amendments to the code, or any waivers of its requirements, on our website or in a Current Report on Form 8-K.

Board Leadership Structure and Board's Role in Risk Oversight

Currently, the role of chairman of the board of directors is separated from the role of Chief Executive Officer. Our Chief Executive Officer is responsible for recommending strategic decisions and capital allocation to the board of directors and to ensure the execution of the recommended plans. The chairman of the board of directors is responsible for leading the board of directors in its fundamental role of providing advice to and independent oversight of management. Our board of directors recognizes the time, effort, and energy that the Chief Executive Officer is required to devote to his position in the current business environment, as well as the commitment required of the chairman of our board of directors, particularly as the board of directors' oversight responsibilities continue to grow. While our amended and restated bylaws that will become effective upon the effectiveness of the registration statement of which this prospectus is a part and corporate governance guidelines will not require that our chairman and Chief Executive Officer positions be separate, our board of directors believes that having separate positions is the appropriate leadership structure for us at this time and demonstrates our commitment to good corporate governance.

Risk is inherent with every business, and how well a business manages risk can ultimately determine its success. We face a number of risks, including risks relating to our financial condition, development and commercialization activities, operations, strategic direction and intellectual property as more fully discussed in the section titled "Risk Factors" appearing elsewhere in this prospectus. Management is responsible for the day-to-day management of risks we face, while our board of directors, as a whole and through its committees, has responsibility for the oversight of risk management. In its risk oversight role, our board of directors has the responsibility to satisfy itself that the risk management processes designed and implemented by management are adequate and functioning as designed.

The role of the board of directors in overseeing the management of our risks is conducted primarily through committees of the board of directors, as disclosed in the descriptions of each of the committees above and in the charters of each of the committees. The full board of directors (or the appropriate board committee in the case of risks that are under the purview of a particular committee) discusses with management our major risk exposures, their potential impact on us, and the steps we take to manage them. When a board committee is responsible for evaluating and overseeing the management of a particular risk or risks, the chairman of the relevant committee reports on the discussion to the full board of directors during the committee reports portion of the next board meeting. This enables the board of directors and its committees to coordinate the risk oversight role, particularly with respect to risk interrelationships.

Limitation on Liability and Indemnification Matters

As permitted by Delaware law, provisions in our second amended and restated certificate of incorporation which will become effective immediately prior to the closing of this offering, and amended and restated bylaws which will become effective upon the effectiveness of this registration statement, limit or eliminate the personal liability of directors for a breach of their fiduciary duty of care as a director. The duty of care generally requires that, when acting on behalf of the corporation, a director exercise an informed business judgment based on all material information reasonably available to him or her. Consequently, a director will not be personally liable to us or our stockholders for monetary damages or breach of fiduciary duty as a director, except for liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;

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- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law; or
- any transaction from which the director derived an improper personal benefit.

These limitations of liability do not limit or eliminate our rights or any stockholder's rights to seek non-monetary relief, such as injunctive relief or rescission. These provisions will not alter a director's liability under other laws, such as the federal securities laws or other state or federal laws. Our second amended and restated certificate of incorporation that will become effective immediately prior to the closing of this offering also authorizes us to indemnify our officers, directors and other agents to the fullest extent permitted under Delaware law.

As permitted by Delaware law, our amended and restated bylaws to be effective upon the effectiveness of this registration statement will provide that:

- we will indemnify our directors, officers, employees and other agents to the fullest extent permitted by law;
- we must advance expenses to our directors and officers, and may advance expenses to our employees and other agents, in connection with a legal proceeding to the fullest extent permitted by law; and
- the rights provided in our amended and restated bylaws are not exclusive.

If Delaware law is amended to authorize corporate action further eliminating or limiting the personal liability of a director or officer, then the liability of our directors or officers will be so eliminated or limited to the fullest extent permitted by Delaware law, as so amended. Our amended and restated bylaws to be effective upon the effectiveness of this registration statement will also permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in connection with their services to us, regardless of whether our bylaws permit such indemnification. We have obtained such insurance.

In addition to the indemnification that will be provided for in our second amended and restated certificate of incorporation to be effective immediately prior to the closing of this offering and amended and restated bylaws to be effective upon the effectiveness of this registration statement, we plan to enter into separate indemnification agreements with each of our directors and executive officers, which may be broader than the specific indemnification provisions contained in the Delaware General Corporation Law. These indemnification agreements may require us, among other things, to indemnify our directors and executive officers for some expenses, including attorneys' fees, expenses, judgments, fines and settlement amounts incurred by a director or executive officer in any action or proceeding arising out of his service as one of our directors or executive officers or any other company or enterprise to which the person provides services at our request. We believe that these provisions and agreements are necessary to attract and retain qualified individuals to serve as directors and executive officers.

This description of the indemnification provisions of our second amended and restated certificate of incorporation to be effective immediately prior to the closing of this offering, our amended and restated bylaws to be effective upon the effectiveness of this registration statement and our indemnification agreements is qualified in its entirety by reference to these documents, each of which is attached as an exhibit to the registration statement of which this prospectus forms a part.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable.

There is no pending litigation or proceeding naming any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

EXECUTIVE COMPENSATION**Executive Compensation Overview**

The following discussion contains forward-looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. The actual amount and form of compensation and the compensation policies and practices that we adopt in the future may differ materially from the currently planned programs as summarized in this discussion.

The compensation provided to our named executive officers for the fiscal years ended December 31, 2019 and 2020 is detailed in the Summary Compensation Table and accompanying footnotes and narrative that follow this table. Our named executive officers for the fiscal year ended December 31, 2020, which consists of our Chief Executive Officer and our two most highly compensated executive officers other than our Chief Executive Officer, are:

- Owen Hughes, our Chief Executive Officer;
- Patrick Baeuerle, Ph.D., our Acting Chief Scientific Officer, Biologics; and
- Jon Wigginton, M.D., our Chief Medical 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.

<u>Name and principal position</u>	<u>Year</u>	<u>Salary (\$)</u>	<u>Bonus (\$)(1)</u>	<u>Stock Awards (\$)(2)</u>	<u>Option Awards (\$)(2)</u>	<u>All Other Compensation (\$)(3)</u>	<u>Total (\$)</u>
Owen Hughes	2020	461,250	37,500	530,320	5,301,175	14,250	6,344,495
Chief Executive Officer	2019	450,000	96,800	—	—	14,000	560,800
Patrick Baeuerle, Ph.D.(4)	2020	436,997	37,500	491,284	4,124,284	34,800	5,124,866
Acting Chief Scientific Officer, Biologics	2019	420,895	107,502	—	—	34,400	562,797
Jon Wigginton, M.D.	2020	321,122	—	—	3,959,525	5,375	4,286,022
Chief Medical Officer							

- (1) The amounts reported for 2020 represent cash bonuses paid to our named executive officers in connection with the equity exchange described above under “Reorganization—Reorganization Equity Exchange.” The amount of discretionary cash bonuses to be paid by us to our named executive officers for the fiscal year ended December 31, 2020 has not yet been determined, but is expected to be determined and paid in the first quarter of 2021 and will be reported at such time as required by SEC rules. The amounts reported for 2019 represent discretionary cash bonuses paid by us for the fiscal year ended December 31, 2019, based on our named executive officers’ performance during such fiscal year.
- (2) This amount represents the aggregate grant date fair value of the restricted unit awards and option awards granted to the named executive officers during our fiscal year ended December 31, 2020, computed in accordance with FASB ASC Topic 718. Please see “Notes to Condensed Consolidated Financial Statements (Unaudited)—(13) Subsequent Events” for more information. This amount does not correspond to the actual value that may be recognized by the named executive officer upon vesting or exercise of the applicable award or sale of the underlying equity.
- (3) The amounts reported represent 401(k) matching contributions with respect to Mr. Hughes and Dr. Wigginton and the value of corporate apartments provided by us to Dr. Baeuerle.
- (4) The amounts reported have been converted from euros to U.S. dollars using the exchange rates in effect on the date payments were made to Dr. Baeuerle in 2019 and 2020.

Narrative to summary compensation table

Base salary

During the fiscal year ended December 31, 2019 and 2020, the annual base salary for Owen Hughes was \$450,000 and \$461,250, respectively, and the annualized consulting fees for Dr. Baeuerle were €370,000 and €379,250, respectively. During the fiscal year ended December 31, 2020, the annual base salary for Dr. Wigginton was \$430,000.

Bonus Arrangements

Pursuant to the terms of their offer letter agreements, Mr. Hughes and Dr. Wigginton are eligible for retention and performance bonuses of up to 30% and 40% of their base salary. Dr. Baeuerle is eligible for retention and performance bonuses of up to 33% of his annualized base consulting fees under the terms of his consulting agreement. The board has not yet determined the amount of discretionary bonuses to be paid to the named executive officers with respect to performance during fiscal year 2020. Based on its evaluation of the performance of the named executive officers during fiscal year 2019, the board awarded discretionary bonuses to Mr. Hughes and Dr. Baeuerle as set forth in the Summary Compensation Table above, which were approximately equal to 22% and 26% of their respective annual base salary or consulting fees. Dr. Wigginton commenced employment with the Company in 2020 and was therefore not eligible for a fiscal year 2019 bonus.

In connection with the equity exchange described above under “Reorganization—Reorganization Equity Exchange,” each of Mr. Hughes and Dr. Baeuerle received a cash bonus award of \$37,500.

Equity compensation

We have historically compensated our employees with equity both in the Company in the form of incentive units and in our subsidiaries in the form of restricted stock. However, we undertook an equity exchange in 2020 to exchange the equity of our subsidiaries with equity in the Company in the form of restricted units and we also began granting options.

In connection with the equity exchange described above under “Reorganization—Reorganization Equity Exchange,” the following anti-dilution and make-whole option grants were awarded to our named executive officers under the 2020 Unit Plan: Mr. Hughes, anti-dilution options in respect of 2,878,240 common units and make-whole options in respect of 3,188,348 common units; and Dr. Baeuerle, anti-dilution options in respect of 1,845,026 common units and make-whole options in respect of 2,871,868 common units. The Company also awarded options in respect of 4,450,259 common units to Dr. Wigginton. All of the options granted to our named executive officers in 2020 have an exercise price of \$0.61 per common unit and vest as to 25% of the number of common units subject to the award on the first anniversary of the vesting commencement date, with the remaining portion of the award vesting over the following 36 months in equal monthly installments.

Employment or service arrangements with our named executive officers in effect prior to this IPO

We initially entered into an offer letter agreement with each of Mr. Hughes and Dr. Wigginton and a consulting agreement with Dr. Baeuerle in connection with his employment or other service relationship with us. The offer letter agreements and consulting agreements with our named executive officers set forth the terms and conditions of each of the named executive officer’s employment or other service relationship.

Owen Hughes

On May 1, 2017, we, through our wholly-owned subsidiary, Cullinan Management, entered into an offer letter with Mr. Hughes, who currently serves as our Chief Executive Officer. The offer letter provides for Mr. Hughes’ at-will employment and sets forth his initial annual base salary, his initial target annual bonus opportunity, his initial equity grant and his eligibility to participate in our employee benefit plans generally. In

addition, the offer letter also provides that in each instance where an “asset subsidiary” is formed and invested in by the Company, Mr. Hughes is entitled to an equity grant target of 2% of such subsidiary’s fully-diluted capitalization (which grants are included in the “Outstanding equity awards at fiscal year end” table below). In the event that Mr. Hughes’ employment is terminated by Cullinan Management without “cause,” as defined in Mr. Hughes’ offer letter, subject to Mr. Hughes’ execution of an effective release of claims in favor of the Company, Mr. Hughes will be entitled to cash severance equal to six (6) months of base salary, paid ratably in accordance with the Company’s regular payroll cycle. Mr. Hughes is subject to a confidentiality and assignment agreement with Cullinan Management, which includes non-competition and non-solicitation protections covering the three-month period following Mr. Hughes’ termination of employment.

Patrick Baeuerle, Ph.D.

On January 1, 2019, we, through our wholly-owned subsidiary, Cullinan Management, entered into a consulting agreement, or the Baeuerle Consulting Agreement, with Dr. Baeuerle, who currently serves as our Acting Chief Scientific Officer, Biologics. The Baeuerle Consulting Agreement provides for Dr. Baeuerle’s service relationship with the Company and sets forth his consulting fees and initial target annual bonus opportunity as well as proprietary information and inventions provisions. The Baeuerle Consulting Agreement provides for his initial equity grant that entitles Dr. Baeuerle to incentive units equating to an ownership interest entitling him to 2.5% of distributions made by the LLC entity with respect to common units (which grant is included in the “Outstanding equity awards at fiscal year end” table below).

Jon Wigginton, M.D.

On March 20, 2020, we, through our wholly-owned subsidiary, Cullinan Management, entered into an offer letter with Jon Wigginton, who currently serves as our Chief Medical Officer. The offer letter provides for Dr. Wigginton’s at-will employment and sets forth his initial annual base salary, his initial target annual bonus opportunity, his initial equity grant and his eligibility to participate in our employee benefit plans generally. In addition, the offer letter also provides that in each instance where an “asset subsidiary” is formed and invested in by the Company, Dr. Wigginton is entitled to an equity grant target of 1.5% of such subsidiary’s fully-diluted capitalization (which grants are included in the “Outstanding equity awards at fiscal year end” table below). In the event that Dr. Wigginton’s employment is terminated by Cullinan Management without “cause,” as defined in Dr. Wigginton’s offer letter, subject to Dr. Wigginton’s execution of an effective release of claims in favor of the Company, Dr. Wigginton will be entitled to cash severance equal to six (6) months of base salary, paid ratably in accordance with the Company’s regular payroll cycle, and six (6) months of health benefit continuation. Dr. Wigginton is subject to a confidentiality and assignment agreement with Cullinan Management, which includes non-solicitation protections covering the three-month period following Dr. Wigginton’s termination of employment.

Employment Agreements Entered into in Connection with our Initial Public Offering

In December 2020, we entered into new employment agreements with each of Owen Hughes and Jon Wigginton, M.D., which shall supersede each such named executive officer’s existing offer letter effective upon the Initial Public Offering. Each employment agreement sets forth such executive officer’s base salary, target bonus opportunity, and eligibility to participate in our benefit plans generally. In December 2020, we also entered into a new service agreement with Patrick Baeuerle, Ph.D., effective upon the Initial Public Offering. Each of Mr. Hughes and Dr. Wigginton is also subject to a confidentiality, assignment and nonsolicitation 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.

Owen Hughes

In connection with the Initial Public Offering, we entered into an employment agreement with Mr. Hughes, who currently serves as our Chief Executive Officer. This employment agreement supersedes the prior letter

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agreement entered into between Mr. Hughes and the Company on May 1, 2017. The employment agreement provides for an annual base salary of \$545,000, an annual target bonus equal to 50% of Mr. Hughes's annual base salary and eligibility to participate in our benefit plans generally. The employment agreement also provides that, while public, the Company will cause Mr. Hughes to be nominated for election to our board of directors and to be recommended to our stockholders for election to our board of directors. The equity awards previously held by Mr. Hughes continue to be governed by the terms and conditions of the Company's applicable equity incentive plan(s) and the applicable award agreement(s). Mr. Hughes shall also be entitled to reimbursement for all reasonable business expenses incurred during the term of his employment, in accordance with the policies and procedures then in effect and established by the Company for its executive officers.

Under Mr. Hughes's new employment agreement, in the event that Mr. Hughes's employment is terminated by us without "cause" or Mr. Hughes resigns for "good reason" (as such terms are defined in the employment agreement), 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 base salary plus a pro-rata portion of his annual target bonus, and (ii) if Mr. Hughes 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; provided, however, if we determine that we 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 we shall convert such payments to payroll payments directly to him for the time period specified in the employment agreement. The employment agreement also provides that, in lieu of the payments and benefits described above, in the event that Mr. Hughes's employment is terminated by us without cause or Mr. Hughes resigns for good reason, in either case within 12 months following a "change in control" (as defined in the employment agreement), 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 18 months of his then-current base salary (or his base salary in effect immediately prior to the change in control, if higher) plus 1.5 times 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. Hughes 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 18 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; provided, however, if we determine that we 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 we shall convert such payments to payroll payments directly to him for the time period specified in the employment agreement.

The employment agreement also provides that in the event Mr. Hughes's employment ends as a result of death or disability, 25% of his then-unvested "equity awards" (as defined in the employment agreement), plus an additional 5% for each full year of service to the Company, shall 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. Hughes's employment is terminated by us without cause or Mr. Hughes resigns for good reason, in either case within 12 months following a change in control, then any outstanding equity awards shall immediately accelerate and become fully vested and exercisable or nonforfeitable on the date of termination.

Jon Wigginton, M.D.

In connection with the Initial Public Offering, we entered into an employment agreement with Dr. Wigginton, who currently serves as our Chief Medical Officer. This employment agreement supersedes the prior letter agreement entered into between Dr. Wigginton and the Company on March 20, 2020. The employment agreement provides for an annual base salary of \$440,000, an annual target bonus equal to 40% of

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Dr. Wigginton's annual base salary and eligibility to participate in our benefit plans generally. The equity awards previously held by Dr. Wigginton continue to be governed by the terms and conditions of the Company's applicable equity incentive plan(s) and the applicable award agreement(s). Dr. Wigginton shall also be entitled to reimbursement for all reasonable business expenses incurred during the term of his employment, in accordance with the policies and procedures then in effect and established by the Company for its executive officers.

Under Dr. Wigginton's new employment agreement, in the event that Dr. Wigginton's employment is terminated by us without "cause" or Dr. Wigginton resigns for "good reason" (as such terms are defined in the employment agreement), 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 9 months of his base salary plus a pro-rata portion of his annual target bonus, and (ii) if Dr. Wigginton 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 9 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; provided, however, if we determine that we 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 we shall convert such payments to payroll payments directly to him for the time period specified in the employment agreement. The employment agreement also provides that, in lieu of the payments and benefits described above, in the event that Dr. Wigginton's employment is terminated by us without cause or Dr. Wigginton resigns for good reason, in either case within 12 months following a "change in control" (as defined in the employment agreement), 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 one times 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 Dr. Wigginton 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; provided, however, if we determine that we 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 we shall convert such payments to payroll payments directly to him for the time period specified in the employment agreement.

The employment agreement also provides that in the event Dr. Wigginton's employment ends as a result of death or disability, 25% of his then-unvested "equity awards" (as defined in the employment agreement), plus an additional 5% for each full year of service to the Company, shall immediately accelerate and become fully vested and exercisable or nonforfeitable on the date of termination. The employment agreement further provides that in the event Dr. Wigginton's employment is terminated by us without cause or Dr. Wigginton resigns for good reason, in either case within 12 months following a change in control, then any outstanding equity awards shall immediately accelerate and become fully vested and exercisable or nonforfeitable on the date of termination.

Patrick Baeuerle, Ph.D.

In connection with the Initial Public Offering, we entered into a service agreement with Dr. Baeuerle, who currently serves as our Acting Chief Scientific Officer—Biologics. 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 initial consulting fees of \$450,000 per year, an annual target bonus equal to 40% of Dr. Baeuerle's "annualized consulting fees" (as defined in the service agreement). The equity awards previously held by Dr. Baeuerle continue to be governed by the terms and conditions of the Company's applicable equity incentive plan(s) and the applicable award agreement(s). Dr. Baeuerle shall also be entitled to reimbursement for all reasonable business expenses incurred during the term in performing services under the service agreement, in

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accordance with the policies and procedures then in effect and established by the Company for its executive officers.

Under Dr. Baeuerle’s new service agreement, in the event that Dr. Baeuerle’s engagement is terminated by us without “cause” or Dr. Baeuerle resigns for “good reason” (as such terms are defined in the service agreement), 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 9 months of his 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” (as defined in the service agreement), 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 annualized consulting fee (or his annualized consulting fee in effect immediately prior to the change in control if higher) plus 1.0 times 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 death or disability, 25% of his then-unvested “equity awards” (as defined in the service agreement), plus an additional 5% for each full year of service to the Company, shall 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, then any outstanding equity awards shall immediately accelerate and become fully vested and exercisable or nonforfeitable on the date of termination.

Outstanding equity awards at fiscal year end

The following table presents the outstanding equity awards held by each of our named executive officers as of December 31, 2020.

Name	Vesting Commencement Date	Option Awards				Stock Awards	
		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)
Owen Hughes	9/1/2018	230,005	178,893(2)	\$ 4.30	10/30/2030	—	—
	5/4/2019	179,294	273,660(2)	\$ 4.30	10/30/2030	—	—
	8/1/2017	—	—	—	—	73,135(3)	\$ 1,426,132.50
	12/1/2018	—	—	—	—	19,122(4)	\$ 372,878.00
	12/16/2019	—	—	—	—	11,707(4)	\$ 228,286.50
Patrick Baeuerle, Ph.D.	12/16/2019	—	—	—	—	8,320(4)	\$ 162,240.00
	9/1/2018	147,439	114,675(2)	\$ 4.30	10/30/2030	—	—
	5/15/2019	161,497	246,496(2)	\$ 4.30	10/30/2030	—	—
	3/8/2017	—	—	—	—	17,580(3)	\$ 342,810.00
	12/1/2018	—	—	—	—	16,732(4)	\$ 326,274.00
Jon Wigginton, M.D.	12/16/2019	—	—	—	—	11,707(4)	\$ 228,286.50
	12/16/2019	—	—	—	—	8,320(4)	\$ 162,240.00
	4/7/2020	—	379,337(2)	\$ 4.30	10/30/2030	—	—
	4/7/2020	—	252,891	\$ 4.30	10/30/2030	—	—

(1) Assumes an initial public offering price of \$19.50 per share, which is the midpoint of the estimated price range set forth on the cover page of this prospectus.

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- (2) Represents options to purchase common units in the LLC entity, which vest as follows: 25% of the units subject to the underlying option vest on the first anniversary of the vesting commencement date and the remaining units vest over 36 months in equal monthly installments, subject in each case to the executive continuing to have a service relationship with us at such time.
- (3) Represents incentive units in the LLC entity that are intended to qualify as profits interests and vest as follows: 25% of the units vested on the first anniversary of the vesting commencement date and the remaining units vest over 36 months in equal monthly installments, subject in each case to the executive continuing to have a service relationship with us at such time.
- (4) Represents restricted units granted in connection with the equity exchange described above under “Reorganization—Reorganization Equity Exchange.” The restricted units vest as follows: 25% of the units vest on the first anniversary of the vesting commencement date and the remaining units vest over 36 months in equal monthly installments, subject in each case to the executive continuing to have a service relationship with us at such time.

IPO Grants

At the time of effectiveness of the 2021 Plan, our board of directors will grant options to purchase shares of our common stock to our named executive officers, with an exercise price equal to the initial public offering price per share. On such date, Mr. Hughes, Dr. Baeuerle, and Dr. Wigginton will be granted 433,332, 286,665 and 116,666 options to purchase shares of our common stock, respectively.

Employee benefits and stock plans

2021 Stock Option and Incentive Plan

Our 2021 Stock Option and Incentive Plan, or the 2021 Stock Plan, was adopted by our board of directors in December 2020 and our stockholders in January 2021. The 2021 Stock Plan will become effective on the date immediately prior to the date on which the registration statement of which this prospectus is part is declared effective by the SEC. The 2021 Stock Plan will provide flexibility to our compensation committee to use various equity-based incentive awards as compensation tools to motivate our workforce.

We will initially reserve 12,546,386 shares of our common stock, or the Initial Limit, for the issuance of awards under the 2021 Stock Plan. The 2021 Stock Plan provides that the number of shares reserved and available for issuance under the plan will automatically increase each January 1, beginning on January 1, 2022, by 5% of the outstanding number of shares of our common stock on the immediately preceding December 31, or such lesser number of shares as determined by our compensation committee. This is referred to herein as the Annual Increase. This number will be subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization.

The shares we issue under the 2021 Stock Plan will be authorized but unissued shares or shares that we reacquire. The shares of common stock underlying any awards that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by us prior to vesting, satisfied without any issuance of stock, expire or are otherwise terminated (other than by exercise) under the 2021 Stock Plan will be added back to the shares of common stock available for issuance under the 2021 Stock Plan.

The maximum aggregate number of shares that may be issued in the form of incentive stock options may not exceed the Initial Limit cumulatively increased on January 1, 2022, and on each January 1 thereafter by the lesser of (i) the Annual Increase for such year or (ii) 12,546,386 shares of common stock.

The grant date fair value of all awards made under our 2021 Stock Plan and all other cash compensation paid by us to any non-employee director in any calendar year may not exceed \$750,000 for the first year of service and \$500,000 for each year of service thereafter.

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The 2021 Stock Plan will be administered by our compensation committee. Our compensation committee will have full power to select, from among the individuals eligible for awards, the individuals to whom awards will be granted, to make any combination of awards to participants, and to determine the specific terms and conditions of each award, subject to the provisions of the 2021 Stock Plan. Persons eligible to participate in the 2021 Stock Plan will be those full or part-time employees, non-employee directors and consultants of the Company and its affiliates, as selected from time to time by our compensation committee in its discretion.

The 2021 Stock Plan will permit the granting of both options to purchase common stock intended to qualify as incentive stock options under Section 422 of the Internal Revenue Code, or the Code, and options that do not so qualify. The option exercise price of each option will be determined by our compensation committee but may not be less than 100% of the fair market value of our common stock on the date of grant. The term of each option will be fixed by our compensation committee and may not exceed ten years from the date of grant. Our compensation committee will determine at what time or times each option may be exercised.

Our compensation committee will be able to award stock appreciation rights subject to such conditions and restrictions as it may determine. Stock appreciation rights will entitle the recipient to shares of common stock or cash, equal to the value of the appreciation in our stock price over the exercise price. The exercise price of each stock appreciation right may not be less than 100% of the fair market value of the common stock on the date of grant. The term of each stock appreciation right will be fixed by our compensation committee and may not exceed ten years from the date of grant. Our compensation committee will determine at what time or times each stock appreciation right may be exercised.

Our compensation committee will be able to award restricted shares of common stock and restricted stock units to participants subject to such conditions and restrictions as it may determine. These conditions and restrictions may include the achievement of certain performance goals and/or continued employment or service relationship with us through a specified vesting period. Our compensation committee may also be permitted to grant shares of common stock that are free from any restrictions under the 2021 Stock Plan. Unrestricted stock may be granted to participants in recognition of past services or other valid consideration and may be issued in lieu of cash compensation due to such participant.

Our compensation committee will be able to grant cash bonuses under the 2021 Stock Plan to participants, subject to the achievement of certain performance goals.

The 2021 Stock Plan will provide that upon the effectiveness of a “sale event,” as defined in the 2021 Stock Plan, an acquirer or successor entity may assume, continue or substitute outstanding awards under the 2021 Stock Plan. To the extent that awards granted under our 2021 Stock Plan are not assumed or continued or substituted by the successor entity, except as may be otherwise provided in the relevant award certificate, all awards with time-based vesting, conditions or restrictions will become fully vested and nonforfeitable as of the effective time of the sale event, and all awards with conditions and restrictions relating to the attainment of performance goals may become vested and nonforfeitable in connection with a sale event in the compensation committee’s discretion or to the extent specified in the relevant award certificate. Upon the effective time of the sale event, all outstanding awards granted under the 2021 Stock Plan will terminate to the extent not assumed, continued or substituted for. In the event of such termination, individuals holding options and stock appreciation rights will be permitted to exercise such options and stock appreciation rights (to the extent exercisable) within a specified period of time prior to the sale event. In addition, in connection with the termination of the 2021 Stock Plan upon a sale event, we may make or provide for a payment, in cash or in kind, to participants holding vested and exercisable options and stock appreciation rights equal to the difference between the per share cash consideration payable to stockholders in the sale event and the exercise price of the options or stock appreciation rights and we may make or provide for a payment, in cash or in kind, to participants holding other vested awards.

Our board of directors will be able to amend or discontinue the 2021 Stock Plan and our compensation committee will be permitted to amend the exercise price of options and amend or cancel outstanding awards for

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purposes of satisfying changes in law or any other lawful purpose but no such action may adversely affect rights under an award without the holder's consent. Certain amendments to the 2021 Stock Plan will require the approval of our stockholders.

No awards will be granted under the 2021 Stock Plan after the date that is 10 years from the date of stockholder approval. No awards under the 2021 Stock Plan will be made prior to the date of this prospectus.

2021 Employee Stock Purchase Plan

Our 2021 Employee Stock Purchase Plan, or the ESPP, was adopted by our board of directors in December 2020 and our stockholders in January 2021. The ESPP will become effective on the date immediately prior to the date on which the registration statement of which this prospectus is part is declared effective by the SEC. The ESPP will initially reserve and authorize the issuance of up to a total of 416,665 shares of common stock to participating employees. The ESPP will provide that the number of shares reserved and available for issuance will automatically increase each January 1, beginning on January 1, 2022, by the lesser of 833,330 shares of our common stock, 1% of the outstanding number of shares of our common stock on the immediately preceding December 31, or such lesser number of shares as determined by our compensation committee. This number will be subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization.

Unless otherwise determined by the compensation committee, all employees whose customary employment is for more than 20 hours per week and who have completed at least 30 days of employment will be eligible to participate in the ESPP. Any employee who owns 5% or more of the total combined voting power or value of all classes of stock will not be eligible to purchase shares under the ESPP.

We will make one or more offerings each year to our employees to purchase shares under the ESPP. Offerings will usually begin every six months and will continue for six-month periods, referred to as offering periods. Each eligible employee may elect to participate in any offering by submitting an enrollment form at least 15 business days before the relevant offering date.

Each employee who is a participant in the ESPP may purchase shares by authorizing contributions of between 1% and 15% of his or her compensation during an offering period. Unless the participating employee has previously withdrawn from the offering, his or her accumulated contributions will be used to purchase shares on the last business day of the purchase period at a price equal to 85% of the fair market value of the shares on the first business day of the offering period or the last business day of the purchase period, whichever is lower. Under applicable tax rules, an employee may purchase no more than \$25,000 worth of shares of common stock, valued at the start of the offering period, under the ESPP for each calendar year in which a purchase right is outstanding.

The accumulated contributions of any employee who is not a participant on the last day of a purchase period will be refunded. An employee's rights under the ESPP terminate upon voluntary withdrawal from the plan or when the employee ceases employment with us for any reason.

The ESPP may be terminated or amended by our board of directors at any time, but will automatically terminate on the 10-year anniversary of this offering. An amendment that increases the number of shares of common stock that are authorized under the ESPP and certain other amendments will require the approval of our stockholders. The plan administrator may adopt subplans under the ESPP for employees of our non-U.S. subsidiaries, if any.

Senior Executive Cash Incentive Bonus Plan

In December 2020, we adopted a Senior Executive Cash Incentive Bonus Plan, or the Bonus Plan, that will become effective upon the completion of this offering. The Bonus Plan will provide for cash bonus payments based upon the attainment of performance targets established by our compensation committee. The payment targets will be related to financial and operational measures or objectives with respect to our company, or corporate performance goals, as well as individual performance objectives.

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Our compensation committee may select corporate performance goals from among the following: developmental, publication, clinical or regulatory milestones; cash flow (including, but not limited to, operating cash flow and free cash flow); revenue; corporate revenue; earnings before interest, taxes, depreciation and amortization; net income (loss) (either before or after interest, taxes, depreciation and/or amortization); changes in the market price of our common stock; economic value-added; acquisitions or strategic transactions; operating income (loss); return on capital, assets, equity, or investment; stockholder returns; return on sales; gross or net profit levels; productivity; expense efficiency; margins; operating efficiency; customer satisfaction; working capital; earnings (loss) per share of our common stock; bookings, new bookings or renewals; sales or market shares; number of customers, number of new customers or customer references; operating income and/or net annual recurring revenue, any of which may be measured in absolute terms, as compared to any incremental increase, in terms of growth, or as compared to results of a peer group.

Each executive officer who is selected to participate in the Bonus Plan will have a target bonus opportunity set for each performance period. The bonus formulas will be adopted in each performance period by the compensation committee and communicated to each executive. The corporate performance goals will be measured at the end of each performance period after our financial reports have been published or such other appropriate time as the compensation committee determines. If the corporate performance goals and individual performance objectives are met, payments will be made as soon as practicable following the end of each performance period, but not later than 74 days after the end of the fiscal year in which such performance period ends. Subject to the rights contained in any agreement between the executive officer and us, an executive officer must be employed by us on the bonus payment date to be eligible to receive a bonus payment. The Bonus Plan will also permit the compensation committee to approve additional bonuses to executive officers in its sole discretion.

401(k) plan and other benefits

Our eligible U.S. employees participate in a tax-qualified retirement plan sponsored by ADP Retirement Services 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 Code limits. The plan sponsor has the ability to make discretionary contributions to the 401(k) plan, but has not done so to date. The 401(k) plan is intended to be qualified under Section 401(a) of the Code with the 401(k) plan's related trust intended to be tax exempt under Section 501(a) of the Code. As a tax-qualified retirement plan, contributions to the 401(k) plan and earnings on those contributions are not taxable to the participants until distributed from the 401(k) plan.

DIRECTOR COMPENSATION

Director Compensation Overview

Prior to this offering, non-employee directors generally received a director fee and were reimbursed for travel, food, lodging and other expenses directly related to their activities as directors. During the fiscal year ended, December 31, 2020, Ansbert Gadicke, M.D., Thomas Ebeling, Morana Jovan-Embiricos, Ph.D., Anthony Rosenberg, and Stephen Webster received director fees, including for service on board committees, as set forth in the table below. Dr. Gadicke, who serves as chair of our board of directors, was also eligible to receive a bonus equal to 20% of his annual director fee based on achievement of corporate goals, but such bonus was not paid with respect to fiscal year 2020. Directors who also serve as employees receive no additional compensation for their service as directors. During the fiscal year ended December 31, 2020, Mr. Hughes received no additional compensation for his service as a director. See the section titled “Executive Compensation—Summary Compensation Table” for more information about Mr. Hughes’ compensation for the fiscal year ended December 31, 2020.

The following table provides certain information concerning compensation earned by our non-employee directors during the year ended December 31, 2020.

Name(1)	Fees Earned or Paid in Cash (\$)	Option Awards \$(2)	All Other Compensation \$(3)	Total (\$)
Ansbert Gadicke, M.D.	50,000	2,058,466	—	2,108,466
Thomas Ebeling	50,000	497,870	—	547,870
Morana Jovan-Embiricos, Ph.D.	100,000	823,387	—	923,387
Anthony Rosenberg	121,667	1,228,845	—	1,350,522
Tim Anderson(4)	—	—	—	—
Stephen Webster(5)	—	164,050	—	164,050

- (1) As of December 31, 2020, Dr. Gadicke, Mr. Ebeling, Dr. Jovan-Embiricos, and Mr. Rosenberg held 1,980,000, 475,200, 792,000, and 316,800 outstanding incentive units in the form of profits interests (of which 123,750, 79,200, 49,500, and 52,800 units were unvested), respectively. As of December 31, 2020, Mr. Webster held no incentive units in the form of profits interests.
- (2) Amounts represent the aggregate grant-date fair value of option awards granted to our directors in 2020, computed in accordance with FASB ASC Topic 718 excluding any estimates of forfeitures related to service-based vesting conditions. These amounts do not correspond to the actual value that may be recognized by the directors upon exercise of the applicable awards or sale of the underlying security. There were no equity awards other than option awards granted to directors in 2020. The aggregate number of unexercised option awards outstanding for each director at December 31, 2020 is as follows:

	Aggregate Number of Units Subject to Options
Ansbert Gadicke, M.D.	2,470,259
Thomas Ebeling	592,862
Morana Jovan-Embiricos, Ph.D.	988,104
Anthony Rosenberg	1,463,304
Stephen Webster	178,010

- (3) Represents consulting fees paid to Globeways of which Dr. Jovan Embiricos is the sole beneficial owner.
- (4) Mr. Anderson was appointed to our board of directors on December 18, 2019. As of December 31, 2020, Mr. Anderson had received no director fees and held no equity awards.

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(5) Mr. Webster was appointed to our board of directors on September 16, 2020. As of December 31, 2020, Mr. Webster had received no director fees.

Consulting Agreement with Globeways Holdings Limited

On April 1, 2020, we entered into a consulting agreement, or the 2020 Consulting Agreement, with Globeways Holdings Limited, or Globeways. Globeways and entities affiliated with F2 Ventures beneficially own in the aggregate greater than five percent of our outstanding units and Globeways is beneficially owned by Morana Jovan Embiricos, a member of our board of directors. Pursuant to the 2020 Consulting Agreement, Dr. Jovan-Embiricos provides leadership and advice regarding our scientific, clinical, product development and related activities and operations. Pursuant to the 2020 Consulting Agreement, we pay Globeways a consulting fee at a monthly rate of \$25,000. As the sole beneficial owner of Globeways, Dr. Jovan-Embiricos receives all of the compensation paid to Globeways under the 2020 Consulting Agreement.

Non-Employee Director Compensation Policy

In December 2020, we adopted a non-employee director compensation policy that will become effective upon the completion of this offering and will be designed to enable us to attract and retain, on a long-term basis, highly qualified non-employee directors. Under the policy, each director who is not an employee will be paid cash compensation from and after the completion of this offering, as set forth below:

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

In addition, the non-employee director compensation policy provides that, upon initial election to our board of directors, each non-employee director will be granted an equity award with a grant date fair value of \$250,000, or the Initial Grant. The Initial Grant will vest 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 following the completion of this offering, each non-employee director who continues as a non-employee director following such meeting will be granted an annual equity award with a grant date fair value of \$150,000, or 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. Such awards are subject to full accelerated vesting upon the sale of the company.

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

Reorganization Equity Exchange

In connection with the equity exchange described above under “Reorganization—Reorganization Equity Exchange,” the following anti-dilution and make-whole option grants were awarded to our non-employee directors under the 2020 Unit Plan: Dr. Gadicke, anti-dilution options in respect of 1,845,026 common units and make-whole options in respect of 625,233 common units; Mr. Ebeling, anti-dilution options in respect of 442,806 common units and make-whole options in respect of 150,056 common units; Dr. Jovan-Embiricos, anti-dilution options in respect of 738,010 common units and make-whole options in respect of 250,094 common units; and Mr. Rosenberg, anti-dilution options in respect of 1,213,210 common units and make-whole options in respect of 250,094 common units. Mr. Anderson did not receive any anti-dilution or make-whole option grants. These options have an exercise price of \$0.61 per common unit and vest as to 25% of the number of common units subject to the award on the first anniversary of the vesting commencement date, with the remaining portion of the award vesting over the following 36 months in equal monthly installments.

CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS

In addition to the compensation arrangements, including employment, consulting, termination of employment and change in control arrangements and indemnification arrangements, discussed in the sections titled “Management” and “Executive and Director Compensation” and the registration rights described in the section titled “Description of Capital Stock—Registration Rights,” the following is a description of each transaction since January 1, 2017 and each currently proposed transaction in which:

- we have been or are to be a participant;
- the amount involved exceeded or exceeds the lesser of (i) \$120,000 and (ii) the percent of the average of our total assets for the last two completed fiscal years; and
- any of our directors, executive officers, or holders of more than five percent of our capital stock, or any immediate family member of, or person sharing the household with, any of these individuals, had or will have a direct or indirect material interest.

Private Placements of Securities

Series C Preferred Unit Financing

In December 2020, we sold 66,599,045 Series C preferred units, or the Series C Preferred Units, at a purchase price of \$1.97 per unit for an aggregate purchase price of approximately \$131.2 million. The following table summarizes purchases of our Series C Preferred Units by related persons:

<u>Member</u>	<u>SERIES C PREFERRED UNITS</u>	<u>TOTAL PURCHASE PRICE</u>
UBS Oncology Impact Fund L.P.(1)	4,568,528	\$ 9,000,000.16
Entities affiliated with F2 Ventures(2)	3,527,919	\$ 6,950,000.43
Entities affiliated with Cowen Healthcare Investments(3)	1,591,315	\$ 3,134,890.55
Foresite Capital Fund V, L.P.(4)	17,766,497	\$ 34,999,999.09
Entities affiliated with The Baupost Group, L.L.C.(5)	1,193,486	\$ 2,351,167.42

- (1) UBS Oncology Impact Fund L.P., or OIF, beneficially owns more than five percent of our outstanding units. Certain of our executive officers, including Dr. Baeuerle, our Acting Chief Scientific Officer, Biologics, and Dr. Zawel, our Chief Scientific Officer, Small Molecules, serve as Executive Partners/Principals at OIF. Dr. Gadick, a member of our board of directors, serves as Managing Director of OIF.
- (2) Entities affiliated with F2 Ventures, including F2 Bio TD, LLC, F2 MC, LLC, F2 TPO Investments LLC and F2 MG Limited, collectively, beneficially own more than five percent of our outstanding units. Dr. Jovan-Embiricos, a member of our board of directors, serves as Managing Partner of F2 Ventures.
- (3) Entities affiliated with CHI Advisors LLC, including Cowen Healthcare Investments II LP, CHI EF II LP, Cowen Healthcare Investments III LP and CHI EF III LP, collectively, beneficially own more than five percent of our outstanding units. Mr. Anderson, a member of our board of directors, is a Partner, Head of Research at Cowen Healthcare Investments.
- (4) Foresite Capital Fund V, L.P. beneficially owns more than five percent of our outstanding units.
- (5) Entities affiliated with The Baupost Group, L.L.C. collectively beneficially own more than five percent of our outstanding units.

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Series B Preferred Unit Financing

In October 2019, with subsequent closings in December 2019, February 2020 and March 2020, we sold 63,141,020 Series B Preferred Units, or the Series B Preferred Units, at a purchase price of \$1.56 per unit for an aggregate purchase price of approximately \$98.5 million. The following table summarizes purchases of our Series B Preferred Units by related persons:

Member	SERIES B PREFERRED UNITS	TOTAL PURCHASE PRICE
UBS Oncology Impact Fund L.P.(1)	16,025,641	\$ 24,999,999.96
Entities affiliated with F2 Ventures(2)	4,487,179	\$ 6,999,999.25
Entities affiliated with Cowen Healthcare Investments(3)	12,820,512	\$ 19,999,998.72
Entities affiliated with The Baupost Group, L.L.C.(4)	9,615,384	\$ 14,999,999.04

- (1) OIF beneficially owns more than five percent of our outstanding units. Certain of our executive officers, including Dr. Baeuerle, our Acting Chief Scientific Officer, Biologics, and Dr. Zawel, our Chief Scientific Officer, Small Molecules, serve as Executive Partners/Principals at OIF. Dr. Gadick, a member of our board of directors, serves as Managing Director of OIF.
- (2) Entities affiliated with F2 Ventures, including F2 TPO Investments LLC and F2 MG Limited, collectively, beneficially own more than five percent of our outstanding units. Dr. Jovan-Embiricos, a member of our board of directors, serves as Managing Partner of F2 Ventures.
- (3) Entities affiliated with CHI Advisors LLC, including Cowen Healthcare Investments II LP, CHI EF II LP, Cowen Healthcare Investments III LP and CHI EF III LP, collectively, beneficially own more than five percent of our outstanding units. Mr. Anderson, a member of our board of directors, is a Partner, Head of Research at Cowen Healthcare Investments.
- (4) Entities affiliated with The Baupost Group, L.L.C. collectively beneficially own more than five percent of our outstanding units.

Series A Preferred Unit Financing

In April 2017, we sold 50,000,000 shares of our Series A1 Preferred Units, or the Series A Preferred Units, at a purchase price of \$1.00 per unit for an aggregate amount of \$50.0 million. The following table summarizes purchases of our Series A Preferred Units by related persons:

Members	SERIES A PREFERRED UNITS	TOTAL PURCHASE PRICE
UBS Oncology Impact Fund L.P.(1)	25,000,000	\$ 25,000,000
Entities affiliated with F2 Ventures(2)	25,000,000	\$ 25,000,000

- (1) OIF beneficially owns more than five percent of our outstanding units. Certain of our executive officers, including Dr. Baeuerle, our Acting Chief Scientific Officer, Biologics, and Dr. Zawel, our Chief Scientific Officer, Small Molecules, serve as Executive Partners/Principals at OIF. Dr. Gadick, a member of our board of directors, serves as Managing Director of OIF.
- (2) Entities affiliated with F2 Ventures, including F2 Vision SCS and F2 Bioscience I 2017 Limited, beneficially own more than five percent of our outstanding units. Dr. Jovan-Embiricos, a member of our board of directors, serves as Managing Partner of F2 Ventures.

Agreements with our Subsidiaries

Services Agreements

In connection with the formation of our partially-owned subsidiaries Cullinan Amber, Cullinan Pearl, Cullinan Florentine, Cullinan Apollo, and our investment in Cullinan MICA, collectively, the Asset Subsidiaries, each of our Asset Subsidiaries entered into a shared services agreement, or Shared Services Agreement, with our

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wholly-owned subsidiary Cullinan Management, pursuant to which Cullinan Management provides ongoing services to each Asset Subsidiary in areas such as accounting operations, human resources and administration management, research and development, information technology, and corporate development and strategy. In exchange for these services, each Asset Subsidiary pays Cullinan Management, a fee equal to the cost of services, with a 10% markup. During the years ended December 31, 2019 and 2018, the Asset Subsidiaries incurred an aggregate of \$1.9 million and \$1.1 million, respectively, of expenses related to services provided to them by Cullinan Management. The form of services agreement is filed as Exhibit 10.20.

Agreements with Stockholders

Royalty Transfer Agreements

In connection with the formation of the Asset Subsidiaries and our investment in partially-owned subsidiary Cullinan MICA, the Asset Subsidiaries each entered into Royalty Transfer Agreements, or Royalty Agreements, with UBS Optimus Foundation and Oncology Charitable Foundation, Inc., or collectively, the Charitable Entities, pursuant to which each Asset Subsidiary is obligated to pay the Charitable Entities a low single digit royalty percentage of all global net sales relating to any of the subsidiary's products that are received by the subsidiary, its licensees or its affiliates during the prior calendar year.

Unless earlier terminated, each Royalty 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 Charitable Entities are affiliated with OIF, which beneficially owns more than five percent of our outstanding units, and Dr. Ansbert, a member of our board of directors.

Simultaneously with the execution of each Royalty Transfer Agreement, each Asset Subsidiary also entered into a letter agreement, or LLC Royalty Letter, with the Charitable Entities and the LLC entity pursuant to which the parties agreed that a portion of the cash consideration paid by the LLC entity to the 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 Asset Subsidiary, or the Royalty Stream. Further, effective immediately subsequent to the purchase by the LLC entity of the Royalty Stream, the LLC entity transferred its rights under the Royalty Stream to the Charitable Entities by directing the Asset Subsidiary to execute, deliver, and perform a Royalty Transfer Agreement. The form of royalty transfer agreement is filed as Exhibit 10.21.

Operating Agreement

In connection with our Series C preferred unit financing, we entered into a third amended and restated limited liability agreement, or the Operating Agreement, as well as management rights letters containing registration rights, information rights, voting rights and rights of first refusal, among other things, with certain holders of our preferred units. The management rights letters provide for certain information rights and rights to consult with our management. In connection with the Reorganization, this Operating Agreement will terminate and a registration rights agreement will be entered into with our members. See "Reorganization" for further detail regarding these transactions and "Description of our capital stock" for further detail regarding the registration rights under the Registration Rights Agreement (as defined below). In addition, the management rights letters will terminate upon the closing of this offering.

Registration Rights Agreements

In connection with this offering, pursuant to the Operating Agreement, promptly following a conversion, merger or reorganization event, we intend to enter into a registration rights agreement with each holder of our preferred units, or the Registration Rights Agreement. See "Description of our capital stock" for further detail regarding the registration rights under the Registration Rights Agreement.

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.

Employment 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 Globeways Holdings Limited

On April 1, 2020, we entered into a consulting agreement, or the 2020 Consulting Agreement, with Globeways Holdings Limited, or Globeways, Globeways and entities affiliated with F2 Ventures beneficially own in the aggregate greater than five percent of our outstanding units and Globeways is beneficially owned by Morana Jovan Embiricos, a member of our board of directors. Pursuant to the 2020 Consulting Agreement, Dr. Jovan-Embiricos provides leadership and advice regarding our scientific, clinical, product development and related activities and operations. Pursuant to the 2020 Consulting Agreement, we pay Globeways a consulting fee at a monthly rate of \$25,000. As the sole beneficial owner of Globeways, Dr. Jovan-Embiricos receives all of the compensation paid to Globeways under the 2020 Consulting Agreement.

Consulting Agreement with Patrick Baeuerle, Ph.D.

On January 1, 2019, we entered into a consulting agreement with Patrick Baeuerle, Ph.D. our co-founder and Acting Chief Scientific Officer, Biologics. Pursuant to the consulting agreement, Dr. Baeuerle provides services to the Company in his role as Acting Chief Scientific Officer, Biologics. The consulting agreement has a term that expires on the last date on which Dr. Baeuerle provides services to the Company. Pursuant to the consulting agreement, we have agreed to pay Dr. Baeuerle a consulting fee at a monthly rate of EUR30,833.33, and Dr. Baeuerle is eligible to receive a 33% annual performance bonus subject to approval of our board of directors. In connection with this offering, we have entered into a Services Agreement with Dr. Baeuerle, pursuant to which we have agreed to pay Dr. Baeuerle a consulting fee of \$450,000 per year and Dr. Baeuerle is eligible to receive a 40% annual performance bonus subject to approval of our board of directors. The services agreement has a term that expires on the last date on which Dr. Baeuerle provides services to the Company. A copy of the Services Agreement is being filed as Exhibit 10.25 to this Registration Statement.

Consulting Agreement with Corinne Savill, Ph.D.

On January 1, 2019, we entered into a consulting agreement with Corinne Savill, Ph.D. our Acting Chief Business Officer. Pursuant to the consulting agreement, Dr. Savill provides services to the Company in her role as Acting Chief Business Officer. The consulting agreement has a term that expires on the last date on which Dr. Savill provides services to the Company. Pursuant to the consulting agreement, we have agreed to pay Dr. Savill a consulting fee at a monthly rate of \$31,666.66, and Dr. Savill is eligible to receive a 30% annual performance bonus subject to approval of our board of directors. In connection with this offering, we have entered into a Services Agreement with Dr. Savill pursuant to which we have 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. The services agreement has a term that expires on the last date on which Dr. Savill provides services to the Company.

Director Compensation

See the section titled “Director Compensation” for information regarding compensation of our directors.

Limitation of Liability and Indemnification of Officers and Directors

We plan to enter into indemnification agreements with each of our directors and executive officers, the form of which is attached as an exhibit to the registration statement of which this prospectus is a part. The indemnification agreements and our second amended and restated certificate of incorporation to be effective immediately prior to the closing of the offering and amended and restated bylaws to be effective upon the effectiveness of this registration statement require us to indemnify our directors and officers to the fullest extent permitted by Delaware law.

Policies for Approval of Related Party Transactions

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. Prior to this offering, the material facts as to the related party’s relationship or interest in the transaction were disclosed to our board of directors prior to their consideration of such transaction, and the transaction was not considered approved by our board of directors unless a majority of the directors who are not interested in the transaction approved the transaction. Further, when stockholders are entitled to vote on a transaction with a related party, the material facts of the related party’s relationship or interest in the transaction were disclosed to the stockholders, who must approve the transaction in good faith.

In connection with this offering, we expect to adopt a written related party transactions policy that will provide that such transactions must be approved by our audit committee. This policy will become effective on the date on which the registration statement of which this prospectus forms a part is declared effective by the SEC. 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 will be 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.

PRINCIPAL STOCKHOLDERS

The following table sets forth information with respect to the beneficial ownership of our common stock, as of December 31, 2020 by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our common stock;
- each of our directors;
- each of our named executive officers; and
- all of our executive officers and directors as a group.

The column entitled “Percentage of Shares Beneficially Owned - Before Offering” is based on 29,818,075 shares of our common stock (which includes 2,010,177 shares of restricted common stock, including 320,228 shares of restricted common stock granted pursuant to the Restricted Stock Contribution Agreement subsequent to September 30, 2020) deemed to be outstanding as of December 31, 2020. The column entitled “Percentage of Shares Beneficially Owned—After Offering” is based on 39,818,075 shares of our common stock to be outstanding after this offering, including the shares of our common stock that we are selling in this offering, but not including any additional shares issuable pursuant to the underwriters’ option to purchase additional shares.

The number of shares beneficially owned by each stockholder is determined under rules issued by the SEC and includes voting or investment power with respect to securities. Under these rules, beneficial ownership includes any shares as to which the individual or entity has sole or shared voting power or investment power. In computing the number of shares beneficially owned by an individual or entity and the percentage ownership of that person, shares of common stock subject to options, warrants, or other rights held by such person that are currently exercisable or will become exercisable within 60 days after December 31, 2020 are considered outstanding, although these shares are not considered outstanding for purposes of computing the percentage ownership of any other person. Unless otherwise indicated, the address of all listed stockholders is One Main Street, Suite 520, Cambridge, MA 02142. Each of the stockholders listed has sole voting and investment power with respect to the shares beneficially owned by the stockholder unless noted otherwise, subject to community property laws where applicable.

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The following table does not reflect any shares of common stock that may be purchased pursuant to our directed share program described under “Underwriting—Directed Share Program.”

Name of Beneficial Owner	Shares Beneficially Owned	Percentage of Shares Beneficially Owned	
		Before Offering	After Offering
Greater-than-5% Stockholders			
Entities affiliated with F2 Ventures ⁽¹⁾	5,826,832	19.54%	14.63%
UBS Oncology Impact Fund L.P. ⁽²⁾	7,613,887	25.53%	19.12%
Entities affiliated with Foresite Capital ⁽³⁾	2,524,008	8.46%	6.34%
Entities affiliated with Cowen ⁽⁴⁾	2,047,422	6.87%	5.14%
Entities affiliated with The Baupost Group, L.L.C. ⁽⁵⁾	1,535,560	5.15%	3.86%
Named Executive Officers and Directors			
Owen Hughes ⁽⁶⁾	957,455	3.16%	2.38%
Patrick Baeuerle, Ph.D. ⁽⁷⁾	683,753	2.27%	1.70%
Jon Wigginton, M.D.	—	—	—
Thomas Ebeling ⁽⁸⁾	141,201	*0%	*0%
Ansbert Gadicke, M.D. ⁽⁹⁾	624,894	2.07%	1.56%
Morana Jovan-Embiricos, Ph.D. ⁽¹⁰⁾	6,076,789	20.29%	15.21%
Anthony Rosenberg ⁽¹¹⁾	226,900	*0%	*0%
Tim Anderson	—	—	—
Stephen Webster	—	—	—
All executive officers and directors as a group (14 persons) ⁽¹²⁾	9,381,771	29.64%	22.52%

* Less than one percent

- (1) Consists of (i) 1,136,525 shares of common stock issuable upon conversion of shares of Series Seed convertible preferred stock held by Globeways Holdings Limited, or Globeways, (ii) 2,912,345 shares of common stock issuable upon conversion of shares of Series A convertible preferred stock held by F2 Vision SCS, or F2 Vision, (iii) 639,295 shares of common stock issuable upon conversion of shares of Series A convertible preferred stock held by F2 Bioscience I 2017 Limited, or F2 Bioscience 2017, (iv) 455,338 shares of common stock issuable upon conversion of shares of Series B convertible preferred stock and 71,599 shares of common stock issuable upon conversion of Series C convertible preferred stock held by F2 TPO Investments LLC, or F2 TPO, (v) 182,135 shares of common stock issuable upon conversion of shares of Series B convertible preferred stock and 143,198 shares of common stock issuable upon conversion of Series C convertible preferred stock held by F2 MG Limited, or F2 MG, (vi) 71,599 shares of common stock issuable upon conversion of Series C convertible preferred stock held by F2 Bio TD, LLC, or F2 Bio, and (vii) 214,798 shares of common stock issuable upon conversion of Series C convertible preferred stock held by F2 MC, LLC, or F2 MC. Dr. Morana Jovan-Embiricos is a member of our board of directors and is the founding director of Globeways, which is the appointed manager of each F2 Bioscience 2017 and F2 MG. Dr. Morana Jovan-Embiricos is also the founder of Globeways’ wholly-owned subsidiary Globeways Holdings II Limited, or Globeways II, which is the appointed manager of F2 TPO, F2 MC and F2 Bio. Dr. Morana Jovan-Embiricos is also the founder of Globeways’ wholly-owned subsidiary F2 Vision Management Sàrl, or 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. Dr. Morana Jovan-Embiricos expressly disclaims beneficial ownership of the securities held by F2 Bioscience 2017, F2 MG, F2 TPO, and F2 Bio, F2 MC, and F2 Vision. The address for correspondence of Dr. Morana Jovan-Embiricos, Globeways, F2 Bioscience 2017 and F2 MG is 8, Rue Saint-Leger, CH 1205, Geneva, Switzerland. The address for correspondence of F2 TPO, F2 Bio and F2 MC is 8 West 38th Street, Suite 1001, New York, NY 10018, USA, and the address for correspondence of F2 Vision is 74, Grand-Rue, L-1660 Luxembourg.
- (2) Consists of (i) 1,136,525 shares of common stock issuable upon conversion of shares of Series Seed convertible preferred stock, (ii) 3,551,640 shares of common stock issuable upon conversion of shares of Series A convertible preferred stock, (iii) 2,276,692 shares of common stock issuable upon conversion of shares of Series B convertible preferred stock, and (iv) 649,030 shares of common stock issuable upon conversion of shares of Series C convertible preferred stock, in each case held by UBS Oncology Impact Fund L.P., or OIF. The general partner of OIF is Oncology Impact Fund (Cayman) Management L.P., or OIF GP.

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The general partner of OIF GP is MPM Oncology Impact Management L.P. The general partner of MPM Oncology Impact Management L.P. is MPM Oncology Impact Management GP LLC. Dr. Ansbert Gadicke is a member of our board of directors and is a managing member and the managing director of MPM Oncology Impact Management GP LLC. 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.

- (3) Consists of (i) 1,893,006 shares of common stock issuable upon conversion of Series C convertible preferred stock held by Foresite Capital V, L.P., or Fund V, and (ii) 631,002 shares of common stock issuable upon conversion of Series C convertible preferred stock held by Foresite Capital Opportunity Fund V, L.P., or Opportunity Fund V. Foresite Capital Management V, LLC is the general partner of Fund V and may be deemed to have sole voting and dispositive power over the shares held by Fund V; and Foresite Capital Opportunity Management V, LLC is the general partner of Opportunity Fund V and may be deemed to have sole voting and dispositive power over the shares held by Opportunity Fund V. The address of Fund V and Opportunity Fund V is 600 Montgomery Street, Suite 4500, San Francisco, CA 94111.
- (4) Consists of (i) 424,638 shares of common stock issuable upon conversion of shares of Series B convertible preferred stock and 52,651 shares of common stock issuable upon conversion of Series C convertible preferred stock held by Cowen Healthcare Investments II LP, (ii) 30,700 shares of common stock issuable upon conversion of shares of Series B convertible preferred stock and 3,865 shares of common stock issuable upon conversion of Series C convertible preferred stock held by CHI EF II LP, (iii) 1,328,793 shares of common stock issuable upon conversion of shares of Series B convertible preferred stock and 164,933 shares of common stock issuable upon conversion of Series C convertible preferred stock held by Cowen Healthcare Investments III LP, and (iv) 37,222 shares of common stock issuable upon conversion of shares of Series B convertible preferred stock and 4,620 shares of common stock issuable upon conversion of Series C convertible preferred stock held by CHI EF III LP. CHI Advisors LLC, the investment adviser of each of these entities, has voting and investment power with respect to their shares. Mr. Anderson, a member of our board of directors, is a Partner and Head of Research at Cowen Healthcare Investments. The principal business address for these entities is 599 Lexington Avenue, 19th Floor, New York, NY 10022.
- (5) Consists of 1,366,012 shares of common stock issuable upon conversion of Series B convertible preferred stock and 169,548 shares of common stock issuable upon conversion of Series C convertible preferred stock held by entities affiliated with The Baupost Group L.L.C. The Baupost Group, L.L.C. is a registered investment adviser and acts as the investment adviser to certain private investment limited partnerships on whose behalf these securities were purchased. The Baupost Group, L.L.C., Baupost Group GP, L.L.C. and Seth A. Klarman have shared voting and investment power over these shares of common stock. Baupost Group GP, L.L.C. and Mr. Klarman disclaim beneficial ownership of such securities except to the extent of their pecuniary interest therein, if any. The principal business address for The Baupost Group, L.L.C. is 10 St. James Avenue, Suite 1700, Boston, MA 02116.
- (6) Consists of (i) 503,727 shares of restricted common stock held by Mr. Hughes and a grantor retained annuity trust and (ii) 453,728 shares subject to options held by Mr. Hughes which are vested and exercisable within 60 days of December 31, 2020.
- (7) Consists of (i) 341,435 shares of restricted common stock held by an entity of which Dr. Baeuerle is Managing Director and has sole voting and investment power over these shares and (ii) 342,318 shares subject to options held by Dr. Baeuerle which are vested and exercisable within 60 days of December 31, 2020.
- (8) Consists of (i) 67,504 shares of restricted common stock held by Mr. Ebeling and (ii) 73,697 shares subject to options held by Mr. Ebeling which are vested and exercisable within 60 days of December 31, 2020.
- (9) Consists of (i) 281,268 shares of restricted common stock held by Dr. Gadicke and (ii) 343,626 shares subject to options held by Dr. Gadicke which are vested and exercisable within 60 days of December 31, 2020.
- (10) Consists of (i) 112,507 shares of restricted common stock held by Dr. Jovan-Embiricos, (ii) 1,136,525 shares of common stock issuable upon conversion of shares of Series Seed convertible preferred stock held by Globeways Holdings Limited, or Globeways, (iii) 2,912,345 shares of common stock issuable upon conversion of shares of Series A convertible preferred stock held by F2 Vision SCS, or F2 Vision, (iv) 639,295 shares of common stock issuable upon conversion of shares of Series A convertible preferred stock held by F2 Bioscience I 2017 Limited, or F2 Bioscience 2017, (v) 455,338 shares of common stock issuable upon conversion of shares of Series B convertible preferred stock and 71,599 shares of common stock issuable upon conversion of Series C convertible preferred stock held by F2 TPO Investments LLC, or F2 TPO, (vi) 182,135 shares of common stock issuable upon conversion of shares of Series B convertible preferred stock and 143,198 shares of common stock issuable upon conversion of Series C convertible preferred stock held by F2

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MG Limited, or F2 MG, (vi) 71,599 shares of common stock issuable upon conversion of Series C convertible preferred stock held by F2 Bio TD, LLC, or F2 Bio, (vii) 214,798 shares of common stock issuable upon conversion of Series C convertible preferred stock held by F2 MC, LLC, or F2 MC, and (viii) 137,450 shares subject to options held by Dr. Jovan-Embiricos which are vested and exercisable within 60 days of December 31, 2020. Dr. Morana Jovan-Embiricos is a member of our board of directors and is the founding director of Globeways, which is the appointed manager of each F2 Bioscience 2017 and F2 MG. Dr. Morana Jovan-Embiricos is also the founder of Globeways' wholly-owned subsidiary Globeways Holdings II Limited, or Globeways II, which is the appointed manager of F2 TPO, F2 MC and F2 Bio. Dr. Morana Jovan-Embiricos is also the founder of Globeways' wholly-owned subsidiary F2 Vision Management S rl, or 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. Dr. Morana Jovan-Embiricos expressly disclaims beneficial ownership of the securities held by F2 Bioscience 2017, F2 MG, F2 TPO, and F2 Bio, F2 MC, and F2 Vision. The address for correspondence of Dr. Morana Jovan-Embiricos, Globeways, F2 Bioscience 2017 and F2 MG is 8, Rue Saint-Leger, CH 1205, Geneva, Switzerland. The address for correspondence of F2 TPO, F2 Bio and F2 MC is 8 West 38th Street, Suite 1001, New York, NY 10018, USA, and the address for correspondence of F2 Vision is 74, Grand-Rue, L-1660 Luxembourg.

- (11) Consists of (i) 45,002 shares of restricted common stock held by Mr. Rosenberg and (ii) 181,898 shares subject to options held by Mr. Rosenberg which are vested and exercisable within 60 days of December 31, 2020.
- (12) See notes 6 through 11 above; also includes 367,413 shares of restricted common stock held by Raymond Keane, Jennifer Michaelson, Ph.D., Corinne Savill, Ph.D., and Leigh Zawel, Ph.D., our Chief Legal Officer, our Chief Development Officer, Biologics, our Acting Chief Business Officer, and our Chief Scientific Officer, Small Molecules, respectively, as well as 303,366 shares subject to options held by Drs. Michaelson, Savill and Zawel, which are vested and exercisable within 60 days of December 31, 2020.

DESCRIPTION OF CAPITAL STOCK

The following description of our capital stock and provisions of our second amended and restated certificate of incorporation as they will be in effect immediately prior to the completion of this offering and amended and restated bylaws as they will be in effect upon the effectiveness of this registration statement are summaries and are qualified in their entirety by reference to our second amended and restated certificate of incorporation that will be effective immediately prior to the completion of this offering and amended and restated bylaws that will be in effect upon the effectiveness of this registration statement of which this prospectus is a part, the forms of which are filed as exhibits to the registration statement of which this prospectus forms a part. The description of our common stock reflects the completion of the Reorganization, which will occur immediately prior to the effectiveness of the registration statement. See “Reorganization” for more information concerning the Reorganization.

Common Stock

The holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of the stockholders. The holders of our common stock do not have any cumulative voting rights. Holders of our common stock are entitled to receive ratably any dividends declared by our board of directors out of funds legally available for that purpose, subject to any preferential dividend rights of any outstanding preferred stock. Our common stock has no preemptive rights, conversion rights or other subscription rights or redemption or sinking fund provisions.

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in all assets remaining after payment of all debts and other liabilities and any liquidation preference of any outstanding preferred stock. The shares to be issued by us in this offering will be, when issued and paid for, validly issued, fully paid and non-assessable.

Preferred Stock

Upon the consummation of this offering, our board of directors will have the authority, without further action by our stockholders, to issue up to 10,000,000 shares of convertible preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of common stock. The issuance of our convertible preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon our liquidation. In addition, the issuance of convertible preferred stock could have the effect of delaying, deferring or preventing a change in control of our company or other corporate action. Immediately after consummation of this offering, no shares of convertible preferred stock will be outstanding, and we have no present plan to issue any shares of convertible preferred stock.

Registration Rights

In connection with the Reorganization, we will be entering into a registration rights agreement with certain of our shareholders. Upon the completion of this offering, certain holders of shares of our common stock will be entitled to rights with respect to the registration of these securities under the Securities Act. These rights will be provided under the terms of the registration rights agreement. The registration rights agreement will include demand registration rights, short-form registration rights and piggyback registration rights. All fees, costs and expenses incurred in connection with registrations under the registration rights agreement will be borne by us, and all selling expenses, including underwriting discounts and selling commissions, will be borne by the holders of the shares being registered.

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Form S-1 Demand Registration Rights

180 days after the effective date of the registration statement for this offering, the holders of our registrable securities will be entitled to demand registration rights. Under the terms of our registration rights agreement, we will be required, upon the request of a holder of at least a majority of our then outstanding registrable securities, to file a registration statement and use reasonable best efforts to effect the registration for public resale of these shares and any additional registrable securities requested to be included in such registration by any other holders of our registrable securities.

Form S-3 Demand Registration Rights

Upon the completion of this offering, the holders of our registrable securities will also be entitled to short-form registration rights. Pursuant to our registration rights agreement, at any time that we are eligible to file a registration statement on Form S-3, upon the request of a holder of our registrable securities, we will be required to use our reasonable best efforts to effect a registration of such shares and any additional registrable securities requested to be included in such registration by any other holders of our registrable securities. We will be required to effect up to two registrations in any twelve-month period pursuant to this provision of the registration rights agreement.

Piggyback Registration Rights

The holders of our registrable securities will be entitled to piggyback registration rights. If we register any of our securities either for our own account or for the account of other security holders, the holders of our outstanding registrable securities will be entitled to include their shares in the registration. Subject to certain exceptions contained in the registration rights agreement, we and the underwriters may limit the number of shares included in the underwritten offering if the underwriters determine that marketing factors require a limitation of the number of shares to be underwritten.

Indemnification

Our registration rights agreement contains customary cross-indemnification provisions, under which we will be obligated to indemnify holders of registrable securities in the event of material misstatements or omissions in the registration statement attributable to us, and they will be obligated to indemnify us for material misstatements or omissions attributable to them.

Expenses of Registration

We will pay the registration expenses, subject to certain limited exceptions contained in the registration rights agreement, of the holders of the shares registered pursuant to the demand, short-form and piggyback registration rights described above, including the expenses of one counsel for the selling holders.

Expiration of Registration Rights

The registration rights granted under the registration rights agreement will terminate upon the earliest to occur of: (i) such time after our initial public offering when all registrable securities could be sold under Rule 144 of the Securities Act or a similar exemption without limitation during a three-month period without registration; (ii) the consummation of a transaction or series of transactions in which a person, or a group of persons, acquires from our stockholders, shares representing more than 50% of our outstanding voting stock; and (iii) the consummation of a transaction or series of transactions in which a person, or group of persons, acquires the right to receive the majority of the proceeds in a final liquidation, dissolution or termination, voluntary or involuntary, of the company.

Authorized but Unissued Capital Stock

The Delaware General Corporation Law does not require stockholder approval for any issuance of authorized shares. However, the listing requirements of Nasdaq, which would apply so long as our common stock remains listed on Nasdaq, require stockholder approval of certain issuances equal to or exceeding 20% of the then outstanding voting power or then outstanding number of shares of common stock. These additional shares may be used for a variety of corporate purposes, including future public offerings, to raise additional capital or to facilitate acquisitions.

One of the effects of the existence of unissued and unreserved common stock or preferred stock may be to enable our board of directors to issue shares to persons friendly to current management, which issuance could render more difficult or discourage an attempt to obtain control of our company by means of a merger, tender offer, proxy contest or otherwise, and thereby protect the continuity of our management and possibly deprive our stockholders of opportunities to sell their shares of common stock at prices higher than prevailing market prices.

Anti-Takeover Effects of Provisions of Delaware Law and Our Second Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws

Certain provisions of the Delaware General Corporation Law and of our second amended and restated certificate of incorporation that will become effective upon the completion of this offering and amended and restated bylaws that will become effective upon the effectiveness of this registration statement could have the effect of delaying, deferring or discouraging another party from acquiring control of us. These provisions, which are summarized below, are expected to discourage certain types of coercive takeover practices and inadequate takeover bids and, as a consequence, they might also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions are also designed in part to encourage anyone seeking to acquire control of us to first negotiate with our board of directors. These provisions might also have the effect of preventing changes in our management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders might otherwise deem to be in their best interests. However, we believe that the advantages gained by protecting our ability to negotiate with any unsolicited and potentially unfriendly acquirer outweigh the disadvantages of discouraging such proposals, including those priced above the then-current market value of our common stock, because, among other reasons, the negotiation of such proposals could improve their terms.

Board Composition and Filling Vacancies

Our second amended and restated certificate of incorporation will provide for the division of our board of directors into three classes serving staggered three-year terms, with one class being elected each year. Our certificate of incorporation also will provide that directors may be removed only for cause and then only by the affirmative vote of the holders of two-thirds or more of the shares then entitled to vote at an election of directors. Furthermore, any vacancy on our board of directors, however occurring, including a vacancy resulting from an increase in the size of our board, may only be filled by the affirmative vote of a majority of our directors then in office even if less than a quorum. The classification of directors, together with the limitations on removal of directors and treatment of vacancies, has the effect of making it more difficult for stockholders to change the composition of our board of directors.

No Written Consent of Stockholders

Our second amended and restated certificate of incorporation will provide that all stockholder actions are required to be taken by a vote of the stockholders at an annual or special meeting, and that stockholders may not take any action by written consent in lieu of a meeting. This limit may lengthen the amount of time required to take stockholder actions and would prevent the amendment of our bylaws or removal of directors by our stockholders without holding a meeting of stockholders.

Meetings of Stockholders

Our second amended and restated certificate of incorporation and amended and restated bylaws will provide that only a majority of the members of our board of directors then in office may call special meetings of stockholders and only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders. Our bylaws limit the business that may be conducted at an annual meeting of stockholders to those matters properly brought before the meeting.

Advance Notice Requirements

Our amended and restated bylaws will establish advance notice procedures with regard to stockholder proposals relating to the nomination of candidates for election as directors or new business to be brought before meetings of our stockholders. These procedures provide that notice of stockholder proposals must be timely given in writing to our corporate secretary prior to the meeting at which the action is to be taken. Generally, to be timely, notice must be received at our principal executive offices not less than 90 days nor more than 120 days prior to the first anniversary date of the annual meeting for the preceding year. Our bylaws specify the requirements as to form and content of all stockholders' notices. These requirements may preclude stockholders from bringing matters before the stockholders at an annual or special meeting.

Amendment to Certificate of Incorporation and Bylaws

Any amendment of our certificate of incorporation must first be approved by a majority of our board of directors, and if required by law or our second amended and restated certificate of incorporation, must thereafter be approved by a majority of the outstanding shares entitled to vote on the amendment and a majority of the outstanding shares of each class entitled to vote thereon as a class, except that the amendment of the provisions relating to stockholder action, board composition, and limitation of liability must be approved by not less than two-thirds of the outstanding shares entitled to vote on the amendment, and not less than two-thirds of the outstanding shares of each class entitled to vote thereon as a class. Our amended and restated bylaws may be amended by the affirmative vote of a majority of the directors then in office, subject to any limitations set forth in the bylaws; and may also be amended by the affirmative vote of a majority of the outstanding shares entitled to vote on the amendment, voting together as a single class, except that the amendment of the provisions relating to notice of stockholder business and nominations and special meetings must be approved by not less than two-thirds of the outstanding shares entitled to vote on the amendment, and not less than two-thirds of the outstanding shares of each class entitled to vote thereon as a class, or, if our board of directors recommends that the stockholders approve the amendment, by the affirmative vote of the majority of the outstanding shares entitled to vote on the amendment, in each case voting together as a single class.

Undesignated Preferred Stock

Our second amended and restated certificate of incorporation provides for 10,000,000 authorized shares of preferred stock. The existence of authorized but unissued shares of preferred stock may enable our board of directors to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise. For example, if in the due exercise of its fiduciary obligations, our board of directors were to determine that a takeover proposal is not in the best interests of our stockholders, our board of directors could cause shares of preferred stock to be issued without stockholder approval in one or more private offerings or other transactions that might dilute the voting or other rights of the proposed acquirer or insurgent stockholder or stockholder group. In this regard, our certificate of incorporation grants our board of directors broad power to establish the rights and preferences of authorized and unissued shares of preferred stock. The issuance of shares of preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of common stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring or preventing a change in control of us.

Choice of Forum

Our amended and restated bylaws will provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for any 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, and employees to us or our stockholders, (3) any action asserting a claim arising pursuant to the Delaware General Corporation Law, our certificate of incorporation or our 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 that is governed by the internal affairs doctrine; provided, however, that this provision shall not apply to any causes of action arising under the Securities Act or Exchange Act. In addition, our amended and restated bylaws will provide that, unless we consent in writing to the selection of an alternative forum, the United States District Court for the District of Delaware shall be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. Any person or entity purchasing or otherwise acquiring any interest in our securities shall be deemed to have notice of and consented to these forum provisions. These forum provisions may impose additional costs on stockholders, may limit our stockholders' ability to bring a claim in a forum they find favorable, and the designated courts may reach different judgments or results than other courts. In addition, there is uncertainty as to whether the federal forum provision for Securities Act claims will be enforced, which may impose additional costs on us and our stockholders.

Delaware Takeover Statute

Upon completion of this offering, we will be subject to the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

- before the stockholder became interested, our board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances, but not the outstanding voting stock owned by the interested stockholder; or
- at or after the time the stockholder became interested, the business combination was approved by our board of directors and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, lease, pledge, exchange, mortgage or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or

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- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

Limitations of Liability and Indemnification

See “Executive and Director Compensation—Limitation on Liability and Indemnification Matters.”

Nasdaq Global Select Market Listing

Our common stock has been approved for listing on The Nasdaq Global Select Market under the trading symbol “CGEM”.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock will be Computershare Trust Company, N.A. The transfer agent and registrar’s address is 250 Royall Street, Canton, Massachusetts 02021, and its telephone number is (800) 962-4284.

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for shares of our common stock. We cannot predict the effect, if any, that future sales of shares of common stock, or the availability for future sale of shares of common stock, will have on the market price of shares of our common stock prevailing from time to time. The sale of substantial amounts of shares of our common stock in the public market, or the perception that such sales could occur, could harm the prevailing market price of shares of our common stock.

Currently, no shares of our common stock are outstanding. Upon the completion of this offering, we will have a total of 39,497,847 shares of our common stock outstanding (or 40,997,847 shares of common stock if the underwriters exercise in full their option to purchase additional shares of common stock). Of the outstanding shares, all of the shares sold in this offering will be freely tradable (excluding any shares sold to our directors and officers in the directed share program), except that any shares, including shares sold to an entity affiliated with an existing shareholder that may purchase shares in this offering, held by our affiliates, as that term is defined in Rule 144 under the Securities Act, may only be sold in compliance with the limitations described below.

Rule 144

In general, a person who has beneficially owned restricted stock for at least six months would be entitled to sell their securities provided that (i) such person is not deemed to have been one of our affiliates at the time of, or at any time during the 90 days preceding, a sale and (ii) we are subject to the Exchange Act, periodic reporting requirements for at least 90 days before the sale. Persons who have beneficially owned restricted shares for at least six months but who are our affiliates at the time of, or any time during the 90 days preceding, a sale, would be subject to additional restrictions, by which such person would be entitled to sell within any three-month period only a number of securities that does not exceed the greater of either of the following:

- 1% of the number of shares then outstanding, which will equal approximately 394,978 shares immediately after this offering assuming no exercise of the underwriters' option to purchase additional shares, based on the number of shares outstanding as of September 30, 2020; or
- the average weekly trading volume of our common stock on the Nasdaq Global Select Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale;

provided, in each case, that we are subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale. Such sales both by affiliates and by non-affiliates must also comply with the current public information and, with respect to sales by affiliates, the manner of sale, current public information and notice provisions of Rule 144.

Rule 701

Rule 701 under the Securities Act, as in effect on the date of this prospectus, permits resales of shares in reliance upon Rule 144 but without compliance with certain restrictions of Rule 144, including the holding period requirement. Most of our employees, executive officers, or directors who purchased shares under a written compensatory plan or contract may be entitled to rely on the resale provisions of Rule 701, but all holders of Rule 701 shares are required to wait until 90 days after the date of this prospectus before selling their shares. However, substantially all Rule 701 shares are subject to lock-up agreements as described below and under "Underwriting" included elsewhere in this prospectus and will become eligible for sale upon the expiration of the restrictions set forth in those agreements.

Lock-Up Agreements

We, along with our directors, executive officers and certain other stockholders, representing approximately 95% of our current stockholders, have agreed with the underwriters that for a period ending 180 days (the

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restricted period), after the date of this prospectus, subject to specified exceptions, we or they will not offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of, directly or indirectly, any shares of common stock or any securities convertible into or exercisable or exchangeable for shares of common stock, or enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the common stock. Upon expiration of the “restricted” period, certain of our stockholders will have the right to require us to register their shares under the Securities Act of 1933, as amended, or the Securities Act. See “—Registration Rights” below and “Description of Capital Stock—Registration Rights.”

After this offering, certain of our employees, including our shareholders, executive officers and/or directors, may enter into written trading plans that are intended to comply with Rule 10b5-1 under the Exchange Act. Sales under these trading plans would not be permitted until the expiration of the lock-up agreements relating to the offering described above.

Registration Rights

Upon completion of this offering, certain holders of our securities will be entitled to various rights with respect to registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in these shares becoming fully tradable without restriction under the Securities Act immediately upon the effectiveness of the registration. See the section entitled “Description of Capital Stock—Registration Rights” appearing elsewhere in this prospectus for more information.

Stock Options and Restricted Stock

As soon as practicable after the completion of this offering, we intend to file a Form S-8 registration statement under the Securities Act to register shares of our common stock subject to options and restricted stock reserved for issuance under our 2021 Stock Option and Incentive Plan. This registration statement will become effective immediately upon filing, and shares covered by this registration statement will thereupon be eligible for sale in the public markets, subject to vesting restrictions, the lock-up agreements described above and Rule 144 limitations applicable to affiliates. For a more complete discussion of our stock plans, see “Executive Compensation—Employee Benefit and Stock Plans.”

Material U.S. Federal Income Tax Considerations for Non-U.S. Holders

The following discussion is a summary of certain material U.S. federal income tax considerations applicable to non-U.S. holders (as defined below) with respect to their ownership and disposition of shares of our common stock issued pursuant to this offering. For purposes of this discussion, a non-U.S. holder means a beneficial owner of our common stock that is for U.S. federal income tax purposes:

- a non-resident alien individual;
- a corporation or other organization taxable as a corporation for U.S. federal income tax purposes that is created or organized in or under laws other than the laws of the United States, any state thereof, or the District of Columbia;
- an estate the income of which is not subject to U.S. federal income tax on a net income basis; or
- a trust the income of which is not subject to U.S. federal income tax on a net income basis and that (1) is not subject to the primary supervision of a court within the United States or over which no U.S. persons have authority to control all substantial decisions and (2) has not made an election to be treated as a U.S. person.

This discussion does not address the tax treatment of partnerships or other entities that are pass-through entities for U.S. federal income tax purposes or persons that hold their common stock through partnerships or other pass-through entities. A partner in a partnership or other pass-through entity that will hold our common stock should consult his, her or its tax advisor regarding the tax consequences of acquiring, holding and disposing of our common stock through a partnership or other pass-through entity, as applicable.

This discussion is based on current provisions of the U.S. Internal Revenue Code of 1986, as amended, which we refer to as the Code, existing and proposed U.S. Treasury Regulations promulgated thereunder, current administrative rulings and judicial decisions, all as in effect as of the date of this prospectus and, all of which are subject to change or to differing interpretation, possibly with retroactive effect. Any such change or differing interpretation could alter the tax consequences to non-U.S. holders described in this prospectus. There can be no assurance that the Internal Revenue Service, which we refer to as the IRS, will not challenge one or more of the tax consequences described herein. We assume in this discussion that a non-U.S. holder holds shares of our common stock as a capital asset within the meaning of Section 1221 of the Code, which is generally property held for investment.

This discussion does not address all aspects of U.S. federal income taxation that may be relevant to a particular non-U.S. holder in light of that non-U.S. holder's individual circumstances nor does it address any U.S. state, local or non-U.S. tax considerations, the alternative minimum tax, the Medicare tax on net investment income, the rules regarding qualified small business stock within the meaning of Section 1202 of the Code, or any other aspect of any U.S. federal tax other than the income tax. This discussion also does not consider any specific facts or circumstances that may apply to a non-U.S. holder and does not address the special tax rules applicable to particular non-U.S. holders, such as:

- insurance companies;
- tax-exempt or governmental organizations;
- financial institutions;
- brokers or dealers in securities;
- regulated investment companies;
- pension plans;
- "controlled foreign corporations," "passive foreign investment companies," and corporations that accumulate earnings to avoid U.S. federal income tax;

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- “qualified foreign pension funds,” or entities wholly-owned by a “qualified foreign pension fund”;
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- persons who have elected to mark securities to market;
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation;
- persons subject to special tax accounting rules as a result of any item of gross income with respect to the common stock being taken into account in an applicable financial statement under Section 451(b) of the Code;
- persons that hold our common stock as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment; and
- certain U.S. expatriates.

This discussion is for general information only and is not tax advice. Accordingly, all prospective non-U.S. holders of our common stock should consult their tax advisors with respect to the U.S. federal, state, local and non-U.S. tax consequences of the purchase, ownership and disposition of our common stock.

Distributions on Our Common Stock

Distributions, if any, on our common stock will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the non-U.S. holder’s investment, up to such holder’s tax basis in the common stock. Any remaining excess will be treated as capital gain, subject to the tax treatment described below in “Gain on Sale, or Other Taxable Disposition of Our Common Stock.” Any such distributions will also be subject to the discussions below under the sections titled “Backup Withholding and Information Reporting” and “Withholding and Information Reporting Requirements—FATCA.”

Subject to the discussion in the following two paragraphs in this section, dividends paid to a non-U.S. holder generally will be subject to withholding of U.S. federal income tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder’s country of residence. If we or another withholding agent apply over-withholding or if a non-U.S. holder does not timely provide us with the required certification, the non-U.S. holder may be entitled to a refund or credit of any excess tax withheld by timely filing an appropriate claim with the IRS.

Dividends that are treated as effectively connected with a trade or business conducted by a non-U.S. holder within the United States and, if an applicable income tax treaty so provides, that are attributable to a permanent establishment or a fixed base maintained by the non-U.S. holder within the United States, are generally exempt from the 30% withholding tax if the non-U.S. holder satisfies applicable certification and disclosure requirements. However, such U.S. effectively connected income, net of specified deductions and credits, is taxed at the same graduated U.S. federal income tax rates applicable to United States persons (as defined in the Code). Any U.S. effectively connected income received by a non-U.S. holder that is a corporation may also, under certain circumstances, be subject to an additional “branch profits tax” at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder’s country of residence.

A non-U.S. holder of our common stock who claims the benefit of an applicable income tax treaty between the United States and such holder’s country of residence generally will be required to provide a properly executed IRS Form W-8BEN or W-8BEN-E (or successor form), as applicable, to the applicable withholding agent and satisfy applicable certification and other requirements. Non-U.S. holders are urged to consult their tax advisors regarding their entitlement to benefits under a relevant income tax treaty. A non-U.S. holder that is eligible for a reduced rate of U.S. withholding tax under an income tax treaty may obtain a refund or credit of any excess amounts withheld by timely filing a U.S. tax return with the IRS.

Gain on Sale or Other Taxable Disposition of Our Common Stock

Subject to the discussions below under “Backup Withholding and Information Reporting” and “Withholding and Information Reporting Requirements—FATCA,” a non-U.S. holder generally will not be subject to any U.S. federal income tax on any gain realized upon such holder’s sale or other taxable disposition of shares of our common stock unless:

- the gain is effectively connected with the non-U.S. holder’s conduct of a U.S. trade or business and, if an applicable income tax treaty so provides, is attributable to a permanent establishment or a fixed-base maintained by such non-U.S. holder in the United States, in which case the non-U.S. holder generally will be taxed on a net income basis at the graduated U.S. federal income tax rates applicable to United States persons (as defined in the Code) and, if the non-U.S. holder is a foreign corporation, the branch profits tax described above in “Distributions on Our Common Stock” also may apply;
- the non-U.S. holder is a nonresident alien individual who is present in the United States for a period or periods aggregating 183 days or more in the taxable year of the disposition and certain other conditions are met, in which case the non-U.S. holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder’s country of residence) on the net gain derived from the disposition, which may be offset by certain U.S. source capital losses of the non-U.S. holder, if any (even though the individual is not considered a resident of the United States), provided that the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses; or
- we are, or have been, at any time during the five-year period preceding such sale or other taxable disposition (or the non-U.S. holder’s holding period, if shorter) a “U.S. real property holding corporation,” unless our common stock is regularly traded on an established securities market and the non-U.S. holder holds no more than 5% of our outstanding common stock, directly or indirectly, actually or constructively, during the shorter of the 5-year period ending on the date of the disposition or the period that the non-U.S. holder held our common stock. Generally, a corporation is a U.S. real property holding corporation only if the fair market value of its U.S. real property interests equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. Although there can be no assurance, we do not believe that we are, or have been, a U.S. real property holding corporation, or that we are likely to become one in the future. No assurance can be provided that our common stock will be regularly traded on an established securities market for purposes of the rules described above.

Backup Withholding and Information Reporting

We must report annually to the IRS and to each non-U.S. holder the gross amount of the distributions on our common stock paid to such holder and the tax withheld, if any, with respect to such distributions. Non-U.S. holders may have to comply with specific certification procedures to establish that the holder is not a United States person (as defined in the Code) in order to avoid backup withholding at the applicable rate with respect to dividends on our common stock. Dividends paid to non-U.S. holders subject to withholding of U.S. federal income tax, as described above in “Distributions on Our Common Stock,” generally will be exempt from U.S. backup withholding.

Information reporting and backup withholding will generally apply to the proceeds of a disposition of our common stock by a non-U.S. holder effected by or through the U.S. office of any broker, U.S. or foreign, unless the holder certifies its status as a non-U.S. holder and satisfies certain other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a non-U.S. holder where the transaction is effected outside the United States through a non-U.S. office of a broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker.

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Non-U.S. holders should consult their tax advisors regarding the application of the information reporting and backup withholding rules to them. Copies of information returns may be made available to the tax authorities of the country in which the non-U.S. holder resides or is incorporated under the provisions of a specific treaty or agreement. Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a non-U.S. holder can be refunded or credited against the non-U.S. holder's U.S. federal income tax liability, if any, provided that an appropriate claim is filed with the IRS in a timely manner.

Withholding and Information Reporting Requirements—FATCA

The Foreign Account Tax Compliance Act and guidance issued thereunder, or FATCA, imposes withholding taxes on certain types of payments made to “foreign financial institutions” and certain other foreign entities (including financial intermediaries). FATCA generally imposes withholding at a rate of 30% on payments to certain foreign entities of dividends (including deemed dividends on warrants) on our common stock and certain other withholdable payments, unless various U.S. information reporting and due diligence requirements (generally relating to ownership by U.S. persons of interests in or accounts with those entities) have been satisfied or the entity otherwise qualifies for an exemption. An intergovernmental agreement between the United States and an applicable foreign country may modify these requirements. Such withholding may apply to gross proceeds from the sale or other disposition of our common stock, although under recently proposed U.S. Treasury Regulations, no withholding would apply to such gross proceeds. The preamble to the proposed regulations specifies that taxpayers (including withholding agents) are permitted to rely on the proposed regulations pending finalization. You should consult your tax advisor regarding the application of FATCA.

UNDERWRITING

Under the terms and subject to the conditions in an underwriting agreement dated the date of this prospectus, the underwriters named below, for whom Morgan Stanley & Co. LLC, SVB Leerink LLC, and Evercore Group LLC are acting as representatives, have severally agreed to purchase, and we have agreed to sell to them, severally, the number of shares indicated below:

<u>Name</u>	<u>Number of Shares</u>
Morgan Stanley & Co. LLC	
SVB Leerink LLC	
Evercore Group LLC	
H.C. Wainwright & Co., LLC	
Total:	<u>10,000,000</u>

The underwriters and the representatives are collectively referred to as the “underwriters” and the “representatives,” respectively. The underwriters are offering the shares of common stock subject to their acceptance of the shares from us and subject to prior sale. The underwriting agreement provides that the obligations of the several underwriters to pay for and accept delivery of the shares of common stock offered by this prospectus are subject to the approval of certain legal matters by their counsel and to certain other conditions. The underwriters are obligated to take and pay for all of the shares of common stock offered by this prospectus if any such shares are taken. However, the underwriters are not required to take or pay for the shares covered by the underwriter’s option to purchase additional shares described below.

The underwriters initially propose to offer part of the shares of common stock directly to the public at the offering price listed on the cover page of this prospectus and part to certain dealers at a price that represents a concession not in excess of \$ _____ per share under the public offering price. After the initial offering of the shares of common stock, the offering price and other selling terms may from time to time be varied by the representatives.

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to 1,500,000 additional shares of common stock at the public offering price listed on the cover page of this prospectus, less underwriting discounts and commissions. To the extent the option is exercised, each underwriter will become obligated, subject to certain conditions, to purchase about the same percentage of the additional shares of common stock as the number listed next to the underwriter’s name in the preceding table bears to the total number of shares of common stock listed next to the names of all underwriters in the preceding table.

The following table shows the per share and total public offering price, underwriting discounts and commissions, and proceeds before expenses to us. These amounts are shown assuming both no exercise and full exercise of the underwriters’ option to purchase up to an additional 1,500,000 shares of common stock.

	<u>Per Share</u>	<u>Total</u>	
		<u>No Exercise</u>	<u>Full Exercise</u>
Public offering price	\$	\$	\$
Underwriting discounts and commissions to be paid by us			
Proceeds, before expenses, to us	\$	\$	\$

The estimated offering expenses payable by us, exclusive of the underwriting discounts and commissions, are approximately \$2,900,000. We have agreed to reimburse the underwriters for expenses relating to clearance of this offering with the Financial Industry Regulatory Authority, or FINRA, for up to \$35,000.

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The underwriters have informed us that they do not intend sales to discretionary accounts to exceed 5% of the total number of shares of common stock offered by them.

Our common stock has been approved for listing on The Nasdaq Global Select Market under the trading symbol “CGEM”.

We have agreed that for a period ending 180 days after the date of this prospectus, or the restricted period, we will not, subject to certain exceptions, (1) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of common stock or any securities convertible into or exercisable or exchangeable for common stock or (2) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the common stock, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of common stock or such other securities, in cash or otherwise or (3) file any registration statement with the SEC relating to the offering of any shares of common stock or any securities convertible into or exercisable or exchangeable for common stock.

All of our directors and officers and certain other stockholders, representing approximately 95% of our current holders of units or other interests in Cullinan Oncology, LLC, have entered into lock-up agreements with the underwriters prior to the commencement of this initial public offering pursuant to which each of these persons or entities, has agreed not to, during the restricted period, without the prior written consent of the representatives: (1) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock or units of Cullinan Oncology, LLC beneficially owned (as such term is used in Rule 13d-3 of the Exchange Act, by the party subject to the lock-up restrictions or any other securities so owned convertible into or exercisable or exchangeable for common stock, units of Cullinan Oncology, LLC or such other securities or (2) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of common stock, units of Cullinan Oncology, LLC or such other securities, whether any such transaction described in (1) or (2) above is to be settled by delivery of common stock, units of Cullinan Oncology, LLC or such other securities, in cash or otherwise. The foregoing sentence shall not apply to any actions that the party subject to the lock-up restrictions may be required to take or may be necessary to take in connection with the reorganization; provided that any such securities shall remain subject to the terms of the lock-up agreement.

The restrictions described in the immediately preceding paragraph do not apply to:

(a) transactions relating to shares of common stock or other securities acquired in this public offering (other than any issuer directed shares of common stock purchased in this public offering) or in open market transactions after the completion of this public offering, *provided* that no filing under Section 16(a) of the Exchange Act shall be required or shall be voluntarily made in connection with subsequent sales of common stock or other securities acquired in such open market transactions;

(b) transfers of shares of common stock or any security convertible into or exercisable or exchangeable for common stock (i) as a bona fide gift or to a charitable organization or educational institution in a transfer not involving a disposition for value or (ii) if the party subject to the lock-up restrictions is a corporation, partnership or other business entity, as part of a disposition, transfer or distribution without consideration to limited partners or stockholders of such entity;

(c) transfers or dispositions of common stock or any security convertible into or exercisable or exchangeable for common stock to any member of the immediate family of the party subject to the lock-up restrictions or any trust for the direct or indirect benefit of the party subject to the lock-up restrictions or the immediate family of such person in a transaction not involving a disposition for value;

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(d) transfers or dispositions of common stock or any security convertible into or exercisable or exchangeable for common stock (i) by will, other testamentary document or intestate succession to the legal representative, heir, beneficiary or a member of the immediate family of the party subject to the lock-up restrictions upon the death of the party subject to the lock-up restrictions or (ii) by operation of law pursuant to orders of a court or regulatory agency, in connection with a negotiated divorce settlement or pursuant to a qualified domestic relations order;

(e) if the party subject to the lock-up restrictions is an entity, (x) transfers or distributions of common stock or any security convertible into common stock to general or limited partners, members or stockholders of such entity, its direct or indirect affiliates (as defined in Rule 405 promulgated under the Securities Act of 1933, as amended) or to an investment fund or other entity that controls or manages, or is under common control with, the party subject to the lock-up restrictions, or (y) distributions of common stock or any security convertible into common stock to partners, members, stockholders, beneficiaries or other equity holders of such entity;

(f) transfers or dispositions of common stock or any security convertible into or exercisable or exchangeable for common stock to the Company pursuant to any contractual arrangement in effect on the date of the lock-up agreement and disclosed to the underwriters in writing that provides for the repurchase of the party subject to the lock-up restrictions' common stock or other securities by the Company or in connection with the termination of the party subject to the lock-up restrictions' employment with or service to the Company; *provided* that any filing under Section 16(a) of the Exchange Act reporting a reduction in beneficial ownership of Common Stock shall indicate by footnote disclosure or otherwise the nature of the transfer or disposition;

(g) transfers or dispositions of common stock or other securities to the Company in connection with the conversion of any convertible security into, or the exercise of any option or warrant for, common stock (including by way of "net" or "cashless" exercise solely to cover withholding tax obligations in connection with such exercise and any transfer to the Company for the payment of taxes as a result of such exercise); *provided* that (i) any such common stock received by the party subject to the lock-up restrictions shall be subject to the terms of the lock-up agreement and (ii) no filing under Section 16 of the Exchange Act, reporting a reduction in beneficial ownership of common stock, or other public announcement shall be required or shall be voluntarily made during the restricted period (other than a filing on a Form 4 that reports such disposition under the transaction code "F" and indicates by footnote disclosure or otherwise the nature of the transfer or disposition);

(h) the establishment of a trading plan on behalf of a shareholder, officer or director of the Company pursuant to Rule 10b5-1 under the Exchange Act for the transfer of shares of common stock, *provided* that (i) such plan does not provide for the transfer of common stock during the restricted period and (ii) to the extent a public announcement or filing under the Exchange Act, if any, is required of or voluntarily made by or on behalf of the party subject to the lock-up restrictions or the Company regarding the establishment of such plan, such announcement or filing shall include a statement to the effect that no transfer of common stock may be made under such plan during the restricted period; or

(i) (i) transfers of common stock (or any securities convertible into or exercisable or exchangeable for common stock) pursuant to a bona fide third-party tender offer for shares of the Company's capital stock made to all holders of the Company's securities, merger, consolidation or other similar transaction approved by the Company's board of directors the result of which is that any person (as defined in Section 13(d)(3) of the Exchange Act), or group of persons, other than the Company, becomes the beneficial owner (as defined in Rules 13d-3 and 13d-5 of the Exchange Act) of more than 50% of the total voting power of the voting stock of the Company and (ii) entry into any lock-up, voting or similar agreement pursuant to which the party subject to the lock-up restrictions may agree to transfer, sell, tender or otherwise dispose of common stock or such other securities in connection with a transaction described in (i) above; *provided* that in the event that such change of control transaction is not completed, the common stock (or any security convertible into or exercisable or exchangeable for common stock) owned by the party subject to the lock-up restrictions shall remain subject to the restrictions contained in the lock-up agreement;

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provided that in the case of any transfer or distribution pursuant to (b), (c), (d) or (e) above, (i) each transferee, donee or distributee shall sign and deliver a lock-up letter substantially in the form of this letter and (ii) no filing under Section 16(a) of the Exchange Act, reporting a reduction in beneficial ownership common stock, or other public announcement shall be required or shall be voluntarily made during the restricted period (other than, in the case of a transfer or other disposition pursuant to (d) above, any Form 4 or Form 5 required to be filed under the Exchange Act if the party subject to the lock-up restrictions is subject to Section 16 reporting with respect to the Company under the Exchange Act, and any such filing will indicate by footnote disclosure or otherwise the nature of the transfer or disposition).

The representatives, in their sole discretion, may release the common stock and other securities subject to the lock-up agreements described above in whole or in part at any time.

In order to facilitate the offering of the common stock, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of the common stock. Specifically, the underwriters may sell more shares than they are obligated to purchase under the underwriting agreement, creating a short position. A short sale is covered if the short position is no greater than the number of shares available for purchase by the underwriters under their option to purchase additional shares. The underwriters can close out a covered short sale by exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to close out a covered short sale, the underwriters will consider, among other things, the open market price of shares compared to the price available under their option to purchase additional shares. The underwriters may also sell shares in excess of their option to purchase additional shares, creating a naked short position. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in this offering. As an additional means of facilitating this offering, the underwriters may bid for, and purchase, shares of common stock in the open market to stabilize the price of the common stock. These activities may raise or maintain the market price of the common stock above independent market levels or prevent or retard a decline in the market price of the common stock. The underwriters are not required to engage in these activities and may end any of these activities at any time.

We and the underwriters have agreed to indemnify each other against certain liabilities, including liabilities under the Securities Act.

A prospectus in electronic format may be made available on websites maintained by one or more underwriters, or selling group members, if any, participating in this offering. The representatives may agree to allocate a number of shares of common stock to underwriters for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters that may make Internet distributions on the same basis as other allocations.

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. Certain of the underwriters and their respective affiliates have, from time to time, performed, and may in the future perform, various financial advisory and investment banking services for us, for which they received or will receive customary fees and expenses.

In addition, in the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers and may at any time hold long and short positions in such securities and instruments. Such investment and securities activities may involve our securities and instruments. The underwriters and their respective affiliates may also make investment recommendations or publish or express independent research

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views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long or short positions in such securities and instruments.

An investment fund associated with SVB Leerink LLC purchased 507,614 units of our Series C Preferred Units in our December 2020 Series C Preferred Unit financing. Those units of Series C Preferred Units will convert into 72,114 shares of the Company's common stock prior to and in connection with the completion of this offering. As a result, such shares are deemed to be underwriting compensation pursuant to FINRA Rule 5110 and all such shares are subject to the 180-day lock-up restrictions pursuant to FINRA Rule 5110(e).

Pricing of the Offering

Prior to this offering, there has been no public market for our common stock. The initial public offering price was determined by negotiations between us and the representatives. Among the factors considered in determining the initial public offering price were our future prospects and those of our industry in general, our sales, earnings and certain other financial and operating information in recent periods, and the price-earnings ratios, price-sales ratios, market prices of securities, and certain financial and operating information of companies engaged in activities similar to ours.

Directed Share Program

At our request, the underwriters have reserved up to 5% of the shares of common stock to be issued by the Company and offered by this prospectus for sale, at the initial public offering price, to directors, officers, employees, business associates and related persons of the Company. Except for any shares acquired by our directors or officers, shares purchased pursuant to the directed share program will not be subject to lock-up agreements with the underwriters. The number of shares of common stock available for sale to the general public will be reduced to the extent these individuals purchase such reserved shares. Any reserved shares that are not so purchased will be offered by the underwriters to the general public on the same basis as the other shares offered by this prospectus.

Selling Restrictions

Australia

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission, or ASIC, in relation to the offering. This prospectus does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001, or the Corporations Act, and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of the shares may only be made to persons, or the Exempt Investors, who are "sophisticated investors" (within the meaning of section 708(8) of the Corporations Act), "professional investors" (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the shares without disclosure to investors under Chapter 6D of the Corporations Act.

The shares applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring shares must observe such Australian on-sale restrictions.

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This prospectus contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

Bermuda

The shares of our common stock may be offered or sold in Bermuda only in compliance with the provisions of the Investment Business Act of 2003 of Bermuda which regulates the sale of securities in Bermuda. Additionally, non-Bermudian persons (including companies) may not carry on or engage in any trade or business in Bermuda unless such persons are permitted to do so under applicable Bermuda legislation.

British Virgin Islands

The shares of our common stock are not being and may not be offered to the public or to any person in the British Virgin Islands for purchase or subscription by or on our behalf. The common stock may be offered to companies incorporated under the BVI Business Companies Act, 2004 (British Virgin Islands) (each a “BVI Company”), but only where the offer will be made to, and received by, the relevant BVI Company entirely outside of the British Virgin Islands.

This prospectus has not been, and will not be, registered with the Financial Services Commission of the British Virgin Islands. No registered prospectus has been or will be prepared in respect of the common stock for the purposes of the Securities and Investment Business Act, 2010 or the Public Issuers Code of the British Virgin Islands.

Canada

The shares of our common stock may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the shares of our common stock must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser’s province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser’s province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 (or, in the case of securities issued or guaranteed by the government of a non-Canadian jurisdiction, section 3A.4) of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Dubai International Finance Centre

This prospectus relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority, or the DFSA. This prospectus is intended for distribution only to persons of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other

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person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for the prospectus. The shares to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the shares offered should conduct their own due diligence on the shares. If you do not understand the contents of this prospectus you should consult an authorized financial advisor.

European Economic Area

In relation to each Member State of the European Economic Area and the United Kingdom (each, a “Relevant State”), no securities have been offered or will be offered pursuant to the offering to the public in that Relevant State prior to the publication of a prospectus in relation to the securities which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation, except that offers of securities may be made to the public in that Relevant State at any time under the following exemptions under the Prospectus Regulation:

- (a) to any legal entity which is a qualified investor as defined under the Prospectus Regulation;
- (b) to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), subject to obtaining the prior consent of the representatives; or
- (c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation, provided that no such offer of shares shall require us or any of our representatives to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

For the purposes of this provision, the expression an “offer to the public” in relation to any shares in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase any shares, and the expression “Prospectus Regulation” means Regulation (EU) 2017/1129 (as amended).

Hong Kong

The common stock has not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to “professional investors” as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance; or (b) in other circumstances which do not result in the document being a “prospectus” as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of that Ordinance. No advertisement, invitation or document relating to the common stock has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to common stock which is or is intended to be disposed of only to persons outside Hong Kong or only to “professional investors” as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance.

Israel

In the State of Israel this prospectus shall not be regarded as an offer to the public to purchase shares of common stock under the Israeli Securities Law, 5728—1968, which requires a prospectus to be published and authorized by the Israel Securities Authority, if it complies with certain provisions of Section 15 of the Israeli Securities Law, 5728—1968, including, inter alia, if: (i) the offer is made, distributed or directed to not more than 35 investors, subject to certain conditions (the “Addressed Investors”); or (ii) the offer is made, distributed

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or directed to certain qualified investors defined in the First Addendum of the Israeli Securities Law, 5728—1968, subject to certain conditions (the “Qualified Investors”). The Qualified Investors shall not be taken into account in the count of the Addressed Investors and may be offered to purchase securities in addition to the 35 Addressed Investors. The company has not and will not take any action that would require it to publish a prospectus in accordance with and subject to the Israeli Securities Law, 5728—1968. We have not and will not distribute this prospectus or make, distribute or direct an offer to subscribe for our common stock to any person within the State of Israel, other than to Qualified Investors and up to 35 Addressed Investors.

Qualified Investors may have to submit written evidence that they meet the definitions set out in of the First Addendum to the Israeli Securities Law, 5728—1968. In particular, we may request, as a condition to be offered common stock, that Qualified Investors will each represent, warrant and certify to us and/or to anyone acting on our behalf: (i) that it is an investor falling within one of the categories listed in the First Addendum to the Israeli Securities Law, 5728—1968; (ii) which of the categories listed in the First Addendum to the Israeli Securities Law, 5728—1968 regarding Qualified Investors is applicable to it; (iii) that it will abide by all provisions set forth in the Israeli Securities Law, 5728—1968 and the regulations promulgated thereunder in connection with the offer to be issued common stock; (iv) that the shares of common stock that it will be issued are, subject to exemptions available under the Israeli Securities Law, 5728—1968: (a) for its own account; (b) for investment purposes only; and (c) not issued with a view to resale within the State of Israel, other than in accordance with the provisions of the Israeli Securities Law, 5728—1968; and (v) that it is willing to provide further evidence of its Qualified Investor status. Addressed Investors may have to submit written evidence in respect of their identity and may have to sign and submit a declaration containing, inter alia, the Addressed Investor’s name, address and passport number or Israeli identification number.

Korea

The shares have not been and will not be registered under the Financial Investments Services and Capital Markets Act of Korea and the decrees and regulations thereunder (the “FSCMA”), and the shares have been and will be offered in Korea as a private placement under the FSCMA. None of the shares may be offered, sold or delivered directly or indirectly, or offered or sold to any person for re-offering or resale, directly or indirectly, in Korea or to any resident of Korea except pursuant to the applicable laws and regulations of Korea, including the FSCMA and the Foreign Exchange Transaction Law of Korea and the decrees and regulations thereunder (the “FETL”). The shares have not been listed on any of securities exchanges in the world including, without limitation, the Korea Exchange in Korea. Furthermore, the purchaser of the shares shall comply with all applicable regulatory requirements (including but not limited to requirements under the FETL) in connection with the purchase of the shares. By the purchase of the shares, the relevant holder thereof will be deemed to represent and warrant that if it is in Korea or is a resident of Korea, it purchased the shares pursuant to the applicable laws and regulations of Korea.

Malaysia

No prospectus or other offering material or document in connection with the offer and sale of the shares of our common stock has been or will be registered with the Securities Commission of Malaysia (“Commission”) for the Commission’s approval pursuant to the Capital Markets and Services Act 2007. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares of our common stock may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Malaysia other than (i) a closed end fund approved by the Commission; (ii) a holder of a Capital Markets Services License; (iii) a person who acquires the shares, as principal, if the offer is on terms that the shares may only be acquired at a consideration of not less than RM250,000 (or its equivalent in foreign currencies) for each transaction; (iv) an individual whose total net personal assets or total net joint assets with his or her spouse exceeds RM3 million (or its equivalent in foreign currencies), excluding the value of the primary residence of the individual; (v) an individual who has a gross annual income exceeding RM300,000 (or its

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equivalent in foreign currencies) per annum in the preceding 12 months; (vi) an individual who, jointly with his or her spouse, has a gross annual income of RM400,000 (or its equivalent in foreign currencies), per annum in the preceding 12 months; (vii) a corporation with total net assets exceeding RM10 million (or its equivalent in a foreign currencies) based on the last audited accounts; (viii) a partnership with total net assets exceeding RM10 million (or its equivalent in foreign currencies); (ix) a bank licensee or insurance licensee as defined in the Labuan Financial Services and Securities Act 2010; (x) an Islamic bank licensee or takaful licensee as defined in the Labuan Financial Services and Securities Act 2010; and (xi) any other person as may be specified by the Commission; provided that, in the each of the preceding categories (i) to (xi), the distribution of the shares is made by a holder of a Capital Markets Services License who carries on the business of dealing in securities. The distribution in Malaysia of this prospectus is subject to Malaysian laws. This prospectus does not constitute and may not be used for the purpose of public offering or an issue, offer for subscription or purchase, invitation to subscribe for or purchase any securities requiring the registration of a prospectus with the Commission under the Capital Markets and Services Act 2007.

People's Republic of China

This prospectus may not be circulated or distributed in the People's Republic of China, or the PRC, and the common stock may not be offered or sold to any person for re-offering or resale directly or indirectly to any resident of the PRC, except pursuant to applicable laws, rules and regulations of the PRC. For the purpose of this paragraph only, the PRC does not include Taiwan and the special administrative regions of Hong Kong and Macau.

Saudi Arabia

This prospectus may not be distributed in the Kingdom of Saudi Arabia except to such persons as are permitted under the Offers of Securities Regulations as issued by the board of the Saudi Arabian Capital Market Authority (the "CMA") pursuant to resolution number 2-11-2004 dated 4 October 2004 as amended by resolution number 1-28-2008, as amended. The CMA does not make any representation as to the accuracy or completeness of this prospectus and expressly disclaims any liability whatsoever for any loss arising from, or incurred in reliance upon, any part of this prospectus. Prospective purchasers of the shares offered hereby should conduct their own due diligence on the accuracy of the information relating to the shares. If you do not understand the contents of this prospectus, you should consult an authorized financial adviser.

Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the common stock may not be circulated or distributed, nor may the common stock be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor (as defined under Section 4A of the Securities and Futures Act, Chapter 289 of Singapore (the "SFA")) under Section 274 of the SFA, (ii) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA, in each case subject to conditions set forth in the SFA.

Where the shares of common stock are subscribed or purchased under Section 275 of the SFA by a relevant person which is a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor, the securities (as defined in Section 239(1) of the SFA) of that corporation shall not be transferable for 6 months after that corporation has acquired the shares under Section 275 of the SFA except: (1) to an institutional investor under Section 274 of the SFA or to a relevant

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person (as defined in Section 275(2) of the SFA), (2) where such transfer arises from an offer in that corporation's securities pursuant to Section 275(1A) of the SFA, (3) where no consideration is or will be given for the transfer, (4) where the transfer is by operation of law, (5) as specified in Section 276(7) of the SFA, or (6) as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore ("Regulation 32").

Where the shares of common stock are subscribed or purchased under Section 275 of the SFA by a relevant person which is a trust (where the trustee is not an accredited investor (as defined in Section 4A of the SFA)) whose sole purpose is to hold investments and each beneficiary of the trust is an accredited investor, the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferable for 6 months after that trust has acquired the shares under Section 275 of the SFA except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA), (2) where such transfer arises from an offer that is made on terms that such rights or interest are acquired at a consideration of not less than S\$200,000 (or its equivalent in a foreign currency) for each transaction (whether such amount is to be paid for in cash or by exchange of securities or other assets), (3) where no consideration is or will be given for the transfer, (4) where the transfer is by operation of law, (5) as specified in Section 276(7) of the SFA, or (6) as specified in Regulation 32.

Solely for the purposes of our obligations pursuant to Section 309B of the SFA, we have determined, and hereby notify all relevant persons (as defined in the Securities and Futures (Capital Markets Products) Regulations 2018 ("CMP Regulations")) that the shares of common stock are "prescribed capital markets products" (as defined in the CMP Regulations) and Excluded Investment Products (as defined in MAS Notice SFA 04-N12: Notice on the Sale of Investment Products and MAS Notice FAA-N16: Notice on Recommendations on Investment Products).

South Africa

Due to restrictions under the securities laws of South Africa, the shares of our common stock are not offered, and the offer shall not be transferred, sold, renounced or delivered, in South Africa or to a person with an address in South Africa, unless one or other of the following exemptions applies:

- (a) the offer, transfer, sale, renunciation or delivery is to:
 - (i) persons whose ordinary business is to deal in securities, as principal or agent;
 - (ii) the South African Public Investment Corporation;
 - (iii) persons or entities regulated by the Reserve Bank of South Africa;
 - (iv) authorized financial service providers under South African law;
 - (v) financial institutions recognized as such under South African law;
 - (vi) a wholly-owned subsidiary of any person or entity contemplated in (iii), (iv) or (v), acting as agent in the capacity of an authorized portfolio manager for a pension fund or collective investment scheme (in each case duly registered as such under South African law);
or
 - (vii) any combination of the person in (i) to (vi); or
- (b) the total contemplated acquisition cost of the securities, for any single addressee acting as principal is equal to or greater than ZAR1,000,000.

No "offer to the public" (as such term is defined in the South African Companies Act, No. 71 of 2008 (as amended or re-enacted) (the "South African Companies Act")) in South Africa is being made in connection with the issue of the common stock. Accordingly, this document does not, nor is it intended to, constitute a "registered prospectus" (as that term is defined in the South African Companies Act) prepared and registered under the South

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African Companies Act and has not been approved by, and/or filed with, the South African Companies and Intellectual Property Commission or any other regulatory authority in South Africa. Any issue or offering of the common stock in South Africa constitutes an offer of the common stock in South Africa for subscription or sale in South Africa only to persons who fall within the exemption from “offers to the public” set out in Section 96(1)(a) of the South African Companies Act. Accordingly, this document must not be acted on or relied on by persons in South Africa who do not fall within Section 96(1)(a) of the South African Companies Act (such persons being referred to as “SA Relevant Persons”). Any investment or investment activity to which this document relates is available in South Africa only to SA Relevant Persons and will be engaged in South Africa only with SA Relevant Persons.

Switzerland

This document is not intended to constitute an offer or solicitation to purchase or invest in the common stock described herein. The common stock may not be publicly offered, sold or advertised, directly or indirectly, in, into or from Switzerland and will not be listed on the SIX Swiss Exchange or on any other exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the common stock constitutes a prospectus as such term is understood pursuant to article 652a or article 1156 of the Swiss Code of Obligations or a listing prospectus within the meaning of the listing rules of the SIX Swiss Exchange or any other regulated trading facility in Switzerland, and neither this document nor any other offering or marketing material relating to the common stock may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, nor the Company nor the common stock have been or will be filed with or approved by any Swiss regulatory authority. The common stock is not subject to the supervision by any Swiss regulatory authority, e.g., the Swiss Financial Markets Supervisory Authority FINMAG, and investors in the common stock will not benefit from protection or supervision by such authority.

Taiwan

The shares have not been and will not be registered with the Financial Supervisory Commission of Taiwan pursuant to relevant securities laws and regulations and may not be sold, issued or offered within Taiwan through a public offering or in circumstances which constitutes an offer within the meaning of the Securities and Exchange Act of Taiwan that requires a registration or approval of the Financial Supervisory Commission of Taiwan. No person or entity in Taiwan has been authorized to offer, sell, give advice regarding or otherwise intermediate the offering and sale of the shares in Taiwan.

United Arab Emirates

The shares have not been, and are not being, publicly offered, sold, promoted or advertised in the United Arab Emirates (including the Dubai International Financial Centre) other than in compliance with the laws of the United Arab Emirates (and the Dubai International Financial Centre) governing the issue, offering and sale of securities. Further, this prospectus does not constitute a public offer of securities in the United Arab Emirates (including the Dubai International Financial Centre) and is not intended to be a public offer. This prospectus has not been approved by or filed with the Central Bank of the United Arab Emirates, the Securities and Commodities Authority or the Dubai Financial Services Authority.

United Kingdom

Each underwriter has represented and agreed that:

- (a) it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of

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Section 21 of the Financial Services and Markets Act 2000 (“FSMA”) received by it in connection with the issue or sale of the shares of our common stock in circumstances in which Section 21(1) of the FSMA does not apply to us; and

- (b) it has complied and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the shares of our common stock in, from or otherwise involving the United Kingdom.

LEGAL MATTERS

The validity of the common stock offered hereby will be passed upon for us by Goodwin Procter LLP, Boston, Massachusetts and for the underwriters by Ropes & Gray LLP, Boston, Massachusetts.

EXPERTS

The consolidated financial statements of Cullinan Oncology, LLC as of December 31, 2018 and 2019, and for each of the years then ended, have been included herein in reliance upon the report of KPMG LLP, an independent registered public accounting firm, appearing elsewhere herein, and upon the authority of said firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 (File Number 333-251512) under the Securities Act with respect to the common stock we are offering by this prospectus. This prospectus, which constitutes part of the registration statement, does not contain all of the information included in the registration statement. For further information pertaining to us and our common stock, you should refer to the registration statement and to its exhibits. Whenever we make reference in this prospectus to any of our contracts, agreements or other documents, the references are not necessarily complete, and you should refer to the exhibits attached to the registration statement for copies of the actual contract, agreement or other document.

Upon the completion of the offering, we will be subject to the informational requirements of the Exchange Act and will file annual, quarterly and current reports, proxy statements and other information with the SEC. You can read our SEC filings, including the registration statement, at the SEC's website at www.sec.gov. We also maintain a website at www.cullinanoncology.com. The information contained in or accessible from our website is not incorporated into this prospectus, and you should not consider it part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

CULLINAN ONCOLOGY, LLC

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Report of Independent Registered Public Accounting Firm

To the Members and Board of Directors
Cullinan Oncology, LLC.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Cullinan Oncology, LLC and subsidiaries (the Company) as of December 31, 2018 and 2019, the related consolidated statements of operations and comprehensive loss, redeemable preferred units and members' deficit, 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, 2018 and 2019, 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. 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
November 2, 2020

CULLINAN ONCOLOGY, LLC
CONSOLIDATED BALANCE SHEETS
(in thousands, except units and per unit amounts)

	<u>December 31,</u> <u>2018</u>	<u>December 31,</u> <u>2019</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 33,832	\$ 63,250
Prepaid expenses and other current assets	387	1,461
Short term investments	—	35,380
Total current assets	34,219	100,091
Property and equipment, net	233	182
Other assets	188	188
Total assets	<u>\$ 34,640</u>	<u>\$ 100,461</u>
Liabilities, Redeemable Preferred Units and Members' Deficit		
Current liabilities:		
Accounts payable	\$ 296	\$ 934
Accrued expenses and other current liabilities	1,028	1,589
Total current liabilities	1,324	2,523
Long-term liabilities:		
Deferred rent	64	73
Total liabilities	1,388	2,596
Commitments and contingencies (Note 10)		
Redeemable preferred units:		
Series Seed redeemable preferred units, \$0.0001 par value: 16,000,000 units authorized, issued and outstanding (liquidation value: \$4,769) at December 31, 2018 and December 31, 2019.	3,956	3,956
Series A1 redeemable preferred units, \$0.0001 par value: 50,000,000 units authorized, issued and outstanding (liquidation value: \$58,030) at December 31, 2018 and December 31, 2019.	49,946	49,946
Series B redeemable preferred units, \$0.0001 par value: 64,200,000 authorized, 0 and 54,006,407 units issued and outstanding (liquidation value: \$85,469) at December 31, 2018 and December 31, 2019, respectively.	—	83,872
Total redeemable preferred units	53,902	137,774
Members' deficit:		
Non-voting incentive units, \$0.0001 par value: 23,860,000 units authorized, 12,276,000 and 11,896,500 units issued and outstanding at December 31, 2018 and December 31, 2019, respectively	1	1
Common units, \$0.0001 par value: no shares authorized, issued and outstanding at December 31, 2018 and 2019	—	—
Noncontrolling interest in subsidiaries	1	864
Additional paid-in capital	214	770
Accumulated other comprehensive loss	—	(4)
Accumulated deficit	(20,866)	(41,540)
Total members' deficit	(20,650)	(39,909)
Total liabilities, redeemable preferred units and members' deficit	<u>\$ 34,640</u>	<u>\$ 100,461</u>

See accompanying notes to consolidated financial statements.

CULLINAN ONCOLOGY, LLC
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except units and per unit amounts)

	Year Ended December 31,	
	2018	2019
Operating expenses:		
Research and development	\$ 9,584	\$ 16,788
General and administrative	5,002	5,482
Total operating expenses	<u>14,586</u>	<u>22,270</u>
Loss from operations	(14,586)	(22,270)
Other income (expense):		
Interest income	397	620
Other income (expense), net	—	(4)
Net loss	<u>(14,189)</u>	<u>(21,654)</u>
Net loss attributable to noncontrolling interest	—	(97)
Net loss attributable to Cullinan	<u>\$ (14,189)</u>	<u>\$ (20,657)</u>
Net loss per unit attributable to common and non-voting incentive unitholders, basic and diluted	<u>\$ (5.56)</u>	<u>\$ (3.23)</u>
Total weighted-average common and non-voting incentive units used in computing net loss per unit, basic and diluted	<u>2,549,865</u>	<u>6,397,443</u>
Comprehensive loss:		
Net loss	\$ (14,189)	\$ (21,654)
Unrealized loss on investments	—	(4)
Comprehensive loss	<u>(14,189)</u>	<u>\$ (21,658)</u>
Comprehensive loss attributable to noncontrolling interest	—	(97)
Comprehensive loss attributable to Cullinan	<u>\$ (14,189)</u>	<u>\$ (20,661)</u>
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)		<u>\$ (1.80)</u>
Total weighted-average common stock outstanding used in computing pro forma net loss per unit, basic and diluted (unaudited)		<u>11,449,625</u>

See accompanying notes to consolidated financial statements.

CULLINAN ONCOLOGY, LLC
CONSOLIDATED STATEMENTS OF REDEEMABLE PREFERRED UNITS AND MEMBERS' DEFICIT
(in thousands, except units and per unit amounts)

	Redeemable Preferred Units		Non-Voting Incentive Units		Noncontrolling Interest in Subsidiaries	Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Members' Deficit
	Units	Amount	Units	Amount					
Balances at December 31, 2017	66,000,000	\$ 53,923	11,088,000	\$ 1	\$ 1	\$ —	\$ —	\$ (6,707)	\$ (6,705)
Issuance cost of Series A preferred units	—	(21)	—	—	—	—	—	—	—
Issuance costs of subsidiary preferred stock	—	—	—	—	—	—	—	(9)	(9)
Issuance of non-voting incentive units	—	—	1,188,000	—	—	—	—	—	—
Issuance of subsidiary common stock	—	—	—	—	1	214	—	—	215
Dissolution of subsidiaries	—	—	—	—	(1)	—	—	39	38
Net loss	—	—	—	—	—	—	—	(14,189)	(14,189)
Balances at December 31, 2018	66,000,000	\$ 53,902	12,276,000	\$ 1	\$ 1	\$ 214	\$ —	\$ (20,866)	\$ (20,650)
Issuance of Series B preferred units net of issuance costs of \$378	54,006,407	83,872	—	—	—	—	—	—	—
Issuance subsidiary preferred stock	—	—	—	—	1,860	—	—	(17)	1,843
Forfeiture of non-voting incentive units	—	—	(379,500)	—	—	—	—	—	—
Stock based compensation	—	—	—	—	—	17	—	—	17
Issuance of subsidiary common stock	—	—	—	—	—	539	—	—	539
Unrealized loss on investments	—	—	—	—	—	—	(4)	—	(4)
Net loss	—	—	—	—	(997)	—	—	(20,657)	(21,654)
Balances at December 31, 2019	120,006,407	\$ 137,774	11,896,500	\$ 1	\$ 864	\$ 770	\$ (4)	\$ (41,540)	\$ (39,909)

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31,	
	2018	2019
Operating activities:		
Net loss	\$ (14,189)	\$ (21,654)
Adjustments to reconcile net loss to net cash used in operating activities:		
License expense in exchange for subsidiary common stock	214	539
Depreciation and amortization	43	70
Share-based compensation expense	—	17
Dissolution of subsidiaries	38	—
Unrealized loss on investments	—	(4)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(176)	(1,074)
Accounts payable	225	639
Accrued expenses and other current liabilities	232	560
Deferred rent	64	10
Net cash used in operating activities	<u>(13,549)</u>	<u>(20,897)</u>
Investing activities:		
Purchases of property and equipment	(261)	(20)
Purchase of available-for-sale securities	—	(35,380)
Net cash used in investing activities	<u>(261)</u>	<u>(35,400)</u>
Financing activities:		
Proceeds from issuance of Series B Redeemable Preferred Units	—	84,250
Proceeds from issuance of noncontrolling interests	—	1,860
Payment of issuance costs related to Series B Redeemable Preferred Units	(21)	(378)
Issuance costs of subsidiary preferred stock	(9)	(17)
Proceeds from issuance of subsidiary common stock	1	—
Net cash (used in)/provided by financing activities	<u>(29)</u>	<u>85,715</u>
Net (decrease)/increase in cash and cash equivalents	(13,839)	29,418
Cash and cash equivalents at beginning of year	47,671	33,832
Cash and cash equivalents at end of year	<u>\$ 33,832</u>	<u>\$ 63,250</u>

See accompanying notes to consolidated financial statements.

CULLINAN ONCOLOGY, LLC
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(1) Nature of Business and Basis of Presentation

Organization

Cullinan Oncology, LLC (the LLC), together with its consolidated subsidiaries (Cullinan or the Company), is a biopharmaceutical company developing a diversified pipeline of targeted oncology and immuno-oncology therapies with transformative potential for cancer patients.

Each therapeutic candidate is developed within a separate subsidiary of the LLC. At December 31, 2018, the LLC had three development subsidiaries: Cullinan Apollo Corp. (Apollo), Cullinan Pearl Corp. (Pearl) and Cullinan Polykine Corp. (Polykine), in addition to its wholly owned operating subsidiary, Cullinan Management, Inc. (Management). At December 31, 2019, the LLC had four development subsidiaries: Apollo, Pearl, Cullinan Amber Corp. (Amber), and Cullinan Florentine Corp. (Florentine), in addition to Management (together, the Subsidiaries). In 2018, Cullinan Alaras Corp. (Alaras), Cullinan Senovax Corp. (Senovax) and Cullinan Wittelsbach Corp. (Wittelsbach) were liquidated, and in 2019, Polykine was liquidated following management's decision to terminate research and development. See Note 4 for further detail.

The Company is 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. The Company's therapeutic programs will require significant additional research and development efforts, including pre-clinical 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 the Company's research and development will be successfully completed, that adequate protection for the Company's intellectual property will be obtained, that any products developed will obtain necessary government regulatory approval or that any approved products will be commercially viable.

Liquidity

The Company has funded its operations primarily through the sale of redeemable preferred units. As of December 31, 2019, the LLC has received from investors \$137.8 million in cumulative net proceeds. See Note 5 for further detail.

The Company has incurred operating losses and has had negative cash flows from operations since its inception. The Company's net loss was \$14.2 million and \$21.7 million for the years ended December 31, 2018 and 2019, respectively. As of December 31, 2019, the Company has an accumulated deficit of \$41.5 million. The Company expects to continue to generate operating losses for the foreseeable future. The Company expects that its cash, cash equivalents, and short term investments as of December 31, 2019 of \$98.6 million, along with the \$14.3 million received from the sale of its Series B Redeemable Preferred Units in February and March 2020 (see Notes 5 and 13) will be sufficient to fund its operating expenses and capital expenditure requirements through at least the next twelve months from the date of issuance of these consolidated financial statements. The future viability of the Company is dependent on the success of its research and development and its ability to access additional capital to fund its operations. There can be no assurance that the current operating plan will be achieved or that additional funding will be available on terms acceptable to the Company, or at all.

CULLINAN ONCOLOGY, LLC
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(2) Summary of Significant Accounting Policies***Basis of Presentation and Use of Estimates***

The accompanying consolidated financial statements of the Company have been prepared in conformity with accounting principles generally accepted in the United States of America (GAAP) and include the accounts of the LLC and its consolidated subsidiaries. All intercompany balances have been eliminated in consolidation. Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification (ASC) and Accounting Standards Updates (ASUs) of the Financial Accounting Standards Board (FASB).

The preparation of financial statements in accordance with GAAP requires the Company's management to make estimates and judgments that may affect the reported amounts of assets, liabilities, expenses, and related disclosure of contingent assets and liabilities. On an ongoing basis, the Company's management evaluates the estimates, including those related to expenses and accruals. The Company's management bases its estimates on historical experience, and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Estimates and assumptions reflected in these consolidated financial statements include but are not limited to the fair value of the royalty transfer agreements, accrued research and development costs, the valuation of the non-voting incentive units, as well as restricted stock awards and common stock issued by the LLC's subsidiaries. Actual results may differ from these estimates under different assumptions or conditions.

Principles of Consolidation

The LLC consolidates entities in which it has a controlling financial interest. The LLC 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. The LLC has concluded that none of its subsidiaries is a VIE and has consolidated each subsidiary under the voting interest model. Under the voting interest model, 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 has either created or made investments in the following entities:

<u>Consolidated Entities</u>	<u>Relationship as of December 31, 2019</u>	<u>Date Control First Acquired</u>
Cullinan Management, Inc.	Wholly-owned Subsidiary	September 2016
Cullinan Apollo Corp.	Partially-owned Subsidiary	November 2018
Cullinan Pearl Corp.	Partially-owned Subsidiary	November 2018
Cullinan Amber Corp.	Partially-owned Subsidiary	December 2019
Cullinan Florentine Corp.	Partially-owned Subsidiary	December 2019

Noncontrolling Interests

To the extent that ownership interests in the Subsidiaries are held by entities other than the LLC, management reports these as noncontrolling interests on the consolidated balance sheets. Earnings or losses are attributed to noncontrolling interests under the hypothetical liquidation at book value (HLBV) method. The HLBV method is a point in time calculation that utilizes inputs to determine the amount that the Company and

CULLINAN ONCOLOGY, LLC
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

the noncontrolling interest holders would receive upon a hypothetical liquidation at each balance sheet date based on the liquidation provisions of the respective articles of incorporation. At December 31, 2018, a licensor held a noncontrolling interest in Apollo, and at December 31, 2019, licensors held noncontrolling interests in Apollo and Pearl, as described further in Note 4. Under the HLBV method, \$1.0 million of losses in Pearl were attributed to noncontrolling interests in 2019 because the licensor also owned preferred stock. In 2018 and 2019, no loss was allocated to the licensors or restricted stockholders that held noncontrolling interests in Apollo.

Comprehensive Loss

Comprehensive 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. For the year ended December 31, 2018, comprehensive loss was equal to net loss. For the year ended December 31, 2019, the Company recognized less than \$0.1 million in unrealized loss on investments.

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 United States.

Concentration of Credit Risk and Other Risks and Uncertainties

The Company has no significant off-balance sheet risk. Cash and cash equivalents are primarily maintained with two major financial institutions in the United States. Deposits at banks may exceed the insurance provided on such deposits. These deposits may be redeemed upon demand, and therefore, bear minimal risk.

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, Cash Equivalents, and Short Term Investments

The Company considers all highly liquid investments with original maturities of three months or less at the time of purchase to be cash equivalents. Investments not classified as cash equivalents with maturities of less than twelve months are classified as short-term available-for-sale marketable securities. Available-for-sale marketable securities are carried at estimated fair value, with unrealized gains or losses included in accumulated other comprehensive loss in members' deficit. The fair value of marketable securities is based on available market information. The amortized cost of debt securities is adjusted for amortization of premiums and accretion

CULLINAN ONCOLOGY, LLC
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of discounts to maturity. Such amortization is included in interest income. Interest and dividends are also included in interest income. Declines in fair value judged to be other-than-temporary on available-for-sale securities, if any, are included in other income (expense), net.

As of December 31, 2018, the Company's financial assets were comprised entirely of cash and cash equivalents.

The Company recognized its short term investment marketable securities by security type at December 31, 2019:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
		(in thousands)		
Corporate notes	\$ 19,718	\$ 2	\$ (6)	\$ 19,714
Commercial paper	5,571	—	—	5,571
Asset-backed securities	5,068	—	—	5,068
U.S. government notes	5,027	—	—	5,027
	<u>\$ 35,384</u>	<u>\$ 2</u>	<u>\$ (6)</u>	<u>\$ 35,380</u>

Fair Value of Financial Instruments

Certain assets and liabilities are carried at fair value under GAAP. The fair value hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets (Level 1) and the lowest priority to unobservable inputs (Level 3). As required by FASB ASC Topic 820, *Fair Value Measurement* (ASC Topic 820) the Company's financial assets are classified within the fair value hierarchy based on the lowest level of input that is significant to the fair value measurement. The three levels of the fair value hierarchy under ASC Topic 820, and its applicability to the Company's financial assets, are described below:

Level 1—Unadjusted quoted prices in active markets that are accessible at the measurement date of identical, unrestricted assets.

Level 2—Quoted prices for similar assets, or inputs that are observable, either directly or indirectly, for substantially the full term through corroboration with observable market data.

Level 3—Pricing inputs are unobservable for the asset, that is, inputs that reflect the reporting entity's own assumptions about the assumptions market participants would use in pricing the asset.

Asset-backed securities, commercial paper, and corporate and U.S. government notes are primarily valued using market quotations or prices obtained from independent pricing sources which may employ various pricing methods to value the investments including matrix pricing.

As of December 31, 2018, the Company's financial assets, comprising of cash and cash equivalents, are classified as Level 1 assets.

CULLINAN ONCOLOGY, LLC
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

The following table sets forth the fair value of the Company's financial assets as of December 31, 2019, allocated into Level 1, Level 2, and Level 3, that was measured on a recurring basis (in thousands):

	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
Cash and cash equivalents				
Cash	\$ 8,240	\$ —	\$ —	\$ 8,240
Money market funds	52,597	—	—	52,597
Corporate notes	—	2,413	—	2,413
Short term investments				
Corporate notes	—	19,714	—	19,714
Commercial paper	—	5,571	—	5,571
Asset-backed securities	—	5,068	—	5,068
U.S. government notes	—	5,027	—	5,027
	<u>\$60,837</u>	<u>\$37,793</u>	<u>\$ —</u>	<u>\$98,630</u>

Prepaid expenses and other current assets, accounts payable and accrued expenses and other current liabilities are carried at cost, which management believes approximates fair value due to their short term nature.

Property and Equipment

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

Computers	3 years
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 sale or retirement of assets, the cost and accumulated depreciation and amortization are removed from the consolidated balance sheet and any resulting gain or loss is reflected in the consolidated statement of operations and comprehensive loss in the period realized.

Property and equipment consisted of the following:

	<u>December 31,</u>	
	<u>2018</u>	<u>2019</u>
	(in thousands)	
Computers	\$ 46	\$ 60
Office furniture and equipment	130	134
Leasehold improvements	103	105
Total property and equipment, gross	279	299
Less: accumulated depreciation	(46)	(117)
Total property and equipment, net	<u>\$233</u>	<u>\$ 182</u>

Depreciation and amortization expense were less than \$0.1 million for each of the years ended December 31, 2018 and 2019.

CULLINAN ONCOLOGY, LLC
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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. There was no impairment of long-lived assets for any of the periods presented.

Research and Development Costs

Research and development costs are expensed as incurred and consist primarily of funds for employee wages and funds paid to 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 United States. The payments related to these agreements are recorded as research and development expenses as incurred. The Company records accrued liabilities for estimated ongoing research 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. To date, there have been no material differences between the Company's accrued costs and actual costs.

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 loss.

Classification of the Redeemable Preferred Units

The Company has classified all of its outstanding redeemable Series Seed preferred units (the Series Seed Redeemable Preferred Units), redeemable Series A1 preferred units (the Series A Redeemable Preferred Units), redeemable Series B preferred units (the Series B Redeemable Preferred Units) or, collectively, the Redeemable Preferred Units, outside of members' deficit in the accompanying consolidated balance sheets because these units contain certain redemption features that are not solely within the control of the Company. See Note 5. Once the redemption of the Redeemable Preferred Units becomes probable of occurring, the carrying amount of the Redeemable Preferred Units will be accreted to their redemption value.

CULLINAN ONCOLOGY, LLC
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Equity-Based Compensation

Equity-based compensation is measured at the grant date for all equity-based awards made to employees and non-employees based on the fair value of the awards and is recognized as expense on a straight-line basis over the requisite service period, which is generally the vesting period. The Company has elected to recognize the actual forfeitures by reducing the equity-based compensation in the same period as the forfeitures occur.

The LLC has granted non-voting incentive units to employees and non-employees. These awards generally have only a service condition and vest over a period of up to four years. The Company's subsidiaries have granted stock options that are exercisable in the underlying entity's common stock and have issued restricted stock awards in the underlying entity's common stock to employees and non-employees. These awards generally have only a service condition and generally vest over a period of up to four years. None of the awards issued by the subsidiaries are issued for the LLC members' capital.

Because there is no public market for the Company's non-voting incentive units or the Subsidiaries' restricted stock awards, as it is a private company, the Company's board of directors has determined the fair value of non-voting incentive units and restricted stock awards by considering a number of objective and subjective factors, including having contemporaneous and retrospective valuations of its equity performed by a third-party valuation specialist, valuations of comparable peer public companies, sales of its redeemable preferred units, operating and financial performance, the lack of liquidity of the Company's common and non-voting incentive units, and general and industry-specific economic outlook. The fair value of the Company's non-voting incentive units and restricted stock awards are determined by its board of directors.

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

Income Taxes

The LLC has elected to be treated under the Partnership provisions of the Internal Revenue Code. Accordingly, the Company is not viewed as a tax-paying entity in any jurisdiction and all income and deductions of the LLC are reported on the members' individual income tax returns and no income taxes are recorded by the LLC. The LLC does not have any operations.

The Subsidiaries are taxed as corporations for federal and state income tax purposes. The Subsidiaries account for income taxes using the asset and liability method in accordance with FASB ASC Topic 740, *Income Taxes*. Current income taxes are based on taxable income for federal and state reporting purposes. Deferred income 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 using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. A valuation allowance is provided when it is more likely than not that some portion, or all of a deferred tax asset will not be realized. Due to the Subsidiaries' lack of earnings history, the net deferred tax assets have been fully offset by a valuation allowance at both December 31, 2018 and 2019.

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

CULLINAN ONCOLOGY, LLC
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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.

As described in “Recently Adopted Accounting Pronouncements” below, the Company early adopted multiple accounting standards, as 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.

Net Loss per Unit

The holders of the Company’s Redeemable Preferred Units are entitled to receive distributions, including cumulative returns on their units outstanding, prior and in preference to any distributions on any of the Company’s Common Units and Non-Voting Incentive Units, which are also entitled to cumulative returns. For the years ended December 31, 2018 and 2019, the Company determined that its common stock equivalents are its Common Units and vested Non-Voting Incentive Units.

The Company follows the two-class method when computing net loss per unit as the Company has issued units that meet the definition of participating securities. The two-class method determines net income (loss) per unit for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common unitholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed. For the years ended December 31, 2018 and 2019, the Company considers its Redeemable Preferred Units to be participating securities as they are entitled to participate in undistributed earnings along with Common Unit and vested Non-Voting Incentive Unit members. Unvested Non-Voting Incentive Units are not considered participating securities.

Basic net loss per unit attributable to common non-voting incentive unit holders is computed by dividing the net loss attributable to common non-voting incentive unit holders by the weighted average number of common non-voting incentive units outstanding for the period. Diluted net loss attributable to common non-voting incentive unit holders is computed by adjusting net loss attributable to common non-voting incentive unit holders to reallocate undistributed earnings based on the potential impact of dilutive securities. Diluted net loss per unit attributable to common non-voting incentive unit holders is computed by dividing the diluted net loss attributable to common non-voting incentive unit holders by the weighted average number of common non-voting incentive unit units outstanding for the period, including potential dilutive common non-voting incentive unit units. For purposes of this calculation, unvested Non-Voting Incentive Units and Redeemable Preferred Units are considered potential dilutive common units.

The Company’s Redeemable Preferred Units contractually entitle the holders of such units to participate in dividends but does not contractually require the holders of such units to participate in losses of the Company. Accordingly, in periods in which the Company reports a net loss attributable to common unit holders, such losses

CULLINAN ONCOLOGY, LLC
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are not allocated to such participating securities. In periods in which the Company reports a net loss attributable to common unitholders, diluted net loss per unit attributable to common unitholders is the same as basic net loss per unit attributable to common unit holders, since dilutive common units are not assumed to have been issued if their effect is anti-dilutive. The Company reported a net loss attributable to Common Unit holders for the years ended December 31, 2018 and 2019.

Unaudited Pro Forma Net Loss per Share

The unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the year ended December 31, 2019 has been prepared to give effect to the exchange of all outstanding redeemable preferred units and vested non-voting incentive units of the LLC into shares of common stock of the Corporation upon the Reorganization as if the Reorganization had occurred on the later of the beginning of the period or the issuance date of the redeemable preferred units and to give effect for a one-for-7.0390 reverse share split of its issued and outstanding common shares.

Recently Adopted Accounting Pronouncements

In November 2015, the FASB issued ASU 2015-17 *Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes* (ASU 2015-17), which simplifies the presentation of deferred taxes in a classified balance sheet by eliminating the requirement to separate deferred income tax liabilities and assets into current and noncurrent amounts. Instead, ASU 2015-17 requires that all deferred tax liabilities and assets be shown as noncurrent in a classified balance sheet. ASU 2015-17 is effective for fiscal years beginning after December 15, 2017 and may be applied either prospectively or retrospectively to all periods presented. The Company adopted this guidance on January 1, 2018. The consolidated balance sheets as of December 31, 2018 and 2019 are presented in accordance with this guidance.

Recently Issued Accounting Pronouncements Not Yet Adopted

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, to increase transparency and comparability among organizations by recognizing a right-of-use asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either operating or financing, with such classifications affecting the pattern of expense recognition in the income statement. ASU 2016-02 is effective for fiscal years beginning after December 15, 2019, and early adoption is permitted. ASU 2016-02 was recently delayed for emerging growth companies that elected to adopt new accounting standards on the adoption date required for private companies and will be effective for the Company's annual reporting period beginning on January 1, 2022 and interim periods beginning first quarter of 2023. The Company is evaluating the impact ASU 2016-02 will have on its consolidated financial statements and associated disclosures.

In August 2018, the FASB issued ASU No. 2018-13, *Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurements*, which changes the fair value measurement disclosure requirements of ASC Topic 820. The updated guidance improves the disclosure requirements on fair value measurements and is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted upon issuance of the standard for disclosures modified or removed with a delay of adoption of the additional disclosures until their effective date. The adoption of ASU 2018-13 is not expected to materially impact the Company's consolidated financial statements and associated disclosures.

In November 2018, the FASB issued ASU No. 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction Between Topic 808 and Topic 606* (ASU 2018-18). The amendments in this update clarify that certain transactions between collaborative arrangement participants should be accounted for as revenue when the collaborative arrangement participant is a customer in the context of a unit of account and

CULLINAN ONCOLOGY, LLC
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precludes recognizing as revenue consideration received from a collaborative arrangement participant if the participant is not a customer. The standard is effective for the Company beginning January 1, 2021. The Company is currently evaluating the potential impact ASU 2018-18 may have on its consolidated financial position and consolidated results of operations upon adoption.

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* (ASU 2019-12), which is intended to simplify the accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. The new standard will be effective beginning January 1, 2022. The Company does not expect the adoption of ASU 2019-12 to have a material impact on its consolidated financial position and consolidated results of operations upon adoption.

In August 2020, FASB issued ASU No. 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity’s Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity’s Own Equity*, which, among other things, provides guidance on how to account for contracts on an entity’s own equity. This ASU simplifies the accounting for certain financial instruments with characteristics of liabilities and equity. Specifically, the ASU eliminated the need for the Company to assess whether a contract on the entity’s own equity (1) permits settlement in unregistered shares, (2) whether counterparty rights rank higher than shareholder’s rights, and (3) whether collateral is required. In addition, the ASU requires incremental disclosure related to contracts on the entity’s own equity and clarifies the treatment of certain financial instruments accounted for under this ASU on earnings per share. This ASU may be applied on a full retrospective or modified retrospective basis. This ASU is effective January 1, 2022 including interim periods presented within that year. Early adoption of the ASU is permitted by the Company effective January 1, 2021. The Company is in the process of assessing the adoption of the ASU on the Company’s consolidated financial statements.

(3) Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

	December 31, 2018	2019
	(in thousands)	
Accrued bonus	\$ 480	\$ 523
Consultants fees	263	231
Professional fees	199	152
Research and development costs	59	656
Other	27	27
	<u>\$1,028</u>	<u>\$1,589</u>

(4) License and Collaboration Agreements (Subsidiary – Licensor/Collaborator)

Alaras—ADT Pharmaceuticals, Inc.

In May 2017, Alaras entered into a license and collaboration agreement with ADT Pharmaceuticals, Inc. (ADT) to discover and develop a first-in-class pan-RAS inhibitor (ADT Agreement). Under the terms of the ADT Agreement, Alaras paid a nonrefundable up-front license fee and issued shares of common stock to ADT in exchange for the worldwide, exclusive rights to research and develop ADT’s RAS inhibitors. In addition, Alaras

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agreed to pay ADT an annual research and consulting fee of \$0.5 million, payable monthly in arrears, for a four-year period, unless otherwise terminated as specified in the ADT Agreement. Research and consulting fees totaling \$0.1 million are recorded in research and development expenses in the accompanying consolidated statements of operations and comprehensive loss for the year ended December 31, 2018.

In February 2018, research and development did not generate data to support further advancement of the program and Alaras provided notice of termination to ADT under the ADT Agreement. Following the required notice period and upon consent of the Alaras' board of directors, Alaras was dissolved in June 2018.

Senovax—Avidea Technologies, Inc.

In October 2017, Senovax entered into a research, option and license agreement with Avidea Technologies, Inc. (Avidea) for Avidea to perform contracted research for Senovax on its vaccine technology platform (Avidea Agreement). The Avidea Agreement provides Senovax with an exclusive right and option to acquire licenses at a future date. Under the terms of the Avidea Agreement, Senovax paid a nonrefundable up-front collaboration fee. Senovax also agreed to pay Avidea research and consulting fees of \$0.3 million under the work plan specified in the Avidea Agreement. The up-front collaboration fee and the research and consulting fees were recorded as research and development expense in the accompanying consolidated statements of operations and comprehensive loss for the year ended December 31, 2018.

Early research and development did not generate data to support further advancement of the program and, in September 2018, Senovax provided notice of termination to Avidea under the Avidea Agreement. In November 2018, upon consent of the Senovax's board of directors, Senovax was dissolved.

Wittelsbach—MAB Discovery GmbH

In January 2018, Wittelsbach entered into an option and license agreement with MAB Discovery GmbH (MAB) to develop a novel agonistic antibody (MAB Agreement). Under the terms of the MAB Agreement, Wittelsbach paid a nonrefundable option fee and issued shares of its common stock to MAB in exchange for the worldwide, exclusive rights to research and develop the MAB antibody. The option fee of \$0.6 million was recorded as research and development expense in the accompanying consolidated statement of operations and comprehensive loss for the year ended December 31, 2018.

In September 2018, Wittelsbach decided the data did not support advancement of the program and provided notice of termination to MAB under the MAB Agreement. Following the required notice period and upon consent of the Wittelsbach's board of directors, Wittelsbach was dissolved in December 2018.

Management—Adimab

In November 2018, Management entered into a collaboration agreement with Adimab, LLC (Adimab) (the Adimab Collaboration Agreement). Pursuant to the Adimab Collaboration Agreement, Management 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, Management 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, Management has a non-exclusive worldwide license under Adimab's technology to perform certain research activities and to evaluate the program antibodies to determine whether Management wants to exercise its option to obtain a royalty-free, fully paid, non-exclusive license to exploit such antibodies and sublicense through multiple tiers.

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Under the Adimab Collaboration Agreement, Management paid a one-time, non-creditable, non-refundable technology access fee. Management 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. Management 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 recorded research and development expenses in the consolidated statements of operations and comprehensive loss related to the Adimab Collaboration Agreement of \$0.1 million and \$0.8 million for the years ended December 31, 2018 and 2019, respectively.

Furthermore, Management 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.

Management 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.

Apollo—The Wistar Institute

In December 2018, Apollo entered into a license agreement with The Wistar Institute (Wistar) to discover and develop a novel Epstein-Barr Nuclear Antigen 1 (EBNA1) inhibitor (the Wistar Agreement). Under the terms of the Wistar Agreement, Apollo paid a nonrefundable up-front option and license fee and issued shares of Apollo common stock to Wistar in exchange for the worldwide, exclusive rights to research and develop Wistar's EBNA1 inhibitor. The up-front license fee and fair value of the common stock granted of \$3.2 million are recorded as research and development expense in the accompanying consolidated statements of operations and comprehensive loss for the year ended December 31, 2018. The Wistar Agreement also provides for Wistar to receive milestone payments upon achievement of patent rights and product development targets and royalties on future sales of licensed products. In December 2018, the Company also entered into a Collaborative Research Agreement with Wistar to continue preclinical research and development with potential product candidate. These studies are budgeted to cost \$1.5 million over a three-year timeline. The Company recorded research and development expenses of zero dollars and \$0.5 million in the consolidated statements of operations and comprehensive loss related to these agreements for the years ended December 31, 2018 and 2019, respectively.

Pearl—Taiho Pharmaceuticals, Co. Ltd

In February 2019, Pearl entered into a license and collaboration agreement with Taiho Pharmaceuticals, Co. Ltd (Taiho Pharma) to develop a novel epidermal growth factor receptor (EGFR) inhibitor (the Taiho License Agreement).

As consideration for the license for worldwide exclusive development rights, excluding Japan, Pearl paid an initial, non-refundable, non-creditable license fee and issued an affiliate of Taiho Pharma a percentage of Pearl's outstanding capital stock. In addition, Pearl is obligated to pay non-refundable, non-creditable research and development and regulatory milestone payments up to \$44.5 million in aggregate and sales milestone payments up to \$110.0 million in aggregate upon the occurrence of certain events. Each milestone is payable only once. No milestones have been achieved to date under the Taiho License Agreement. The up-front license fee and fair

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value of the common stock granted are recorded as research and development expense in the accompanying consolidated statements of operations and comprehensive loss for the year ended December 31, 2019.

Furthermore, Pearl is required to pay running low single digit to low double digit royalty percentages of annual aggregate net sales on a country-by-country and product-by-product basis during the royalty term, subject to certain offsets, deductions or reductions related to loss or impairment of exclusivity in the territory. The obligation to pay royalties is imposed only once with respect to net sales of the same unit of a licensed product. 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 patent which covers a product in such country, (b) the expiration of any exclusivity granted by a regulatory authority and (c) a low double-digit anniversary following the first commercial sale of a product in such country.

In the event (i) Taiho Pharma does not exercise its right of negotiation with respect to a licensed product or (ii) Taiho Pharma does exercise its right of negotiation, but the parties do not consummate a transaction, then at the time Pearl enters into a subsequent transaction with a third party for (a) less than all or less than substantially all of Pearl's rights in a licensed product, Pearl is also obligated to pay Taiho Pharma a mid single digit to low double digit percentage of revenue from such transactions or (b) all or substantially all of Pearl's rights in a licensed product, Pearl is obligated to pay Taiho Pharma a low single digit to mid single digit percentage of revenue from such transactions, provided, however, that such payment under (b) shall not be required following the consummation of Pearl's initial public offering.

In parallel with the execution of the Taiho License Agreement, Pearl entered into a Series A Preferred Stock Purchase Agreement with the LLC and Taiho Ventures, LLC (Taiho Ventures) to sell up to 23,000,000 shares of Pearl's Series A Preferred Stock for \$1.00 per share. The LLC and Taiho Ventures invested \$14.0 million in the initial closing. The Series A Preferred Stock Purchase Agreement obligated Pearl to sell, and the LLC and Taiho Ventures to purchase, at \$1.00 per share, an aggregate of 9,000,000 shares of Pearl's Series A Preferred Stock at a subsequent closing, which shall occur on the approval of Pearl's board of directors or if the cash balance of Pearl is below \$1.0 million. The Company determined that Pearl's second Series A Preferred Stock tranche is separable and therefore a freestanding instrument, but the fair value of the tranche right is not material as of and for the year ended December 31, 2019. Pearl completed the second closing in August 2020. See Note 13. The Company recorded research and development expenses of zero and \$3.0 million in the consolidated statements of operations and comprehensive loss related to this license agreement, for the years ended December 31, 2018 and 2019, respectively.

Amber—Massachusetts Institute of Technology

In December 2019, Amber entered into an Exclusive Patent License Agreement with Massachusetts Institute of Technology (MIT) to develop a cancer immunotherapy product worldwide (the MIT License Agreement). Under the terms of the MIT License Agreement, Amber paid an upfront nonrefundable license fee upon execution. Additionally, Amber issued shares of its common stock to MIT and founder upon execution of its Series A Preferred financing in April 2020 as consideration for the licenses granted.

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 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. During the year ended December 31, 2019, the Company recognized research and development expense in the statements of operations and comprehensive loss of less than \$0.1 million in connection with this agreement.

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Additionally, Amber shall pay certain non-refundable, non-creditable milestone payments up to \$7.0 million and \$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, Amber is required to pay a specified change in control fee and Amber's clinical and regulatory milestone payments shall be increased by 100%.

Furthermore, 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. 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.

(5) Redeemable Preferred Units

In October 2016, the LLC issued 16,000,000 units of Series Seed Redeemable Preferred Units at a price of \$0.25 per share, resulting in net proceeds of \$4.0 million. In April 2017, the LLC issued 50,000,000 of Series A Redeemable Preferred Units at a price of \$1.00 per share, resulting in net proceeds of \$49.9 million. In 2019, the LLC authorized a \$100.0 million Series B Redeemable Preferred Unit financing. Upon the first two closings during 2019, the LLC issued 54,006,407 of Series B Redeemable Preferred Units at \$1.56 per share, resulting in net proceeds of \$83.9 million. Two subsequent closings were completed in February and March 2020. See Note 13 for further detail.

Outstanding Redeemable Preferred Units consist of the following:

	As of December 31, 2018		
	Units Issued and Outstanding	Original Issue Price Per Unit	Carrying Value (thousands)
Seed Redeemable Preferred Units	16,000,000	\$ 0.25	\$ 3,956
Series A Redeemable Preferred Units	50,000,000	\$ 1.00	49,946
Total Redeemable Preferred Units as of December 31, 2018	66,000,000		\$ 53,902

	As of December 31, 2019		
	Units Issued and Outstanding	Original Issue Price Per Unit	Carrying Value (thousands)
Seed Redeemable Preferred Units	16,000,000	\$ 0.25	\$ 3,956
Series A Redeemable Preferred Units	50,000,000	\$ 1.00	49,946
Series B Redeemable Preferred Units	54,006,407	\$ 1.56	83,872
Total Redeemable Preferred Units as of December 31, 2019	120,006,407		\$ 137,774

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The preferred unit holders are not liable for any debt, obligation, or liability of the LLC. The rights, preferences, and privileges of the Series Seed Redeemable Preferred Units, the Series A Redeemable Preferred Units, and the Series B Redeemable Preferred Units (collectively the Redeemable Preferred Units) are as follows:

Voting

The holders of Redeemable Preferred Units vote together with the holders of the Common Units as a single class. Each holder is entitled to one vote per unit. The holders of the Redeemable Preferred Units must consent to certain material changes in the LLC entity. The LLC is managed by a board of directors which consists of seven members. At all times during which the Series A Redeemable Preferred Unit holders hold at least 10% of the originally issued Series A Redeemable Preferred Units, the Series A Redeemable Preferred unitholders are entitled to elect two directors. At all times during which certain Series B Redeemable Preferred unitholders hold at least 10% of the originally issued Series B Redeemable Preferred Units, the Series B Redeemable Preferred unitholders are entitled to elect one director. The three directors appointed by the Series A and Series B Redeemable Preferred unitholders are referred to as the Preferred Directors. The remaining board members consist of the LLC's chief executive officer (CEO); two people mutually acceptable to a majority of the other members of the board, including each of the three Preferred Directors (the Independent Directors); and one independent person who shall be designated by a majority of the Preferred Directors and who does not have an affiliation with any of the board members or the Company.

Dividends

The holders of Redeemable Preferred Units are entitled to receive cumulative accruing dividends upon liquidation or redemption of the Company. Dividends accrue at the rate of 6% per annum of the original issuance price of the Redeemable Preferred Units commencing on the date of issuance of the Redeemable Preferred Units and ending at the date of liquidation. At December 31, 2019, \$0.8 million, \$8.0 million and \$1.2 million of dividends have accrued on the Series Seed Redeemable Preferred Units, Series A Redeemable Preferred Units, and Series B Redeemable Preferred Units, respectively. At December 31, 2018, \$0.5 million and \$5.0 million of dividends were accrued on the Series Seed Redeemable Preferred Units and Series A Redeemable Preferred Units, respectively. The dividends are only payable upon liquidation or redemption of the LLC and therefore are not accrued on the consolidated balance sheets and are not a part of the net loss per unit calculation.

Liquidation

At the written consent of the board of directors and a vote of two-thirds of the outstanding majority interest of the holders of Redeemable Preferred Units, the Company may effect a merger or other change in control event, as defined, or may be liquidated and dissolved.

Upon merger, change in control, liquidation, dissolution or winding-up of the Company, the holders of the Series B Redeemable Preferred Units are entitled to be paid first out of assets available for distribution for the amount equal to the Series B Redeemable Preferred Unit original issuance price per unit plus accrued, cumulative dividends. Second, the holders of the Series Seed Redeemable Preferred Units and Series A Redeemable Preferred Units are entitled to be paid on a pari pasu basis the amount equal to the Series Seed Redeemable Preferred Unit and Series A Redeemable Preferred Unit original issuance price per unit plus accrued, cumulative dividends. Third, the Common Unit and Non-Voting Incentive Unit holders are then entitled to be paid pro rata an amount equal to the Series Seed Redeemable Preferred Unit issuance price per unit. Fourth, the Common Unit holders, Non-Voting Incentive Unit holders and Series Seed Redeemable Preferred Unit holders are entitled to be paid pro rata an amount per unit such that cumulative proceeds upon liquidation equal the Series A Redeemable Preferred Unit issuance price per unit, subject to any adjustment ratios in effect, if any.

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Fifth, the Common Unit holders, Non-Voting Incentive Unit holders, Series Seed Redeemable Preferred Unit holders and Series A Redeemable Preferred Unit holders are entitled to be paid pro rata an amount per unit such that cumulative proceeds upon liquidation equal the Series B Redeemable Preferred Unit issuance price per unit. Finally, all Redeemable Preferred Unit holders, Common Unit holders, and vested Non-Voting Incentive Unit holders share pro rata in any remaining proceeds.

(6) Common Units, Non-Voting Incentive Units and Noncontrolling Interest in Subsidiaries

Common Units

As of December 31, 2018 and 2019, per the Second Amended and Restated LLC Agreement (the LLC Agreement), no Common Units were authorized. Common Units are entitled to one vote per unit and to receive dividends when and if declared by the board of directors of the LLC. The Common Unit holders are not liable for any debt, obligation, or liability of the LLC.

Non-Voting Incentive Units

As of December 31, 2019, the LLC Agreement provides for the issuance of up to 23,860,000 Non-Voting Incentive Units for grant under Amendment No. 1 of the 2016 Equity Incentive Plan (the Plan). In 2018, the LLC issued Non-Voting Incentive Units at a purchase price of \$0.0001 per share under the Plan, as further detailed below in Note 7. In 2019, the LLC did not issue any Non-Voting Incentive Units. Non-Voting Incentive Units do not carry the right to vote.

Noncontrolling Interest in Subsidiaries

Certain Subsidiaries issue common stock in connection with licensing agreements, as further detailed in Note 4, and to employees, directors and consultants pursuant to subsidiary equity incentive plans.

In 2018, upon inception, Apollo reserved 15,000,000 shares of common stock, Wittelsbach reserved 17,000,000 shares of common stock and Polykine reserved 50,000,000 shares of common stock for future issuances upon conversion of preferred shares and issuance of equity grants under the Subsidiaries' respective equity incentive plans. In 2018, Apollo, Pearl, Polykine and Wittelsbach issued restricted shares of their common stock under their equity incentive plans at a purchase price of \$0.0001 per share, as further detailed below in Note 7.

In 2018, within one month of inception, Pearl reserved 2,800,000 shares of common stock for issuances upon equity grants under its 2018 Equity Incentive Plan and authorized 23,000,000 shares of Series A Preferred Stock. In 2019, Pearl issued shares of common stock to Taiho Pharma as compensation for the Taiho License Agreement and, to complete the initial close of its Series A Preferred Stock financing, issued 14,000,000 shares of Series A Preferred Stock, a portion of which were purchased by Taiho Ventures. In 2019, Pearl issued 93,000 common stock options to certain of its directors under its equity incentive plan at a fair value of \$0.18 per share and recorded less than \$0.1 million of stock compensation expense, recorded as general and administrative expense. Under the HLBV method, \$1.0 million of losses were attributed to non-controlling interests in 2019 due to Taiho Ventures' preferred stock ownership in Pearl, as further detailed in Note 4.

In 2019, upon inception, Amber reserved 2,400,200 shares of common stock and Florentine reserved 2,337,857 shares of common stock for future issuances upon equity grants under the Subsidiaries' respective 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 Series A Preferred Stock.

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(7) Equity-Based Compensation

Non-Voting Incentive Units

The LLC's 2016 Equity Incentive Plan (the Plan) provides for the grant of Non-Voting Incentive Units to employees, consultants, advisors and directors, as determined by the board of directors. Vesting is determined by the board of directors. Awards typically provide for vesting of 25% of units at the end of the first year of service with the remaining 75% vesting ratably on a monthly basis over the following three-year period. Unvested Non-Voting Incentive Units may not be sold or transferred by the holder and are subject to repurchase by the LLC if service terminates prior to vesting at a price equal to the amount the recipient paid for the Non-Voting Incentive Units. These restrictions lapse according to the time-based vesting conditions of each award. Non-Voting Incentive Units are granted at a price of not less than the fair value of the Common Unit on the date of grant.

During the year ended December 31, 2018, the Company issued 1,188,000 Non-Voting Incentive Units. The Company did not issue any Non-Voting Incentive Units during the year ended December 31, 2019. On the grant date, the fair value of the LLC's Common Units for accounting purposes is determined by the board of directors, with input from management. Compensation expense was recognized on the Non-Voting Incentive Units using the fair value on the date of grant of \$0.0001 per unit. Given the early stage nature of the underlying technology and inherent risks associated with obtaining regulatory approval and achieving commercialization, the Company used the current value method to fair value the Non-Voting Incentive Units granted since inception and during the year ended December 31, 2018. As of December 31, 2019, there were 11,963,500 Non-Voting Incentive Units available for future grant under the Plan.

A summary of the Non-Voting Incentive Unit activity for the years ended December 31, 2018 and 2019 is as follows:

	Number of Units	Weighted Average Grant Date Fair Value Per Unit
Outstanding unvested as of December 31, 2017	11,088,000	\$ 0.0001
Granted	1,188,000	0.0001
Vested	(4,791,600)	0.0001
Cancelled	—	—
Outstanding unvested as of December 31, 2018	7,484,400	\$ 0.0001
Granted	—	—
Vested	(3,019,500)	0.0001
Cancelled	(379,500)	—
Outstanding unvested as of December 31, 2019	4,085,400	\$ 0.0001
Outstanding vested as of December 31, 2019	7,811,100	\$ 0.0001

Restricted Stock Grants

The respective boards of directors of certain Subsidiaries have authorized equity incentive plans for the grant of stock options and restricted stock awards in the Subsidiaries to employees, consultants, advisors and directors. Vesting is determined by each Subsidiaries' board of directors. Unvested restricted shares may not be sold or transferred by the holder and are subject to repurchase by the Subsidiaries if service terminates prior to vesting at a price equal to the amount the recipient paid for the restricted stock. These restrictions lapse according

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to the time-based vesting conditions of each award. Awards typically provide for vesting of 25% of units at the end of the first year of service with the remaining 75% vesting ratably on a monthly basis over the following three-year period. Restricted common stock are granted at a price of not less than the fair value of the common stock on the date of grant.

Active Subsidiaries:

Restricted common stock and stock option award activity for the years ended December 31, 2018 and 2019 was:

	Amber	Apollo	Florentine	Pearl
Approved Pool 2018	—	2,120,000	—	2,800,000
Restricted common stock granted	—	(1,480,710)	—	(1,959,405)
Available Pool	—	639,290	—	840,595
Approved Pool 2019	2,400,200	—	2,337,857	—
Restricted common stock granted	(511,530)	—	(728,678)	—
Stock options granted	—	—	—	(93,000)
Forfeited	—	67,690	—	89,573
Available Pool	<u>1,888,670</u>	<u>706,980</u>	<u>1,609,179</u>	<u>837,168</u>

The fair values of Apollo and Pearl common stock in 2018, and of Amber and Florentine in 2019, for accounting purposes was determined by their respective boards of directors, with input from management, at \$0.0001 per share. Refer to Note 6 for discussion of the fair value of awards issued from Pearl in 2019.

A summary of the restricted common stock activity for the years ended December 31, 2018 and 2019 is as follows:

	Amber	Apollo	Florentine	Pearl	Weighted Average Grant Date Fair Value Per Unit
Outstanding unvested as of December 31, 2017	—	—	—	—	
Granted	—	1,480,710	—	1,959,407	\$ 0.0001
Outstanding unvested as of December 31, 2018	—	1,480,710	—	1,959,407	0.0001
Granted	511,530	—	728,678	—	0.0001
Vested	—	(353,257)	—	(467,460)	0.0001
Cancelled	—	(67,690)	—	(89,573)	0.0001
Outstanding unvested as of December 31, 2019	<u>511,530</u>	<u>1,059,763</u>	<u>728,678</u>	<u>1,402,374</u>	<u>\$ 0.0001</u>
Outstanding vested as of December 31, 2019	<u>—</u>	<u>353,257</u>	<u>—</u>	<u>467,460</u>	<u>\$ 0.0001</u>

Dissolved Subsidiaries:

During the year ended December 31, 2018, Polykine issued 4,040,000 restricted common stock, all of which were cancelled upon liquidation of Polykine in May 2019. During the year ended December 31, 2018, Wittelsbach issued 1,600,015 restricted common stock, all of which were cancelled upon liquidation of Wittelsbach in December 2018. During the year ended December 31, 2018, all restricted stock issued during 2017 were cancelled at Alaras and Senovax upon liquidation of the subsidiaries in 2018.

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Equity-based compensation:

The Company recorded equity-based compensation in the following expense categories in the consolidated statement of operations and comprehensive loss:

	Year ended December 31,	
	2018	2019
	(in thousands)	
Research and development	\$ —	\$ —
General and administrative	—	17
Total equity-based compensation	<u>\$ —</u>	<u>\$ 17</u>

As of December 31, 2019, the unrecognized equity-based compensation is nominal.

(8) Related Party Transactions

MPM Capital is a significant investor in the Company through one of its managed funds. In October 2016, the Company also began receiving consulting and management services pursuant to agreements with a Managing Director at MPM Capital and a principal at F2 Ventures, also a significant investor in the Company. For the years ended December 31, 2018 and 2019, the Company incurred \$0.2 million and \$0.3 million, respectively, for management and advisory services in connection with those agreements and were recorded as general and administrative expense.

In 2018, the Company paid MPM Capital less than \$0.1 million for temporary office space and other operational support. For the year ended December 31, 2019, the Company paid MPM Capital less than \$0.1 million for other operational support. These expenses were recorded as general and administrative expense.

During the years ended December 31, 2018 and 2019, the Company provided temporary office space to a private biotech company financed by MPM Capital. The Company charged the private biotech company for its desk and received \$0.1 million and less than \$0.1 million in payments from the private biotech company for the years ended December 31, 2018 and 2019, respectively, and were recorded as a reduction to general and administrative expense.

In October and December 2019, the Company's subsidiaries Amber, Apollo, Florentine, and Pearl entered into royalty transfer agreements with MPM Oncology Charitable Foundation, Inc. and UBS Optimus Foundation (together, the Foundations). Under these agreements, each Foundation is entitled to receive a royalty equal to 0.5% (1.0% in aggregate) of all global net sales of any products developed by the 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. Management has concluded that these instruments had no value at the inception of the agreements or at December 31, 2019.

As of December 31, 2019, Amber and Florentine had options to programs in pre-clinical research, while Apollo and Pearl's programs were in phase 1 clinical trials. Given that these programs are all still in early stages of development and face inherent technical, regulatory, and competitive risks associated with achieving approval and commercialization, the Company ascribed no value to the royalty agreement as of December 31, 2019. The Company currently does not have any net sales or license income and as a result has paid no royalties under these obligation as of December 31, 2019 nor has the Company accrued any liability as of December 31, 2019. The Company will monitor these instruments for changes in fair value at each reporting date.

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(9) Income Taxes

For financial reporting purposes, the Subsidiaries' loss before taxes for the years ended December 31, 2018 and 2019 were as follows (in thousands):

	Year ended December 31,	
	2018	2019
	(in thousands)	
Management	\$ (4,956)	\$ (8,094)
Alaras	(338)	—
Senovax	(381)	—
Polykine	(219)	(12)
Wittelsbach	(3,244)	—
Apollo	(4,629)	(4,531)
Pearl	(547)	(7,497)
Amber	—	(515)
Florentine	—	(1,092)
	<u>\$ (14,314)</u>	<u>\$ (21,741)</u>

A reconciliation of the Company's statutory income tax rate to the Company's effective income tax rate is as follows for the years ended December 31, 2018 and 2019:

	Year ended December 31,	
	2018	2019
Federal statutory rate	21%	21%
State taxes, net of Federal benefit	6.37%	6.22%
Permanent differences	0.16%	0.06%
Tax credits	1.13%	2.54%
Valuation allowance	(15.37%)	(30.65%)
Writeoff of deferred taxes for Alaras, Senovax, and Wittelsbach	(12.74%)	0.00%
Other	(0.55%)	0.83%
	<u>—</u>	<u>—</u>

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The principal components of the Company's deferred tax assets and liabilities at December 31, 2018 and 2019 are as follows (in thousands):

	December 31,	
	2018	2019
	(in thousands)	
Deferred tax assets:		
Net operating loss	\$ 2,921	\$ 8,031
Capitalized organizational and start-up expenses	187	173
Licenses	815	1,622
Accrued expenses	72	163
Research and development credit	150	682
Gross deferred tax assets	4,145	10,671
Valuation allowance	(4,110)	(10,653)
Net deferred tax asset	35	18
Deferred tax liability		
Depreciation and amortization	(35)	(18)
Net deferred tax asset	\$ —	\$ —

As of December 31, 2019, the Company had federal and state net operating loss (NOL) carryforwards of \$28.5 million and \$32.5 million, respectively. The Company generated federal net operating losses of \$3.0 million prior to 2018, which begin to expire in 2037. State losses also begin to expire in 2037. The Company generated combined federal NOLs of \$25.5 million in 2018 and 2019 which can be carried forward indefinitely. As of December 31, 2019, the Company had federal and state research and development tax credit carryforwards of \$0.6 million and \$0.1 million, respectively, which begin to expire in 2037 and 2033, respectively.

Utilization of the net operating loss carryforwards and research and development tax credits may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986 (Section 382) due to ownership change limitations that have occurred previously or that could occur in the future in accordance with Section 382, as well as similar state provisions. These ownership changes may limit the amount of NOL carryforwards that can be utilized annually to offset future taxable income. In general, an ownership change as defined by Section 382 results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50 percentage points over a three-year period.

CULLINAN ONCOLOGY, LLC
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Cullinan has evaluated the positive and negative evidence bearing upon its ability to realize the deferred tax assets, which are comprised principally of net operating loss carryforwards, licenses, and research and development credit carryforwards. Management has considered the Company's history of net losses since inception and its lack of commercialization of any products and has concluded that it is more likely than not the Company will not realize the benefits of the deferred tax assets. The Company's valuation allowance increased during the years ended December 31, 2018 and 2019 due primarily to the generation of net operating losses, as follows (in thousands):

	Year ended December 31,	
	2018	2019
Valuation allowance at beginning of year	\$ 1,930	\$ 4,110
Increases recorded to income tax provision	2,180	6,543
Valuation allowance at end of year	<u>\$ 4,110</u>	<u>\$ 10,653</u>

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. ASC 740 states that a tax benefit from an uncertain tax position may be recognized 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 in accordance with ASC 740 and adjusts these liabilities when its judgment changes as a result of the evaluation of new information not previously available. Because of 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, 2018 and 2019, the Company has not recorded 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 statement of operations and comprehensive loss. As of December 31, 2018 and 2019, no accrued interest or penalties are included in the consolidated balance sheet.

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 United States. There are currently no pending tax examinations. The Company thus is still open under the U.S. statute from 2016 to the present. 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 Internal Revenue Service and the state tax authorities to the extent utilized in a future period. The Company had not, as yet, conducted a study of research and development tax credit carryforwards. This study may result in an adjustment to the Company's research and development credit carryforwards; however, until a study is completed, and any adjustment is known, no amounts are being presented as an uncertain tax position. A full valuation allowance has been provided against the Company's research and development credits and, if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Thus, there would be no impact to the balance sheets or statements of operations and comprehensive loss if an adjustment was required.

On March 27, 2020, the United States enacted the Coronavirus Aid, Relief and Economic Security Act (CARES Act). The CARES Act is an emergency economic stimulus package that includes spending and tax

CULLINAN ONCOLOGY, LLC
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

breaks to strengthen the United States economy and fund a nationwide effort to curtail the effect of COVID-19. While the CARES Act provides sweeping tax changes in response to the COVID-19 pandemic, some of the more significant provisions include removal of certain limitations on utilization of net operating losses, increasing the loss carryback period for certain losses to five years, and increasing the ability to deduct interest expense, as well as amending certain provisions of the previously enacted Tax Cuts and Jobs Act. The CARES Act does not have a material impact on the Company's financial position, results of operations or cash flows.

(10) Commitments and Contingencies

Operating Lease

Rent expense for each of the years ended December 31, 2018 and 2019 was \$0.5 million.

In December 2017, the LLC signed an operating lease for 7,531 rentable square feet of office space in Cambridge, Massachusetts to commence on February 1, 2018. The lease expires on June 30, 2024. Rent expense will be recorded ratably over the lease period. The lease includes escalating rental payments, which are also being charged to rent expense ratably over the lease period.

The following table summarizes future minimum payments due under the operating lease as of December 31, 2019 (in thousands):

<u>Years Ending December 31,</u>	
2020	\$ 590
2021	599
2022	608
2023	618
2024	313
	<u>\$2,728</u>

(11) Employee Benefit Plan

The Company maintains a defined contribution 401(k) plan (the 401(k) Plan) in which employees may contribute a portion of their compensation, subject to statutory maximum contribution amounts. The Company assumes all administrative costs of the 401(k) Plan. For each of the years ended December 31, 2018 and 2019, the expense relating to the matching contribution was less than \$0.1 million.

CULLINAN ONCOLOGY, LLC
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(12) Net Loss per Unit

The following table sets forth the calculation of basic and diluted net loss per unit:

	2018	Year ended December 31, 2019
	(in thousands, except unit and per unit data)	
Numerator:		
Net loss attributable to Common and Non-Voting Incentive unitholders	\$ (14,189)	\$ (20,657)
Denominator		
Total weighted-average Common and Non-Voting Incentive units used in computing net loss per unit, basic and diluted	2,549,865	6,397,443
Net Loss per Unit:	\$ (5.56)	\$ (3.23)

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

	Year ended December 31,	
	2018	2019
Redeemable Preferred Units	66,000,000	120,006,407
Unvested Non-Voting Incentive Units	7,484,400	4,085,400
Total	73,484,400	124,091,807

Unaudited Pro Forma Net Loss per Share

The unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the year ended December 31, 2019 has been prepared to give effect to the exchange of all outstanding Redeemable Preferred Units and Non-Voting Incentive Units of the LLC into shares of common stock of the newly formed corporation upon the reorganization as if the reorganization had occurred on the later of the beginning of the period or the issuance date of the Redeemable Preferred Units and to give effect for a one-for-7.0390 reverse share split of its issued and outstanding common shares.

CULLINAN ONCOLOGY, LLC
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Unaudited pro forma basic and diluted net loss per share attributable to common stockholders was calculated as follows:

	<u>Year Ended</u> <u>December 31, 2019</u> (in thousands, except share and per share data)
Numerator:	
Loss attributable to Common and Non-Voting Incentive units	\$ (20,657)
Pro forma adjustments to loss attributable to Common stockholders	—
Pro forma net loss attributable to Common stockholders	<u>\$ (20,657)</u>
Denominator:	
Total weighted-average Common and Non-Voting Incentive units outstanding—basic and diluted	—
Pro forma adjustment to reflect the assumed exchange of outstanding units upon the reorganization	11,449,625
Pro forma total weighted-average common stock outstanding—basic and diluted	<u>11,449,625</u>
Net Loss per Share:	
Pro forma net loss per share attributable to common stockholders—basic and diluted	<u>\$ (1.80)</u>

(13) Subsequent Events

Series B Redeemable Preferred Unit—Financing

In February and March of 2020, the Company received an additional \$14.3 million of funding under its Series B Redeemable Preferred Unit purchase agreement.

Apollo—Wistar License Termination

In May 2020, Apollo terminated the licensing and collaboration agreement with Wistar and decided to discontinue further development of the EBNA1 inhibitor associated with that agreement, VK-2019.

Cullinan—Mica Acquisition

On May 28, 2020 (the Acquisition Date), the Company purchased 5,385,787 shares of Series A Senior Preferred Stock of PDI Therapeutics, Inc., which was concurrently renamed Cullinan Mica (Mica) for \$7.1 million. As part of the transaction, Mica increased the size of its board from four to five directors, including three Series A directors that would be designated by the Company. In addition to the equity purchase and board seats, the Company holds most of the key officer roles in Mica. Accordingly, the Company obtained a controlling interest in Mica on the Acquisition Date. Further, the Company evaluated the Mica transaction and determined that Mica is not a variable interest entity; however, due to the controlling interest in Mica, the Company will consolidate Mica under the voting interest model. In addition to acquiring the Series A Senior Preferred Stock, the Company could be required to participate in two subsequent closings of the Series A Senior Preferred Stock if certain clinical milestones are achieved by Mica.

Amber—Series A Preferred Stock Financing

In April 2020, Amber initially issued 3,000,000 shares of its Series A Preferred Stock to the LLC for gross proceeds of \$3.0 million. At any time following the initial closing, upon election of Amber's board of directors,

CULLINAN ONCOLOGY, LLC
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Amber shall sell, and each purchaser shall purchase, up to an aggregate of 9,000,000 shares of its Series A Preferred Stock at one or more subsequent closings.

Florentine—Series A Preferred Stock Financing

In August 2020, Florentine entered into a Series A Preferred Stock purchase agreement with the LLC. The initial closing took place in August and Florentine sold 6,000,000 shares of its Series A Preferred stock for gross proceeds of \$6.0 million. At any time following the initial closing, upon the election of Florentine's board of directors, Florentine shall sell, and each purchaser shall purchase, up to an aggregate of 12,000,000 shares of its Series A Preferred Stock at one or more subsequent closings at \$1.00 per share.

Florentine—Tübingen License Agreement

In August 2020, Florentine entered into an Exclusive License Agreement (the Tübingen License Agreement) with Deutsches Krebsforschungszentrum, (DKFZ), Eberhard Karls University of Tübingen Faculty of Medicine, (the University of Tübingen), and Universitätsmedizin Gesellschaft für Forschung und Entwicklung mbH, Tübingen, (UFE). Pursuant to the Tübingen License Agreement, DKFZ and the University of Tübingen, collectively referred to as the Licensor, granted to 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 within the field.

Florentine shall pay to the Licensor an upfront non-refundable, non-creditable option exercise fee and, as partial consideration for the licenses, has issued to DKFZ and UFE a certain number of shares of common stock that amount to a mid single-digit percentage of the total shares outstanding. DKFZ and UFE were also granted the right to appoint one representative to the board of directors of Florentine.

Additionally, Florentine shall pay certain non-refundable, non-creditable milestone payments to the Licensor upon the occurrence of certain clinical and regulatory events by a licensed product. Each milestone payment is paid one time only up to a certain payment amount. No milestones have been achieved to date under the Tübingen License Agreement.

Pearl—Series A Preferred Stock Financing

In August 2020, Pearl issued 9,000,000 additional shares of its Series A Preferred Stock for \$9.0 million under the Series A Preferred Stock Agreement described in Note 4. Pursuant to the Series A Preferred Stock Agreement between Pearl and Taiho Pharma, Pearl issued additional shares of its common stock as anti-dilution shares, in exchange for no additional consideration as set forth in the license agreement.

The LLC Adoption of 2020 Unit Option and Grant Plan, Issuance of Options, and Contribution Agreement

On October 29, 2020, the board of directors of the LLC adopted the 2020 Unit Option and Grant Plan (the 2020 Plan), reserving 37.0 million common units for issuance pursuant to the 2020 Plan, and decreased the 2016 Equity Incentive Plan (the 2016 Plan) such that no more non-voting incentive units could be issued under the 2016 Plan. In addition, the board of directors of the LLC determined the fair market value of a common unit would be \$0.61 based on a hybrid of market based and option pricing methods. Following the adoption of the 2020 Plan, the LLC issued 32.5 million options to purchase common units to the LLC's employees, consultants, and directors, and reserved 4.5 million common units for future issuance.

CULLINAN ONCOLOGY, LLC
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

COVID-19 Impact

In December 2019, a novel strain of COVID-19 was reported in China. Since then, COVID-19 has spread globally. The spread of COVID-19 from China to other countries has resulted in the World Health Organization (WHO) declaring the outbreak of COVID-19 as a pandemic, or a worldwide spread of a new disease, on March 11, 2020. Many countries around the world have imposed quarantines and restrictions on travel and mass gatherings to slow the spread of the virus and have closed non-essential businesses, and many local jurisdictions continue to have such restrictions in place.

As local jurisdictions continue to put restrictions in place, the Company's ability to continue to operate its business may also be limited. 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 the Company's business, financial condition and results of operations. In response to COVID-19, the Company implemented remote working and thus far, has not experienced a significant disruption or delay in its operations as it relates to the clinical development or drug production of the Company's product candidates.

The spread of COVID-19, which has caused a broad impact globally, may materially affect the Company economically. While the ultimate economic impact brought by, and the duration of, the COVID-19 pandemic may be difficult to assess or predict, including new information which may emerge concerning the severity of COVID-19 and the actions to contain COVID-19 or treat its impact, among others, the pandemic has resulted in significant disruptions in the general commercial activity and the global economy and caused financial market volatility and uncertainty in significant and unforeseen ways in the recent months. A continuation or worsening of the levels of market disruption and volatility seen in the recent past could have an adverse effect on the Company's ability to access capital, which could in the future negatively affect the Company's liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect the Company's business.

To date, COVID-19 has not had a financial impact on the Company. However, COVID-19 has impacted the pace of our enrollment in our clinical trials and our preclinical studies. The full extent and duration of the impact of COVID-19 on the Company's operations and financial performance is currently unknown and depends on future developments that are uncertain and unpredictable.

CULLINAN ONCOLOGY, LLC
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except units and per unit amounts)
(unaudited)

	December 31, 2019	September 30, 2020	Pro Forma September 30, 2020
Assets			
Current assets:			
Cash and cash equivalents	\$ 63,250	\$ 41,297	\$ 165,997
Prepaid expenses and other current assets	1,461	2,138	2,138
Short term investments	35,380	53,595	53,595
Total current assets	100,091	97,030	221,730
Property and equipment, net	182	146	146
Other assets	188	141	141
Total assets	<u>\$ 100,461</u>	<u>\$ 97,317</u>	<u>\$ 222,017</u>
Liabilities, Redeemable Preferred Units and Members' Deficit			
Current liabilities:			
Accounts payable	\$ 934	\$ 3,487	\$ 3,487
Accrued expenses and other current liabilities	1,589	4,245	4,245
Total current liabilities	2,523	7,732	7,732
Long-term liabilities:			
Deferred rent	73	74	74
Total liabilities	2,596	7,806	7,806
Commitments and contingencies (Note 10)			
Redeemable preferred units:			
Series Seed redeemable preferred units, \$0.0001 par value: 16,000,000 units authorized, issued and outstanding at December 31, 2019 and September 30, 2020 (liquidation value: \$4,949)	3,956	3,956	—
Series A1 redeemable preferred units, \$0.0001 par value: 50,000,000 units authorized, issued and outstanding at December 31, 2019 and September 30, 2020 (liquidation value: \$60,282)	49,946	49,946	—
Series B redeemable preferred units, \$0.0001 par value: 64,200,000 authorized at December 31, 2019 and September 30, 2020; 54,006,407 and 63,141,020 units issued and outstanding at December 31, 2019 and September 30, 2020, respectively (liquidation value \$105,246)	83,872	97,909	—
Total redeemable preferred units	137,774	151,811	—
Members' deficit:			
Non-voting incentive units, \$0.0001 par value: 23,860,000 units authorized, 11,896,500 units issued and outstanding at December 31, 2019 and September 30, 2020	1	1	—
Common units, \$0.0001 par value: no shares authorized, issued and outstanding	—	—	—
Common stock, \$0.0001 par value; no shares authorized, issued or outstanding, actual; 160,000,000 shares authorized, 29,497,847 shares issued and outstanding, pro forma			3
Noncontrolling interest in subsidiaries	864	1,863	1,863
Additional paid-in capital	770	770	277,279
Accumulated other comprehensive (loss) income	(4)	59	59
Accumulated deficit	(41,540)	(64,993)	(64,993)
Total members' deficit	(39,909)	(62,300)	214,211
Total liabilities, redeemable preferred units and members' deficit	<u>\$ 100,461</u>	<u>\$ 97,317</u>	<u>\$ 222,017</u>

See accompanying notes to condensed consolidated financial statements.

CULLINAN ONCOLOGY, LLC
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except units and per unit amounts)
(unaudited)

	Nine Months ended September 30,	
	2019	2020
Operating expenses:		
Research and development	\$ 12,986	\$ 26,582
General and administrative	4,305	4,580
Total operating expenses	<u>17,291</u>	<u>31,162</u>
Loss from operations	(17,291)	(31,162)
Other income:		
Interest income	368	809
Other income, net	—	1
Net loss	<u>(16,923)</u>	<u>(30,352)</u>
Net loss attributable to noncontrolling interest	(835)	(6,899)
Net loss attributable to Cullinan	<u>\$ (16,088)</u>	<u>\$ (23,453)</u>
Net loss per unit attributable to common and non-voting incentive unit holders, basic and diluted	<u>\$ (2.67)</u>	<u>\$ (2.62)</u>
Total weighted-average common and non-voting incentive units used in computing net loss per unit, basic and diluted	<u>6,017,973</u>	<u>8,960,373</u>
Comprehensive loss:		
Net loss	\$ (16,923)	\$ (30,352)
Unrealized gain on investments	—	63
Comprehensive loss	<u>(16,923)</u>	<u>(30,289)</u>
Comprehensive loss attributable to noncontrolling interest	(835)	(6,899)
Comprehensive loss attributable to Cullinan	<u>\$ (16,088)</u>	<u>\$ (23,390)</u>
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)		<u>\$ (1.21)</u>
Total weighted-average common stock outstanding used in computing pro forma net loss per share, basic and diluted (unaudited)		<u>19,361,467</u>

See accompanying notes to condensed consolidated financial statements.

CULLINAN ONCOLOGY, LLC
CONDENSED CONSOLIDATED STATEMENTS OF REDEEMABLE PREFERRED UNITS AND MEMBERS' DEFICIT
(in thousands, except units and per unit amounts)
(unaudited)

	Redeemable Preferred Units		Non-Voting Incentive Units		Noncontrolling Interest in Subsidiaries	Additional Paid-In Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Members' Deficit
	Units	Amount	Units	Amount					
Balances at December 31, 2018	66,000,000	\$ 53,902	12,276,000	\$ 1	\$ 1	\$ 214	\$ —	\$ (20,866)	\$ (20,650)
Issuance costs of Series B preferred units	—	(42)	—	—	—	—	—	—	—
Issuance subsidiary preferred stock	—	—	—	—	1,860	—	—	(17)	1,843
Stock based compensation	—	—	—	—	—	17	—	—	17
Issuance of subsidiary common stock	—	—	—	—	—	539	—	—	539
Net loss	—	—	—	—	(835)	—	—	(16,088)	(16,923)
Balances at September 30, 2019	<u>66,000,000</u>	<u>\$ 53,860</u>	<u>12,276,000</u>	<u>\$ 1</u>	<u>\$ 1,026</u>	<u>\$ 770</u>	<u>\$ —</u>	<u>\$ (36,971)</u>	<u>\$ (35,174)</u>

	Redeemable Preferred Units		Non-Voting Incentive Units		Noncontrolling Interest in Subsidiaries	Additional Paid-In Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Members' Deficit
	Units	Amount	Units	Amount					
Balances at December 31, 2019	120,006,407	\$ 137,774	11,896,500	\$ 1	\$ 864	\$ 770	\$ (4)	\$ (41,540)	\$ (39,909)
Issuance of Series B preferred units net of issuance costs of \$213	9,134,613	14,037	—	—	—	—	—	—	—
Noncontrolling interest acquired in Mica	—	—	—	—	5,673	—	—	—	5,673
Issuance of subsidiary preferred stock	—	—	—	—	1,206	—	—	—	1,206
Issuance of subsidiary common stock	—	—	—	—	1,019	—	—	—	1,019
Unrealized gain on investments	—	—	—	—	—	—	63	—	63
Net loss	—	—	—	—	(6,899)	—	—	(23,453)	(30,352)
Balances at September 30, 2020	<u>129,141,020</u>	<u>\$ 151,811</u>	<u>11,896,500</u>	<u>\$ 1</u>	<u>\$ 1,863</u>	<u>\$ 770</u>	<u>\$ 59</u>	<u>\$ (64,993)</u>	<u>\$ (62,300)</u>

See accompanying notes to the condensed consolidated financial statements.

CULLINAN ONCOLOGY, LLC
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

	Nine Months Ended September 30,	
	2019	2020
Operating activities:		
Net loss	\$(16,923)	\$ 30,352
Adjustments to reconcile net loss to net cash used in operating activities:		
License expense in exchange for subsidiary common stock	539	1,019
Depreciation and amortization	53	47
Share-based compensation expense	17	—
Acquired in-process research and development assets	—	6,447
Amortization/accretion on marketable securities	—	146
Changes in operating assets and liabilities, net of acquired balances:		
Prepaid expenses and other current assets	(397)	(526)
Accounts payable	798	1,064
Accrued expenses and other current liabilities	(123)	1,771
Deferred rent	8	1
Other assets	—	47
Net cash used in operating activities	<u>(16,028)</u>	<u>(20,336)</u>
Investing activities:		
Purchases of property and equipment	(15)	(11)
Net cash acquired upon consolidation of Mica	—	1,450
Purchase of available-for-sale securities	—	(48,264)
Proceeds from sale or maturity of investments	—	29,965
Net cash used in investing activities	<u>(15)</u>	<u>(16,860)</u>
Financing activities:		
Proceeds from issuance of Series B Redeemable Preferred Units	—	14,250
Proceeds from issuance of noncontrolling interest	1,860	1,206
Payment of issuance costs related to Series B Redeemable Preferred Units	(42)	(213)
Issuance costs of subsidiary preferred equity	(17)	—
Net cash provided by financing activities	<u>1,801</u>	<u>15,243</u>
Net decrease in cash and cash equivalents	(14,242)	(21,953)
Cash and cash equivalents at beginning of period	33,832	63,250
Cash and cash equivalents at end of period	<u>\$ 19,590</u>	<u>\$ 41,297</u>

See accompanying notes to condensed consolidated financial statements.

CULLINAN ONCOLOGY, LLC
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

(1) Nature of Business and Basis of Presentation

Organization

Cullinan Oncology, LLC (the LLC), together with its consolidated subsidiaries (Cullinan or the Company), is a biopharmaceutical company developing a diversified pipeline of targeted oncology and immuno-oncology therapies with transformative potential for cancer patients.

Each therapeutic candidate is developed within a separate subsidiary of the LLC. At September 30, 2020, the LLC had five development subsidiaries: Cullinan Amber Corp. (Amber), Cullinan Apollo Corp. (Apollo), Cullinan Florentine Corp. (Florentine), Mica Corp. and Cullinan Pearl Corp. (Pearl), in addition to its wholly owned management company, Cullinan Management, Inc. (Management) (together the Subsidiaries). At December 31, 2019, the LLC had four development subsidiaries: Amber, Apollo, Florentine, and Pearl, in addition to its wholly owned management company, Management.

Liquidity

The Company has funded its operations primarily through the sale of redeemable preferred units. As of September 30, 2020, the investors have provided \$151.8 million in cumulative net proceeds.

The Company has incurred operating losses and has had negative cash flows from operations since its inception. The Company's net loss was \$16.9 million and \$30.4 million for the nine months ended September 30, 2019 and 2020, respectively. As of September 30, 2020, the Company has an accumulated deficit of \$65.0 million. The Company expects to continue to generate operating losses for the foreseeable future. The Company expects that its cash, cash equivalents, and short term investments as of September 30, 2020 of \$94.9 million will be sufficient to fund its operating expenses and capital expenditure requirements through at least the next twelve months from the date of issuance of these condensed consolidated financial statements. The future viability of the Company is dependent on the success of its research and development and its ability to access additional capital to fund its operations. There can be no assurance that the current operating plan will be achieved or that additional funding will be available on terms acceptable to the Company, or at all.

(2) Summary of Significant Accounting Policies

Basis of Presentation and Use of Estimates

The accompanying condensed consolidated financial statements of the Company have been prepared in conformity with accounting principles generally accepted in the United States of America (GAAP) and include the accounts of the LLC and its consolidated subsidiaries. All intercompany balances have been eliminated in consolidation. Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification (ASC) and Accounting Standards Updates (ASUs) of the Financial Accounting Standards Board (FASB).

The preparation of financial statements in accordance with GAAP requires the Company's management to make estimates and judgments that may affect the reported amounts of assets, liabilities, expenses, and related disclosure of contingent assets and liabilities. On an ongoing basis, the Company's management evaluates the estimates, including those related to expenses and accruals. The Company's management bases its estimates on historical experience, and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Estimates and

CULLINAN ONCOLOGY, LLC
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

assumptions reflected in these condensed consolidated financial statements include but are not limited to the fair value of the royalty transfer agreements, accrued research and development costs, the valuation of the non-voting incentive units, as well as restricted stock awards and common stock issued by the LLC's subsidiaries. Actual results may differ from these estimates under different assumptions or conditions.

Unaudited Interim Financial Statements

The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to present fairly the Company's financial position as of September 30, 2020, and its results of operations and comprehensive loss, cash flows, redeemable preferred units and members' deficit for the nine months ended September 30, 2019 and 2020. The financial data and the other financial information contained in these notes to the condensed consolidated financial statements related to the nine-month periods are also unaudited. The results of operations for the nine months ended September 30, 2020 are not necessarily indicative of the results to be expected for the year ending December 31, 2020 or for any other future annual or interim period. These unaudited interim condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements included elsewhere in this prospectus.

Unaudited Pro Forma Balance Sheet

Prior to the completion of an Initial Public Offering (IPO), the Company intends to engage in a series of transactions, which are referred to collectively as the Reorganization. As a result of the Reorganization, the LLC will merge with and into Cullinan Management, Inc., or the Corporation, with the Corporation being the surviving entity of such merger.

As part of the Reorganization, the holders of existing units in the LLC will exchange those units for shares of stock of the Corporation as of immediately prior to the completion of the IPO.

The accompanying unaudited pro forma balance sheet as of September 30, 2020 has been prepared to give effect to (i) the issuance and sale of 66,599,045 Series C preferred units after September 30, 2020, (ii) the exchange of all the outstanding redeemable preferred units and vested non-voting incentive units into 29,497,847 shares of common stock of the Company upon the Reorganization as if the Reorganization had occurred on September 30, 2020 based on an IPO price of \$19.50 per share and (iii) to give effect for a one-for-7.0390 reverse share split of its issued and outstanding common shares.

Non-Voting Incentive Units that have not vested as of the Reorganization will be exchanged for shares of the Corporation's restricted common stock, which will be subject to time-based vesting conditions in accordance with the terms and conditions of the Non-Voting Incentive Units of the LLC from which such shares are exchanged. As such, these units have been excluded from this calculation.

Principles of Consolidation

The LLC consolidates entities in which it has a controlling financial interest. The LLC 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 LLC has concluded that none of its subsidiaries is a VIE and has consolidated each subsidiary under the voting interest model.

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The Company has either created or made investments in the following entities:

<u>Consolidated Entities</u>	<u>Relationship as of September 30, 2020</u>	<u>Date Control First Acquired</u>
Cullinan Management, Inc.	Wholly-owned Subsidiary	September 2016
Cullinan Apollo Corp.	Partially-owned Subsidiary	November 2018
Cullinan Pearl Corp.	Partially-owned Subsidiary	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

Noncontrolling Interests

As of September 30, 2020, the Company has noncontrolling interests in certain of its consolidated subsidiaries. These balances are reported as separate components as part of members' deficit in the condensed consolidated balance sheets.

The Company adjusts the carrying value of noncontrolling interest to reflect the book value attributable to noncontrolling shareholders of consolidated partially-owned entities when there is a change in the hypothetical liquidation at book value (HLBV) during the respective reporting period. During the nine months ended September 30, 2019 and 2020, such adjustments in the aggregate amounts of \$0.8 million and \$6.9 million, respectively, were recorded as a net loss and disclosed within the noncontrolling interest in subsidiaries column in the condensed consolidated statements of redeemable preferred units and members' deficit.

Comprehensive Loss

Comprehensive 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. For the nine months ended September 30, 2019, comprehensive loss was equal to net loss. For the nine months ended September 30, 2020, the Company recognized less than \$0.1 million in unrealized gains on short term investments.

Cash, Cash Equivalents, and Short Term Investments

The Company considers all highly liquid investments with maturities of three months or less at the time of purchase to be cash equivalents. Investments not classified as cash equivalents with maturities of less than twelve months are classified as short term, available-for-sale marketable securities. Available-for-sale marketable securities are carried at estimated fair value, with unrealized gains or losses included in accumulated other comprehensive loss in members' deficit. The fair value of marketable securities is based on available market information. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization is included in interest income. Interest and dividends are included in interest income. Declines in fair value judged to be other-than-temporary on available-for-sale securities, if any, are included in other income, net.

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The Company recognized its short-term investment marketable securities by security type as follows:

	As of December 31, 2019			Estimated Fair Value
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	
	(in thousands)			
Corporate notes	\$ 19,718	\$ 2	\$ (6)	\$ 19,714
Commercial paper	5,571	—	—	5,571
Asset-backed securities	5,068	—	—	5,068
U.S. government notes	5,027	—	—	5,027
	<u>\$ 35,384</u>	<u>\$ 2</u>	<u>\$ (6)</u>	<u>\$ 35,380</u>

	As of September 30, 2020			Estimated Fair Value
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	
	(in thousands)			
Corporate notes	\$ 23,802	\$ 30	\$ —	\$ 23,832
Commercial paper	15,875	—	—	15,875
Asset-backed securities	6,354	7	—	6,361
U.S. government notes	7,505	22	—	7,527
	<u>\$ 53,536</u>	<u>\$ 59</u>	<u>\$ —</u>	<u>\$ 53,595</u>

Fair Value of Financial Instruments

The following tables present information about the Company's financial assets measured at fair value on a recurring basis and indicates the level of the fair value hierarchy utilized to determine such fair values as of December 31, 2019 and September 30, 2020.

	As of December 31, 2019			Total
	Level 1	Level 2	Level 3	
	(in thousands)			
Cash and cash equivalents				
Cash	\$ 8,240	\$ —	\$ —	\$ 8,240
Money market funds	52,597	—	—	52,597
Corporate notes	—	2,413	—	2,413
Short term investments				
Corporate notes	—	19,714	—	19,714
Commercial paper	—	5,571	—	5,571
Asset-backed securities	—	5,069	—	5,069
U.S. government notes	—	5,026	—	5,026
	<u>\$60,837</u>	<u>\$37,793</u>	<u>\$ —</u>	<u>\$98,630</u>

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	As of September 30, 2020			Total
	Level 1	Level 2	Level 3	
	(in thousands)			
Cash and cash equivalents				
Cash	\$24,164	\$ —	\$ —	\$24,164
Money market funds	17,133	—	—	17,133
Short-term investments				
Corporate notes	—	23,832	—	23,832
Commercial Paper	—	15,875	—	15,875
Asset-backed securities	—	6,361	—	6,361
U.S. government notes	—	7,527	—	7,527
	<u>\$41,297</u>	<u>\$53,595</u>	<u>\$ —</u>	<u>\$94,892</u>

Accounts payable and accrued expenses are carried at cost, which management believes approximates fair value.

Property and Equipment

Property and equipment consisted of the following:

	December 31, 2019	September 30, 2020
		(in thousands)
Computers	\$ 60	\$ 70
Office furniture and equipment	134	134
Leasehold improvements	105	105
Total property and equipment, gross	299	309
Less: accumulated depreciation	(117)	(163)
Total property and equipment, net	<u>\$ 182</u>	<u>\$ 146</u>

Asset Acquisitions

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

Net Loss per Unit

The Company follows the two-class method when computing net loss per unit as the Company has issued units that meet the definition of participating securities. The two-class method determines net income (loss) per unit for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common unit holders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed.

Basic net income (loss) per unit attributable to common unit holders is computed by dividing the net income (loss) attributable to common and non-voting incentive unit holders by the weighted average number of common

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and non-voting incentive units outstanding for the period. Diluted net income (loss) attributable to common and non-voting incentive unit holders is computed by adjusting net income (loss) attributable to common unit holders to reallocate undistributed earnings based on the potential impact of dilutive securities. Diluted net income (loss) per unit attributable to common and non-voting incentive unit holders is computed by dividing the diluted net income (loss) attributable to common and non-voting incentive unit holders by the weighted average number of common and non-voting incentive units outstanding for the period, including potential dilutive common and non-voting incentive units. For purposes of this calculation, unvested non-voting incentive units, and Redeemable Preferred Units are considered potential dilutive common units.

The Company's Redeemable Preferred Units contractually entitles the holders of such units to participate in dividends but does not contractually require the holders of such units to participate in losses of the Company. Accordingly, in periods in which the Company reports a net loss attributable to common and non-voting incentive unit holders, such losses are not allocated to such participating securities. In periods in which the Company reports a net loss attributable to common and non-voting incentive unit holders, diluted net loss per unit attributable to common and non-voting incentive unit holders is the same as basic net loss per unit attributable to common and non-voting incentive unit holders, since dilutive common and non-voting incentive units are not assumed to have been issued if their effect is anti-dilutive. The Company reported a net loss attributable to common and non-voting incentive unit holders for the nine months ended September 30, 2019 and 2020.

Unaudited Pro Forma Net Loss per Share

The unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the nine months ended September 30, 2020 has been prepared to give effect to the exchange of all outstanding redeemable preferred units and vested non-voting incentive units of the LLC into shares of common stock of the Corporation upon the Reorganization as if the Reorganization had occurred on the later of the beginning of the period or the issuance date of the redeemable preferred units and to give effect for a one-for-7.0390 reverse share split of its issued and outstanding common shares.

(3) Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

	December 31, 2019	September 30, 2020
	(in thousands)	
Research and development costs	\$ 656	\$ 3,003
Accrued bonuses	523	605
Professional fees	152	396
Consultants fees	231	195
Other	27	46
Total	<u>\$ 1,589</u>	<u>\$ 4,245</u>

(4) License and Collaboration Agreements

The following table summarizes the impact of the research and development costs related to the collaboration and license agreements on the Company's condensed consolidated statements of operations and comprehensive loss for the nine months ended September 30, 2019 and 2020. For details on the structure and accounting treatment for the Company's collaboration and license agreements, refer to the annual consolidated

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financial statements included elsewhere in this prospectus.

	Nine Months Ended September 30,	
	2019	2020
	(in thousands)	
Management - Adimab	\$ 716	\$ 318
Apollo - Wistar	469	304
Pearl - Taiho	3,039	531
Amber - MIT	—	276
Florentine - Tubingen	—	912
Total license and collaboration fees	<u>\$ 4,224</u>	<u>\$ 2,341</u>

Florentine—Tübingen License Agreement

In August 2020, Florentine entered into an Exclusive License Agreement, or the Tübingen License Agreement, with Deutsches Krebsforschungszentrum, or DKFZ, Eberhard Karls University of Tübingen, Faculty of Medicine, or University of Tübingen, and Universitätsmedizin Gesellschaft für Forschung und Entwicklung mbH, Tübingen, or 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 to Licensor an upfront, non-refundable, non-creditable option exercise fee and, as partial consideration for the licenses, has issued to DKFZ and UFE a certain number of shares of common stock that amount to a mid single-digit percentage of the total Florentine shares outstanding. DKFZ and UFE were also granted the right to appoint one representative to the board of directors of Florentine.

Additionally, Florentine shall pay certain non-refundable, non-creditable milestone payments to Tübingen 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. No milestones have been achieved to date under the Tübingen License Agreement.

(5) Cullinan—Mica Transaction

Asset Acquisition

On May 28, 2020 (the Acquisition Date), in accordance with the Series A Senior Preferred Stock Purchase Agreement (the Purchase Agreement), the LLC purchased 5,385,787 shares of Series A Senior Preferred Stock (the Series A Senior Preferred Stock) of PDI Therapeutics, Inc. (PDI Therapeutics), for \$7.1 million, and certain existing PDI Therapeutics shareholders purchased approximately 702,495 shares of the Series A Senior Preferred Stock for \$0.9 million. Concurrently with the Series A Senior Preferred Stock purchase, PDI Therapeutics was renamed Mica Corp. The terms of the Purchase Agreement included two additional milestone-dependent closings for total proceeds of up to \$26.0 million. Each additional closing is based on clinical development milestones of Mica's lead candidate, CLN-619. Neither milestone occurred as of September 30, 2020.

On the Acquisition Date, PDI Therapeutics authorized the issuance of 72,890,797 shares, of which 39,000,000 was designated as common stock and 33,890,797 was designated as preferred stock. Of the

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authorized preferred stock, PDI Therapeutics designated 1,999,998 shares as Series A Junior Preferred Stock, 652,371 shares as Series A-1 Junior Preferred Stock, 11,451,514 shares as Series A-2 Junior Preferred Stock, and 19,786,914 as Series A Senior Preferred Stock (collectively the Series Preferred Stock). Following the initial close in May 2020, Mica had 22,829,406 shares outstanding, including 6,088,282 shares of Series A Senior Preferred Stock (of which the LLC held 5,385,787 shares), 602,784 shares of common stock, 2,034,457 shares of common stock underlying options (of which 1,826,402 was reserved for future issuances to Mica's directors and officers, as well as former employees of PDI Therapeutics), and the 14,103,883 shares of Series A, A-1, and A2 Junior Preferred Stock described above.

Other than the Series A-1 Junior Preferred Stock, which shares are non-voting, the Series Preferred Stock vote equally with the shares of Common Stock. In addition to any other vote or consent, the vote or written consent of a majority of the holders of Series A Senior Preferred Stock is required for certain actions, including redemptions, dividends, distributions, dissolutions, creation of new classes of stock, mergers, sale of Mica or its assets, and amendments to the certificate of incorporation, as well as other actions. The other classes of Series Preferred Stock have voting rights pertaining to the increase or decrease in the authorized number of shares of their respective classes.

The LLC's initial purchase represented approximately 23.6% of Mica's fully diluted shares outstanding, including shares reserved for future issuance, and 88.5% of the Series A Senior Preferred Stock outstanding. The LLC can increase its ownership to approximately 53% of Mica's fully diluted shares outstanding by participating in the additional milestone-dependent closings. Additionally, as part of the transaction and as outlined in the Voting Agreement dated May 28, 2020, among the LLC and other stockholders of Mica, Mica increased the size of its board of directors from four to five directors, of which three directors are designated by the LLC.

The LLC also entered into a Services Agreement with Mica under which Cullinan Management will perform functions required for Mica's operations, including accounts payable, cash management, record keeping, research and development, and accounting services.

Given the LLC's ownership of the Series A Senior Preferred Stock and its majority representation on Mica's board of directors, the LLC obtained a controlling interest in Mica on the Acquisition Date. Further, the LLC evaluated the Mica transaction and determined that Mica is not a variable interest entity; however, due to the controlling interest in Mica, the LLC will consolidate Mica under the voting interest model.

The LLC evaluated the change in control of Mica and concluded that the change in control is an asset acquisition rather than a business combination as substantially all of the value in Mica resides in CLN-619, the in-process research and development IPR&D asset developed by Mica. The cost of the assets was calculated as the sum of the fair value of the LLC's investment in Mica, the fair value of the noncontrolling interests in Mica and the LLC's transaction costs. This cost was allocated to the assets acquired and liabilities assumed in the transaction based on their relative fair values. The amount allocated to the IPR&D acquired was \$6.4 million and was charged to research and development expense within the condensed consolidated statements of operations and comprehensive loss during the nine months ended September 30, 2020 as it had no alternative future use at the time of the acquisition.

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(6) Redeemable Preferred Units

As of September 30, 2020, the LLC Agreement provided for the issuance of Seed Redeemable Preferred Units, Series A Redeemable Preferred Units, and Series B Redeemable Preferred Units. Outstanding redeemable preferred units consist of the following:

	As of December 31, 2019		
	Units Issued and Outstanding	Original Issue Price Per Unit	Carrying Value (thousands)
Series Seed Redeemable Preferred Units	16,000,000	\$ 0.25	\$ 3,956
Series A Redeemable Preferred Units	50,000,000	\$ 1.00	49,946
Series B Redeemable Preferred Units	54,006,407	\$ 1.56	83,872
Total Redeemable Preferred Units as of December 31, 2019	120,006,407		\$ 137,774

	As of September 30, 2020		
	Units Issued and Outstanding	Original Issue Price Per Unit	Carrying Value (thousands)
Series Seed Redeemable Preferred Units	16,000,000	\$ 0.25	\$ 3,956
Series A Redeemable Preferred Units	50,000,000	\$ 1.00	49,946
Series B Redeemable Preferred Units	63,141,020	\$ 1.56	97,909
Total Redeemable Preferred Units as of September 30, 2020	129,141,020		\$ 151,811

(7) Non-Voting Incentive Units and Noncontrolling Interest in Subsidiaries

Non-Voting Incentive Units

As of September 30, 2020, the LLC Agreement provides for the issuance of up to 23,860,000 non-voting incentive units for grant under Amendment No. 1 of the 2016 Equity Incentive Plan (the Plan). During the nine months ended September 30, 2019 and 2020, the LLC did not issue any non-voting incentive units. Non-voting incentive units do not carry the right to vote. As of September 30, 2020, there were 11,963,500 incentive units available for future grant under the plan.

Noncontrolling Interest in Subsidiaries

Certain Subsidiaries issue common stock in connection with licensing agreements, as further detailed in Note 4, and to its employees, directors and consultants pursuant to subsidiary equity incentive plans.

In 2018, Apollo reserved 2,120,000 shares of common stock for future issuances of equity grants under its 2018 equity incentive plan. In December 2018, Apollo entered into a Series A Preferred Stock purchase agreement with Cullinan Oncology, LLC. The initial closing took place in December and Apollo sold 7,000,000 subsidiary shares of Series A Preferred Stock for gross proceeds of \$7.0 million. At any time following the initial closing, upon the election of the Apollo's Board of Directors, Apollo may sell up to an aggregate of 11,000,000 Series A Preferred Stock shares at one or more subsequent closings at \$1.00 per share.

In 2019, upon inception, Amber reserved 2,400,200 shares of common stock for future issuances of equity grants under its 2019 equity incentive plan. In 2020, in connection with its Series A Preferred Stock financing,

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Amber authorized a total of 16,001,332 shares of common stock for issuance pursuant to preferred stock conversions and issuances related to equity grants, and issued 3,000,000 shares of its Series A Preferred Stock to the LLC for gross proceeds of \$3.0 million. At any time following the initial closing, upon election of Amber's Board of Directors, Amber may sell up to an aggregate of 9,000,000 shares of Amber's Series A Preferred Stock at one or more subsequent closings at \$1.00 per share.

In April 2020, pursuant to the license agreement between Amber and the Massachusetts Institute of Technology, Amber issued 400,132 shares of its common stock, in exchange for no additional consideration as set forth in the license agreement. Accordingly, under the HLBV method, \$0.2 million of Amber's net loss was attributed to noncontrolling interests and \$0.4 million of net loss was attributed to the LLC for the nine months ended September 30, 2020.

In 2019, upon inception, Florentine reserved 2,337,857 shares of common stock for future issuances of equity grants under its 2019 equity incentive plan. In August 2020, Florentine entered into a Series A Preferred Stock purchase agreement with the LLC. The initial closing took place in August 2020 and Florentine sold 6,000,000 subsidiary shares of Series A Preferred Stock for gross proceeds of \$6.0 million. At any time following the initial closing, upon the election of the Florentine's Board of Directors, Florentine may sell up to an aggregate of 12,000,000 shares of Series A Preferred Stock at one or more subsequent closings at \$1.00 per share.

In August 2020, pursuant to the Tübingen License Agreement, Florentine issued 725,118 shares of its common stock, in exchange for no additional consideration as set forth in the license agreement. Accordingly, under the HLBV method, \$0.3 million of Florentine's net loss was attributed to noncontrolling interests and \$7.3 million of net loss was attributed to the LLC for the nine months ended September 30, 2020.

As described further in Note 5 to the condensed consolidated financial statements, in May 2020, Mica issued 6,088,282 million shares of Series A Senior Preferred Stock, including 5,385,787 to the LLC, at \$1.31 per share. Following the transaction, Mica had 22,829,406 shares outstanding, which, in addition to the Series A Senior Preferred Stock, included the following:

- 1,999,998 shares as Series A Junior Preferred Stock
- 652,371 shares as Series A-1 Junior Preferred Stock
- 11,451,514 shares as Series A-2 Junior Preferred Stock
- 2,637,241 shares of common stock (of which 1,826,402 was reserved for future issuances to Mica's directors and officers, as well as former employees of PDI Therapeutics)

Using a market-based approach and an option-pricing allocation method, Mica determined the fair market value of Mica's equity at acquisition was \$12.8 million, of which \$7.1 million was allocated to the LLC's Series A Senior Preferred Stock position, and \$5.7 million was allocated to noncontrolling interests, including the Junior Preferred and Common Stock holders. Further, Mica had \$4.7 million of net assets as of September 30, 2020. Given this value was below the liquidation preference of the Series A Senior Preferred Stock, the noncontrolling interest claim on the net assets was \$0.6 million as of September 30, 2020, which represented the pro-rata portion of Series A Senior Preferred Stock not held by the LLC. Accordingly, under the HLBV method, \$6.1 million of Mica's net loss was attributed to noncontrolling interests and \$3.8 million of net loss was attributed to the LLC for the nine months ended September 30, 2020.

In August 2020, Pearl issued 9,000,000 additional subsidiary shares of Series A Preferred Stock for \$9.0 million pursuant to a purchase agreement with the LLC, and Taiho Ventures, LLC (Taiho Ventures). Pearl

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issued 1,206,000 additional shares of its common stock as anti-dilution shares, in exchange for no additional consideration as set forth in the license agreement.

In 2019, Pearl provided Taiho Pharmaceuticals, Co. Ltd. (Taiho Pharma) with 1,860,000 shares of common stock as compensation for a license and collaboration agreement with Taiho Pharma (the Taiho License Agreement). In 2019, Pearl increased the reserved shares of common stock to 31,000,000. Further in 2019, Pearl issued 93,000 options under its equity incentive plan at a fair market value of \$0.18 per share and recorded less than \$0.1 million of stock compensation expense. In August 31, 2020, Pearl increased its shares available for issuance under the Plan from 2,800,000 shares to 4,600,059 shares. For the nine months ended September 30, 2019 and 2020, under the HLBV method, \$0.8 million and \$1.3 million, respectively, of losses were attributed to noncontrolling interests due to the preferred ownership of Taiho Ventures in Pearl.

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 Series A Preferred Stock.

(8) Equity-Based Compensation

Non-Voting Incentive Units

The LLC's 2016 Equity Incentive Plan (the Plan) provides for the grant of non-voting incentive units to employees, consultants, advisors and directors, as determined by the Board of Directors. During the nine months ended September 30, 2019 and 2020, the Company did not issue any LLC non-voting incentive units.

A summary of the LLC's non-voting incentive unit activity for the nine months ended September 30, 2020 is as follows:

	<u>Number of Units</u>	<u>Weighted Average Grant Date Fair Value Per Unit</u>
Outstanding unvested as of December 31, 2019	4,085,400	\$ 0.0001
Vested	(2,153,250)	0.0001
Outstanding unvested as of September 30, 2020	<u>1,932,150</u>	<u>\$ 0.0001</u>
Outstanding vested as of September 30, 2020	<u>9,964,350</u>	<u>\$ 0.0001</u>

Equity-based compensation

The Company recorded a nominal amount of equity-based compensation in the condensed consolidated statement of operations and comprehensive loss for the nine months ended September 30, 2019 and 2020. As of September 30, 2020, the unrecognized equity-based compensation is nominal.

(9) Related Party Transactions

MPM Capital is a significant investor in the Company through one of its managed funds. In October 2016, the Company also began receiving consulting and management services pursuant to agreements with a Managing Director at MPM Capital and a principal at F2 Ventures, also a significant investor in the Company. For the nine months ended September 30, 2019 and 2020, the Company incurred \$0.2 million and \$0.1 million, respectively, for management and advisory services, in addition to their director compensation, in connection with those agreements.

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On April 1, 2020, the Company entered into a consulting agreement, or the 2020 Consulting Agreement, with Globeways Holdings Limited, or Globeways. Globeways and entities affiliated with F2 Ventures beneficially own in the aggregate greater than five percent of the Company's outstanding units and Globeways is beneficially owned by a member of the LLC's board of directors. Pursuant to the 2020 Consulting Agreement, the board member provides leadership and advice regarding the Company's scientific, clinical, product development and related activities and operations. Pursuant to the 2020 Consulting Agreement, the LLC pays Globeways a consulting fee at a monthly rate of \$25,000. As the sole beneficial owner of Globeways, this board member receives all of the compensation paid to Globeways under the Globeways Agreements. For the nine months ended September 30, 2020, the Company incurred \$0.2 million in costs related to this agreement.

Royalty Transfer Agreements

In October and December 2019, May 2020 the Company's subsidiaries Amber, Apollo, Florentine, Mica, and Pearl entered into royalty transfer agreements with MPM Oncology Charitable Foundation, Inc. and UBS Optimus Foundation. Under these agreements, each investor is entitled to receive a royalty equal to 0.5% (1.0% in aggregate) of all global net sales of any products developed by the 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.

As of September 30, 2020, Amber and Florentine had options to programs in pre-clinical research, while Apollo and Pearl's programs were in phase 1 clinical trials. Given that these programs are all still in early stages of development and face inherent technical, regulatory, and competitive risks associated with achieving approval and commercialization, the Company ascribed no value to the royalty agreement as of September 30, 2020. The Company currently does not have any net sales or license income and as a result has paid no royalties under this obligation as of September 30, 2020 nor has the Company accrued any liability as of September 30, 2020. The Company will monitor these instruments for changes in fair value at each reporting date.

(10) Commitments and Contingencies

Operating Lease

Rent expense for the nine months ended September 30, 2019 and 2020 was \$0.4 million and \$0.4 million, respectively.

In December 2017, the LLC signed an operating lease for 7,531 rentable square feet of office space in Cambridge, Massachusetts to commence on February 1, 2018. The lease expires on June 30, 2024. Rent expense will be recorded ratably over the lease period. The lease includes escalating rental payments, which are also being charged to rent expense ratably over the lease period.

(11) Employee Benefit Plan

The Company maintains a defined contribution 401(k) plan (the 401(k) Plan) in which employees may contribute a portion of their compensation, subject to statutory maximum contribution amounts. The Company assumes all administrative costs of the 401(k) Plan. For the nine months ended September 30, 2019 and 2020, the expense relating to the matching contribution was less than \$0.1 million and \$0.1 million, respectively.

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(12) Net Loss per Unit

The following table sets forth the calculation of basic and diluted net loss per unit:

	Nine Months Ended September 30,	
	2019	2020
	(in thousands, except unit and per unit data)	
Numerator:		
Net loss attributable to common and vested non-voting incentive unit holders	\$ (16,088)	\$ (23,453)
Denominator:		
Total weighted-average common and vested non-voting incentive units used in computing net loss per unit, basic and diluted	6,017,973	8,960,373
Net loss per unit:	<u>\$ (2.67)</u>	<u>\$ (2.62)</u>

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

	Nine Months Ended September 30,	
	2019	2020
Redeemable preferred units	66,000,000	129,141,020
Unvested non-voting incentive units	4,803,150	1,932,150
	<u>70,803,150</u>	<u>131,073,170</u>

Unaudited Pro Forma Net Loss per Share

The unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the nine months ended September 30, 2020 has been prepared to give effect to the exchange of all outstanding redeemable preferred units and vested non-voting incentive units of the LLC into shares of common stock of the Company upon the reorganization as if the reorganization had occurred on the later of the beginning of the period or the issuance date of the redeemable preferred units and to give effect for a one-for-7.0390 reverse share split of its issued and outstanding common shares.

CULLINAN ONCOLOGY, LLC
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Unaudited pro forma basic and diluted net loss per share attributable to common stockholders was calculated as follows:

	<u>Nine Months Ended September 30, 2020</u> (in thousands, except share and per share data)
Numerator:	
Loss attributable to common and non-voting incentive units	\$ (23,453)
Pro forma adjustments to loss attributable to common and non-voting incentive units	—
Pro forma net loss attributable to common and non-voting incentive units	<u>\$ (23,453)</u>
Denominator:	
Total weighted-average common and non-voting incentive units outstanding—basic and diluted	—
Pro forma adjustment to reflect the assumed exchange of outstanding units upon the Reorganization	19,361,467
Pro forma total weighted-average common stock outstanding—basic and diluted	<u>19,361,467</u>
Net Loss per Share:	
Pro forma net loss per share attributable to common stockholders—basic and diluted	<u>\$ (1.21)</u>

(13) Subsequent Events

The LLC Adoption of 2020 Unit Option and Grant Plan, Issuance of Options and Contribution Agreement

On October 29, 2020, the Company adopted the 2020 Unit Option and Grant Plan, reserving 36,972,854 common units for issuance and decreased the 2016 Equity Incentive Plan such that no more non-voting incentive units could be issued under that plan. These options have an exercise price of \$0.61 per common unit and vest as to 25% of the number of common units subject to the award on the first anniversary of the vesting commencement date, with the remaining portion of the award vesting over the following 36 months in equal monthly installments. Following the plan adoption, the LLC issued 32,493,491 options.

In addition, in November 2020, the LLC entered into a Contribution Agreement (the Restricted Stock Contribution Agreement), with each holder of restricted stock of Amber, Pearl, and Florentine. Pursuant to the Restricted Stock Contribution Agreement, each holder contributed their respective shares of restricted stock and in exchange received 2,231,363 restricted common units of the LLC entity under the 2020 Unit Plan with an aggregate value equal to the value of the restricted stock contributed to the LLC (the Restricted Stock Contribution). Simultaneous with the Restricted Stock Contribution, the board of directors of Amber, Pearl, and Florentine determined to accelerate the vesting of the shares of unvested restricted stock immediately prior to the contribution of such stock pursuant to the Restricted Stock Contribution Agreement described above and then terminated their respective stock option and grant plans and the remaining shares reserved for issuance under each respective stock option and grant plan were retired to the status of authorized and unissued shares.

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The board of directors of Cullinan Pearl further authorized the entry into a Common Unit Purchase Agreement with the LLC pursuant to which Pearl purchased 22,868 common units of the LLC for a purchase price of \$0.61 per common unit, for an aggregate of \$13,950 (the Unit Purchase). Pearl then transferred those common units to two directors of Pearl in exchange for the cancellation of 46,500 stock options issued to those Directors. In addition, the LLC entered into subscription agreements with Pearl pursuant to which the LLC purchased an aggregate of 2,730,225 shares of Pearl's common stock at a purchase price of \$0.44 per share, for an aggregate amount of \$1.2 million. The intent of each transaction was for the LLC to increase its ownership in Pearl.

As discussed in note 13 to the consolidated financial statements as of and for the years ended December 31, 2018 and 2019, the board of directors of the LLC initially determined that the fair value of a common unit was \$0.61 per unit as of October 29, 2020. Given developments in the Company's capital structure and progress toward the completion of an initial public offering after that date, in December 2020, the Company performed a retrospective valuation of the fair market value of a common unit of the LLC as of October 29, 2020. The retrospective valuation was prepared with the assistance of a third-party valuation specialist using a hybrid of market based and option pricing methods and concluded that the fair market value of a common unit for accounting purposes was \$1.16 per unit as of October 29, 2020. The compensation expense based on the grant date fair value of the options and restricted common units granted in October and November 2020 is expected to be approximately \$28.5 million for the options and \$2.6 million for restricted common units, and will be recorded on a straight-line basis over a weighted-average period of 2.3 years for the options and 2.6 years for the restricted common units as of September 30, 2020. The unit and per unit values described above do not include the impact of the Reorganization and a one-for-7.0390 reverse split of Cullinan Management's common stock, which will become effective immediately prior to the effectiveness of the Company's registration statement.

Series C Redeemable Preferred Unit - Financing

In December 2020, the LLC entered into a Series C Preferred Unit Purchase Agreement to issued up to \$132 million Series C Redeemable Preferred Units. On December 16, 2020, the LLC issued 66,599,045 of Series C Redeemable Preferred Units at \$1.97 per unit, resulting in net proceeds of \$124.7 million. Upon the closing of the Series C Preferred Unit Purchase Agreement, the Series B Preferred Unit Purchase Agreement, dated as of October 4, 2019, was terminated and the LLC will not issue any additional Series B Preferred Units.

Florentine – Series A Preferred Financing

In December 2020, Florentine issued 6,000,000 additional shares of its Series A Preferred Stock for proceeds of \$6,000,000 under the Florentine Series A Preferred Stock purchase agreement described in Note 7. Pursuant to the Series A Preferred Stock Agreement, Florentine will issue additional shares of its common stock to DFKZ and UFE as anti-dilution shares, in exchange for no additional consideration as set forth in the license agreement.

Pearl – Zai Lab License Agreement

In December 2020, Pearl entered into a license agreement (Zai License Agreement) with Zai Lab Shanghai Company, Limited (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 China, Hong Kong, Macau and Taiwan. In partial consideration of the license and rights granted to Zai Lab, Zai Lab will pay Pearl a one-time, irrevocable, nonrefundable license fee of \$20 million. In addition to the upfront fee, Zai Lab is obligated to pay Pearl, research and development, regulatory and sales milestone payments upon the occurrence of certain milestone events in the aggregate amount of up to \$211 million, and tiered royalty payments based on annual net

CULLINAN ONCOLOGY, LLC
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sales of the licensed product. Pearl will be obligated to pay Taiho a mid teen percentage of the \$20 million upfront payment from Zai Lab, as well as potential future revenue received from Zai Lab under the Zai License Agreement. No milestones have been achieved to date under the Zai License Agreement.

Mica Equity Transactions

In December 2020, the stockholders and the board of directors of Mica approved an amendment to its equity plan that decreased the authorized amount of shares under its equity plan such that no further grants could be made under its equity plan. Any authorized but unissued shares under the equity plan were returned to the status of authorized, unissued shares of common stock. Pursuant to a Subscription Agreement, the LLC entity subsequently purchased an aggregate of 3,367,804 shares of common stock of Mica for \$774,595. As a result of these transactions, the LLC entity's ownership percentage in Mica increased to 34.6% as of December 31, 2020.

Reorganization

On December 16, 2020, the board of directors approved the Company to enter into a number of transactions whereby the LLC will merge with and into Management and Management will be the surviving entity (the Reorganization), immediately prior to the effectiveness of the Company's initial public offering. Management will be the registrant in the initial public offering and the Company's financial statements will be reported by Management. Upon the effectiveness of the Reorganization, all outstanding preferred units, non-voting incentive units, options for common units and restricted common units, will convert into shares of Management common stock. See Note 2 for further details.

Reverse Stock Split

On December 31, 2020, the board of directors also approved a one-for-7.0390 reverse stock split of the common stock outstanding immediately following the Reorganization, which will become effective immediately prior to the effectiveness of the Company's registration statement.

Option and Incentive Plans

The 2016 Equity Plan, prior to the completion of the merger of the LLC with and into Management, will be terminated and all incentive units issued under the 2016 Equity plan will be terminated. Vested incentive units under the 2016 Equity Plan will convert to common stock and unvested units will continue to have the same vesting terms and will convert to restricted common stock.

The 2021 Stock Option and Incentive Plan (the 2021 Stock Plan), was adopted by the board of directors in December 2020 and the Company expects the stockholders will approve the plan in January 2021, prior to the completion of the Company's initial public offering. The 2021 Stock Plan will become effective on the day immediately prior to the effectiveness of the Company's registration statement. The Company has initially reserved 12,546,386 shares of common stock for issuance of awards under the 2021 Stock Plan, which includes (x) 320,228 shares of restricted stock to be issued under the 2021 Stock Plan in connection with the Reorganization and (y) split-adjusted equity awards comprised of (i) 4,616,187 shares of common stock issuable upon the exercise of stock options at a weighted average exercise price of \$4.30; and (ii) an aggregate of 1,753,316 shares of common stock, which will be granted to certain executive officers and other employees at the time of effectiveness of the 2021 Plan with an exercise price equal to the initial public offering price per share. 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, beginning on January 1, 2022, 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 compensation committee. This number is subject to adjustment in the event of a stock split, stock dividend or other change in capitalization.

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2021 Employee Stock Purchase Plan

The 2021 Employee Stock Purchase Plan (the ESPP), was adopted by our board of directors in December 2020 and the Company expects the stockholders will approve the plan in January 2021, prior to the completion of the Company's initial public offering. The ESPP will become effective on the day immediately prior to the effectiveness of the Company's initial public offering. The Company has initially reserved 416,665 shares of common stock for issuance to participating employees. The ESPP provides that the number of shares reserved and available for issuance under the ESPP will automatically increase each January 1, beginning on January 1, 2022, by the lesser of 833,330 shares of our 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. This number is subject to adjustment in the event of a stock split, stock dividend or other change in capitalization.

COVID-19 Impact

In December 2019, a novel strain of COVID-19 was reported in China. Since then, COVID-19 has spread globally. The spread of COVID-19 from China to other countries has resulted in the World Health Organization (WHO) declaring the outbreak of COVID-19 as a pandemic, or a worldwide spread of a new disease, on March 11, 2020. Many countries around the world have imposed quarantines and restrictions on travel and mass gatherings to slow the spread of the virus and have closed non-essential businesses, and many local jurisdictions continue to have such restrictions in place.

As local jurisdictions continue to put restrictions in place, the Company's ability to continue to operate its business may also be limited. 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 the Company's business, financial condition and results of operations. In response to COVID-19, the Company implemented remote working and thus far, has not experienced a significant disruption or delay in its operations as it relates to the clinical development or drug production of the Company's product candidates.

The spread of COVID-19, which has caused a broad impact globally, may materially affect the Company economically. While the ultimate economic impact brought by, and the duration of, the COVID-19 pandemic may be difficult to assess or predict, including new information which may emerge concerning the severity of COVID-19 and the actions to contain COVID-19 or treat its impact, among others, the pandemic has resulted in significant disruptions in the general commercial activity and the global economy and caused financial market volatility and uncertainty in significant and unforeseen ways in the recent months. A continuation or worsening of the levels of market disruption and volatility seen in the recent past could have an adverse effect on the Company's ability to access capital, which could in the future negatively affect the Company's liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect the Company's business.

To date, COVID-19 has not had a financial impact on the Company. However, COVID-19 has impacted the pace of our enrollment in our clinical trials and our preclinical studies. The full extent and duration of the impact of COVID-19 on the Company's operations and financial performance is currently unknown and depends on future developments that are uncertain and unpredictable.

10,000,000 Shares



Common Stock

PRELIMINARY PROSPECTUS

Joint Book-Running Managers

MORGAN STANLEY

SVB LEERINK

EVERCORE ISI

Lead-Manager

H.C. WAINWRIGHT & CO.

Until _____, 2021, all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

PART II
INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth the fees and expenses, other than underwriting discounts and commissions, payable in connection with the registration of the common stock hereunder. All amounts are estimates except the SEC registration fee.

	Amount Paid or to be Paid
SEC registration fee	\$ 25,093
FINRA filing fee	35,000
Nasdaq Global Select Market listing fee	170,000
Legal fees and expenses	1,250,000
Accounting fees and expenses	882,995
Printing and mailing expenses	475,000
Transfer agent and registrar fees and expenses	15,500
Miscellaneous	46,412
Total	<u>\$ 2,900,000</u>

Item 14. Indemnification of directors and officers

Section 145 of the Delaware General Corporation Law, or the DGCL, authorizes a corporation to indemnify its directors and officers against liabilities arising out of actions, suits and proceedings to which they are made or threatened to be made a party by reason of the fact that they have served or are currently serving as a director or officer to a corporation. The indemnity may cover expenses (including attorneys' fees) judgments, fines and amounts paid in settlement actually and reasonably incurred by the director or officer in connection with any such action, suit or proceeding. Section 145 permits corporations to pay expenses (including attorneys' fees) incurred by directors and officers in advance of the final disposition of such action, suit or proceeding. In addition, Section 145 provides that a corporation has the power to purchase and maintain insurance on behalf of its directors and officers against any liability asserted against them and incurred by them in their capacity as a director or officer, or arising out of their status as such, whether or not the corporation would have the power to indemnify the director or officer against such liability under Section 145.

We have adopted provisions in our certificate of incorporation and bylaws to be in effect upon the closing of this offering that limit or eliminate the personal liability of our directors to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended. Consequently, a director will not be personally liable to us or our stockholders for monetary damages or breach of fiduciary duty as a director, except for liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- any unlawful payments related to dividends or unlawful stock purchases, redemptions or other distributions; or
- any transaction from which the director derived an improper personal benefit.

These limitations of liability do not alter director liability under the federal securities laws and do not affect the availability of equitable remedies such as an injunction or rescission.

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In addition, our bylaws provide that:

- we will indemnify our directors, officers and, in the discretion of our board of directors, certain employees to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended; and
- we will advance reasonable expenses, including attorneys' fees, to our directors and, in the discretion of our board of directors, to our officers and certain employees, in connection with legal proceedings relating to their service for or on behalf of us, subject to limited exceptions.

We intend to enter into indemnification agreements with each of our directors and executive officers. These agreements provide that we will indemnify each of our directors, certain of our executive officers and, at times, their affiliates to the fullest extent permitted by Delaware law. We will advance expenses, including attorneys' fees (but excluding judgments, fines and settlement amounts), to each indemnified director or executive officer in connection with any proceeding in which indemnification is available and we will indemnify our directors and officers for any action or proceeding arising out of that person's services as a director or officer brought on behalf of us or in furtherance of our rights. Additionally, certain of our directors or officers may have certain rights to indemnification, advancement of expenses or insurance provided by their affiliates or other third parties, which indemnification relates to and might apply to the same proceedings arising out of such director's or officer's services as a director referenced herein. Nonetheless, we have agreed in the indemnification agreements that our obligations to those same directors or officers are primary and any obligation of such affiliates or other third parties to advance expenses or to provide indemnification for the expenses or liabilities incurred by those directors are secondary.

We also maintain general liability insurance which covers certain liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers, including liabilities under the Securities Act of 1933, as amended (the Securities Act).

The underwriting agreement filed as Exhibit 1.1 to this registration statement provides for indemnification of us and our directors and officers by the underwriters against certain liabilities under the Securities Act and the Securities Exchange Act of 1934.

Item 15. Recent Sales of Unregistered Securities.

Set forth below is information regarding securities we have issued within the past three years that were not registered under the Securities Act. Amounts below do not give effect to the Reorganization.

(a) Issuances of Capital Stock

In April 2017, certain investors purchased an aggregate of 50,000,000 of our Series A Preferred Units for \$50,000,000.00 at a price of \$1.00 per unit.

In October 2019, certain investors purchased an aggregate of 30,128,204 of our Series B Preferred Units for \$46,999,998.24 at a price of \$1.56 per unit.

In December 2019, certain investors purchased an aggregate of 23,878,203 of our Series B Preferred Units for \$37,249,996.68 at a price of \$1.56 per unit.

In February 2020, certain investors purchased an aggregate of 6,891,025 of our Series B Preferred Units for \$10,749,999.00 at a price of \$1.56 per unit.

In March 2020, certain investors purchased an aggregate of 2,243,584 of our Series B Preferred Units for \$3,499,997.28 at a price of \$1.56 per unit.

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In November 2020, Cullinan Pearl purchased 22,868 common units for \$13,950.00 at a price of \$0.61 per common unit.

In December 2020, certain investors purchased an aggregate of 66,599,045 of our Series C Preferred Units for \$131,200,118.65 at a price of \$1.97 per unit.

No underwriters were involved in the foregoing sales of securities. Unless otherwise stated, the sales of securities described above were deemed to be exempt from registration pursuant to Section 4(a)(2) of the Securities Act, including Regulation D and Rule 506 promulgated thereunder, as transactions by an issuer not involving a public offering. All of the purchasers in these transactions represented to us in connection with their purchase that they were acquiring the securities for investment and not distribution, that they could bear the risks of the investment and could hold the securities for an indefinite period of time. Such purchasers received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration or an available exemption from such registration. All of the foregoing securities are deemed restricted securities for the purposes of the Securities Act.

(b) Grants and Exercises of Stock Options

Through December 31, 2020, we have granted an aggregate of 12,276,000 nonvoting incentive units, with a grant date fair value of \$0.0001 per unit, 2,254,231 restricted common units with a retrospective grant date fair value of \$1.16 per unit, and 32,493,491 common unit options with a strike price of \$0.61 per unit, to employees, directors and consultants pursuant to the 2016 Equity Incentive Plan and 2020 Unit Option and Grant Plan. Of those awards, 379,500 have been forfeited, 91,863 have been exercised and 46,552,359 remain outstanding.

The issuances of the securities described above were deemed to be exempt from registration pursuant to Section 4(a)(2) of the Securities Act or Rule 701 promulgated under the Securities Act as transactions pursuant to compensatory benefit plans. The shares of common stock issued upon the exercise of options are deemed to be restricted securities for purposes of the Securities Act.

Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits

<u>Exhibit Number</u>	<u>Description</u>
1.1*	<u>Form of Underwriting Agreement.</u>
2.1*	<u>Form of Agreement and Plan of Merger by and between Cullinan Oncology, LLC and Cullinan Management, Inc.</u>
3.1*	<u>Certificate of Incorporation of the Registrant, as currently in effect.</u>
3.2*	<u>Form of Second Amended and Restated Certificate of Incorporation of the Registrant, to be in effect immediately prior to completion of this offering.</u>
3.3*	<u>Bylaws of the Registrant, as currently in effect.</u>
3.4*	<u>Form of Amended and Restated Bylaws of the Registrant, to be in effect upon the effectiveness of this registration statement.</u>
3.5*	<u>Form of Certificate of Amendment to Certificate of Incorporation of the Registrant, to be in effect immediately prior to the Reorganization.</u>
3.6*	<u>Form of Amended and Restated Certificate of Incorporation of the Registrant, to be in effect in connection with the Reorganization.</u>

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<u>Exhibit Number</u>	<u>Description</u>
3.7*	<u>Form of Certificate of Amendment to Amended and Restated Certificate of Incorporation, to be in effect prior to the effectiveness of this registration statement.</u>
4.1*	<u>Specimen Common Stock Certificate.</u>
4.2*	<u>Third Amended and Restated Limited Liability Company Agreement, dated December 16, 2020, by and among Cullinan Oncology, LLC and its members.</u>
4.3*	<u>Form of Registration Rights Agreement, among the Registrant and certain of its stockholders, to be in effect immediately prior to completion of this offering.</u>
5.1	<u>Opinion of Goodwin Procter LLP.</u>
10.1#*	<u>2021 Stock Option and Incentive Plan and form of award agreements thereunder.</u>
10.2#*	<u>2021 Employee Stock Purchase Plan.</u>
10.3#*	<u>Senior Executive Cash Incentive Bonus Plan.</u>
10.4#*	<u>Form of Indemnification Agreement, between the Registrant and each of its directors.</u>
10.5#*	<u>Form of Indemnification Agreement, between the Registrant and each of its executive officers.</u>
10.6†*	<u>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.</u>
10.7†*	<u>Collaboration Agreement, dated November 28, 2018, by and between Adimab, LLC and Cullinan Management, Inc.</u>
10.8†*	<u>License and Collaboration Agreement, dated February 4, 2019, by and between Taiho Pharmaceutical, Co., Ltd. and Cullinan Pearl Corp.</u>
10.9†*	<u>Exclusive License Agreement, dated August 31, 2020, by and among Deutsches Krebsforschungszentrum, Eberhard Karls University of Tuebingen, Faculty of Medicine, Universitätsmedizin Gesellschaft für Forschung und Entwicklung mbH, Tübingen and Cullinan Florentine Corp.</u>
10.10#*	<u>Offer Letter, dated June 16, 2017, by and between Cullinan Management, Inc. and Leigh Zawel.</u>
10.11#*	<u>Offer Letter, dated May 1, 2017, by and between Cullinan Management, Inc. and Owen Hughes.</u>
10.12#*	<u>Offer Letter, dated August 25, 2020, by and between Cullinan Management, Inc. and Jeffrey Trigilio.</u>
10.13#*	<u>Form of Executive Employment Agreement</u>
10.14#*	<u>Consulting Agreement, dated January 1, 2019, by and between Cullinan Management, Inc. and Corinne Savill.</u>
10.15#*	<u>Consulting Agreement, dated January 1, 2019, by and between Cullinan Management, Inc. and Patrick Baeuerle.</u>
10.16#*	<u>Consulting Agreement, dated April 1, 2020, by and between Cullinan Management, Inc. and Globeways Holdings Limited.</u>
10.17*	<u>Sublease, effective as of December 14, 2017, by and between Teva Pharmaceuticals USA, Inc. and Cullinan Management, Inc.</u>
10.18*	<u>Form of Voting Agreement</u>
10.19*	<u>Form of Investors Rights Agreement</u>

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<u>Exhibit Number</u>	<u>Description</u>
10.20*	Form of Services Agreement
10.21*	Form of Royalty Transfer Agreements
10.22*	Form of Contribution Agreement by and between Cullinan Oncology, LLC and Cullinan Management, Inc.
10.23##*	Non-Employee Director Compensation Policy.
10.24†*	License Agreement, dated December 24, 2020, by and between Cullinan Pearl Corp. and Zai Lab (Shanghai) Co., Ltd.
10.25##*	Services Agreement, by and between the Company and Patrick Baeuerle.
21.1*	List of Subsidiaries of the Registrant.
23.1	Consent of KPMG LLP independent registered public accounting firm.
23.2	Consent of Goodwin Procter LLP (included in Exhibit 5.1).
24*	Power of Attorney (included on signature page).

* Previously filed.

Indicates a management contract or compensatory plan, contract or arrangement.

† Portions of this exhibit (indicated by asterisks) have been omitted in accordance with the rules of the Securities and Exchange Commission.

(b) Financial Statement Schedules

None.

Item 17. Undertakings.

Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act of 1933 and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes that:

(a) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(b) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the city of Cambridge, Massachusetts on January 6, 2021.

Cullinan Management, Inc.

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

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

<u>Name</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Owen Hughes</u> Owen Hughes	President, Chief Executive Officer, and Director (Principal Executive Officer)	January 6, 2021
<u>/s/ Jeffrey Trigilio</u> Jeffrey Trigilio	Chief Financial Officer (Principal Financial and Accounting Officer)	January 6, 2021
<u>*</u> Tim Anderson	Director	January 6, 2021
<u>*</u> Thomas Ebeling	Director	January 6, 2021
<u>*</u> Ansbert Gadicke, M.D.	Director	January 6, 2021
<u>*</u> Morana Jovan-Embiricos, Ph.D.	Director	January 6, 2021
<u>*</u> Anthony Rosenberg	Director	January 6, 2021
<u>*</u> Stephen Webster	Director	January 6, 2021

*By: /s/ Owen Hughes
Owen Hughes
Attorney-in-fact



Goodwin Procter LLP
100 Northern Avenue
Boston, MA 02210

goodwinlaw.com

+1 617 570 1000

January 6, 2021

Cullinan Management, Inc.
One Main Street, Suite 520
Cambridge, MA 02142

Re: Securities Registered under Registration Statement on Form S-1

We have acted as counsel to you in connection with your filing of a Registration Statement on Form S-1 (File No. 333-251512) (as amended or supplemented, the "Registration Statement") pursuant to the Securities Act of 1933, as amended (the "Securities Act"), relating to the registration of the offering by Cullinan Management, Inc., a Delaware corporation (the "Company") of up to 11,500,000 shares (the "Shares") of the Company's Common Stock, \$0.0001 par value per share, including 1,500,000 shares purchasable by the underwriters upon their exercise of an over-allotment option granted to the underwriters by the Company. The Shares are being sold to the several underwriters named in, and pursuant to, an underwriting agreement among the Company and such underwriters (the "Underwriting Agreement").

We have reviewed such documents and made such examination of law as we have deemed appropriate to give the opinions set forth below. We have relied, without independent verification, on certificates of public officials and, as to matters of fact material to the opinions set forth below, on certificates of officers of the Company.

The opinion set forth below is limited to the Delaware General Corporation Law.

Based on the foregoing, we are of the opinion that the Company Shares have been duly authorized and, upon issuance and delivery against payment therefor in accordance with the terms of the Underwriting Agreement, the Company Shares will be validly issued, fully paid and non-assessable.

We hereby consent to the inclusion of this opinion as Exhibit 5.1 to the Registration Statement and to the references to our firm under the caption "Legal Matters" in the Registration Statement. In giving our consent, we do not admit that we are in the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations thereunder.

Very truly yours,

/s/ Goodwin Procter LLP

GOODWIN PROCTER LLP

Consent of Independent Registered Public Accounting Firm

The Board of Directors
Cullinan Oncology, LLC:

We consent to the use of our report included herein and to the reference to our firm under the heading “Experts” in the prospectus.

/s/ KPMG LLP

Boston, Massachusetts
January 6, 2021