

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2021

OR

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

Commission File Number: 001-39856

CULLINAN ONCOLOGY, INC.

(Exact name of Registrant as specified in its Charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

One Main Street
Suite 520
Cambridge, MA
(Address of principal executive offices)

81-3879991
(I.R.S. Employer
Identification No.)

02142
(Zip Code)

Registrant's telephone number, including area code: (617) 410-4650

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

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer
Non-accelerated filer

Accelerated filer
Smaller reporting company
Emerging growth company

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

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES NO

The number of shares of the registrant's common stock outstanding as of April 30, 2021 was 43,516,125.

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Summary of the Material and Other Risks Associated with Our Business

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

- Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.
- We have incurred significant losses since inception, and we expect to incur losses over the next several years and may not be able to achieve or sustain revenues or profitability in the future.
- We will require substantial additional funding to develop and commercialize our product candidates and identify and invest in new product candidates. If we are unable to raise capital when needed, we would be compelled to delay, reduce or eliminate our product development programs or other operations.
- We may not be successful in our efforts to 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 immunology 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.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These statements involve risks, uncertainties, and other factors that may cause actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. All statements, other than statements of historical facts, contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management and expected market growth are forward-looking statements. The words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

These forward-looking statements include, among other things, 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;
- 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 Quarterly Report on Form 10-Q. 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 Quarterly Report on Form 10-Q and the documents that we reference herein and have filed or incorporated by reference as exhibits hereto completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

This Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q, 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 Quarterly Report on Form 10-Q.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	December 31, 2020 (1)	March 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 168,198	\$ 293,537
Prepaid expenses and other current assets	2,072	6,419
Short term investments	42,008	147,337
Total current assets	212,278	447,293
Property and equipment, net	130	115
Other assets	2,300	147
Long term investments	—	32,111
Total assets	<u>\$ 214,708</u>	<u>\$ 479,666</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 9,679	\$ 3,879
Accrued expenses and other current liabilities	4,641	6,015
Total current liabilities	14,320	9,894
Long-term liabilities:		
Deferred rent	74	73
Total liabilities	14,394	9,967
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Common stock, \$0.0001 par value, 34,900,878 and 150,000,000 shares authorized as of December 31, 2020 and March 31, 2021, respectively; 29,381,125 and 43,516,125 shares issued and outstanding as of December 31, 2020 and March 31, 2021, respectively	3	4
Additional paid-in capital	292,348	560,366
Accumulated other comprehensive loss	(2)	(60)
Accumulated deficit	(93,339)	(93,409)
Total Cullinan stockholders' equity	199,010	466,901
Noncontrolling interests	1,304	2,798
Total stockholders' equity	200,314	469,699
Total liabilities and stockholders' equity	<u>\$ 214,708</u>	<u>\$ 479,666</u>

See accompanying notes to the unaudited consolidated financial statements.

(1) The consolidated balance sheet as of December 31, 2020 is derived from the audited consolidated financial statements as of that date and was retroactively adjusted, including shares and per share amounts, as a result of the Reorganization and Reverse Stock Split. See Note 3 to the consolidated financial statements for additional details.

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

	Three Months Ended March 31,	
	2020	2021
License revenue	\$ —	\$ 18,943
Operating expenses:		
Research and development	4,173	12,415
General and administrative	1,368	5,156
Total operating expenses	5,541	17,571
Income/(loss) from operations	(5,541)	1,372
Other income (expense):		
Interest income	378	49
Other income (expense), net	—	(2)
Net Income/(loss)	(5,163)	1,419
Net income/(loss) attributable to noncontrolling interest	(190)	1,489
Net loss attributable to common stockholders of Cullinan	\$ (4,973)	\$ (70)
Net loss per share, basic and diluted	\$ (0.27)	\$ (0.00)
Total weighted-average shares used in computing net loss per share, basic and diluted	18,747,004	41,977,336
Comprehensive income/(loss):		
Net income/(loss)	\$ (5,163)	\$ 1,419
Unrealized gain/(loss) on investments	30	(58)
Comprehensive income/(loss)	(5,133)	1,361
Comprehensive income/(loss) attributable to noncontrolling interest	(190)	1,489
Comprehensive income/(loss) attributable to Cullinan	\$ (4,943)	\$ (128)

See accompanying notes to the unaudited consolidated financial statements.

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

	Common Stock		Noncontrolling Interest in Subsidiaries	Additional Paid-In Capital	Accumulated Other Comprehensive Income/(Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount					
Balances at December 31, 2019 (1)	18,738,734	\$ 2	\$ 864	138,543	(4)	\$ (41,540)	97,865
Issuance of common stock equivalents (1) net of issuance costs of \$213	1,297,700	—	—	14,037	—	—	14,037
Unrealized gain on investments	—	—	—	—	30	—	30
Net loss	—	—	(190)	—	—	(4,973)	(5,163)
Balances at March 31, 2020	20,036,434	\$ 2	\$ 674	\$ 152,580	\$ 26	\$ (46,513)	\$ 106,769
Balances at December 31, 2020 (1)	29,831,125	\$ 3	\$ 1,304	\$ 292,348	\$ (2)	\$ (93,339)	\$ 200,314
Initial public offering net of issuance costs of \$22,870	13,685,000	1	—	264,515	—	—	264,516
Stock based compensation	—	—	5	3,503	—	—	3,508
Unrealized loss on investments	—	—	—	—	(58)	—	(58)
Net income/(loss)	—	—	1,489	—	—	(70)	1,419
Balances at March 31, 2021	43,516,125	\$ 4	\$ 2,798	\$ 560,366	\$ (60)	\$ (93,409)	\$ 469,699

See accompanying notes to the unaudited consolidated financial statements.

(1) The consolidated balance sheets as of December 31, 2019 and 2020 are derived from the audited consolidated financial statements as of those dates and were retroactively adjusted, including shares and per share amounts, as a result of the Reorganization and Reverse Stock Split. Changes in stockholders' equity for the three months ended March 31, 2020 were also retroactively adjusted, including shares and per share amounts, as a result of the Reorganization and Reverse Stock Split. See Note 3 to the consolidated financial statements for additional details.

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

	Three Months Ended March 31,	
	2020	2021
Operating activities:		
Net income/(loss)	\$ (5,163)	\$ 1,419
Adjustments to reconcile net income/(loss) to net cash used in operating activities:		
Depreciation and amortization	16	15
Equity-based compensation expense	—	3,508
Amortization or accretion on marketable securities	25	229
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	693	(4,352)
Accounts payable	170	(4,124)
Accrued expenses and other current liabilities	(756)	1,790
Net cash used in operating activities	<u>(5,015)</u>	<u>(1,515)</u>
Investing activities:		
Purchases of property and equipment	(3)	—
Purchase of available-for-sale securities	(31,087)	(149,763)
Proceeds from sales and maturities of investments	4,200	12,037
Net cash used in investing activities	<u>(26,890)</u>	<u>(137,726)</u>
Financing activities:		
Proceeds from issuance of common stock equivalents (1)	14,250	—
Proceeds from initial public offering	—	267,268
Payment of issuance costs related to common stock equivalents (1)	(213)	—
Payment of deferred offering costs	—	(2,688)
Net cash provided by financing activities	<u>14,037</u>	<u>264,580</u>
Net (decrease)/increase in cash and cash equivalents	<u>(17,868)</u>	<u>125,339</u>
Cash and cash equivalents at beginning of period	63,250	168,198
Cash and cash equivalents at end of period	<u>\$ 45,382</u>	<u>\$ 293,537</u>
SUPPLEMENTAL NONCASH DISCLOSURE		
Noncash financing activities		
Deferred offering costs paid in the prior year	<u>\$ —</u>	<u>\$ 65</u>

See accompanying notes to the unaudited consolidated financial statements.

(1) Changes in equity activities for the three months ending March 31, 2020 were retroactively adjusted, including shares and per share amounts, as a result of the Reorganization and Reverse Stock Split. See Note 3 to the consolidated financial statements for additional details.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)**(1) Nature of Business and Basis of Presentation*****Organization***

Cullinan Oncology, Inc., together with its consolidated subsidiaries (Cullinan or the Company), is a biopharmaceutical company developing a diversified pipeline of targeted oncology and immuno-oncology therapies for cancer patients. Cullinan's predecessor company, Cullinan Pharmaceuticals, LLC was formed in September 2016 and was subsequently renamed Cullinan Oncology, LLC (the LLC) in November 2017. The LLC's wholly-owned subsidiary, Cullinan Management, Inc. (Management), was formed in September 2016 and became the surviving entity in a reverse merger with the LLC in January 2021. In February 2021, the Company changed its name from Cullinan Management, Inc., to Cullinan Oncology, Inc.

As of December 31, 2020 and March 31, 2021, the Corporation had five development subsidiaries: Cullinan Apollo Corp. (Apollo), Cullinan Pearl Corp. (Pearl), Cullinan Amber Corp. (Amber), Cullinan Florentine Corp. (Florentine) and Cullinan MICA Corp. (MICA).

Reorganization, Reverse Stock Split and Initial Public Offering

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

Immediately prior to the effectiveness of the Company's registration statement, the Company completed its reorganization, whereby the LLC merged with and into Cullinan Management and Cullinan Management was the surviving entity (the Reorganization). Cullinan Management was the registrant in the IPO. Pursuant to the Reorganization, all outstanding Redeemable Preferred Units, Non-Voting Incentive Units and common units converted into shares of Cullinan Management common stock while common unit options were exchanged for stock options. Immediately following the Reorganization, the Company effected a one-for-7.0390 reverse stock split of its issued and outstanding shares of common stock (the Reverse Stock Split).

Accordingly, all share and per share amounts for all periods presented in the accompanying unaudited consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect the effect of the Reorganization and Reverse Stock Split. Refer to Note 3 for additional details relating to the Reorganization and Reverse Stock Split.

Liquidity

The Company has incurred operating losses and negative cash flows from operations since its inception and expects to continue to generate operating losses for the foreseeable future. The Company's ultimate success depends on the outcome of its research and development activities as well as the ability to commercialize the Company's product candidates. The Company is subject to a number of risks including, but not limited to, the need to obtain adequate additional funding for the ongoing and planned clinical development of its product candidates. Due to the numerous risks and uncertainties associated with pharmaceutical products and development, the Company is unable to accurately predict the timing or amount of funds required to complete development of its product candidates, and costs could exceed the Company's expectations for a number of reasons, including reasons beyond the Company's control. The Company incurred net losses of \$5.2 million for the three months ended March 31, 2020 and recorded net income of \$1.4 million for the three months ended March 31, 2021. As of March 31, 2021, the Company had an accumulated deficit of \$93.4 million.

Since inception, the Company has funded its operations primarily through the sale of equity securities. The Company expects that its cash, cash equivalents and short term investments as of March 31, 2021 of \$440.9 million, along with long term investments of \$32.1 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 unaudited consolidated financial statements.

(2) Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited consolidated financial statements of the Company have been prepared in conformity with accounting principles generally accepted in the United States of America (GAAP) and in accordance with applicable rules and regulations of the U.S. Securities and Exchange Commission (SEC) for interim financial reporting. The unaudited financial statements include accounts of the Company 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 unaudited consolidated financial statements have been prepared on the same basis as the annual financial statements and in the opinion of the Company's management, reflect all adjustments, consisting of normal and recurring adjustments, considered necessary for a fair statement of the Company's financial position, its results of operations and comprehensive income (loss) and its cash flows for the periods presented.

The unaudited consolidated financial statements herein do not include all of the disclosures required by GAAP for a complete set of annual audited financial statements, as is permitted by such rules and regulations. The accompanying financial information should be read in conjunction with the consolidated financial statements and notes thereto contained in the Company's Annual Report on Form 10-K filed with the SEC on March 30, 2021 for the year ended December 31, 2020 (the 2020 Form 10-K).

Use of Estimates

The preparation of the accompanying unaudited consolidated 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, revenues, 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 unaudited 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 acquired in process research and development asset and the fair value of equity awards issued by the Company and its subsidiaries prior to the IPO. Actual results may differ from these estimates under different assumptions or conditions.

Principles of Consolidation

The Company consolidates entities in which it has a controlling financial interest. The Company evaluates each of its subsidiaries to determine whether the entity represents a variable interest entity (VIE) for which consolidation should be evaluated under the VIE model, or alternatively, if the entity is a voting interest entity, for which consolidation should be evaluated using the voting interest model (VOE). The Company concluded that none of its subsidiaries is a VIE and has consolidated each subsidiary under the VOE.

The Company has either created or made investments in the following entities:

Consolidated Entities	Relationship as of March 31, 2021	Date Control First Acquired
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

To the extent that ownership interests in the Subsidiaries are held by entities other than the Company, 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 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 March 31, 2020, licensors held noncontrolling interests in Apollo and Pearl. At March 31, 2021, investors and licensors held noncontrolling interests in Apollo, Pearl, Amber, Florentine and MICA. Refer to Note 5 for details relating to the license agreements and Note 7 for details relating to the noncontrolling interests.

For the three months ended March 31, 2020 and 2021, \$0.2 million of net loss and \$1.5 million of net income, respectively, were attributable to noncontrolling interests and recorded in the consolidated statements of operations and comprehensive income (loss) and disclosed within the noncontrolling interests in subsidiaries column in the consolidated statements of stockholders' equity.

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less at the time of purchase to be cash equivalents. As of December 31, 2020 and March 31, 2021, cash equivalents consist of commercial paper and government-backed money market funds.

Investments

The Company determines the appropriate classification of its investments in debt securities at the time of purchase and re-evaluates such determination at each balance sheet date. The Company periodically reviews its investments in debt securities for impairment and adjusts these investments to their fair value when a decline in market value is deemed to be other than temporary. If losses on these securities are considered to be other than temporary, the loss is recognized in earnings.

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

Available-for-sale marketable securities are carried at estimated fair value, with unrealized gains or losses included in accumulated other comprehensive income (loss) in stockholders' equity. 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 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.

The Company recognized its short-term investment marketable securities by security type at December 31, 2020:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
		(in thousands)		
Corporate notes	\$ 12,780	\$ —	\$ (3)	\$ 12,777
Commercial paper	24,473	—	—	24,473
Asset-backed securities	4,757	1	—	4,758
	<u>\$ 42,010</u>	<u>\$ 1</u>	<u>\$ (3)</u>	<u>\$ 42,008</u>

The Company recognized its short-term investment marketable securities and long-term investment by security type at March 31, 2021:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
	(in thousands)			
Short term investments				
Corporate notes	\$ 43,468	\$ 0	\$ (24)	\$ 43,444
Commercial paper	94,051	2	—	94,053
Asset-backed securities	9,841	—	(1)	9,840
Long term investments				
Corporate notes	32,146	—	(35)	32,111
	<u>\$ 179,506</u>	<u>\$ 2</u>	<u>\$ (60)</u>	<u>\$ 179,448</u>

Fair Value of Financial Instruments

The following table sets forth the fair value of the Company's financial assets as of December 31, 2020, allocated into Level 1, Level 2 and Level 3, that was measured on a recurring basis:

	Level 1	Level 2	Level 3	Total
	(in thousands)			
Cash and cash equivalents				
Cash	\$ 22,007	\$ —	\$ —	\$ 22,007
Money market funds	146,191	—	—	146,191
Short-term investments				
Corporate notes	—	12,777	—	12,777
Commercial paper	—	24,473	—	24,473
Asset-backed securities	—	4,758	—	4,758
	<u>\$ 168,198</u>	<u>\$ 42,008</u>	<u>\$ —</u>	<u>\$ 210,206</u>

The following table sets forth the fair value of the Company's financial assets as of March 31, 2021, allocated into Level 1, Level 2 and Level 3, that was measured on a recurring basis:

	Level 1	Level 2	Level 3	Total
	(in thousands)			
Cash and cash equivalents				
Cash	\$ 39,021	\$ —	\$ —	\$ 39,021
Money market funds	254,516	—	—	254,516
Short-term investments				
Corporate notes	—	43,444	—	43,444
Commercial paper	—	94,053	—	94,053
Asset-backed securities	—	9,840	—	9,840
Long-term investments				
Corporate notes	—	32,111	—	32,111
	<u>\$ 293,537</u>	<u>\$ 179,448</u>	<u>\$ —</u>	<u>\$ 472,985</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.

Deferred Offering Costs

The Company capitalizes costs that are directly associated with in-process equity financings until such financings are consummated at which time such costs are recorded against the gross proceeds of the offering. Should the in-process equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the consolidated statements of operations and comprehensive income (loss). The Company incurred \$2.7 million of deferred offering costs and recorded such amounts against the gross proceeds of our IPO within the statements of stockholders' equity during the three months ended March 31, 2021.

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.

Revenue Recognition

The Company recognizes revenue in accordance with ASC Topic 606, Revenue from Contracts with Customers, or ASC 606. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

The Company enters into licensing arrangements for research and development, manufacturing and commercialization activities, which have components within the scope of ASC 606. Payments pursuant to these arrangements typically include non-refundable, upfront payments, milestone payments upon achieving significant development events, research and development reimbursements, sales milestones and royalties on future product sales. The amount of variable consideration is constrained until it is probable that the revenue is not at a significant risk of reversal in a future period. The contracts into which the Company enters generally do not include significant financing components. As part of the accounting for these arrangements, the Company must use significant judgment to determine: a) the number of performance obligations based on the determination under step (ii) above; b) the transaction price under step (iii) above; c) the stand-alone selling price for each performance obligation identified in the contract for the allocation of transaction price in step (iv) above, and d) the measure of progress in step (v) above. The Company uses judgment to determine whether milestones or other variable consideration, except for royalties, should be included in the transaction price as described further below.

Non-Exclusive Licenses

If the license to the Company's intellectual property is determined to be distinct from the other promises or performance obligations identified in the arrangement, the Company recognizes revenue from non-refundable, upfront fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. In assessing whether a promise or performance obligation is distinct from the other elements, the Company considers factors such as the research, development, manufacturing and commercialization capabilities of the collaboration partner and the availability of the associated expertise in the general marketplace. In addition, the Company considers whether the collaboration partner can benefit from a promise for its intended purpose without the receipt of the remaining elements, whether the value of the promise is dependent on the unsatisfied promise, whether there are other vendors that could provide the remaining promise and whether it is separately identifiable from the remaining promise. For licenses that are combined with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. The measure of progress, and thereby periods over which revenue should be recognized, are subject to estimates by management and may change over the course of the agreement. Such a change could have a material impact on the amount of revenue the Company records in future periods.

Milestone Payments

At the inception of each arrangement that includes milestone payments, the Company evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The Company evaluates factors such as the scientific, clinical, regulatory, commercial and other risks that must be overcome to achieve the respective milestone in making this assessment. There is considerable judgment involved in determining whether it is probable that a significant revenue reversal would not occur. At the end of each subsequent reporting period, the Company reevaluates the probability of achievement of all milestones subject to constraint and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

Royalties

For arrangements that include sales-based royalties, including milestone payments based on a level of sales, and the license of intellectual property is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue resulting from any of its licensing arrangements.

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 income (loss).

Equity-based Compensation

Equity-based compensation is measured at the grant date for all equity-based awards made to employees and non-employees 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 expense in the same period as the forfeitures occur.

The Company estimated the fair value of the stock options using the Black-Scholes option pricing model, which requires the input of objective and subjective assumptions. Certain assumptions used, including the fair value of the Company's common stock prior to the time of the IPO and stock price volatility, represent management's estimates and involve inherent uncertainties and the application of management's judgment. As a result, if factors change and management uses different assumptions, equity-based compensation expense could be materially different for future awards.

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

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A reduction in the carrying value of the deferred tax assets is required when it is not more likely than not that such deferred tax assets are not realizable.

Net Loss per Share

Basic and diluted net loss per share is determined by dividing net loss attributable to common stockholders by the weighted-average shares of common stock outstanding during the period, without consideration for potential dilutive shares of common stock, such as stock options, unvested restricted stock awards and shares issuable under the employee stock purchase plan. Accordingly, in periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, since dilutive shares of common stock are not assumed to have been issued if their effect is anti-dilutive. Therefore, the weighted-average shares used to calculate both basic and diluted net loss per share are the same. The Company excluded unvested shares of restricted stock awards, stock options and shares issuable under the employee stock purchase plan from the computation of diluted weighted-average shares outstanding as they would be antidilutive.

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 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.

(3) Reorganization and Reverse Stock Split

Immediately prior to the completion of the IPO in January 2021, the LLC completed the Reorganization. Prior to the Reorganization, Management was a wholly-owned subsidiary of the LLC. The LLC was also the direct parent company of the Company's development subsidiaries. Pursuant to the Reorganization, Management acquired all the assets of the LLC, including all of the stock the LLC owns of Apollo, Florentine, Amber, Pearl and MICA (collectively the Asset Subsidiaries), and assumed all of the LLC's liabilities and obligations.

Following the Reorganization, all of Management's outstanding preferred stock automatically converted on a 1-for-1 basis into common stock of Management. The Company then effected a one-for-7.0390 reverse split of its common stock (the Reverse Stock Split). Immediately prior to completion of the Company's IPO, the existing units of the LLC were cancelled and the number of shares of common stock exchanged and issued to the LLC's unitholders in the Reorganization is shown in the below table by unit class, on a split adjusted basis:

Cullinan Oncology, LLC Unit Type	Number of Management's Shares Issued	Adjusted for the Reverse Stock Split
Series C Preferred Units	66,599,045	9,461,414
Series B Preferred Units	63,141,016	8,970,154
Series A1 Preferred Units	50,000,000	7,103,280
Series Seed Preferred Units	16,000,000	2,273,050
Non-Voting Incentive Units	11,896,500	1,689,949
Common Units	34,747,722	4,936,415
Total shares issued	242,384,283	34,434,262

The amount presented for Non-Voting Incentive Units included unvested outstanding Non-Voting Incentive Units that were exchanged for restricted stock of Management. The amount presented for Common Units included the unvested outstanding Restricted Common Units, exchanged for Management's restricted stock, and issued and unvested Common Unit Options, that were exchanged for Management's stock options. The unvested awards are subject to the same time-based vesting conditions as the original awards.

The Reorganization was accounted for as a reverse acquisition, where the LLC was determined to be the accounting acquirer and Management to be the legal acquiree, and recapitalization for financial reporting purposes. Accordingly, the historical financial statements of the LLC became the Company's historical financial statements, including the comparative prior periods. All share and per share amounts in these unaudited consolidated financial statements and related notes have been retroactively adjusted, where applicable, for all periods presented. The shares of the Company's common stock for periods prior to the Reorganization represent the outstanding units of the LLC recalculated to give effect to the Reorganization and Reverse Stock Split.

All LLC units that were previously reported as Redeemable Preferred Units, or temporary equity, were converted to common stock of the Company upon the execution of the Reorganization and have been reclassified to stockholders' equity for all periods presented, as if the Reorganization occurred at the beginning of the earliest period presented in the Company's financial statements for the year ending December 31, 2020, as follows:

	As of December 31, 2019		
	As Reported	Adjustment	As Adjusted
	(in thousands)		
Redeemable Preferred Units			
Series Seed Redeemable Preferred Units	\$ 3,956	\$ (3,956)	\$ —
Series A1 Redeemable Preferred Units	49,946	(49,946)	—
Series B Redeemable Preferred Units	83,872	(83,872)	—
Series C Redeemable Preferred Units	—	—	—
Total Redeemable Preferred Units	137,774	(137,774)	—
Stockholders' Equity (Members' Deficit)			
Non-Voting Incentive Units	1	(1)	—
Common Stock	—	2	2
Additional paid-in capital	770	137,773	138,543
Accumulated other comprehensive loss	(4)	—	(4)
Accumulated deficit	(41,540)	—	(41,540)
Total Cullinan Stockholders' Equity (Members' Deficit)	(40,773)	137,774	97,001
Non-controlling interests in subsidiaries	864	—	864
Total Stockholders' Equity (Members' Deficit)	\$ (39,909)	\$ 137,774	\$ 97,865

	As of December 31, 2020		
	As Reported	Adjustment	As Adjusted
	(in thousands)		
Redeemable Preferred Units			
Series Seed Redeemable Preferred Units	\$ 3,956	\$ (3,956)	\$ —
Series A1 Redeemable Preferred Units	49,946	(49,946)	—
Series B Redeemable Preferred Units	97,909	(97,909)	—
Series C Redeemable Preferred Units	124,841	(124,841)	—
Total Redeemable Preferred Units	<u>276,652</u>	<u>(276,652)</u>	<u>—</u>
Stockholders' Equity (Members' Deficit)			
Non-Voting Incentive Units	1	(1)	—
Common Stock	—	3	3
Additional paid-in capital	15,698	276,650	292,348
Accumulated other comprehensive loss	(2)	—	(2)
Accumulated deficit	(93,339)	—	(93,339)
Total Cullinan Stockholders' Equity (Members' Deficit)	<u>(77,642)</u>	<u>276,652</u>	<u>199,010</u>
Non-controlling interests in subsidiaries	1,304	—	1,304
Total Stockholders' Equity (Members' Deficit)	<u>\$ (76,338)</u>	<u>\$ 276,652</u>	<u>\$ 200,314</u>

(4) Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

	December 31,	March 31,
	2020	2021
	(in thousands)	
Accrued bonus	\$ 1,763	\$ 563
Professional fees	1,018	851
Research and development costs	1,829	1,510
Other	31	91
	<u>\$ 4,641</u>	<u>\$ 3,015</u>

(5) 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 consolidated statements of operations and comprehensive (income) loss for the three months ended March 31, 2020 and 2021. For details on the structure and accounting treatment for the Company's collaboration and license agreements, refer to the annual consolidated financial statements and notes contained in the 2020 Form 10-K.

	Three Months Ended March 31,	
	2020	2021
	(in thousands)	
Cullinan Management - Adimab	\$ 104	\$ —
Apollo - Wistar	136	—
Pearl - Taiho	—	3,000
	<u>\$ 240</u>	<u>\$ 3,000</u>

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. Zai will be primarily responsible for substantially all the costs related to the operations and control over the significant activities related to the exploitation of the licensed IP.

As partial consideration of the license and rights granted to Zai Lab, Zai Lab paid Pearl a one-time, irrevocable, nonrefundable license fee of \$20.0 million in January 2021. In addition to the upfront fee, Zai Lab will be 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 \$211.0 million, and tiered royalty payments based on the annual net sales of the licensed product. The Company recognized the upfront license fee in revenue. The Company will also recognize milestone and royalty payments in revenue once they are earned. No milestones have been achieved to date under the Zai License Agreement.

The upfront payment received by Pearl was subject to foreign tax withholdings. When the licensed IP and technology know-how was transferred to Zai Lab in January 2021, Pearl recognized revenue of \$18.9 million, which represented the upfront fee less the foreign tax withholdings as Pearl does not expect to recover the amounts relating to the foreign tax withholdings.

In connection with the Taiho License Agreement, Pearl is obligated to pay Taiho Pharmaceutical, Co., Ltd. (Taiho Pharma) a percentage of future revenue received from Zai Lab, including the upfront payment that was received in January 2021. Upon receipt of the upfront payment, Pearl recognized \$3.0 million within research and development expenses in the consolidated statements of operations and comprehensive (income) loss.

(6) Cullinan-MICA Asset Acquisition

On May 28, 2020 (the Acquisition Date), in accordance with the Series A Senior Preferred Stock Purchase Agreement (the Purchase Agreement), the Company 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 Cullinan 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 March 31, 2021.

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 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, and 14,103,883 shares of Series A, A-1 and A2 Junior Preferred Stock described above. In addition, there were 2,034,457 shares of common stock underlying options reserved under the 2019 Equity Incentive Plan (of which 1,826,402 was reserved for future issuances to MICA's directors and officers, as well as former employees of PDI Therapeutics).

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 Company's initial purchase represented approximately 24% 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 Company can increase its ownership to approximately 54% 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 Company 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 Company.

The Company also entered into a Services Agreement with MICA under which the Company will perform functions required for MICA's operations, including accounts payable, cash management, record keeping, research and development and accounting services.

Given the Company's ownership of the Series A Senior Preferred Stock and its majority representation on MICA's board of directors, the Company's 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.

The Company 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 Company's investment in MICA, the fair value of the noncontrolling interests in MICA and the Company'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 consolidated statements of operations and comprehensive income (loss) during the twelve months ended December 31, 2020 as it had no alternative future use at the time of the acquisition.

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.

(7) Common Stock and Noncontrolling Interest in Subsidiaries

Common Stock

As of December 31, 2020 and March 31, 2021, 34,900,878 and 150,000,000 shares of common stock were authorized, respectively. Each share of common stock entitles the holder to one vote and to receive dividends when and if declared by the board of directors of the Company. No dividends have been declared through March 31, 2021.

The LLC's outstanding Non-Voting Incentive Units have been retroactively adjusted to reflect the effect of the Reorganization and Reverse Stock Split. Refer to Note 3 for additional details relating to the Reorganization and Reverse Stock Split.

Noncontrolling Interest in Subsidiaries

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

In November 2020, the LLC entered into a Restricted Stock Contribution Agreement (Contribution Agreement) with Amber, Pearl and Florentine where the LLC exchanged common units of the LLC for restricted common stock held by LLC employees at each of the Subsidiaries. The LLC's outstanding restricted common units have been retroactively adjusted to reflect the effect of the Reorganization and Reverse Stock Split. Refer to Note 3 for additional details relating to the Reorganization and the Reverse Stock Split.

Cullinan Apollo Corp.

In December 2018, Apollo entered into a Series A Preferred Stock purchase agreement with the Company. 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 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.

The Company did not allocate any losses to the noncontrolling interests for the three months ended March 31, 2020 and 2021.

Cullinan Pearl Corp.

In February 2019, Pearl entered into a Series A Preferred Stock Purchase Agreement with the Company 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. Pearl completed the initial closing of its Series A Preferred Stock where Pearl issued 14,000,000 shares of Series A Preferred Stock for \$14.0 million to the Company and Taiho Ventures. In connection with the license agreement with Taiho Pharma, Pearl issued 1,860,000 shares of common stock as anti-dilution shares, in exchange for no cash consideration.

In August 2020, Pearl issued 9,000,000 additional subsidiary shares of Series A Preferred Stock for \$9.0 million to the Company and Taiho Ventures. In connection with the license agreement, Pearl then issued 1,206,000 additional shares of its common stock as anti-dilution shares, in exchange for no additional consideration.

In November 2020, pursuant to a Subscription Agreement between the Company and Pearl, the Company purchased 2,730,227 shares of Pearl's common stock at \$0.44 per share, for an aggregate purchase price of \$1.2 million.

Under the HLBV method, \$0.2 million of losses and \$1.7 million of income were attributed to noncontrolling interests for the three months ended March 31, 2020 and 2021, respectively, due to Taiho Ventures' preferred stock ownership in Pearl.

Cullinan Amber Corp.

In April 2020, in connection with its Series A Preferred Stock financing, Amber issued 3,000,000 shares of its Series A Preferred Stock to the Company 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.

The Company did not allocate any losses to the noncontrolling interests for the three months ended March 31, 2020 and 2021.

Cullinan Florentine Corp.

In August 2020, Florentine entered into a Series A Preferred Stock purchase agreement with the Company. 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 additional 6,000,000 shares of Series A Preferred Stock at one or more subsequent closings at \$1.00 per share. 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.

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. Florentine issued additional 381,810 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.

The Company did not allocate any losses to the noncontrolling interests for the three months ended March 31, 2020 and 2021.

Cullinan MICA Corp.

In May 2020, MICA issued 6,088,282 million shares of Series A Senior Preferred Stock, including 5,385,787 to the Company, at \$1.31 per share. See Note 6 for further details.

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 Company's Series A Senior Preferred Stock position, and \$5.7 million was initially allocated to noncontrolling interests, including the Junior Preferred and Common Stockholders.

In December 2020, the MICA board authorized the issuance of 3,367,804 shares of MICA common stock to the Company, at a purchase price of \$0.23 per share for aggregate proceeds to MICA of \$0.8 million. As a result of these transactions, the Company's ownership interests in MICA increased to 35% as of December 31, 2020.

Under the HLBV method, \$0.2 million of losses were attributed to noncontrolling interests for the three months ended March 31, 2021.

(8) Equity-Based Compensation

2021 Stock Options and Incentive Plan

The 2021 Stock Option and Incentive Plan (the 2021 Stock Plan) was adopted by the board of directors in December 2020 and the stockholders approved the plan in January 2021, prior to the completion of the Company's IPO. The 2021 Stock Plan became effective on the day immediately prior to the effectiveness of the Company's registration statement. The 2020 Unit Option and Grant Plan was terminated once the 2021 Stock Plan was effective. The Company initially reserved 12,546,386 shares of common stock for issuance of awards under the 2021 Stock Plan, which included (x) split-adjusted 320,228 shares of restricted stock 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 issuable upon the exercise of the stock options, with an exercise price equal to the IPO price per share, which were granted to certain executive officers, employees, and affiliates.

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.

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

	Three Months Ended March 31,	
	2020	2021
	(in thousands)	
Research and development	\$ —	\$ 1,569
General and administrative	—	1,939
Total equity-based compensation	\$ —	\$ 3,508

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 stockholders approved the plan in January 2021, prior to the completion of the Company's IPO. The ESPP became effective on the day immediately prior to the effectiveness of the Company's IPO. 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.

For the Company recorded less than \$0.1 million of compensation expense relating to the ESPP for the three months ended March 31, 2021.

(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 three months ended March 31, 2020, the Company incurred less than \$0.1 million for management and advisory services in connection with those agreements. The Company did not incur any expenses relating to these management and advisory services agreements for the three months ended March 31, 2021.

For the three months ended March 31, 2020 and 2021, the Company paid MPM Capital less than \$0.1 million for other operational support. These expenses were recorded as general and administrative expense.

In April 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 Company'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 three months ended March 31, 2021, the Company incurred less than \$0.1 million in costs related to this agreement. We do not expect to incur any further expenses as this agreement expired as of March 31, 2021.

Royalty Transfer Agreements

In October and December 2019 and 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 (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, 2020 and March 31, 2021.

As of March 31, 2021, Amber, Florentine and MICA's programs all remained in pre-clinical research, while Apollo and Pearl's programs were in phase 1/2a 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 transfer agreements as of December 31, 2020 and March 31, 2021. The Company currently does not have any applicable net sales and as a result has paid no royalties under these obligation as of December 31, 2020 and March 31, 2021 nor has the Company accrued any liability as of December 31, 2020 and March 31, 2021. The Company will monitor these instruments for changes in fair value at each reporting date.

(10) Income Taxes

The Company recorded no provision for income taxes for the three months ended March 31, 2020 and 2021.

Deferred tax assets and deferred tax liabilities are recognized based on temporary differences between the financial reporting and tax bases of assets and liabilities using statutory rates. Management of the Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets, which are comprised principally of net operating loss carryforwards and research and development credits. Under the applicable accounting standards, management has considered the Company's history of losses and concluded that it is more likely than not that the Company will not recognize the benefits of federal and state deferred tax assets. Accordingly, a full valuation allowance has been established against the Company's otherwise recognizable net deferred tax assets.

(11) Commitments and Contingencies**Operating Lease**

Rent expense for each of the three months ended March 31, 2020 and 2021 was \$0.2 million.

In December 2017, the Company 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 March 31, 2021:

	(in thousands)	
Remainder of 2021	\$	451
2022		608
2023		618
2024		313
	\$	<u>1,990</u>

(12) 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 three months ended March 31, 2020 and 2021, the expense relating to the matching contribution was less than \$0.1 million.

(13) Net Loss per Share

The following table sets forth the calculation of basic and diluted net loss per share:

	Three Months Ended March 31,	
	2020	2021
	(in thousands, except share and per share data)	
Numerator:		
Net loss attributable to common stockholders of Cullinan	\$ (4,973)	\$ (70)
Denominator		
Total weighted-average shares used in computing net loss per share, basic and diluted	18,747,004	41,977,336
Net Loss per Share:	\$ (0.27)	\$ (0.00)

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

	<u>Three Months Ended March 31,</u>	
	<u>2020</u>	<u>2021</u>
Restricted stock awards	478,293	242,411
Stock options	—	6,600,953
Estimated shares issuable under the ESPP	—	10,101
Total	<u>478,293</u>	<u>6,853,465</u>

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

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited consolidated financial statements and the related notes appearing elsewhere in this Quarterly Report on Form 10-Q and our audited financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2020, our Annual Report, filed with the Securities and Exchange Commission, or the SEC, on March 30, 2021. This discussion and other parts of this Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q.

Overview

We are a biopharmaceutical company developing a diversified pipeline of targeted oncology and immuno-oncology therapies. 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. Our current pipeline includes seven novel oncology programs. We have internally developed or in-licensed these candidates by leveraging our hub-and-spoke business model, which includes a central operating company and separate subsidiaries that are established as needed to hold and advance individual therapeutic candidates. We currently employ or have consulting agreements with all of our team members.

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 (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.

We have five partially-owned development subsidiaries, together the Asset Subsidiaries, or “spokes:” 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 decided to discontinue development of in May 2020 (we intend to dissolve Cullinan Apollo after completing trial wind-down activity); 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. Our earlier-stage programs, Cullinan NexGem, Cullinan Opal and Cullinan Jade, are currently held in Cullinan.

Since inception, we have funded our operations primarily through the sale of equity securities. As of March 31, 2021, we have received net proceeds of \$541.2 million from equity financings, inclusive of our net proceeds of \$264.5 million from our IPO. Furthermore, we received \$18.9 million in net collaboration revenue from the license agreement (Zai License Agreement) with Zai Lab Shanghai Company, Limited (Zai Lab).

As of March 31, 2021, we had cash, cash equivalents, and short-term investments of \$440.9 million and long-term investments of \$32.1 million. We have incurred operating losses and have had negative cash flows from operations since our inception. For the three months ended March 31, 2020 the Company incurred \$5.2 million of net losses. For the three months ended March 31, 2021, the Company generated \$1.4 million of net income. As of March 31, 2021, we had an accumulated deficit of \$93.4 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.

Impact of COVID-19 Pandemic

In December 2019, a novel strain of coronavirus, or 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, declaring the outbreak of COVID-19 as a pandemic, or a worldwide spread of a new disease, on March 11, 2020. 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; however, COVID-19 has impacted the pace of enrollment in our clinical trials and our preclinical studies.

The COVID-19 pandemic continues to present a substantial public health and economic challenge around the world, and to date has led to the implementation of various responses, including government-imposed quarantines, stay-at-home orders, travel restrictions, mandated business closures and other public health safety measures. 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. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, our research programs, healthcare systems or the global economy and we cannot presently predict the scope and severity of any potential business shutdowns or disruptions. 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.

We continue to monitor the impact of the COVID-19 pandemic on all aspects of our business, including how it has and will continue to impact our operations and the operations of our vendors and contractors, and may take further precautionary and preemptive action as may be required by federal, state or local authorities. 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.

Basis of Presentation and Consolidation

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

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 March 31, 2021%(1)</u>
Cullinan Oncology, Inc.	Parent Entity	(2)	N/A
Cullinan Apollo Corp.	Partially-owned Subsidiary	November 2018	71%
Cullinan Pearl Corp.	Partially-owned Subsidiary	November 2018	80%
Cullinan Amber Corp.	Partially-owned Subsidiary	December 2019	90%
Cullinan Florentine Corp.	Partially-owned Subsidiary	December 2019	92%
Cullinan MICA Corp.	Partially-owned Subsidiary	May 2020	35%

(1) Ownership percentages are reflected on a fully-diluted basis.

(2) In January 2021, prior to our initial public offering, we completed a reorganization, pursuant to which the LLC merged with and into Cullinan Management, Inc., or Management, with Management being the surviving entity of such merger, or the Reorganization. In February 2021, our corporate name was changed from Cullinan Management, Inc. to Cullinan Oncology, Inc.

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 non-small cell lung cancer, or 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. Cullinan Pearl also issued to Taiho Ventures, LLC, an affiliate of Taiho Pharma, 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 completed 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 March 31, 2021, we and Taiho Ventures, LLC, or Taiho Ventures, have purchased an aggregate of \$23.0 million in Series A preferred stock of Cullinan Pearl.

As of March 31, 2021, we own 87% and Taiho Ventures owns 13% of the Series A preferred stock. Assuming conversion of the Series A preferred stock, we own 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, we, 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; our chief executive officer, Owen 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. As of March 31, 2021, we own 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%, or an aggregate 10%, 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 us, upon election by the Cullinan Amber board of directors, we 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, us, 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 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 March 31, 2021, we have 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 us 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 of March 31, 2021, we own approximately 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 between Cullinan Florentine, we 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. 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. We 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 us, Cullinan MICA, and other stockholders of Cullinan MICA, we 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. In December 2020, we purchased an aggregate of 3,367,804 shares of common stock of Cullinan MICA. As a result of these transactions, our ownership percentage in Cullinan MICA increased to approximately 35% as of March 31, 2021. Subject to the completion of Cullinan MICA's Series A financing, we will own approximately 54% of the fully diluted capital stock outstanding. Pursuant to a voting agreement, by and among Cullinan MICA, us, and other stockholders of Cullinan MICA, of the five person board of directors, we have the right to appoint three members of the board of directors.

Components of Our Results of Operations

Revenue

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

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

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

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A reduction in the carrying value of the deferred tax assets is required when it is not more likely than not that such deferred tax assets are not realizable.

Results of Operations

Comparison of the Three Months Ended March 31, 2020 and 2021

The following table presents our results of operations for the three months ended March 31, 2020 and 2021:

(in thousands)	Three Months Ended March 31,	
	2020	2021
License revenue	\$ —	\$ 18,943
Operating expenses:		
Research and development	4,173	12,415
General and administrative	1,368	5,156
Total operating expenses	5,541	17,571
Income/(loss) from operations	(5,541)	1,372
Other income (expense):		
Interest income	378	49
Other income (expense), net	—	(2)
Net Income/(loss)	(5,163)	1,419
Net income/(loss) attributable to noncontrolling interest	(190)	1,489
Net loss attributable to common stockholders of Cullinan	\$ (4,973)	\$ (70)
Net loss per share, basic and diluted	\$ (0.27)	\$ (0.00)
Total weighted-average shares used in computing net loss per share, basic and diluted	18,747,004	41,977,336
Comprehensive income/(loss):		
Net income/(loss)	\$ (5,163)	\$ 1,419
Unrealized gain/(loss) on investments	30	(58)
Comprehensive income/(loss):	(5,133)	1,361
Comprehensive income/(loss) attributable to noncontrolling interest	(190)	1,489
Comprehensive income/(loss) attributable to Cullinan	\$ (4,943)	\$ (128)

Research and Development Expenses

(in thousands)	Three Months Ended March 31,		Change
	2020	2021	
Cullinan Pearl (CLN-081)	\$ 1,186	\$ 2,718	\$ 1,532
Cullinan Florentine (CLN-049)	828	1,818	990
Cullinan Mica (CLN-619)	—	1,634	1,634
Cullinan Amber (CLN-617)	77	325	248
Cullinan Apollo (VK-2019)	644	116	(528)
Total Asset Subsidiaries expenses	\$ 2,735	\$ 6,610	\$ 3,875
Early stage research	949	2,567	1,618
Other personnel and unallocated	489	1,670	1,181
Equity-based compensation	—	1,569	1,569
Total research and development expenses	\$ 4,173	\$ 12,415	\$ 8,242

Research and development expenses were \$4.2 million for the three months ended March 31, 2020, compared to \$12.4 million for the three months ended March 31, 2021. We separately disclosed additional details 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, Cullinan MICA and Cullinan Pearl, and certain of our consolidated entities, as we believe they represent key portfolio value drivers. We also disclosed research and development expense detail for Cullinan Apollo, which we are planning to dissolve in the near future.

The increase of \$8.2 million of research and development expenses of the Asset Subsidiaries was primarily ongoing research and development activities subsequent to the acquisition of CLN-619 in May 2020, increase in pre-clinical and CMC costs to support IND-enabling activity for CLN-049, and increased trial enrollment for CLN-081. These increases are offset by a decrease of \$0.5 million from the wind down of clinical trial activities for VK-2019. The remaining increase was primarily related to equity-based compensation expense for stock options, increase in the discovery and development of early stage therapeutic candidates and increased headcount.

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

(in thousands)	Three Months Ended March 31,		Change
	2020	2021	
Personnel-related	\$ 724	\$ 1,272	\$ 548
Occupancy and other fees	247	797	550
Legal fees	199	681	482
Professional services fees	198	467	269
Equity-based compensation	—	1,939	1,939
Total general and administrative expenses	\$ 1,368	\$ 5,156	\$ 3,788

General and administrative expenses were \$1.4 million for the three months ended March 31, 2020 compared to \$5.2 million for the three months ended March 31, 2021. The increase of \$3.8 million was primarily due to increased headcount, equity-based compensation expense for stock options and expansion of our operations in connection with becoming a public company.

Other Income, Net

Other income, net was \$0.4 million during the three months ended March 31, 2020 compared to less than \$0.1 million during the three months ended March 31, 2021. The decrease of \$0.3 million was primarily related to a higher interest income earned in the first quarter of 2020.

Net Income/(Loss) Attributable to Noncontrolling Interest

Net income or 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 \$0.2 million during the three months ended March 31, 2020 compared to net income of \$1.5 million during the three months ended March 31, 2021. The Company recorded net income attributable to noncontrolling interests for the three months ended March 31, 2021 for Cullinan Pearl due to the recognition of the revenue from the Zai License Agreement.

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 equity securities. As of March 31, 2021, we had cash, cash equivalents and short term investments of \$440.9 million and long term investments of \$32.1 million.

In January 2021, the Company completed its IPO and received net proceeds of \$264.5 million from the offering, after deducting underwriting discounts, commissions and other offering expenses. Based on our current operational plans and assumptions, we expect that our current cash, cash equivalents, and short-term and long-term investments, will be sufficient to fund operations 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.

Cash Flows

Comparison of the Three Months Ended March 31, 2021 and 2020

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

<u>(in thousands)</u>	<u>Three Months Ended March 31,</u>	
	<u>2020</u>	<u>2021</u>
Net cash used in operating activities	\$ (5,015)	\$ (1,515)
Net cash used in investing activities	(26,890)	(137,726)
Net cash provided by financing activities	14,037	264,580
Net (decrease) increase in cash and cash equivalents	<u>\$ (17,868)</u>	<u>\$ 125,339</u>

Cash Flow from Operating Activities

For the three months ended March 31, 2020, operating activities used \$5.0 million of cash and primarily consisted of our net loss of \$5.1 million, offset by changes in net operating assets and liabilities of \$0.1 million and non-cash charges of less than \$0.1 million.

For the three months ended March 31, 2021, operating activities used \$1.5 million of cash and primarily consisted of our net income of \$1.4 million, offset by changes in net operating assets and liabilities of \$6.7 million, and non-cash charges of \$3.7 million. Our non-cash charges of \$3.7 million primarily consisted of \$3.5 million from equity-based compensation expense and \$0.2 million in amortization and accretion on marketable securities.

Cash Flow from Investing Activities

For the three months ended March 31, 2020, investing activities used \$26.9 million of cash, of which \$31.1 million was used for the purchase of short term investments offset by \$4.2 million received from the sales and maturities of short term investments.

For the three months ended March 31, 2021, investing activities used \$137.8 million of cash, of which \$149.8 million was used for the purchase of short term and long term investments offset by \$12.0 million received from the sales and maturities of short term investments.

Cash Flow from Financing Activities

For the three months ended March 31, 2020, net cash provided by financing activities was \$14.0 million from the issuance of common stock equivalents of \$14.0 million.

For the three months ended March 31, 2021, net cash provided by financing activities was \$264.5 million of net proceeds from the initial public offering.

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, 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, CLN-619, CLN-617 and CLN-978;
- 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;
- 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.

Based on our current operational plans and assumptions, we expect that 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;
- 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 March 31, 2021 and the effects that such obligations are expected to have on our liquidity and cash flows in future periods:

(in thousands)	Payments Due by Period				
	Total	Less than 1 Year	1 to 3 Years	3 to 5 Years	More Than 5 Years
Operating lease commitments	\$ 1,990	\$ 451	\$ 1,539	\$ —	\$ —

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 sheets as of December 31, 2020 and March 31, 2021, or in the contractual obligations table above.

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 unaudited consolidated financial statements appearing at the beginning of this Quarterly Report, 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 Income/(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 Amber, Cullinan Florentine, 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 Company, 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.

Revenue Recognition

The Company recognizes revenue in accordance with Accounting Standards Codification, or ASC, Topic 606, Revenue from Contracts with Customers, or ASC 606. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

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 activities. We record the estimated costs of research and development activities based upon the estimated amount of services provided but not yet invoiced and include these costs in accrued research and development liabilities in our consolidated balance sheets and within research and development expense in our consolidated statements of operations and comprehensive income (loss). These costs are a significant component of our research and development expenses.

We accrue for these costs based on factors such as estimates of the amount of work completed through discussions with internal personnel and external service providers as to the progress or stage of completion of the services and in accordance with agreements established with our third-party service providers for such services. We make significant judgments and estimates in determining the accrued research and development liabilities balance at each reporting period. As actual costs become known, we adjust our accrued estimates. Although we do not expect our estimates to be materially different from amounts actually incurred, the status and timing of services performed, the number of patients enrolled in clinical trials and the rate of patient enrollment may vary from our estimates and could result in us reporting amounts that are too high or too low in any particular period. Our accrued expenses are dependent, in part, upon the receipt of timely and accurate reporting from clinical research organizations and other third-party service providers. We record advance payments to service providers as prepaid assets, which are expensed as the contracted services are performed. To date, there have been no material differences between our accrued costs and actual costs.

Equity-based Compensation Expense

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 expense in the same period as the forfeitures occur.

The Company estimated the fair value of the stock options using the Black-Scholes option pricing model, which requires the input of objective and subjective assumptions. Certain assumptions used, including the fair value of the Company's common stock prior to the time of the initial public offering and stock price volatility, represent management's estimates and involve inherent uncertainties and the application of management's judgment. As a result, if factors change and management uses different assumptions, equity-based compensation expense could be materially different for future awards.

We classify equity-based compensation in our consolidated statements of operations and comprehensive (income) loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A reduction in the carrying value of the deferred tax assets is required when it is not more likely than not that such deferred tax assets are not realizable.

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.

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Information required by this Item is not applicable as we are electing scaled disclosure requirements available to Smaller Reporting Companies with respect to this Item.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

The Company has established disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) designed to ensure that information required to be disclosed in the reports that the Company files or submits under the Securities Exchange Act of 1934, as amended, or Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and is accumulated and communicated to management, including the principal executive officer (our Chief Executive Officer) and principal financial officer (our Chief Financial Officer), to allow timely decisions regarding required disclosure. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated, as of March 31, 2021, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our disclosure controls and procedures have been designed to provide reasonable assurance of achieving their objectives. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) were effective at the reasonable assurance level as of March 31, 2021.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) that occurred during the fiscal quarter ended March 31, 2021 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 1. Legal Proceedings.

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

Item 1A. 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 Quarterly Report on Form 10-Q, including our consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and the section of this Quarterly Report on Form 10-Q 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.

Cullinan Oncology, LLC, our predecessor entity, began substantive operations in 2017. In January 2021, Cullinan Oncology, LLC contributed all of the stock it owned of each of our subsidiaries to Cullinan Management, Inc. in exchange for common stock of Cullinan Management, Inc., and as a result, our subsidiaries became subsidiaries of Cullinan Management, Inc. Subsequently, Cullinan Oncology, LLC merged with and into Cullinan Management, Inc., with the latter being the surviving entity of such merger. Cullinan Management, Inc. changed its name to Cullinan Oncology, Inc. in February 2021. 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 equity securities.

We have incurred significant net losses in each period since we began substantive operations in September 2017. For the three months ended March 31, 2020 and 2021, we reported net losses of \$5.2 million and net income of \$1.4 million, respectively. As of March 31, 2021, we had an accumulated deficit of \$93.4 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;

- 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, Cullinan 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;
- 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.

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

The development of pharmaceutical products is capital intensive. We are currently advancing 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, we expect to incur significant additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations, which may include raising funding by one or more of our subsidiaries that could dilute our equity interest in the subsidiary. We have estimated our current additional funding needs based on assumptions that may prove to be wrong. 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, 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 \$440.9 million and long-term investments of \$32.1 million as of March 31, 2021. We believe that, based upon our current operating plan, our existing capital resources, 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 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, carried out either by Cullinan 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;
- 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 several, including our partially-owned subsidiaries Cullinan Pearl Corp., or Cullinan Pearl, and Cullinan MICA, Corp., or Cullinan MICA, have raised capital from third party investors. These third parties have certain rights that could delay collaboration, licensing or other arrangement with another third party, and the existence of these rights may adversely impact the ability to attract an acquirer or partner. These rights include rights of negotiation and fees payable upon a sale of assets or change of control of a subsidiary that are contained in license agreements, as well as rights such as drag-along rights in agreements with shareholders of the subsidiary.

For example, 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 March 31, 2021, on a fully-diluted basis, we owned 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 88.5% of Cullinan MICA's Series A Senior Preferred Stock, but approximately 35% of its fully-diluted common stock equivalent outstanding as of March 31, 2021. 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.

In the event that any of our subsidiaries require additional capital and its respective board of directors authorizes the transaction, our equity interest in our subsidiaries may be further reduced to the extent such additional capital is obtained from third party investors rather than from us. However, such transactions would still need to be approved by the board of directors of our respective subsidiary over which we maintain full 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 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 our interests or intentions, 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 March 31, 2021, we had 24 full-time employees upon which we rely for various administrative, research and development, and other support services shared among our other operating subsidiaries. We also have two consultants who we rely on for research and development, business development, and other services. While we believe this structure enables us to reduce certain infrastructure costs, the small size of our centralized team may limit our ability to devote adequate personnel, time, and resources to support the operations of all of our subsidiaries, including their research and development activities, and the management of financial, accounting, and reporting matters. Given that our employees and management are primarily incentivized at the parent company level, these employees and management team members may not be sufficiently incentivized to maximize the overall value of our entire organization. If our centralized team fails to provide adequate administrative, research and development, or other services across our entire organization, our business, financial condition, and results of operations could be harmed.

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

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

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;
- 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 experience delays or challenges in identifying patients with the mutations required for our clinical trials, we may have to reimburse sites for genetic sequencing costs in order to encourage sequencing of additional patients;
- 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 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;
- 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 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 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.

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 or receive FDA acceptance of future INDs for our product candidates, including CLN-049 and CLN-619, on the timelines we expect. For example, we submitted an IND for a Phase 1/2a clinical trial evaluating CLN-049 in January 2021, but based on FDA feedback, we elected to withdraw the IND to determine the most efficient path forward. Additionally, 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 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;
- 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.

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 EGFR / cMET bispecific antibody. We expect that CLN-049 will compete against bispecifics 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 the section of our Annual Report on Form 10-K filed with the SEC titled "Business—Competition."

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

The regulations that govern marketing approvals, pricing, coverage, and reimbursement for new drugs vary widely from country to country. In the 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 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 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 and members of Congress have introduced several pieces of legislation aimed at significantly revising or repealing the ACA. The United States Supreme Court is expected to rule on a legal challenge to the constitutionality of the ACA in early 2021. The implementation of the ACA is ongoing, the law appears likely to continue the downward pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs. Litigation and legislation related to the ACA are likely to continue, with unpredictable and uncertain results.

U.S. federal government agencies currently face potentially significant spending reductions. The Budget Control Act of 2011, 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 would not exceed two percent unless additional Congressional action is taken. President Obama issued the sequestration order on March 1, 2013, and cuts went into effect on April 1, 2013. Pursuant to the Coronavirus Aid, Relief, and Economic Security Act, also known as the CARES Act, and subsequent legislation, these reductions are suspended from May 1, 2020 through December 31, 2021 due to the COVID-19 pandemic.

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. The former Trump administration's budget proposal for fiscal year 2021 included a \$135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the former Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Additionally, the former Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. HHS has already implemented certain measures. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. However, it is unclear whether the Biden administration will challenge, reverse, revoke or otherwise modify these executive and administrative actions after January 20, 2021.

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

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

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

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

Our revenue prospects could be affected by changes in healthcare spending and policy in the 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 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.

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 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;
- 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 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 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. Moreover, in the Consolidated Appropriations Act of 2021, Congress did not further change this interpretation when it clarified that the interpretation codified in FDARA would apply in cases where FDA issued an orphan designation before the enactment of FDARA but where product approval came after the enactment of FDARA. 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 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 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.

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;
- 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 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, when foreign and domestic inspections of facilities were largely placed on hold, the FDA has been working to resume routine surveillance, bioresearch monitoring and pre-approval inspections on a prioritized basis. The FDA has developed 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 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 damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;
- the federal Physician Payment Sunshine Act, created under the ACA and its implementing regulations, which require manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to HHS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state and foreign laws and regulations, such as state and foreign anti-kickback, false claims, consumer protection and unfair competition laws which may apply to pharmaceutical business practices, including but not limited to, research, distribution, sales and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities; state and local laws requiring the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

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

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

Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

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

Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU Member States.

These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the EU Member States.

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

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

In the event we decide to conduct clinical trials or continue to enroll subjects in our ongoing or future clinical trials, we may be subject to additional privacy restrictions. The collection, use, storage, disclosure, transfer, or other processing of personal data regarding individuals in the 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 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. Further, a new California privacy law, the California Privacy Rights Act, or CPRA, was passed by California voters on November 3, 2020. The CPRA will create additional obligations with respect to processing and storing personal information that are scheduled to take effect on January 1, 2023 (with certain provisions having retroactive effect to January 1, 2022). 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. 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 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, 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 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.

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.

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 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 giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. Moreover, the molecules that will be used with our product candidates may be covered by the intellectual property rights of others.

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

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

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

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

Post-grant proceedings provoked by third parties or brought by the USPTO may be necessary to determine the validity or priority of inventions with respect to our owned or in-licensed patents or patent applications. These proceedings are expensive and an unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. In addition to potential USPTO review proceedings, we may become a party to patent opposition proceedings in the 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 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 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;
- 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 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 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.

Additionally, three vaccines for COVID-19 were granted Emergency Use Authorization by the FDA in late 2020 and early 2021, and more are likely to be authorized in the coming months. The resultant demand for vaccines and potential for manufacturing facilities and materials to be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, may make it more difficult to obtain materials or manufacturing slots for the products needed for our clinical trials, which could lead to delays in these trials. 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 March 31, 2021, we had 24 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;
- 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 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 March 31, 2021, we had U.S. federal net operating loss carryforwards of \$0.0 million and U.S. federal and state research and development tax credit carryforwards of \$0.0 million, each of which will begin to expire at various dates through 2036 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.

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 Ownership of Our Common Stock

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

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

- the results of our ongoing, planned or any future preclinical studies, clinical trials or clinical development programs;
- the commencement, enrollment, or results of clinical trials of our product candidates or any future clinical trials we may conduct, or changes in the development status of our product candidates;
- adverse results or delays in preclinical studies and clinical trials, including as a result of clinical holds;
- our decision to initiate a clinical trial, not to initiate a clinical trial, or to terminate an existing clinical trial;
- any delay in our regulatory filings or any adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;
- changes in laws or regulations applicable to our products, including but not limited to clinical trial requirements for approvals;
- adverse developments concerning our manufacturers or our manufacturing plans;

- our inability to obtain adequate product supply for any licensed product or inability to do so at acceptable prices;
- our inability to establish collaborations if needed;
- our failure to commercialize our product candidates;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our product candidates;
- introduction of new products or services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- the size and growth of our initial cancer target markets;
- our ability to successfully treat additional types of cancers or at different stages;
- actual or anticipated variations in quarterly operating results;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or immunotherapy in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- disputes or other developments relating to intellectual property or proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including intellectual property or stockholder litigation;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

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

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

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.

Pursuant to our equity incentive plans, our management is authorized to grant stock options to our employees, directors, and consultants. The number of shares of our common stock reserved for issuance under the 2021 Stock Option and Incentive Plan, or the 2021 Plan, will automatically increase on January 1, 2022 and will automatically increase each January 1 thereafter by 5% of the total number of shares of our capital 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 under the 2021 Plan, our stockholders may experience additional dilution, which could cause our stock price to fall. Additionally, the number of shares of our common stock reserved for issuance under the 2021 Employee Stock Purchase Plan, or 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 under the ESPP, 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 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 do not intend to pay dividends on our common stock, so any returns will be limited to the value of our stock.

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

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

Our executive officers, directors, and 5% stockholders beneficially owned approximately 49.8% of our voting stock, based on 43,516,125 shares of our common stock deemed to be outstanding as of March 31, 2021. These stockholders have the ability to influence us through their ownership position. Accordingly, these stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

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

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act, 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 our periodic reports and proxy statements, and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of our initial public offering, (b) in which we have total annual gross revenue of at least \$1.07 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 our periodic reports and proxy statements. We may take advantage of scaled disclosures available to smaller reporting companies until the fiscal year following the determination that either (i) the market value of our voting and nonvoting common stock held by non-affiliates is greater than \$700 million, as measured on the last business day of the most recently completed second fiscal quarter, or (ii) the market value of our voting and nonvoting common stock held by non-affiliates, as measured on the last business day of our most recently completed second fiscal quarter, is less than \$700 million but greater than \$250 million and our annual revenues during our most recently completed fiscal year are greater than \$100 million. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

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 are now subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which 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 an initial public 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.

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

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

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

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

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

Pursuant to our amended and restated bylaws, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for state law claims for (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, or other employees to us or our stockholders; (3) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law or our certificate of incorporation or bylaws; (4) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or bylaws; or (5) any action asserting a claim governed by the internal affairs doctrine, or the Delaware Forum Provision. The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act or the Exchange Act. Our amended and restated bylaws will further provide that unless we consent in writing to the selection of an alternative forum, the 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. We have begun 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 depends in part on the research and reports that securities or industry analysts publish about us or our business. In the event one or more of the analysts who cover us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

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

Set forth below is information regarding shares of common stock, and stock options granted and exercised by us during the period covered by this Quarterly Report on Form 10-Q that were not registered under the Securities Act. Included is the consideration, if any, we received for such shares and options and information relating to the section of the Securities Act of the Securities and Exchange Commission, under which exemption from registration was claimed. The information presented in this Part II, Item 2 gives effect for a one-for-7.0390 reverse split of our common stock, which was effective on January 7, 2021.

Recent Sales of Unregistered Equity Securities

In January 2021, we issued to direct and indirect holders of Cullinan Oncology, LLC, or the LLC, an aggregate of 34,434,262 shares of our common stock in exchange for, directly and indirectly, all of the outstanding common and preferred units of the LLC, or the Exchange. Included in the exchange were shares issuable under the LLC's 2016 Equity Incentive Plan and 2020 Unit Option and Grant Plan. The Exchange was part of a series of transactions pursuant to which the LLC merged with and into Cullinan Management, Inc., the surviving entity of such merger, or the Merger. This series of transactions is collectively referenced as the Reorganization. Refer to Note 3 in the unaudited financial statements for additional details on the accounting implications.

In January 2021, pursuant to the Merger, the holders of the LLC's Series Seed preferred units received, in aggregate, 2,273,050 shares of Cullinan Management, Inc.'s Series Seed preferred stock, which was subsequently converted on a 1-for-1 basis into our common stock prior to the consummation of our initial public offering (IPO).

In January 2021, pursuant to the Merger, the holders of the LLC's Series A1 preferred units received, in aggregate, 7,103,280 shares of Cullinan Management, Inc.'s Series A preferred stock, which was subsequently converted on a 1-for-1 basis into our common stock prior to the consummation of our initial public offering.

In January 2021, pursuant to the Merger, the holders of the LLC's Series B preferred units received, in aggregate, 8,970,154 shares of Cullinan Management, Inc.'s Series B preferred stock, which was subsequently converted on a 1-for-1 basis into our common stock prior to the consummation of our initial public offering.

In January 2021, pursuant to the Merger, the holders of the LLC's Series C preferred units received, in aggregate, 9,461,414 shares of Cullinan Management, Inc.'s Series C preferred stock, which was subsequently converted on a 1-for-1 basis into our common stock prior to the consummation of our initial public offering.

No underwriters were involved in the foregoing sales of securities. 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 in the connection with their purchase that there 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 purchases received written disclosures that the securities had not been registered under the Section Act and that any resale must be made pursuant to a registration of an available exemption from such registration. All of the foregoing securities are deemed restricted securities for the purposes of the Securities Act.

In January 2021, upon the closing of our initial public offering, or IPO, all 27,807,898 shares of our then-outstanding redeemable convertible preferred stock automatically converted into 27,807,898 shares of common stock. The issuance of such common stock was exempt from the registration requirements of the Securities Act, pursuant to Section 3(a)(9) of the Securities Act, involving an exchange of securities exchanged by the issuer with its existing security holders exclusively where no commission or other remuneration is paid or given directly or indirectly for soliciting such exchange. No underwriters were involved in this issuance of shares.

During the three months ended March 31, 2021, we issued to certain of our employees and advisors, options to purchase an aggregate of 1,753,316 shares of our common stock at an exercise price of \$21.00 per share under the 2021 Stock Option and Incentive Plan, or the 2021 Stock Plan, and 244,500 shares of our common stock at an exercise price of \$48.39 per share under the 2021 Stock Plan. We deemed these issuances to be exempt from registration under the Securities Act either in reliance on Rule 701 of the Securities Act as sales and offers under compensatory benefit.

Use of Proceeds from IPO of Common Stock

On January 7, 2021, our Registration Statement on Form S-1, as amended (Registration No. 333-251512) was declared effective by the SEC for our IPO. At the closing of the offering on January 12, 2021, we sold 13,685,000 shares of common stock, including the exercise in full by the underwriters of their option to purchase up to 1,785,000 additional shares of common stock, at a public offering price of \$21.00 per share. The aggregate net proceeds to us from the public offering, inclusive of the over-allotment exercise and after underwriting discounts and offering expenses, were approximately \$264.5 million. Morgan Stanley & Co. LLC, SVB Leerink LLC, and Evercore Group LLC acted as joint book-running managers for the offering. HC Wainwright & Co, LLC acted as lead manager for the offering. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning 10% or more of any class of our equity securities or to any other affiliates.

Information related to use of proceeds from registered securities is incorporated herein by reference to the “Use of Proceeds” section of our IPO as described in our final prospectus dated January 7, 2021 and filed with the SEC on January 11, 2021 pursuant to Rule 424(b)(4) of the Securities Act. There has been no material change in the planned use of proceeds as described in our final prospectus.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Not applicable.

Item 6. Exhibits.

Exhibit Number	Description
3.1	<u>Second Amended and Restated Certificate of Incorporation of the Registrant, as amended by the Certificate of Amendment, effective as of February 25, 2021 (incorporated by reference to Exhibit 3.1 of the Registrant’s Annual Report on Form 10-K (File No. 001-39856) filed on March 30, 2021).</u>
3.2	<u>Second Amended and Restated Bylaws of Registrant, effective as of February 25, 2021 (incorporated by reference to Exhibit 3.2 of the Registrant’s Annual Report on Form 10-K (File No. 001-39856) filed on March 30, 2021).</u>
4.1	<u>Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 of the Registrant’s Registration Statement on Form S-1 (File No. 333-251512) filed on December 28, 2020).</u>
4.2	<u>Registration Rights Agreement, dated January 7, 2021, among the Registrant and certain of its stockholders. (incorporated by reference to Exhibit 4.2 of the Registrant’s Annual Report on Form 10-K (File No. 001-39856) filed on March 30, 2021).</u>
10.1#	<u>2021 Stock Option and Incentive Plan and form of award agreements thereunder (incorporated by reference to Exhibit 10.1 of the Registrant’s Registration Statement on Form S-1 (File No. 333-251512) filed on January 4, 2021).</u>
10.2#	<u>2021 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.2 of the Registrant’s Registration Statement on Form S-1 (File No. 333-251512) filed on January 4, 2021).</u>
10.3#	<u>Senior Executive Cash Incentive Bonus Plan (incorporated by reference to Exhibit 10.3 of the Registrant’s Registration Statement on Form S-1 (File No. 333-251512) filed on December 18, 2020).</u>

10.4#	<u>Form of Indemnification Agreement, between the Registrant and each of its directors (incorporated by reference to Exhibit 10.4 of the Registrant's Registration Statement on Form S-1 (File No. 333-251512) filed on December 18, 2020).</u>
10.5#	<u>Form of Indemnification Agreement, between the Registrant and each of its executive officers (incorporated by reference to Exhibit 10.5 of the Registrant's Registration Statement on Form S-1 (File No. 333-251512) filed on December 18, 2020).</u>
10.6#	<u>Form of Executive Employment Agreement (incorporated by reference to Exhibit 10.13 of the Registrant's Registration Statement on Form S-1 (File No. 333-251512) filed on December 18, 2020).</u>
10.7#	<u>Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.23 of the Registrant's Registration Statement on Form S-1 (File No. 333-251512) filed on December 18, 2020).</u>
31.1*	<u>Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
31.2*	<u>Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
32.1**	<u>Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

** The certifications furnished in Exhibit 32.1 hereto are deemed to be furnished with this Quarterly Report on Form 10-Q and will not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference.

Indicates a management contract or any compensatory plan, contract or arrangement.

SIGNATURES

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

Cullinan Oncology, Inc.

Date: May 14, 2021

By: /s/ Owen Hughes

Name: Owen Hughes

Title: President and Chief Executive Officer

(Principal Executive Officer)

Date: May 14, 2021

By: /s/ Jeffrey Trigilio

Name: Jeffrey Trigilio

Title: Chief Financial Officer

(Principal Financial and Accounting Officer)

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

I, Owen Hughes, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended March 31, 2021 of Cullinan Oncology, Inc. (the “registrant”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 14, 2021

By: _____ /s/ Owen Hughes
Owen Hughes
President and Chief Executive Officer
(Principal Executive Officer)

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

I, Jeffrey Trigilio, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended March 31, 2021 of Cullinan Oncology, Inc. (the “registrant”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 14, 2021

By: _____ /s/ Jeffrey Trigilio
Jeffrey Trigilio
Chief Financial Officer
(Principal Financial and Accounting Officer)

