

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): March 30, 2021

CULLINAN ONCOLOGY, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-39856
(Commission
File Number)

81-387991
(I.R.S. Employer
Identification No.)

Cullinan Oncology, Inc.
One Main Street, Suite 520
Cambridge, MA 02142
(Address of principal executive offices, including zip code)

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

Cullinan Management, Inc.
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

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

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

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.

Item 2.02 Results of Operations and Financial Condition

On March 30, 2021, Cullinan Oncology, Inc. announced its financial results for the quarter and year ended December 31, 2020. A copy of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K and Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	<u>Press Release issued by Cullinan Oncology, Inc., dated March 30, 2021, furnished herewith.</u>

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Cullinan Oncology, Inc.

Date: March 30, 2021

By: /s/ Owen Hughes

Owen Hughes

President and Chief Executive Officer



**Cullinan Oncology Reports Full Year 2020
Financial Results and Business Highlights**

Pipeline Progress: Clinical and preclinical programs continue to advance, with encouraging initial Cullinan Pearl data and additional INDs to be filed in 2021 for immuno-oncology assets Cullinan Florentine and Cullinan MICA

Balance Sheet: Completion of Series C financing (\$131.2M) in December 2020 and IPO (\$287.4M) in January 2021 enhances cash position, enabling pipeline progression / expansion

Team: Key hires augment immuno-oncology acumen (CMO Jon Wigginton) and enhance business development capabilities (CFO Jeff Trigilio and CLO Ray Keane)

Cambridge, MA, March 30, 2021 – Cullinan Oncology, Inc. (Nasdaq: CGEM) (“Cullinan”), an oncology company seeking to drive shareholder returns by focusing on the patient, today announced its financial results for the full year ended December 31, 2020 and reported on recent business highlights.

“We are proud of the significant progress across many facets of our business in 2020 and intend to maintain that momentum in 2021,” stated Owen Hughes, Chief Executive Officer of Cullinan. “We remain laser focused on delivering results for our various stakeholders through disciplined capital allocation, decisive action, prudent risk taking and creative business development. We look forward to sharing additional clinical and pre-clinical updates as the year unfolds.”

2020 and Recent Portfolio Highlights:

- **Cullinan Pearl:** *Demonstrated encouraging clinical proof of concept for CLN-081 in NSCLC patients with EGFR ex20ins mutations and initiated Phase 2a dose expansion in the 100 mg BID cohort.*

CLN-081 is an orally available, irreversible EGFR inhibitor that is designed to selectively target cells expressing mutant EGFR variants while sparing cells expressing wild type EGFR. Cullinan is evaluating various doses of CLN-081 in a Phase 1/2a trial in patients with NSCLC harboring EGFRex20ins mutations that have progressed post chemotherapy. As of the November 10, 2020 data cut-off, among 25 evaluable patients across all dose cohorts, we observed a best overall response of partial response in 10 patients (confirmed and unconfirmed), stable disease in 14 patients and disease progression in one patient. Cullinan recently initiated Phase 2a dose expansion at the 100 mg BID dosing level, which will enable enrollment of up to 36 patients at this dose level, inclusive of 13 previously enrolled patients. Cullinan is contemplating additional expansion cohorts and intends to provide updated safety and efficacy data in mid-2021.

- **Cullinan MICA:** *Advanced CLN-619 through IND-enabling activities, including drug product manufacturing, to support an IND submission planned for the second quarter of 2021.*

CLN-619 is a MICA/B-targeted, humanized IgG1 monoclonal antibody that Cullinan intends to develop in patients with advanced solid tumors. MICA/B are stress-induced ligands expressed on tumor cells and recognized by the activating NKG2D receptor present on innate and adaptive immune cells. To evade potential cytotoxic destruction by NK cells and T cells, tumors shed MICA/B from the cell surface. CLN-619 is designed to promote an antitumor response through multiple mechanisms of action, including preventing the proteolytic cleavage of MICA/B from cancer cells.

- **Cullinan Florentine:** *Acquired an exclusive license from the German Cancer Research Center (DKFZ) and the University of Tübingen to develop CLN-049, a novel FLT3 x CD3 bispecific antibody for the treatment of patients with acute myeloid leukemia (AML).*

CLN-049 is a humanized bispecific antibody targeting FLT3 on target leukemic cells and CD3 on T cells, triggering cancer cell lysis via T cell cytolytic mechanisms. FLT3 is expressed frequently on AML cells and leukemic blasts but minimally on healthy blood cells, unlike other tumor surface antigens such as CD33 and CD123. Cullinan submitted an IND to the U.S. Food and Drug Administration (“FDA”) for its first-in-human clinical trial evaluating CLN-049 in relapsed or refractory AML patients in January 2021. After receiving FDA feedback, Cullinan is updating the clinical protocol and intends to resubmit its IND in mid-2021.

- **Cullinan Amber:** *Launched Cullinan Amber, a company focused on developing a next generation immuno-oncology platform to deliver immune-stimulatory cytokine combinations with an enhanced therapeutic window for the treatment of cancer.*

Cullinan Amber’s lead program, CLN-617, is a fusion protein uniquely combining in a single agent two potent antitumor cytokines, IL-2 and IL-12, with a collagen-binding domain for the treatment of solid tumors. The collagen-binding domain engineered into CLN-617 is designed to retain cytokines in the tumor microenvironment following intratumoral administration, thereby minimizing systemic dissemination and associated toxicities while prolonging immunostimulatory antitumor activity. In preclinical studies, murine surrogates of CLN-617 demonstrated robust single agent antitumor activity in both injected and non-injected contralateral tumors without inducing systemic toxicity. Cullinan expects to submit an IND for CLN-617 in 2022.

- **Cullinan NexGem:** *Initiated IND-enabling studies for CLN-978, an internally derived asset that seeks to address the limitations of existing CD19 bispecific antibodies.*

CLN-978 is a half-life extended, humanized, single-chain T cell engager designed to simultaneously engage CD19 on target cancer cells and CD3 on T cells, triggering redirected T cells to lyse the target cancer cells. In addition to CD19 and CD3 binding domains, CLN-978 has a human serum albumin binding domain, which is designed to prolong half-life. Several design components of CLN-978, including its high affinity binder to CD19, its serum half-life extension component and its overall stability, are intended to address limitations related to blinatumomab, the only CD19-targeting bispecific T cell engager approved for the treatment of relapsed or refractory B-cell acute lymphoblastic leukemia, or ALL. Cullinan expects to submit an IND for CLN-978 in 2022.

2020 and Recent Corporate Highlights:

- Executed a strategic collaboration and licensing agreement in December 2020 with Zai Lab (Shanghai) Co., Ltd. (“Zai Lab”) to develop and commercialize CLN-081 in Greater China.
- Raised \$131.2 million in gross proceeds from an oversubscribed Series C financing in December 2020, which broadened Cullinan’s shareholder base to include additional leading life sciences focused institutions.
- Completed an oversubscribed initial public offering (IPO). In January 2021, Cullinan announced the closing of its IPO of 13,685,000 shares of common stock, including the exercise in full by the underwriters of their over-allotment option, at a public offering price of \$21.00 per share for gross proceeds of \$287.4 million before deducting underwriting discounts and commissions and other offering expenses.
- Strengthened and expanded Cullinan’s management team and Board of Directors in 2020 by promoting Jennifer Michaelson, PhD, to Chief Development Officer, Biologics, and by adding Jon Wigginton, M.D. as Chief Medical Officer, Jeff Trigilio as Chief Financial Officer, and Raymond T. Keane, Esq. as Chief Legal Officer, along with Stephen Webster to its Board of Directors.

Financial Results for Full Year 2020

- **Cash Position:** Cash, cash equivalents and short-term investments were \$210.2 million as of December 31, 2020, compared to \$98.6 million as of December 31, 2019. This does not include \$264.7 million in net proceeds from the company’s IPO completed in January 2021 nor does it include upfront proceeds from the Zai Lab transaction, which were received in Q1 2021. Net cash used in operating activities was \$29.8 million while net cash provided from financing activities was \$140.1 million for the year ended December 31, 2020.
- **R&D Expenses:** Research and development expenses were \$43.2 million for the year ended December 31, 2020, including \$5.9 million of non-cash equity-based compensation expense and \$6.4 million of non-cash IPR&D expense related to the Cullinan MICA transaction, which was treated as an asset acquisition.
- **G&A Expenses:** General and administrative expenses were \$17.1 million, including \$9.0 million of non-cash equity-based compensation expense.
- **Net loss:** The Company’s net loss was \$59.5 million for the year ended December 31, 2020, which included \$22.8 million of non-cash charges.

About Cullinan Oncology

Cullinan Oncology is a biopharmaceutical company that seeks to drive shareholder returns by focusing on the patient. The Company’s strategy is to build a diversified pipeline of targeted and immuno-oncology therapeutic candidates that are uncorrelated across multiple dimensions, with a focus on assets that it believes have novel technology, employ differentiated mechanisms, are in a more advanced stage of development than competing candidates, or have a combination of these attributes. Learn more about Cullinan at www.cullinanoncology.com.

Forward-Looking Statements

This press release contains forward-looking statements of Cullinan Oncology, Inc. (“Cullinan,” “we” or “our”) within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, but are not limited to, express or implied statements regarding Cullinan’s beliefs and expectations regarding our preclinical and clinical development plans, clinical trial designs, clinical and therapeutic potential, and strategy of our product candidates, including but not limited to: the timing and success of our planned preclinical and clinical development of our programs, and the timing and success of any such continued preclinical and clinical development and planned regulatory submissions, including for CLN-081, CLN-619, CLN-049 and CLN-617; our plans to submit INDs for CLN-619 and CLN-617 in the second quarter of 2021 and in 2022, respectively; our plans to update our clinical protocol and planned resubmission of the IND for CLN-049 in mid-2021; our expectations and beliefs around the safety and activity of CLN-081 in our Phase 1/2a trial in patients with NSCLC harboring EGFRex20ins mutations that have had at least one prior treatment; our ability to evaluate strategic opportunities to accelerate development timelines; our plans to advance and complete preclinical studies for our programs; the presentation of additional data at upcoming scientific conferences in 2021; our ability to optimize the impact of our collaborations and license agreements with external parties, including but not limited to Zai Lab, the German Cancer Research Center and the University of Tübingen; ability to continue its growth and realize the anticipated contribution of the members of its board of directors and executives to its operations and programs; and our expectations regarding our use of capital and other financial results during 2021.

Any forward-looking statements in this press release are based on management’s current expectations and beliefs of future events, and are subject to known and unknown risks and uncertainties that may cause our actual results, performance or achievements to be materially different from any expressed or implied by the forward-looking statements. These risks include, but are not limited to, the following: uncertainty regarding the timing and results of regulatory submissions; success of our clinical trials and preclinical studies; risks related to our ability to protect and maintain our intellectual property position; risks related to manufacturing, supply, and distribution of our therapeutic candidates; risks related to the impact of COVID-19 affecting countries or regions in which we have operations or do business, including potential negative impacts on our employees, customers, supply chain and production as well as global economies and financial markets; the risk that any one or more of our product candidates, including those that are co-developed, will not be successfully developed and commercialized; the risk that the results of preclinical studies or clinical studies will not be predictive of future results in connection with future studies; and success of any collaboration, partnership, license or similar agreements. These and other important risks and uncertainties discussed in our filings with the Securities and Exchange Commission, or SEC, including under the caption “Risk Factors” in our most recent Annual Report on Form 10-K and subsequent filings with the SEC, could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release. Moreover, except as required by law, neither Cullinan nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements included in this press release. Any forward-looking statement included in this press release speaks only as of the date on which it was made. We undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except as required by law.

Cullinan Oncology, LLC
Consolidated Balance Sheets (Unaudited)
(in thousands, except units and per unit amounts)

	December 31, 2019	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 63,250	\$ 168,198
Prepaid expenses and other current assets	1,461	2,072
Short term investments	35,380	42,008
Total current assets	100,091	212,278
Property and equipment, net	182	130
Other assets	188	2,300
Total assets	<u>\$ 100,461</u>	<u>\$ 214,708</u>
Liabilities, Redeemable Preferred Units and Members' Deficit		
Current liabilities:		
Accounts payable	\$ 934	\$ 9,679
Accrued expenses and other current liabilities	1,589	4,641
Total current liabilities	2,523	14,320
Long-term liabilities:		
Deferred rent	73	74
Total liabilities	<u>2,596</u>	<u>14,394</u>
Commitments and contingencies		
Redeemable Preferred Units:		
Series Seed Redeemable Preferred Units, \$0.0001 par value: 16,000,000 units authorized, issued and outstanding (liquidation value: \$5,010) at December 31, 2019 and 2020.	3,956	3,956
Series A1 Redeemable Preferred Units, \$0.0001 par value: 50,000,000 units authorized, issued and outstanding (liquidation value: \$61,038) at December 31, 2019 and 2020.	49,946	49,946
Series B Redeemable Preferred Units, \$0.0001 par value: 64,200,000 authorized and 54,006,407 and 63,141,016 units issued and outstanding (liquidation value: \$105,645) at December 31, 2019 and 2020, respectively.	83,872	97,909
Series C Redeemable Preferred Units, \$0.0001 par value: 66,599,045 units authorized, issued and outstanding (liquidation value: \$131,524) at December 31, 2020.	—	124,841
Total Redeemable Preferred Units	<u>137,774</u>	<u>276,652</u>
Members' deficit:		
Non-Voting Incentive Units, \$0.0001 par value: 11,896,500 units authorized, 11,896,500 units issued and outstanding at December 31, 2019 and 2020.	1	1
Common units, \$0.0001 par value: 36,972,854 units authorized, 0 and 2,346,094 units issued and outstanding at December 31, 2019 and 2020, respectively.	—	—
Noncontrolling interest in subsidiaries	864	1,304
Additional paid-in capital	770	15,698
Accumulated other comprehensive loss	(4)	(2)
Accumulated deficit	<u>(41,540)</u>	<u>(93,339)</u>
Total members' deficit	<u>(39,909)</u>	<u>(76,338)</u>
Total liabilities, redeemable preferred units and members' deficit	<u>\$ 100,461</u>	<u>\$ 214,708</u>

Cullinan Oncology, LLC
Consolidated Statements of Operations and Comprehensive Loss (Unaudited)
(in thousands, except units and per unit amounts)

	<u>Year Ended December 31,</u>	
	<u>2019</u>	<u>2020</u>
Operating expenses:		
Research and development	\$ 16,788	\$ 43,211
General and administrative	5,482	17,124
Total operating expenses	<u>22,270</u>	<u>60,335</u>
Loss from operations	(22,270)	(60,335)
Other income (expense):		
Interest income	620	888
Other income (expense), net	(4)	(11)
Net loss	<u>(21,654)</u>	<u>(59,458)</u>
Net loss attributable to noncontrolling interest	(997)	(7,659)
Net loss attributable to Cullinan	<u>\$ (20,657)</u>	<u>\$ (51,799)</u>
Net loss per unit attributable to Common and Non-Voting Incentive Unitholders, basic and diluted	<u>\$ (3.23)</u>	<u>\$ (5.48)</u>
Total weighted-average Common and Non-Voting Incentive Units used in computing net loss per unit, basic and diluted	<u>6,397,443</u>	<u>9,447,147</u>
Comprehensive loss:		
Net loss	\$ (21,654)	\$ (59,458)
Unrealized gain/(loss) on investments	(4)	2
Comprehensive loss	<u>\$ (21,658)</u>	<u>\$ (59,456)</u>
Comprehensive loss attributable to noncontrolling interest	(997)	(7,659)
Comprehensive loss attributable to Cullinan	<u>\$ (20,661)</u>	<u>\$ (51,797)</u>

Contacts:

Investor Relations
investors@cullinanoncology.com

Jeff Trigilio
+1 617.410.4650
jtrigilio@cullinanoncology.com