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 17, 2022

CULLINAN ONCOLOGY, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-39856**	**81-3879991**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(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)

Not Applicable
(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 (see General Instruction A.2):

☐ 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	Trading 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 17, 2022, Cullinan Oncology, Inc. announced its financial results for the quarter and year ended December 31, 2021. A copy of the press release is being furnished as Exhibit 99.1 to this Report on Form 8-K.

The information in this Item 2.02 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

Exhibit No.	Description
99.1	Press release issued by Cullinan Oncology, Inc. on March 17, 2022, furnished herewith.
104	Cover page from this Current Report on Form 8-K, formatted in Inline XBRL

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.

Dated: March 17, 2022

By: /s/ Jeffrey Trigilio
Jeffrey Trigilio
Chief Financial Officer

Exhibit 99.1

Cullinan Oncology Provides Corporate Update and Reports Fourth Quarter and Full Year 2021 Financial Results

CLN-081 clinical data support a differentiated clinical profile; regulatory update planned for first quarter 2022

CLN-049 and CLN-619 patient dosing initiated in December 2021 for first-in-human clinical trials; initial clinical data expected by mid-2023

Portfolio advancement and expansion highlighted through multiple AACR abstract acceptances and HPK1 protein degrader collaboration with Mount Sinai

Cambridge, MA, March 17, 2022 – Cullinan Oncology, Inc. (Nasdaq: CGEM), a biopharmaceutical company focused on developing a diversified pipeline of targeted therapies for patients with cancer, today reported on recent and upcoming business highlights and announced its financial results for the fourth quarter and full year ended December 31, 2021.

"Cullinan Oncology is dedicated to developing new standards of care in cancer therapy and we made considerable progress toward this goal in 2021, including advancing additional programs into the clinic, adding new assets to our pipeline, and deepening our oncology expertise with new additions to our board and leadership team," said Nadim Ahmed, Chief Executive Officer of Cullinan Oncology. "In the fourth quarter of 2021, we reported compelling data from the ongoing Phase 1/2a trial of our lead program, CLN-081. We were also pleased to announce in January of this year that the FDA granted CLN-081 Breakthrough Therapy Designation, a distinction that further supports its differentiated clinical profile in NSCLC patients with EGFR exon 20 insertion mutations. We look forward to providing a regulatory update in the coming weeks."

Mr. Ahmed continued, "Additionally, we initiated clinical trials for two other differentiated oncology programs, CLN-619 and CLN-049, while further expanding our pipeline with the addition of an HPK1 degrader collaboration with the Icahn School of Medicine at Mount Sinai. Finally, we expanded our late-stage oncology expertise and leadership with the recent appointments of Dr. Jeff Jones as Chief Medical Officer and Dr. Anne-Marie Martin as an independent director. Finishing the year with over $430 million of cash and investments, we remain well positioned to continue advancing our broad pipeline of first- and/or best-in-class oncology molecules as we work toward our mission of developing new therapeutic solutions for people living with cancer."

Portfolio Highlights

- **CLN-081 (Pearl):** During the fourth quarter of 2021, Cullinan reported updated Phase 1/2a data for CLN-081 in NSCLC patients harboring epidermal growth factor (EGFR) exon 20 insertion mutations who have previously received platinum-based systemic chemotherapy. The update included safety and efficacy data from 73 patients treated across all five dose levels (30 – 150mg BID). At the 100mg BID dose level, 35 of 36 (97%) response evaluable patients achieved a best response of partial response or stable disease, with 14 (39%) patients achieving a confirmed partial response. Among patients enrolled in the initial Phase 1 cohort at 100mg BID (n=13), the estimated median duration of response was greater than 15 months and the estimated median progression free survival was 12 months. In January 2022, Cullinan announced that CLN-081 received Breakthrough Therapy Designation. Cullinan will provide a regulatory update on CLN-081 in the first quarter of 2022.

- **CLN-049 (Florentine):** CLN-049 is a FLT3/CD3-bispecific T cell-engaging antibody in an IgG format for the treatment of acute myeloid leukemia (AML). CLN-049 targets the extracellular domain of FLT3, regardless of mutant or wild type-based expression. In December 2021, patient dosing was initiated in a first-in-human clinical trial evaluating CLN-049 in patients with relapsed/refractory AML. A more extensive preclinical characterization of CLN-049 has been published in the Journal for Immunotherapy of Cancer (JITC), titled, "A Novel IgG-based FLT3xCD3 Bispecific Antibody for the Treatment of AML and B-ALL." Initial clinical data are expected by mid-2023.
- **CLN-619 (MICA):** CLN-619 is a first-in-class monoclonal antibody that stabilizes MICA/MICB on the tumor cell surface to promote an antitumor response via activation of both natural killer (NK) cells and certain T cells, with broad therapeutic potential across multiple cancer indications. In December 2021, patient dosing was initiated in a first-in-human clinical trial evaluating CLN-619 in patients with advanced tumors. The trial design includes parallel evaluation of CLN-619 as a monotherapy and in combination with checkpoint inhibitor therapy in separate modules. Initial clinical data are expected by mid-2023.
- **Preclinical Portfolio:** Continued advancement of five additional oncology programs with the following highlights:
    - Preclinical data across five distinct programs will be presented at the American Association for Cancer Research (AACR) 2022 Annual Meeting, including CLN-049, CLN-619, CLN-617 (Amber), CLN-978 (NexGem) and Opal (additional information can be found in this press release on our company website).
    - Cullinan recently announced a collaboration with the Icahn School of Medicine at Mount Sinai to develop oral protein degraders targeting hematopoietic progenitor kinase 1 (HPK1), a key regulator of immune cell activation and a high-priority target in immune-oncology. Preclinical research has shown that a degrader approach to targeting HPK1 may be more effective at controlling tumor growth than inhibition of HPK1 kinase activity.
    - In 2021, Cullinan advanced two programs into IND-enabling studies: CLN-617, a cytokine fusion protein uniquely combining IL-12 and IL-2 with a collagen binding domain for retention in the tumor microenvironment (TME), and CLN-978, a novel CD19/CD3-bispecific construct with extended serum half-life and high potency against target cells expressing very low levels of CD19. Cullinan expects to submit INDs for both programs by the end of the first half of 2023.
- **Organizational Announcements:** Expanded late-stage oncology expertise with appointments of Jeffrey Jones, M.D., MPH, MBA as Chief Medical Officer and Anne-Marie Martin, Ph.D., as an independent director. Dr. Jones joins from Bristol Myers Squibb Company, where he held positions of increasing responsibility in oncology clinical development. Dr. Martin is currently the Senior Vice President, Global Head of the Experimental Medicine Unit at GlaxoSmithKline plc. and joins Cullinan with over 25 years of translational medicine and clinical research expertise.

Fourth Quarter 2021 Financial Results

- **Cash Position:** Cash, cash equivalents and investments were $430.9 million as of December 31, 2021. We expect that this balance will be sufficient to fund operations through 2024.
- **R&D Expenses:** Research and development (R&D) expenses were $20.9 million for the fourth quarter of 2021, compared to $12.7 million for the third quarter of 2021. R&D expenses in the fourth and third quarters of 2021 included $2.6 million and $2.5 million of equity-based compensation expenses, respectively. The increase in R&D expenses is primarily related to expanded clinical and chemistry, manufacturing, and controls (CMC) activity for CLN-081 and discovery and development of our preclinical programs.
- **G&A Expenses:** General and administrative (G&A) expenses were $13.5 million for the fourth quarter of 2021, compared to $5.7 million for the third quarter of 2021. G&A expenses in the fourth and third quarters of 2021 included $9.6 million and $2.1 million of equity-based compensation expenses, respectively. The increase in G&A expenses is primarily related to a non-recurring charge to equity-based compensation expense due to the transition of our chief executive officer.
- **Net Loss:** The Company's net loss (before items attributable to noncontrolling interest) was $34.4 million for the fourth quarter of 2021, compared to $18.4 million for the third quarter of 2021. The increase in net loss related primarily to CLN-081 CMC investment, R&D portfolio advancement, and non-recurring equity-based compensation expenses.

Full Year 2021 Financial Results

- **R&D Expenses:** R&D expenses were $57.8 million for the year ended December 31, 2021, compared to $43.2 million for the year ended December 31, 2020. R&D expenses for the full years 2021 and 2020 included $8.9 million and $5.9 million of equity-based compensation expenses, respectively. The increase in R&D expenses is primarily related to expanded trial enrollment, CMC activities, and a sub-licensing fee relating to CLN-081, as well as increases in pre-clinical and CMC costs to support IND enabling activities for other programs.
- **G&A Expenses:** G&A expenses were $29.1 million for the year ended December 31, 2021, compared to $17.1 million for the year ended December 31, 2020. G&A expenses for the full years 2021 and 2020 included $15.4 million and $9.0 million of equity-based compensation expenses, respectively. The increase in G&A expenses is primarily related to a non-recurring charge to equity-based compensation expense in the fourth quarter due to the transition of our chief executive officer, as well as increased headcount, legal expenses, insurance costs, and IT systems upgrades to support our operations as a public company.
- **Net loss:** The Company's net loss (before items attributable to non-controlling interest) was $67.5 million for the year ended December 31, 2021, compared to $59.5 million for the year ended December 31, 2020. Net loss for the year ended December 31, 2021 included $18.9 million of revenue from the upfront payment pursuant to the license agreement with Zai Lab (Shanghai) Co., Ltd. for the development and commercialization rights to CLN-081 in Greater China, $3.0 million of sub-licensing expense associated with that transaction, and $24.4 million of non-cash equity-based compensation expense.

About Cullinan Oncology

Cullinan Oncology is a biopharmaceutical company with a diversified pipeline of targeted therapeutic candidates across multiple modalities. The Company's strategy is to focus on advanced stage assets with novel technology platforms and differentiated mechanisms, developed through both internal discovery and external collaboration. Learn more about Cullinan at www.cullinanoncology.com.

Forward-Looking Statements

This press release contains forward-looking statements 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; our ability to evaluate strategic opportunities to accelerate development timelines; the presentation of additional data at upcoming scientific conferences in 2022; our ability to optimize the impact of our collaborations and license agreements with external parties; our ability to continue our growth; and our expectations regarding our use of capital. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "hope," "intend," "may," "plan," "potential," "predict," "project," "target," "should," "would," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

Any forward-looking statements in this 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 product 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 (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, except to the extent required by law. 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.

Cullinan Oncology, Inc.
Condensed Consolidated Balance Sheets
(in thousands)

	December 31, 2021 (unaudited)	December 31, 2020 (1)
Cash, cash equivalents and investments	$430,863	$210,206
Total assets	**$437,185**	**$214,708**
Total current liabilities	$ 11,746	$ 14,320
Total liabilities	$ 11,811	$ 14,394
Total stockholders' equity	$425,374	$200,314
Total liabilities and stockholders' equity	**$437,185**	**$214,708**

(1) The condensed consolidated balance sheet as of the year ended December 31, 2020 is derived from the audited consolidated financial statements as of that date.

Cullinan Oncology, Inc.
Consolidated Statements of Operations
(in thousands, except shares and per share amounts)

	Three Months Ended		Twelve Months Ended	
	December 31, 2021 (unaudited)	September 30, 2021 (unaudited)	December 31, 2021 (unaudited)	December 31, 2020 (audited)
License revenue	$ —	$ —	$ 18,943	$ —
Operating expenses:				
Research and development	$ 20,878	$ 12,680	$ 57,751	$ 43,211
General and administrative	13,468	5,695	29,146	17,124
Total operating expenses	34,346	18,375	86,897	60,335
Loss from operations	(34,346)	(18,375)	(67,954)	(60,335)
Other income (expense):				
Interest income	137	118	477	888
Other income (expense)	4	(2)	(8)	(11)
Net loss	$ (34,205)	$ (18,259)	$ (67,485)	$ (59,458)
Net loss attributable to noncontrolling interest	(1,692)	(909)	(1,915)	(7,659)
Net loss attributable to common stockholders	$ (32,513)	$ (17,350)	$ (65,570)	$ (51,799)
Net loss per share, basic and diluted	$ (0.74)	$ (0.40)	$ (1.52)	$ (2.60)
Total weighted-average shares used in computing net loss per share, basic and diluted	43,643,397	43,438,861	43,077,330	19,887,307

Contacts:

Investors

Lee Roth
+1 212.213.0006
Lroth@burnsmc.com

Jeffrey Trigilio
jtrigilio@cullinanoncology.com

Media

Rose Weldon
+1 215.801.7644
rweldon@cullinanoncology.com