

**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): May 16, 2022

CULLINAN ONCOLOGY, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-39856
(Commission
File Number)

81-3879991
(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 May 16, 2022, Cullinan Oncology, Inc. announced its financial results for the quarter ended March 31, 2022. 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by Cullinan Oncology, Inc. on May 16, 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: May 16, 2022

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



**Cullinan Oncology Provides Corporate Update and
Reports First Quarter 2022 Financial Results**

Announced U.S. co-development and co-commercialization agreement for CLN-081 with Taiho Pharmaceutical; updated CLN-081 data accepted for oral presentation at the American Society for Clinical Oncology (ASCO) meeting in June

CLN-049 and CLN-619 Phase I dosing continues with initial clinical data on track for mid-2023; CLN-081 and CLN-978 IND submissions on track for 1H 2023

Cash of \$685 million¹, including upfront payment for the Taiho collaboration, provides expected runway through 2026.

Cambridge, MA, May 16, 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 first quarter ended March 31, 2022.

“We made excellent progress in the first quarter of 2022, substantially advancing our lead asset, CLN-081, and continuing to progress our diversified pipeline,” said Nadim Ahmed, Chief Executive Officer of Cullinan Oncology. “Our March clinical and regulatory update for CLN-081 further affirmed its differentiated profile, and we are looking forward to sharing an additional clinical update in an oral presentation at the upcoming ASCO meeting. We also announced a U.S. co-development and co-commercialization agreement for CLN-081 with Taiho, the original innovators of the molecule, and an ideal partner with whom to advance this asset into later stage development and commercialization. The proceeds from this transaction will also allow us to accelerate and expand the development of our diverse pipeline as well as discover and obtain promising new oncology therapeutic candidates.”

Mr. Ahmed continued, “We are also pleased to continue the progression of our pipeline programs. Dosing in the Phase I trials of CLN-619 and CLN-049 was initiated in December 2021 and the studies are continuing on track to deliver initial data readouts by mid-2023. We are also on track to file INDs for two additional programs, CLN-617 and CLN-978, in the first half of next year. Importantly, we are in an even stronger financial position to continue advancing our strategically built pipeline of diversified assets, each with the potential to be the first or best in their class. We ended the first quarter of 2022 with approximately \$410 million in cash and investments², which, when added to proceeds from the Taiho deal, aggregates to \$685 million, and extends our cash runway through 2026.”

¹ Include cash, cash equivalents, investments, and interest receivable of \$410 million as of March 31, 2022 and \$275 million upfront to be received upon closing.

² Include cash, cash equivalents, investments, and interest receivable.

Portfolio Highlights

- **CLN-081 (Pearl):** Cullinan announced the simultaneous sale of Cullinan Pearl and a U.S. co-development and co-commercialization collaboration of CLN-081 with Taiho Pharmaceutical Co., Ltd. (Taiho). Cullinan will receive \$275 million upfront and is eligible for an additional \$130 million tied to EGFR exon20 NSCLC regulatory milestones, in addition to sharing 50/50 in the future potential U.S. profits and losses for CLN-081. In January, Cullinan announced that CLN-081 was granted Breakthrough Therapy Designation (BTD) for the treatment of non-small cell lung cancer (NSCLC) patients harboring epidermal growth factor (EGFR) exon 20 insertion mutations who have previously received platinum-based systemic chemotherapy. In March, Cullinan reported a clinical and regulatory update for CLN-081, which included an improved 41% confirmed overall response rate at 100mg BID and a continued favorable safety and tolerability profile.
- **CLN-049 (Florentine):** In December 2021, patient dosing was initiated in a first-in-human clinical trial evaluating CLN-049 in patients with relapsed/refractory AML and MDS. Initial clinical data are expected by mid-2023. CLN-049 is a FLT3/CD3-bispecific T cell-engaging antibody in an IgG format for the treatment of acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS). CLN-049 targets the extracellular domain of FLT3, regardless of mutant or wild type expression.
- **CLN-619 (MICA):** In December 2021, patient dosing was initiated in a first-in-human clinical trial evaluating CLN-619 alone and in combination with pembrolizumab in patients with advanced tumors. Initial clinical data are expected by mid-2023. 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.
- **Preclinical Portfolio:** Continued advancement of five additional oncology programs with the following highlights:
 - Preclinical data across five distinct programs were presented at the American Association for Cancer Research (AACR) 2022 Annual Meeting in April, including CLN-049, CLN-619, CLN-617 (Amber), CLN-978 (NexGem) and Opal.
 - Cullinan Oncology continues to advance two programs through Investigational New Drug (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.

First Quarter 2022 Financial Results

- **Cash Position:** Cash and investments² were \$410 million as of March 31, 2022. Including the \$275 million upfront payment related to the Taiho transaction, we expect to have \$685 million in cash and investments². As a result of the transaction and based on current operating plans, we expect to have cash runway through 2026, compared to our previous guidance of through 2024.

- **R&D Expenses:** Research and development (R&D) expenses were \$24.5 million for the first quarter of 2022, compared to \$20.9 million for the fourth quarter of 2021. R&D expenses for each of the first quarter of 2022 and fourth quarter of 2021 included \$2.6 million of equity-based compensation expenses. The increase in R&D expenses is primarily related to expanded clinical and chemistry, manufacturing, and controls (CMC) activity for CLN-081 and CLN-619, IND-enabling activities for CLN-617, and discovery and development of our preclinical programs.
- **G&A Expenses:** General and administrative (G&A) expenses were \$8.1 million for the first quarter of 2022, compared to \$13.5 million for the fourth quarter of 2021. G&A expenses in the first quarter of 2022 and fourth quarter of 2021 included \$3.8 million and \$9.6 million of equity-based compensation expenses, respectively. The decrease in G&A expenses was primarily driven by a decrease in equity-based compensation expenses, partially offset by a \$0.3 million increase in professional services.
- **Net Loss:** The Company's net loss (before items attributable to noncontrolling interest) was \$12.9 million for the first quarter of 2022 compared to \$34.2 million for the fourth quarter of 2021. The decrease in net loss was primarily related income tax benefits recorded for the expected utilization of current quarter losses and the release of valuation allowance of certain historical tax losses against the expected gain on the sale of Cullinan Pearl, as well as a decrease in equity-based compensation expenses, which were partially offset by increases in R&D costs to advance our portfolio.

About Cullinan Oncology

Cullinan Oncology, Inc. (NASDAQ: CGEM) is a biopharmaceutical company dedicated to creating new standards of care for patients with cancer. We innovate without borders to find the most promising clinic-ready cancer therapies, whether from our own discovery efforts or through exceptional engagement with our academic and industry partners. Anchored in a deep understanding of immuno-oncology and translational cancer medicine, we leverage our scientific excellence in small molecules and biologics to create differentiated ideas, identify unique targets, and select the optimal modality to develop transformative therapeutics across cancer indications. Powered by our novel research model, we push conventional boundaries from candidate selection to cancer therapeutic, applying rigorous early experimentation to fast-track only the most promising assets to the clinic and ultimately commercialization. As a result, our diversified pipeline is strategically built with assets that activate the immune system or inhibit key oncogenic drivers across a wide range of modalities, each with the potential to be the best or first in their class.

Our people possess deep scientific expertise, seek innovation openly, and exercise creativity and urgency to deliver on our promise to bring new therapeutic solutions to patients with cancer. Learn more about our Company at www.cullinanoncology.com, and follow us on LinkedIn and Twitter.

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)

	March 31, 2022 <i>(unaudited)</i>	December 31, 2021 <i>(1)</i>
Cash, cash equivalents, investments, and interest receivable	\$410,063	\$ 432,495
Total assets	\$437,463	\$ 437,185
Total current liabilities	\$ 17,257	\$ 11,746
Total liabilities	\$ 17,993	\$ 11,811
Total stockholders' equity	\$418,702	\$ 425,374
Total liabilities and stockholders' equity	\$437,463	\$ 437,185

(1)The condensed consolidated balance sheet as of the year ended December 31, 2021 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	
	March 31, 2022 <i>(unaudited)</i>	December 31, 2021 <i>(unaudited)</i>
License revenue	\$ —	\$ —
Operating expenses:		
Research and development	24,536	20,878
General and administrative	8,121	13,468
Total operating expenses	32,657	34,346
Income/(loss) from operations	(32,657)	(34,346)
Other income (expense):		
Interest income	197	137
Other income (expense), net	—	4
Net income/(loss) before income taxes	(32,460)	(34,205)
Income tax expense/(benefit)	(19,568)	—
Net income/(loss)	(12,892)	(34,205)
Net income/(loss) attributable to noncontrolling interest	(794)	(1,692)
Net loss attributable to common stockholders of Cullinan	\$ (12,098)	\$ (32,513)
Net loss per share, basic and diluted	\$ (0.27)	\$ (0.74)
Total weighted-average shares used in computing net loss per share, basic and diluted	44,431,657	43,643,397

Contacts:**Investors**

Chad Messer

+1 203.464.8900

cmesser@cullinanoncology.com

Media

Rose Weldon

+1 215.801.7644

rweldon@cullinanoncology.com