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): November 14, 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 1350
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 November 14, 2022, Cullinan Oncology, Inc. announced its financial results for the quarter ended September 30, 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

Exhibit No.	Description
99.1	Press release issued by Cullinan Oncology, Inc. on November 14, 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: November 14, 2022

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

Cullinan Oncology Provides Corporate Update and Reports Third Quarter 2022 Financial Results

Initiated pivotal study for zipalertinib (CLN-081/TAS6417)

Increased ownership in MICA subsidiary, which holds worldwide rights to CLN-619, from 54% to 92%

Continued enrollment in CLN-049 and CLN-619 clinical studies with initial clinical data updates on track for mid-2023

Cash and investments of approximately $607 million as of September 30, 2022

CAMBRIDGE, Mass., November 14, 2022 (GLOBE NEWSWIRE) — Cullinan Oncology, Inc. (Nasdaq: CGEM) a biopharmaceutical company focused on modality-agnostic targeted oncology, today reported on recent and upcoming business highlights and announced its financial results for the third quarter ended September 30, 2022.

"We continued to execute across our programs through the third quarter and will deliver multiple important milestones in 2023," said Nadim Ahmed, Chief Executive Officer of Cullinan Oncology. "For our lead program, zipalertinib, we have initiated the pivotal study in patients with EGFR exon 20 non-small cell lung cancer. We remain on track to report initial clinical data for our two additional clinical-stage programs, CLN-049 and CLN-619, in mid-2023 and to file IND applications for CLN-617 and CLN-978 in the first half of 2023, which will advance our portfolio to potentially five clinical stage programs. With $607 million of cash and investments at the end of the quarter, we have cash runway well beyond these important milestones. We will continue to strategically deploy our capital for pipeline investment, acceleration, and expansion, such as our recent purchase of additional ownership in our Cullinan MICA subsidiary. Lastly, we made important additions to our leadership team and Board of Directors with the appointments of Jacquelyn Sumer as Chief Legal Officer and Dr. David Ryan as a new independent director. Both individuals will provide important expertise to support our evolution into a late-stage oncology company."

Portfolio Highlights

- **Zipalertinib (previously CLN-081/TAS6417):** Cullinan Oncology, in collaboration with our partners at Taiho Oncology, Inc., has initiated a pivotal study of zipalertinib in EGFR exon 20 non-small-cell lung cancer patients progressing after prior systemic therapy. As previously planned, the study will enroll patients at the 100 mg BID dose, and will now also include a limited cohort of patients to evaluate safety and efficacy at 150 mg BID administered with food.

- **CLN-049:** CLN-049 is a FLT3/CD3 T cell-engaging bispecific antibody being investigated in patients with relapsed/refractory acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS). CLN-049 is currently in Phase I investigation with initial clinical data expected in mid-2023.
- **CLN-619**: CLN-619 is a monoclonal antibody that stabilizes expression of MICA/MICB on the tumor cell surface to promote tumor cell lysis from both cytotoxic innate and adaptive immune cells. CLN-619 has broad therapeutic potential and is being investigated as both monotherapy and in combination with checkpoint inhibitor therapy in an ongoing Phase I study in patients with advanced solid tumors with initial clinical data expected in mid-2023.
    - Cullinan Oncology presented a poster at the Society for Immunotherapy (SITC) meeting further characterizing the unique mechanism of action of CLN-619. The preclinical data demonstrated the requirement of Fc functionality for the potency of CLN-619, as well as a further potential mechanism of action, antibody dependent cellular phagocytosis (ADCP), to mediate anti-tumor activity.
    - In October, Cullinan Oncology announced that it increased its ownership in its Cullinan MICA Corp. (MICA) subsidiary, which holds the worldwide rights to CLN-619. Ownership increased from 54% to 92% through the purchase of equity from two of MICA's financial investors. The Myeloma Investment Fund, a venture philanthropy fund for the Multiple Myeloma Research Foundation (MMRF), retained its ownership in the entity.
- **CLN-617:** CLN-617 is a cytokine fusion protein uniquely combining IL-12 and IL-2 with a collagen binding domain designed for retention in the tumor microenvironment (TME) following intratumoral injection. Cullinan Oncology remains on track to file an Investigational New Drug (IND) application in the first half of 2023.
    - Cullinan Oncology presented a poster at the recent Society for Immunotherapy (SITC) meeting. The preclinical data demonstrate that CLN-617 can mobilize a systemic, tumor-specific cellular immune response, remodeling the tumor microenvironment in both the injected and distal tumors.
- **CLN-978:** CLN-978 is a novel CD19/CD3-bispecific therapeutic with extended serum half-life and robust potency against target cells expressing low levels of CD19. Cullinan Oncology remains on track to file an IND application in the first half of 2023.

Corporate Updates

- In August, Cullinan Oncology strengthened its leadership team by adding Jacquelyn Sumer as Chief Legal Officer.
- In November, Dr. David Ryan was appointed to Cullinan Oncology's Board of Directors. Dr. Ryan is Chief of Hematology/Oncology, Massachusetts General Hospital (MGH) Cancer Center, the Clinical Director of the MGH Cancer Center, and a Professor of Medicine, Harvard Medical School.

Third Quarter 2022 Financial Results

- **Cash Position:** Cash and investments[1] were $606.7 million as of September 30, 2022. During the third quarter of 2022, we received the remaining $5.0 million of the $275.0 million upfront payment and paid $32.6 million in taxes from the sale of our equity interest in Cullinan Pearl to Taiho Pharmaceutical Co. Ltd. Based on our current estimate, we expect to pay approximately $7 million in cash in the fourth quarter for the remaining tax liability resulting from the transaction. Subsequent to the end of the quarter, we spent an additional $30.7 million in cash to increase our ownership in our Cullinan MICA subsidiary to 92%.
- **R&D Expenses:** Research and development (R&D) expenses were $19.7 million for the third quarter of 2022, compared to $26.4 million for the prior quarter. R&D expenses for the third and second quarters of 2022 included $1.1 million and $4.4 million of equity-based compensation expenses, respectively. The decrease in R&D expenses was primarily related to a decrease in chemistry, manufacturing, and control activities for zipalertinib, CLN-619 and CLN-617 and the initiation of expense reimbursement for zipalertinib due to the collaboration agreement with Taiho Oncology, Inc. in the third quarter.
- **G&A Expenses:** General and administrative (G&A) expenses were $10.1 million for the third quarter of 2022, compared to $10.7 million for prior quarter. G&A expenses in each of the third and second quarters of 2022 included $4.2 million of equity-based compensation expenses. The decrease in G&A expenses is primarily driven by nonrecurring expenses related to the Cullinan Pearl transaction of $1.7 million in the second quarter of 2022, partially offset by an increase in professional services expense.
- **Net Loss:** Net loss (before items attributable to noncontrolling interest) for the third quarter of 2022 was $24.9 million.

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 and timelines, clinical trial designs, clinical and therapeutic potential, and strategy of our product candidates; our ability to evaluate strategic opportunities to accelerate development timelines; our ability to optimize the impact of our collaborations and license agreements with external parties; our ability to continue our growth; our receipt of escrowed funds related to our transaction with Taiho Pharmaceutical; 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, 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)

	September 30, 2022 *(unaudited)*	June 30, 2022 *(unaudited)*
Cash, cash equivalents, investments, and interest receivable	$ 606,737	$ 655,623
Total assets	$ 617,237	$ 667,249
Total current liabilities	$ 27,117	$ 62,035
Total liabilities	31,109	62,631
Total stockholders' equity	586,128	604,618
Total liabilities and stockholders' equity	$ 617,237	$ 667,249

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

	Three Months Ended		Nine Months Ended	
	September 30, 2022 (unaudited)	June 30, 2022 (unaudited)	September 30, 2022 (unaudited)	September 30, 2021 (unaudited)
License revenue	$ —	$ —	$ —	$ 18,943
Operating expenses:				
Research and development	19,680	26,411	70,627	36,873
General and administrative	10,086	10,695	28,902	15,677
Total operating expenses	29,766	37,106	99,529	52,550
Gain on sale of Cullinan Pearl	—	(276,785)	(276,785)	—
Income (loss) from operations	(29,766)	239,679	177,256	(33,607)
Other income (expense):				
Interest income	2,353	697	3,247	340
Other income (expense), net	—	(241)	(241)	(12)
Net income (loss) before income taxes	(27,413)	240,135	180,262	(33,279)
Income tax expense (benefit)	(2,523)	66,070	43,979	—
Net income (loss)	(24,890)	174,065	136,283	(33,279)
Net income (loss) attributable to noncontrolling interests	(86)	(833)	(1,713)	(223)
Net income (loss) attributable to common stockholders of Cullinan	$ (24,804)	$ 174,898	$ 137,996	$ (33,056)
Earnings (net loss) per share:				
Basic	$ (0.54)	$ 3.90	$ 3.07	$ (0.76)
Diluted	$ (0.54)	$ 3.77	$ 2.96	$ (0.76)
Weighted-average shares used in computing earnings (net loss) per share:				
Basic	45,611	44,873	44,966	43,254
Diluted	45,611	46,381	46,580	43,254

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Media

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