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 9, 2023

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 March 9, 2023, Cullinan Oncology, Inc. announced its financial results for the quarter and year ended December 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

Exhibit No.	Description
99.1	Press release issued by Cullinan Oncology, Inc. on March 9, 2023, 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 9, 2023

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

Cullinan Oncology Provides Corporate Update and Reports Fourth Quarter and Full Year 2022 Financial Results

Expanded clinical stage portfolio through licensing of U.S. rights to CLN-418

Received FDA clearance of IND application for CLN-978; submitted IND application for CLN-617

Initial clinical data updates for CLN-049 and CLN-619 on track for mid-2023

Potential for 6 clinical stage programs by year end and cash runway into 2026

CAMBRIDGE, Mass., March 9, 2023 (GLOBE NEWSWIRE) — Cullinan Oncology, Inc. (Nasdaq: CGEM; "Cullinan") a biopharmaceutical company focused on modality-agnostic targeted oncology therapies, today reported on recent and upcoming business highlights and announced its financial results for the fourth quarter and full year ended December 31, 2022.

"2022 was a year of remarkable execution at Cullinan Oncology, and the momentum with which we ended the year has continued into early 2023. With our partners at Taiho Oncology, we initiated the pivotal study of zipalertinib in the fourth quarter, while continuing to advance enrollment in the Phase 1 trials of CLN-049 and CLN-619, with initial clinical data expected mid-year" said Nadim Ahmed, Chief Executive Officer of Cullinan. "The first two months of 2023 have resulted in similarly exciting developments, as we recently expanded our pipeline through the licensing of U.S. development and commercial rights to CLN-418, a potential first-in-class B7H4x4-1BB bispecific immune activator currently in a Phase 1 study across a variety of solid-tumor indications. This transaction provides us with the opportunity to have six programs in the clinic by the end of the year, as we recently received IND clearance for CLN-978 and also recently filed the IND for CLN-617, consistent with prior guidance. Importantly, our cash position following the CLN-418 transaction provides us with runway into 2026 which gives us the flexibility needed to fund our ongoing development efforts and reach multiple potential value creating milestones."

Portfolio Highlights

- **Zipalertinib:** In the fourth quarter of 2022, Cullinan Oncology, in collaboration with our partners at Taiho Oncology, Inc., initiated a pivotal study of zipalertinib in EGFR exon 20 insertion mutation non-small-cell lung cancer patients progressing after prior systemic therapy. As previously planned, the study will enroll patients at the 100mg BID dose under fasted conditions, and also will include a limited cohort of patients to evaluate safety and efficacy at 150mg BID administered with food.

- **CLN-049:** CLN-049 is a FLT3xCD3 T cell-engaging bispecific antibody being investigated in patients with relapsed/refractory acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS). Enrollment continues in the ongoing Phase 1 dose escalation clinical study 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 by 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 1 dose escalation study in patients with advanced solid tumors with initial clinical data expected in mid-2023.
- **CLN-418:** CLN-418 is a B7H4x4-1BB fully human bispecific immune activator designed to achieve conditional activation of 4-1BB by targeting B7H4, a tumor associated antigen that is highly expressed across multiple cancers with minimal expression on normal tissues. Enrollment is ongoing in a Phase 1 dose escalation study at U.S. and Australian sites in patients with advanced solid tumors with initial clinical data expected in 2024.
    - In February, Cullinan Oncology licensed the exclusive U.S. development and commercial rights to CLN-418 from Harbour Biomed for an upfront fee of $25 million, with the potential for up to an additional $148 million in development and regulatory milestones and up to $415 million in sales-based milestones, as well as tiered royalties on potential U.S. commercial sales.
- **CLN-978:** CLN-978 is a novel CD19xCD3-bispecific therapeutic with extended serum half-life and robust potency against target cells expressing low levels of CD19. Consistent with prior guidance, Cullinan received FDA clearance of its Investigational New Drug (IND) application for CLN-978 in January and anticipates initiating a Phase 1 clinical study by the end of 2023.
- **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. Consistent with prior guidance, Cullinan recently filed the IND application for CLN-617 in February 2023 and intends to initiate a Phase 1 clinical study by the end of 2023, pending IND clearance.

Fourth Quarter 2022 Financial Results

- **Cash Position:** Cash and investments were $550.1 million as of December 31, 2022. During the fourth quarter of 2022, Cullinan acquired additional equity in its subsidiary, Cullinan Mica, which holds the worldwide rights to CLN-619, for $33 million, increasing its ownership from 54% to 95% of the entity. In the first quarter of 2023, the Company spent $25 million on the upfront payment under the recently announced licensing agreement for CLN-418 with Harbour Biomed. Cullinan expects its cash resources to provide runway into 2026 based on its current operating plan.

- **R&D Expenses:** Research and development (R&D) expenses were $21.3 million for the fourth quarter of 2022, compared to $19.7 million for the third quarter of 2022. R&D expenses for the fourth and third quarters of 2022 included $2.9 million and $1.1 million of equity-based compensation expenses, respectively. Excluding the impact of equity-based compensation expenses, the decrease in R&D expenses was primarily related to a decrease in preclinical costs, partially offset by increased personnel costs.
- **G&A Expenses:** General and administrative (G&A) expenses were $11.3 million for the fourth quarter of 2022, compared to $10.1 million for the third quarter of 2022. G&A expenses in the fourth and third quarters of 2022 included $4.6 million and $4.2 of equity-based compensation expenses, respectively. The increase in G&A expenses was primarily driven by increased personnel costs.
- **Net Loss:** Net loss (before items attributable to noncontrolling interest) for the fourth quarter of 2022 was $27.1 million, compared with net loss of $24.9 million for the third quarter of 2022. Net losses included the items described above, partially offset by interest income of $3.4 million and $2.4 million and income tax benefit recognized of $1.9 million and $2.5 million in the fourth and third quarters of 2022, respectively.

Full Year 2022 Financial Results

- **R&D Expenses:** R&D expenses were $91.9 million for 2022, compared to $57.8 million for 2021. R&D expenses for 2022 and 2021 included $11.0 million and $8.9 million of equity-based compensation expenses, respectively. The increase in R&D expenses was primarily related to CRO and CMC activities to support our ongoing clinical trials and pre-clinical research and CMC costs to support IND enabling activities.
- **G&A Expenses:** G&A expenses were $40.2 million for 2022, compared to $29.1 million in 2021. G&A expenses in 2022 and 2021 included $16.9 million and $15.4 million of equity-based compensation expenses, respectively. The increase in G&A expenses was primarily driven by increase in personnel and professional services due to increased headcount to support our expanded operations, and non-recurring costs related to the previously announced Cullinan Pearl sale, described below.
- **Gain on sale of Cullinan Pearl**: In June 2022, Cullinan sold its equity interest in its subsidiary, Cullinan Pearl, which has worldwide rights to zipalertinib, excluding Japan and Greater China, to Taiho Pharmaceutical Co., Ltd. (Taiho). Cullinan recognized a gain from the sale of $276.8 million, which includes the upfront payment of $275 million, as well as the impact of net liabilities transferred to Taiho. Cullinan also recognized income tax expenses of $42.1 million as a result of the gain and offsetting operating expenses.
- **Net Income (Loss):** Net income (before items attributable to noncontrolling interest) for 2022 was $109.2 million, compared with a net loss of $67.5 million in 2021. Net income in 2022 was related to the items described above, as well as $6.6 million of interest income. In 2021, operating expenses described above were partially offset by $18.9 million of license revenue.

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; 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)

	December 31, 2022 (unaudited)	September 30, 2022 (unaudited)
Cash, cash equivalents, investments, and interest receivable	$ 550,118	$ 606,737
Total assets	$ 561,117	$ 617,237
Total current liabilities	$ 22,498	$ 27,117
Total liabilities	$ 26,088	$ 31,109
Total stockholders' equity	$ 535,029	$ 586,128
Total liabilities and stockholders' equity	$ 561,117	$ 617,237

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

	Three Months Ended		Year Ended	
	December 31, 2022 (unaudited)	September 30, 2022 (unaudited)	December 31, 2022 (unaudited)	December 31, 2021 (audited)
License revenue	$ —	$ —	$ —	$ 18,943
Operating expenses:				
Research and development	21,321	19,680	91,948	57,751
General and administrative	11,287	10,086	40,189	29,146
Total operating expenses	32,608	29,766	132,137	86,897
Gain on sale of Cullinan Pearl	—	—	276,785	—
Income (loss) from operations	(32,608)	(29,766)	144,648	(67,954)
Other income (expense):				
Interest income	3,364	2,353	6,611	477
Other income (expense), net	298	—	57	(8)
Net income (loss) before income taxes	(28,946)	(27,413)	151,316	(67,485)
Income tax expense (benefit)	(1,858)	(2,523)	42,121	—
Net income (loss)	(27,088)	(24,890)	109,195	(67,485)
Net loss attributable to noncontrolling interests	(306)	(86)	(2,019)	(1,915)
Net income (loss) attributable to common stockholders of Cullinan	$ (26,782)	$ (24,804)	$ 111,214	$ (65,570)
Earnings (net loss) per share:				
Basic	$ (0.59)	$ (0.54)	$ 2.46	$ (1.52)
Diluted	$ (0.59)	$ (0.54)	$ 2.38	$ (1.52)
Weighted-average shares used in computing earnings (net loss) per share:				
Basic	45,751	45,611	45,164	43,077
Diluted	45,751	45,611	46,640	43,077

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