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): August 10, 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)**	**(IRS Employer Identification No.)**

One Main Street **Suite 1350** **Cambridge, Massachusetts**	**02142**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (617) 410-4650

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:

☐ 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 August 10, 2023, Cullinan Oncology, Inc. announced its financial results for the quarter ended June 30, 2023. 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 August 10, 2023, furnished herewith
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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: August 10, 2023

By: /s/ Jeffrey Trigilio

Jeffrey Trigilio
Chief Financial Officer

Cullinan Oncology Provides Corporate Update and Reports Second Quarter 2023 Financial Results

Phase 3 first-line study of zipalertinib in EGFR exon 20 insertion mutation non-small-cell lung cancer (NSCLC) patients (REZILIENT-3) open to enrollment

Initial monotherapy clinical data for CLN-619 presented at ASCO 2023 Annual Meeting; initiated monotherapy expansion cohorts in endometrial and cervical cancers

First patient dosed in Phase 1 study of CLN-978 in relapsed/refractory (R/R) B Cell non-Hodgkin lymphoma (B-NHL)

Cash and investment position of $512.1 million as of June 30, 2023 continues to provide runway into 2026

CAMBRIDGE, Mass., August 10, 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 second quarter ended June 30, 2023.

"We have continued to advance our broad portfolio of modality-agnostic cancer therapies during the first half of this year and are poised to continue our momentum," said Nadim Ahmed, Chief Executive Officer of Cullinan. "With our partners at Taiho Oncology, we recently announced the launch of the REZILIENT-3 study, a randomized Phase 3 trial which will evaluate zipalertinib as a first-line treatment for EGFR exon 20 NSCLC patients. We also shared encouraging initial clinical monotherapy data for CLN-619 at ASCO in June. Based on that data, we announced monotherapy expansion cohorts in endometrial and cervical cancers. We look forward to presenting the first data from the pembrolizumab combination arm at a medical congress in the future. Further, we recently brought our fifth development program into the clinic with the dosing of the first patient in our Phase 1 study of CLN-978 in relapsed/refractory B cell non-Hodgkin lymphoma. Following an IND clearance earlier this year, we remain on track to bring our sixth program, CLN-617, into the clinic by year-end. With $512.1 million in cash and investments at the end of Q2, we remain well capitalized to continue executing on our strategic objectives and creating value for all of our key stakeholders."

Portfolio Highlights

- **Zipalertinib:** In August 2023, Cullinan Oncology, in collaboration with our partners at Taiho Oncology, Inc., announced the initiation of REZILIENT-3, a global Phase 3 study evaluating zipalertinib plus chemotherapy versus chemotherapy alone in patients with EGFR exon 20 insertion mutation non-small-cell lung cancer (EGFRex20 NSCLC) in the first-line setting.

- Enrollment continued in the Phase 2b pivotal study of zipalertinib in patients with EGFRex20 NSCLC who have progressed after prior systemic therapy, as well as in a separate cohort of patients progressing after prior treatment with a currently approved agent for EGFRex20 NSCLC.

- **CLN-619**: CLN-619 is a monoclonal antibody that stabilizes expression of MICA/B 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 a monotherapy and in combination with checkpoint inhibitor therapy in an ongoing Phase 1 dose escalation study in patients with advanced solid tumors.
  - First clinical data for CLN-619 monotherapy in patients with advanced solid tumors were presented during a poster session at the American Society of Clinical Oncology (ASCO) 2023 Annual Meeting in June 2023. Data demonstrated monotherapy anti-tumor activity of CLN-619 in heavily pre-treated patients with multiple tumor types and an acceptable safety profile with no dose limiting toxicities up to the highest dose tested. Best responses among 22 evaluable patients receiving doses ≥1 mg/kg included 1 confirmed complete response (parotid cancer), 2 confirmed partial responses (endometrial cancer), and 7 patients with stable disease (cervical, ovarian, breast, and salivary gland cancers).
  - Based on these clinical observations, Cullinan has initiated monotherapy expansion cohorts in endometrial and cervical cancers and is evaluating potential additional future expansion cohorts.
  - Cullinan intends to present initial data from the combination dose escalation arm of the study at a medical meeting in the future.

- **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).
  - Preliminary safety data from an ongoing first-in-human study were published in abstract form as part of the 2023 EHA Congress in June 2023.
  - Enrollment continues in the ongoing Phase 1 multi-ascending dose study using subcutaneous administration.

- **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 continued in the ongoing Phase 1 dose escalation study in patients with advanced solid tumors. Initial clinical data are expected in 2024.

- **CLN-978:** CLN-978 is a CD19xCD3 T cell engager with extended serum half-life and robust potency against target cells expressing low levels of CD19.
  - In August 2023, Cullinan dosed the first patient in a Phase 1 study of CLN-978 in patients with R/R B-NHL.

- **CLN-617:** CLN-617 is a cytokine fusion protein uniquely combining IL-2 and IL-12 with a collagen binding domain designed for retention in the tumor microenvironment (TME) following intratumoral injection.
    - Cullinan received FDA clearance of its IND application for CLN-617 in March and anticipates initiating a Phase 1 clinical study in the second half of 2023.

Second Quarter 2023 Financial Results

- **Cash Position:** Cash, cash equivalents, investments, and interest receivable were $512.1 million as of June 30, 2023. This balance includes proceeds of approximately $38.4 million from sales of common stock under the company's at-the-market offering program. 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 $27.4 million for the second quarter of 2023, compared to $52.1 million for the first quarter of 2023. R&D expenses for the second and first quarters of 2023 included $3.2 million and $3.1 million of equity-based compensation expenses, respectively. The decrease in R&D expenses was primarily related to a one-time $25 million upfront payment in the first quarter of 2023 to in-license U.S. rights to CLN-418 and higher clinical costs, partially offset by lower chemistry, manufacturing and controls costs.
- **G&A Expenses:** General and administrative (G&A) expenses were $10.2 million for the second quarter of 2023, compared to $10.7 million for the first quarter of 2023. G&A expenses in the second and first quarters of 2023 included $4.7 million and $4.2 million of equity-based compensation expenses, respectively. The decrease in G&A expenses, excluding equity-based compensation, was primarily driven by lower professional services fees.
- **Net Loss:** Net loss (before items attributable to noncontrolling interest) for the second quarter of 2023 was $32.2 million, compared with net loss of $58.1 million for the first quarter of 2023. Net losses included the items described above, partially offset by interest income of $5.3 million and $4.5 million in the second quarter and first quarter of 2023, respectively.

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 expectations regarding our cash runway and use of capital; and our plans regarding future data presentations. 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; 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
(unaudited)
(in thousands)

	June 30, 2023	December 31, 2022
Cash, cash equivalents, investments, and interest receivable	$ 512,117	$ 550,118
Total assets	$ 521,984	$ 561,117
Total current liabilities	$ 19,676	$ 22,498
Total liabilities	$ 22,410	$ 26,088
Total stockholders' equity	$ 499,574	$ 535,029
Total liabilities and stockholders' equity	$ 521,984	$ 561,117

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

	Three Months Ended June 30		Six Months Ended June 30	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 27,391	$ 26,411	$ 79,487	$ 50,947
General and administrative	10,214	10,695	20,874	18,816
Total operating expenses	37,605	37,106	100,361	69,763
Gain on sale of Cullinan Pearl	—	276,785	-	276,785
Income (loss) from operations	(37,605)	239,679	(100,361)	207,022
Other income (expense):				
Interest income	5,322	697	9,830	894
Other income (expense), net	69	(241)	176	(241)
Net income (loss) before income taxes	(32,214)	240,135	(90,355)	207,675
Income tax expense	—	66,070	—	46,502
Net income (loss)	(32,214)	174,065	(90,355)	161,173
Net loss attributable to noncontrolling interests	—	(833)	(179)	(1,627)
Net income (loss) attributable to common stockholders of Cullinan	$ (32,214)	$ 174,898	$ (90,176)	$ 162,800
Net income (loss) per share:				
Basic	$ (0.82)	$ 3.90	$ (2.24)	$ 3.65
Diluted	$ (0.82)	$ 3.77	$ (2.24)	$ 3.51
Weighted-average shares used in computing net income (loss) per share:				
Basic	39,952	44,873	40,315	44,654
Diluted	39,952	46,381	40,315	46,389

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