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 08, 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** **(Address of Principal Executive Offices)**	**02142** **(Zip Code)**

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

(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 November 8, 2023, Cullinan Oncology, Inc. announced its financial results for the quarter ended September 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 November 8, 2023, furnished herewith
104	Cover page from this Current Report on Form 8-K, formatted in Inline XBRL

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: November 8, 2023

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

Exhibit 99.1

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

Cullinan to provide clinical data updates on three novel targeted oncology programs and complete enrollment in the pivotal Phase 2b portion of the zipalertinib REZILIENT1 study in 2024

Initial CLN-619 clinical biomarker data support mechanism of action and demonstrate monotherapy clinical activity in patients with tumors not typically responsive to checkpoint inhibitor therapy

Cash and investment position of $482 million as of September 30, 2023 expected to provide runway into the second half of 2026, vs into 2026 previously

CAMBRIDGE, Mass., November 8, 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 third quarter ended September 30, 2023.

“We have made tremendous strides through the first three quarters of 2023, while positioning Cullinan for a data-rich 2024,” said Nadim Ahmed, Chief Executive Officer of Cullinan Oncology. “We are rapidly progressing CLN-619 and look forward to providing initial data from the combination therapy module, as well as additional monotherapy data, from the Phase 1 dose escalation study in the second quarter of 2024. We also expect to provide initial data from our disease-specific expansion cohorts in the first half of 2025. Our broad zipalertinib development program, being conducted in collaboration with our partners at Taiho, is also continuing, and we expect to complete enrollment in the pivotal Phase 2b portion of the REZILIENT1 study by the end of 2024. We expect to present data for CLN-049 and CLN-418 in the second half of 2024 as well. We finished Q3 with cash and investments of $482 million, which we now expect to provide runway into the second half of 2026, two quarters beyond previous guidance.”

Portfolio Highlights

- **CLN-619 (Anti-MICA/MICB monoclonal antibody)**: Solid tumors
    - Enrollment continues in the ongoing Phase 1 study evaluating CLN-619 as both monotherapy and in combination with checkpoint inhibitor therapy. Accrual to the dose escalation phase of the combination module has been completed. Recruitment continues to the monotherapy disease specific expansion cohorts for patients with endometrial and cervical cancers. Cullinan also continues to evaluate additional disease specific expansion cohorts.

- At the 2023 SITC Annual Meeting, initial biomarker data from the ongoing Phase 1 study of CLN-619 were presented at a poster session, providing evidence for CLN-619's mechanism of action and demonstrating that clinical activity, including objective response, has been observed in patients with tumor characteristics not typically responsive to checkpoint inhibitor therapy.

- **Zipalertinib (EGFR ex20ins inhibitor):** EGFR ex20ins NSCLC
  - In August 2023, Cullinan Oncology, in collaboration with our partners at Taiho Oncology, Inc., announced the initiation of REZILIENT3, 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 (EGFR ex20ins NSCLC) in the first-line setting.
  - Enrollment continues in the pivotal Phase 2b portion of the REZILIENT1 study, evaluating zipalertinib in a cohort of patients with EGFR ex20ins 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 EGFR ex20ins NSCLC.
- **CLN-049 (FLT3xCD3 T cell-engaging bispecific antibody):** AML and MDS
  - Enrollment continues in the ongoing Phase 1 multi-ascending dose study using subcutaneous administration.
- **CLN-418 (B7H4x4-1BB bispecific immune activator):** Solid tumors
  - Preclinical data, including target expression profiling data and robust anti-tumor activity supporting the development of CLN-418 in multiple solid tumors, were presented at the 2023 SITC Annual Meeting.
  - Enrollment continued in the ongoing Phase 1 dose escalation study in patients with advanced solid tumors.
- **CLN-978 (CD19xCD3 T cell engager):** B-NHL
  - In August 2023, Cullinan dosed the first patient in a Phase 1 study of CLN-978 in patients with R/R B-NHL.
  - Preclinical data demonstrating the effectiveness of CLN-978 against lymphoma cells expressing very low levels of CD19 were presented at the 2023 SITC Annual Meeting.
- **CLN-617 (IL-2 and IL-12 cytokine fusion protein):** Solid tumors
  - Cullinan anticipates dosing the first patient in the CLN-617 first-in-human Phase 1 study by year end 2023.
  - A poster at the 2023 SITC Annual Meeting highlighted preclinical data demonstrating the mechanism by which CLN-617 mediates a robust abscopal anti-tumor effect in preclinical models. A Trial in Progress poster for the ongoing Phase 1 study of CLN-617 in combination with pembrolizumab was also presented.

Upcoming Milestones

- **CLN-619**
  - Cullinan expects to report initial data from the combination dose escalation module as well as an update on the monotherapy dose escalation module at a medical conference in the second quarter of 2024.
  - Cullinan expects to report initial data from disease specific dose expansion cohorts in the first half of 2025.
- **Zipalertinib**
  - Cullinan expects completion of enrollment in the pivotal Phase 2b portion of the REZILIENT1 study by year-end 2024.
- **CLN-049**
  - Cullinan expects to provide a clinical data update in the second half of 2024.
- **CLN-418**
  - Cullinan expects to provide a clinical data update in the second half of 2024.

Third Quarter 2023 Financial Results

- **Cash Position:** Cash, cash equivalents, investments, and interest receivable were $481.9 million as of September 30, 2023. Cullinan now expects its cash resources to provide runway into the second half of 2026 based on its current operating plan. The extension from prior guidance is primarily driven by the receipt of approximately $38 million in net proceeds from Cullinan's ATM equity program, increased interest income, and the prioritization of development plans in the longer term. Cullinan's operating plan includes continued advancement of all programs to key data milestones in the near term.
- **R&D Expenses:** Research and development (R&D) expenses were $33.8 million for the third quarter of 2023, compared to $27.4 million for the second quarter of 2023. R&D expenses for the third and second quarters of 2023 included $3.2 million and $3.2 million of equity-based compensation expenses, respectively. The increase in R&D expenses was primarily related to increased chemistry, manufacturing and controls costs and higher clinical costs.
- **G&A Expenses:** General and administrative (G&A) expenses were $11.0 million for the third quarter of 2023, compared to $10.2 million for the second quarter of 2023. G&A expenses in the third and second quarters of 2023 included $4.5 million and $4.7 million of equity-based compensation expenses, respectively. The increase in G&A expenses, excluding equity-based compensation, was primarily driven by higher personnel costs.
- **Net Loss:** Net loss (before items attributable to noncontrolling interest) for the third quarter of 2023 was $39.2 million, compared with net loss of $32.2 million for the second quarter of 2023. Net losses included the items described above, partially offset by interest income of $5.9 million and $5.3 million in the third quarter and second quarter of 2023, respectively.

- **Shares Outstanding:** As of October 31, 2023, Cullinan had 42,780,644 common shares outstanding plus 647,500 shares of non-voting preferred stock outstanding, each of which is convertible into 10 shares of common stock.

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 future results, performance or achievements 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)

	September 30, 2023	December 31, 2022
Cash, cash equivalents, investments, and interest receivable	$ 481,940	$ 550,118
Total assets	$ 494,707	$ 561,117
Total current liabilities	$ 23,444	$ 22,498
Total liabilities	$ 25,890	$ 26,088
Total stockholders' equity	$ 468,817	$ 535,029
Total liabilities and stockholders' equity	$ 494,707	$ 561,117

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

	Three Months Ended		Nine Months Ended	
	September 30, 2023	June 30, 2023	September 30, 2023	September 30, 2022
Operating expenses:				
Research and development	$ 33,821	$ 27,391	$ 113,308	$ 70,627
General and administrative	10,982	10,214	31,856	28,902
Total operating expenses	44,803	37,605	145,164	99,529
Impairment of long-lived assets	(440)	—	(440)	-
Gain on sale of Cullinan Pearl	—	—	—	276,785
Income (loss) from operations	(45,243)	(37,605)	(145,604)	177,256
Other income (expense):				
Interest income	5,880	5,322	15,710	3,247
Other income (expense), net	180	69	356	(241)
Net income (loss) before income taxes	(39,183)	(32,214)	(129,538)	180,262
Income tax expense (benefit)	—	—	—	43,979
Net income (loss)	(39,183)	(32,214)	(129,538)	136,283
Net loss attributable to noncontrolling interests	—	—	(179)	(1,713)
Net income (loss) attributable to common stockholders of Cullinan	$ (39,183)	$ (32,214)	$ (129,359)	$ 137,996
Net income (loss) per share attributable to common stockholders of Cullinan:				
Basic	$ (0.91)	$ (0.82)	$ (3.15)	$ 3.07
Diluted	$ (0.91)	$ (0.82)	$ (3.15)	$ 2.96
Weighted-average shares used in computing net income (loss) per share attributable to common stockholders of Cullinan:				
Basic	42,734	39,952	41,130	44,966
Diluted	42,734	39,952	41,130	46,580

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