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 25, 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 7.01 Regulation FD Disclosure

On May 25, 2023, Cullinan Oncology, Inc. (the "Company" or "Cullinan") issued a press release related to the announcement of the first clinical data from its Phase 1 study of CLN-619 in patients with advanced solid tumors. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Cullinan will host an investor event on Sunday, June 4, 2023, at 7:00 am Central Time, during which its Chief Medical Officer, Dr. Jeff Jones, will present an overview of the CLN-619 data shared at the 2023 American Society of Clinical Oncology ("ASCO") Annual Meeting on June 3, 2023, and Dr. Vicky Makker, MD, Section Head of the Endometrial Cancer Program at Memorial Sloan Kettering Cancer Center, will share an overview of the current treatment landscape for endometrial cancer. Investors and analysts are invited to register to attend in-person by emailing Chad Messer, VP Investor Relations of the Company at cmesser@cullinanoncology.com. A live webcast will be available via the events page of the Company's investor relations website at https://cullinanoncology.com/events-and-presentations/, and a replay will be available shortly after the conclusion of the live event.

The information in this report furnished pursuant to Item 7.01, including Exhibit 99.1 attached hereto, shall not be deemed "filed" for the 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. It may only be incorporated by reference in another filing under the Exchange Act or the Securities Act of 1933, as amended, if such subsequent filing specifically references the information furnished pursuant to Item 7.01 of this report.

Item 8.01 Other Events

On May 25, 2023, the Company announced first clinical data from its Phase 1 study of CLN-619 in patients with advanced solid tumors. CLN-619 is being studied in an ongoing Phase 1 clinical trial both as a monotherapy and in combination with pembrolizumab in patients with advanced solid tumors. The first clinical data demonstrated monotherapy anti-tumor activity of CLN-619, including objective tumor responses, across multiple tumor types, as shown in the table below.

	All Patients (n=37)	Response Evaluable[1] at ≥1 mg/kg (n=22)	Response Evaluable[1] GYN Malignancy[2] (n=10)
Complete Response (CR)	1	1	0
Partial Response (PR)[3]	2	2	2
Stable Disease (SD)	7	7	5
CR + PR + SD	10	10	7
Progressive Disease (PD)	18	12	3
Not Evaluable (NE)	9	N/A	N/A

1 Patients who underwent at least one RECIST response assessment or who had clinically assessed PD prior to first planned response assessment
2 Endometrial, cervical, and ovarian
3 The observed partial responses were unconfirmed but ongoing at time of data cut-off

One complete response was observed in a patient with parotid gland cancer whose cancer had progressed on prior checkpoint inhibitor therapy. Two partial responses (pending confirmation) were observed in patients with endometrial cancer, one whose cancer had progressed on prior checkpoint inhibitor therapy. Stable disease was observed in patients across multiple tumor types, including cervical, ovarian, salivary gland and breast cancers. Patients were heavily pre-treated with prior systemic therapies, ranging from one to seven with a median of three prior systemic therapies, including 54% of the patients previously receiving immune checkpoint inhibitor therapy.

The initial clinical data indicates CLN-619 has an acceptable safety profile across all doses assessed in the monotherapy dose escalation (the dose levels were 0.1, 0.3, 1, 3, 6, and 10mg/kg). There were not any dose-limiting toxicities observed. Consistent with other monoclonal antibodies, infusion-related reactions were limited to the first dose and were all Grade 1 or Grade 2 in patients receiving mandated pre-medication.

Based on the observed clinical activity in gynecological malignances as shown in the table above, Cullinan will initiate monotherapy expansion cohorts in endometrial and cervical cancers. Additional expansion cohorts may be initiated based on clinical activity observed in the current study. The Phase 1 clinical trial continues to enroll in both the monotherapy and combination arms. The first clinical data of CLN-619 will be shared as a poster presentation at the 2023 ASCO Annual Meeting on June 3, 2023.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by Cullinan Oncology, Inc. on May 25, 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: May 25, 2023

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

Exhibit 99.1

Cullinan Oncology to Present First Monotherapy Clinical Data for CLN-619, a Novel Anti-MICA/B Antibody, at ASCO 2023

CLN-619 demonstrated monotherapy activity across a range of tumor types, including in patients whose cancer had progressed on checkpoint inhibitor therapy

Initial data indicate an acceptable safety profile of CLN-619 across all doses assessed

Based on observed clinical activity in gynecological malignancies, Cullinan to initiate monotherapy expansion cohorts in endometrial and cervical cancers

CAMBRIDGE, Mass., May 25, 2023 (GLOBE NEWSWIRE) – Cullinan Oncology, Inc. (Nasdaq: CGEM), a biopharmaceutical company focused on modality-agnostic targeted oncology therapies, today announced first monotherapy clinical data from its Phase 1 study of CLN-619 in patients with advanced solid tumors. Findings from the clinical trial will be shared at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting as a poster presentation during the "Developmental Therapeutics—Immunotherapy" session (poster # 2532) on June 3, 2023 from 8:00 AM-11:00 AM Central Time. CLN-619 is being studied in an ongoing Phase 1 clinical trial both as a monotherapy and in combination with pembrolizumab in patients with advanced solid tumors.

Summary of Key Clinical Results from Monotherapy Arm of Phase 1 Clinical Trial in Patients with Solid Tumors:

- Monotherapy dose escalation demonstrates acceptable safety profile of CLN-619 across all doses assessed (0.1, 0.3, 1, 3, 6, 10mg/kg):
  - No dose-limiting toxicities were observed
  - Consistent with other monoclonal antibodies, infusion-related reactions were limited to the first dose and all grade 1/2 in patients receiving mandated pre-medication
- Data demonstrate monotherapy anti-tumor activity of CLN-619, including objective tumor responses, across multiple tumor types:

	All Patients (n=37)	**Response Evaluable[1] at ≥1 mg/kg (n=22)**	**Response Evaluable[1] GYN Malignancy[2] (n=10)**
Complete Response (CR)	1	1	0
Partial Response (PR)[3]	2	2	2
Stable Disease (SD)	7	7	5
CR + PR + SD	10	10	7
Progressive Disease (PD)	18	12	3
Not Evaluable (NE)	9	NA	NA

1 Patients who underwent at least one RECIST response assessment or who had clinically assessed PD prior to first planned response assessment
2 Endometrial, cervical, and ovarian
3 The observed partial responses were unconfirmed but ongoing at time of data cut-off

- One CR was observed in a patient with parotid gland cancer whose cancer had progressed on prior checkpoint inhibitor therapy
- Two PRs (pending confirmation) were observed in patients with endometrial cancer, one whose cancer had progressed on prior checkpoint inhibitor therapy
- Stable disease was observed in patients across multiple tumor types, including cervical, ovarian, salivary gland, and breast cancers
- Patients were heavily pre-treated with a median of 3 prior systemic therapies (1 – 7), and 54% had received prior immune checkpoint inhibitor therapy
- The trial continues to enroll in both the monotherapy and combination arms.

“We are encouraged by the first clinical data for CLN-619 monotherapy, which demonstrates broad potential across a range of tumor types. Objective responses and sustained stable disease were observed, including in patients whose tumors had relapsed on or were not amenable to checkpoint inhibitor therapy,” said Jeffrey Jones, MD, MPH, MBA, Chief Medical Officer, Cullinan Oncology. “Notably, clinical activity was observed in multiple gynecologic cancer types of high unmet need. Based on these initial efficacy observations, we will initiate expansion cohorts in endometrial and cervical cancer and look to expand in additional tumor-specific cohorts as the data matures. Additionally, the Phase 1 trial continues to evaluate CLN-619 in combination with pembrolizumab, and we look forward to sharing the results at a future medical meeting.”

“These data demonstrate the potential of CLN-619 to treat a range of solid tumors. Along with the monotherapy efficacy of CLN-619, we also observed a favorable safety profile, with most adverse events being grade 2 or lower” said Judy Wang, MD, Florida Cancer Specialists and Research Institute. “We need new ways to help overcome immune evasion mechanisms, and CLN-619 is an antibody that is designed to render cancer cells visible to the immune system by binding to MICA and MICB, stress-induced ligands that engage the activating receptor NKG2D present on both innate and adaptive immune cells, representing a novel approach to enable immune-mediated elimination of tumors.”

“Over 66,000 new cases of endometrial cancer are diagnosed every year in the United States. The incidence has been rising for more than a decade, particularly in the more aggressive subtypes, and uterine cancer is projected to surpass colorectal cancer as the fourth leading cause of cancer death among women by 2040.[1,2] Despite recent advances in endometrial cancer therapeutics, this patient population is often affected by other co-morbidities, so safer and more effective treatment options are urgently needed to address a growing unmet need” said Vicky Makker, MD, Section Head of the Endometrial Cancer Program at Memorial Sloan Kettering Cancer Center. “That need extends across gynecologic cancers. In cervical cancer, treatment options remain limited, and even with improvements in screening to reduce incidence rates, approximately 13,000 new cases of cervical cancer are diagnosed annually and greater than 4,000 women die of this malignancy each year in the U.S.[3]”

CLN-619 Further Development Plan

CLN-619 is being studied in an ongoing Phase 1 clinical trial both as a monotherapy and in combination with pembrolizumab. The study design allows dose level extensions as well as expansion in tumor-specific cohorts. Consistent with prespecified criteria and based on initial safety and efficacy observations, Cullinan will initiate monotherapy expansion cohorts in endometrial cancer and cervical cancer. Additional expansion cohorts may be initiated based upon clinical activity observed in the current trial.

Virtual and Live Investor Event

Cullinan Oncology will host an Investor Event on Sunday, June 4, 2023, at 7:00 am Central Time, during which Dr. Jeff Jones, Chief Medical Officer at Cullinan Oncology, will present an overview of CLN-619 data shared at the 2023 ASCO Annual Meeting, and Dr. Vicky Makker, MD, Section Head of the Endometrial Cancer Program at Memorial Sloan Kettering Cancer Center, will share an overview of the current treatment landscape for endometrial cancer. Investors and analysts are invited to register to attend in-person by emailing Chad Messer, VP Investor Relations (cmesser@cullinanoncology.com). A live webcast will be available via the events page of the Company's investor relations website at https://cullinanoncology.com/events-and-presentations/, and a replay will be available shortly after the conclusion of the live event.

About CLN-619

CLN-619 is a potential first-in-class humanized IgG1 monoclonal antibody that binds to the stress induced ligands, MICA and MICB, which are expressed on a wide variety of solid tumors and hematological malignancies. Engagement of MICA/B by the activating receptor NKG2D, present on both cytotoxic innate and adaptive immune cells, results in target cell lysis. However, tumor cells can shed MICA/B via proteases they release into the tumor microenvironment, resulting in evasion of immune-mediated destruction. CLN-619 functions by restoring MICA/B expression on the surface of tumor cells, enhancing the interaction between MICA and NKG2D, and inducing antibody-dependent cellular toxicity (ADCC), together promoting anti-tumor activity via multiple immune-mediated mechanisms. CLN-619 is being studied in an ongoing Phase 1 clinical trial both as a monotherapy and in combination with pembrolizumab. The study design allows dose level extensions as well as expansion in tumor-specific cohorts.

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 the potential benefits and therapeutic potential of CLN-619; our clinical development plans and timelines; our plans regarding future data presentations and other statements that are not historical facts. 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.

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References:

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2. Rahib L, Wehner MR, Matrisian LM, Nead KT. Estimated projection of US cancer incidence and death to 2040. *JAMA Netw Open*. 2021;4(4):e214708.
3. Cervical Cancer Statistics | CDC