# 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, 2021

# **CULLINAN ONCOLOGY, INC.**

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation) 001-39856 (Commission File Number) 81-3879991 (I.R.S. Employer Identification No.)

Cullinan Oncology, Inc. One Main Street, Suite 520 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)

Dere-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Dere-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:

	Trade	Name of each exchange
Title of each class	Symbol(s)	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  $\boxtimes$ 

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.  $\Box$ 

# Item 2.02 Results of Operations and Financial Condition

On August 10, 2021, Cullinan Oncology, Inc. announced its financial results for the quarter ended June 30, 2021. 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 (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 or the Exchange Act, except as expressly set forth by specific reference in such filing.

#### Item 9.01. Exhibits

Exhibits

- 99.1 Press release issued by Cullinan Oncology, Inc. on August 10, 2021, 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.

Dated: August 10, 2021

# CULLINAN ONCOLOGY, INC.

By: <u>/s/ Jeffrey Trigilio</u>

Jeffrey Trigilio Chief Financial Officer



#### Cullinan Oncology Provides Corporate Update and Reports Second Quarter 2021 Financial Results

Follow-up Cullinan Pearl data from Phase 1 portion of ongoing trial showed increased disease control rate (DCR) of 92% in the 100mg dose cohort

IND clearance of two immuno-oncology pipeline programs, Cullinan MICA and Cullinan Florentine, with clinical trial starts for each program expected in 2H 2021

Strong balance sheet with cash and investments of \$456.3 million as of June 30, 2021

**Cambridge, MA, August 10, 2021** – Cullinan Oncology, Inc. (Nasdaq: CGEM), an oncology company seeking to drive shareholder returns by focusing on the patient, today announced its financial results for the second quarter ended June 30, 2021 and reported on recent business highlights.

"Solid execution led to the advancement of our clinical pipeline this quarter," stated Owen Hughes, Chief Executive Officer of Cullinan Oncology. "We are pleased with the encouraging results of Cullinan Pearl (EGFR exon 20) showcased at ASCO as well as the recent IND clearance for the first two programs in our immuno-oncology pipeline, Cullinan MICA (MICA/B antibody) and Cullinan Florentine (FLT3 bispecific). With over \$456 million of cash and investments on hand, we remain well capitalized to advance our broad pipeline through multiple clinical readouts. In the near term, we expect to provide updated preclinical data on Cullinan Amber at the Next-Gen Cytokine Therapeutics Summit in September as well as a Cullinan Pearl clinical and regulatory update in the fourth quarter."

#### **Q2 2021 Portfolio Highlights**

- <u>Cullinan Pearl</u>: Presented interim data at ASCO 2021 from ongoing Phase 1/2a trial evaluating CLN-081 in non-small cell lung cancer (NSCLC) patients with epidermal growth factor receptor (EGFR) exon 20 mutations (press release).
  - Safety: CLN-081 continues to demonstrate promising overall safety and tolerability, with an encouraging GI toxicity profile.
  - <u>Efficacy</u>: As of the ASCO data cutoff, there were 5 pending partial responses (PR), 4 of which subsequently confirmed. In addition, follow-up data from patients in the 100mg Phase 1 cohort showed the DCR, defined as best response of PR + stable disease <sup>3</sup>6 months, increased to 92% (12 / 13 patients).
  - <u>Phase 1/2a trial status</u>: Cullinan recently completed enrollment of the Phase 2a 100mg expansion cohort (total n=36) and initiated expansion at 150mg (from 7 patients treated to date to 13 total). Cullinan intends to provide a clinical and regulatory update in Q4 2021.

- <u>Cullinan MICA:</u> Received U.S. Food and Drug Administration (FDA) clearance of Investigational New Drug application (IND) for CLN-619, a novel MICA/B-targeted antibody for the treatment of solid tumors (<u>press release</u>). CLN-619 is a first-in-class monoclonal antibody designed to promote an antitumor response by engaging both natural killer (NK) and T cells through the MICA/B–NKG2D axis, with therapeutic potential for both solid and liquid tumor indications. Cullinan intends to initiate a first-in-human (FIH) trial of CLN-619 in 2H 2021, including a dose escalation cohort followed by dose expansion cohorts as a monotherapy and in combination with checkpoint inhibitor therapy.
- <u>Cullinan Florentine</u>: Received FDA clearance of IND for CLN-049, a FLT3 x CD3 bispecific antibody for the treatment of relapsed/refractory acute myeloid leukemia (AML) (press release). CLN-049 is designed to simultaneously bind to FLT3 on target leukemic cells and to CD3 on T cells, triggering the T cells to kill the targeted cancer cells via their intrinsic cytolytic mechanisms. Studies have shown that FLT3 is expressed on AML blasts in over 75% of AML patients, regardless of FLT3 mutational status. Cullinan intends to initiate a FIH trial of CLN-049 in 2H 2021.
- <u>Cullinan Amber:</u> Continued progress towards final candidate selection for CLN-617, a fusion protein combining two potent antitumor cytokines, IL-2 and IL-12, in a single molecule with a collagen-binding tumor retention domain for the treatment of solid tumors. IND-enabling studies are planned to commence in the 2H 2021.
- <u>Cullinan NexGem</u>: Continued to progress CLN-978, an internally developed half-life extended T cell engager designed to simultaneously engage CD19 and CD3, through IND-enabling development.

#### Q2 2021 Financial Results

- **Cash Position:** Cash, cash equivalents and investments were \$456.3 million as of June 30, 2021, compared to \$473.0 million as of March 31, 2021. Net cash used in operating activities for the second quarter of 2021 was \$16.4 million.
- R&D Expenses: Research and development (R&D) expenses were \$11.8 million for the second quarter of 2021, including \$2.3 million of non-cash equity-based compensation expense, compared to \$12.5 million for the second quarter of 2020. The decrease in R&D expenses is primarily related to a non-recurring non-cash charge related to the MICA acquisition in the second quarter of 2020, partially offset by increased expenses from headcount growth as well as expanded clinical and CMC activity from other portfolio programs.
- **G&A Expenses:** General and administrative (G&A) expenses were \$4.8 million for the second quarter of 2021, including \$1.9 million of non-cash equity-based compensation expense, compared to \$1.6 million for the second quarter of 2020. The increase in G&A expenses is primarily related to headcount growth as well as additional costs associated with operations as a public company.
- **Net loss:** The Company's net loss (before items attributable to noncontrolling interest) was \$16.4 million for the second quarter of 2021, compared to \$13.9 million for the second quarter of 2020, driven predominantly by increases in costs associated with public company operations and non-cash equity-based compensation expenses.

#### **About Cullinan Oncology**

Cullinan Oncology is a biopharmaceutical company that strives to deliver results for our various stakeholders through disciplined capital allocation, decisive action, prudent risk taking and creative business development. We seek to drive shareholder returns by focusing on the patient. The Company's strategy is to build a diversified pipeline of targeted and immuno-oncology therapeutic candidates that are uncorrelated across multiple dimensions, with a focus on assets that it believes have novel technology, employ differentiated mechanisms, are in a more advanced stage of development than competing candidates, or have a combination of these attributes. Learn more about Cullinan at <u>www.cullinanoncology.com</u>.

#### **Forward-Looking Statements**

This press release contains forward-looking statements. 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, clinical trial designs, clinical and therapeutic potential, and strategy of our product candidates, including but not limited to: the timing and success of our planned preclinical and clinical development of our programs, including for CLN-081, CLN-619, and CLN-049, and the timing and success of our planned regulatory submissions; our expectations and beliefs around the safety and activity of CLN-081 in our Phase 1/2a trial in patients with NSCLC harboring EGFRex20ins mutations that have had at least one prior treatment; our ability to evaluate strategic opportunities to accelerate development timelines; the presentation of additional data at upcoming scientific conferences in 2021; 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.

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 therapeutic 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 (SEC), 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. Consolidated Balance Sheets (Unaudited) (in thousands, except shares and per share amounts)

	December 31, 2020	June 30, 2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 168,198	\$ 123,670
Short-term investments	42,008	213,035
Prepaid expenses and other current assets	2,072	7,762
Total current assets	212,278	344,467
Property and equipment, net	130	102
Other assets	2,300	147
Long-term investments		119,637
Total assets	\$ 214,708	\$ 464,353
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 9,679	\$ 1,510
Accrued expenses and other current liabilities	4,641	4,233
Total current liabilities	14,320	5,743
Long-term liabilities:		
Deferred rent	74	70
Total liabilities	14,394	5,813
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Common stock, \$0.0001 par value, 34,900,878 and 150,000,000 shares authorized as of December 31, 2020 and June 30, 2021, respectively; 29,831,125 and 43,526,224 shares issued and outstanding as of December 31, 2020		
and June 30, 2021, respectively.	3	4
Additional paid-in capital	292,348	564,705
Accumulated other comprehensive loss	(2)	(115)
Accumulated deficit	(93,339)	(109,045)
Total Cullinan stockholders' equity	199,010	455,549
Noncontrolling interests	1,304	2,991
Total stockholders' equity	200,314	458,540
Total liabilities and stockholders' equity	\$ 214,708	\$ 464,353

# Cullinan Oncology, Inc. Consolidated Statements of Operations and Comprehensive Loss (Unaudited) (in thousands, except shares and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2021	2020	2021
License revenue	\$ —	\$ —	\$ —	\$ 18,943
Operating expenses:				
Research and development	12,496	11,778	16,669	24,193
General and administrative	1,626	4,826	2,994	9,982
Total operating expenses	14,122	16,604	19,663	34,175
Loss from operations	(14,122)	(16,604)	(19,663)	(15,232)
Other income (expense):				
Interest income	246	173	624	222
Other income (expense), net	1	(8)	1	(10)
Net loss	(13,875)	(16,439)	(19,038)	(15,020)
Net income/(loss) attributable to noncontrolling interest	(5,253)	(803)	(5,443)	686
Net loss attributable to common stockholders of Cullinan	\$ (8,622)	\$ (15,636)	\$ (13,595)	\$ (15,706)
Net loss per share, basic and diluted	\$ (0.44)	\$ (0.36)	\$ (0.71)	\$ (0.37)
Total weighted-average shares used in computing net loss per share, basic	10 610 540	42,205,252	10 115 200	12 512 050
and diluted	19,619,748	43,295,372	19,115,380	42,713,059
Comprehensive loss:				
Net loss	\$ (13,875)	\$ (16,439)	\$ (19,038)	\$ (15,020)
Unrealized gain/(loss) on investments	177	(55)	207	(113)
Comprehensive loss	(13,698)	(16,494)	(18,831)	(15,133)
Comprehensive income/(loss) attributable to noncontrolling interest	(5,253)	(803)	(5,443)	686
Comprehensive loss attributable to Cullinan	\$ (8,445)	\$ (15,691)	\$ (13,388)	\$ (15,819)

## **Contacts:**

Investor Relations <u>investors@cullinanoncology.com</u>

Jeffrey Trigilio +1 617.410.4650 jtrigilio@cullinanoncology.com