

**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): February 13, 2023

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 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 1.01 Entry into a Material Definitive Agreement.

On February 13, 2023, Cullinan Oncology, Inc. (the “Company”) and Harbour BioMed US Inc. (“Harbour”) entered into a License and Collaboration Agreement (the “License Agreement”), pursuant to which Harbour granted to the Company an exclusive license for the development, manufacturing and commercialization of HBM7008 (CLN-418) in the U.S.

Under the terms of the License Agreement, the Company paid Harbour an upfront license fee of \$25 million at signing. Harbour will be eligible to receive up to \$148 million in milestone payments based on the achievement of pre-specified development and regulatory milestones. Harbour is also eligible to receive up to an additional \$415 million in sales-based milestones as well as tiered royalties up to high teens on a licensed product-by-licensed product basis, as a percentage of U.S. commercial sales. In addition, under the License Agreement, Harbour will grant the Company certain intellectual property rights to enable the Company to perform its obligations and exercise its rights under the License Agreement.

Unless earlier terminated, the License Agreement will continue in effect until the expiration of the Company’s royalty obligations. The License Agreement may be terminated by either party for a material breach by the other party, subject to notice and cure provisions, or in the event of the other party’s insolvency. The Company may terminate the License Agreement for convenience by providing 90 days’ written notice to Harbour. In the License Agreement, each party made customary representations and warranties and agreed to customary covenants, including, without limitation, with respect to indemnification, for transactions of this type.

A copy of the License Agreement will be filed as an exhibit to the Company’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2023.

Item 2.02 Results of Operations and Financial Condition.

In connection with entering into the License Agreement, the Company is updating its cash runway guidance. The Company ended 2022 with an unaudited cash and investments balance of \$550 million, which included the impact of a \$33 million investment to increase the Company’s ownership in its subsidiary, Cullinan Mica Corp., from 54% to 95%. After deducting the upfront license fee to Harbour, the Company’s cash and investment balance as of December 31, 2022 would have been \$525 million. Based on the Company’s current operating plan, the Company expects its current cash resources to last into 2026. The cash and investments balance represents cash, cash equivalents, investments, and interest receivable.

The information contained in this Item 2.02 is unaudited and preliminary and does not present all information necessary for an understanding of the Company’s financial condition as of December 31, 2022 and its results of operations for the year ended December 31, 2022. The information in this Item 2.02 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 (the “Securities Act”) or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 7.01 Regulation FD Disclosure.

On February 13, 2023, the Company issued a press release announcing it entered into the License Agreement, a copy of which is being furnished as Exhibit 99.1 to this Current Report on Form 8-K. The information in this Item 7.01 and Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed “filed” for purposes of Section 18 of 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 or the Exchange Act, except as expressly set forth by specific reference in such filing.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements, including express or implied statements regarding the Company’s beliefs and expectations regarding the Company’s cash runway. Any forward-looking statements in this Current Report on Form 8-K 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 the Company’s 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 risks and uncertainties discussed in the Company’s filings with the Securities and Exchange Commission (“SEC”), including under the caption “Risk Factors” in the Company’s most recent Annual Report on Form 10-K and subsequent filings with the SEC. While the Company may elect to update such forward-looking statements in the future, it disclaims any obligation to do so, even if subsequent events cause its views to change, except to the extent required by law. These forward-looking statements should not be relied upon as representing the Company’s views as of any date subsequent to the date of this Current Report on Form 8-K. Moreover, except as required by law, neither the Company nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements included in this Current Report on Form 8-K. Any forward-looking statement included in this Current Report on Form 8-K speaks only as of the date on which it was made.

Item 9.01 Financial Statements and Exhibits.**(d) Exhibits**

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by Cullinan Oncology, Inc. on February 13, 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: February 13, 2023

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



**Cullinan Oncology Licenses U.S. Rights to the First Clinical-Stage B7H4 x 4-1BB
Bispecific Immune Activator from Harbour BioMed**

CAMBRIDGE, Mass., February 13, 2023 (GLOBE NEWSWIRE) — Cullinan Oncology, Inc. (Nasdaq: CGEM) and Harbour BioMed (HKEX: 02142) today announced that Cullinan Oncology has entered into an exclusive license with Harbour BioMed for the development and commercial rights of HBM7008 (CLN-418) in the U.S. CLN-418/HBM7008 is a B7H4 x 4-1BB bispecific immune activator developed from next-gen heavy chain only antibody (HCAb)-based multi-specific antibody discovery platform HBICE[®], currently in a Phase 1 clinical study being conducted at U.S. and Australian sites in patients with advanced solid tumors.

“We are pleased to bring CLN-418, a potential first-in-class, clinical-stage bispecific immune activator, into our diversified portfolio. We believe the best approach to conditional activation of 4-1BB is by targeting B7H4, a tumor associated antigen that is highly expressed across multiple cancers and minimally overlaps with PD-L1 expression. CLN-418 is a strong strategic fit for Cullinan, building on our expertise with bispecifics, and placing us at the forefront of bispecific antibody development in solid tumors. Importantly, this transaction adds another clinical-stage asset to our portfolio, and with it, we are on track to have potentially six clinical stage assets in our pipeline by the end of 2023,” said Nadim Ahmed, Chief Executive Officer of Cullinan Oncology. “This transaction is consistent with our goal to strategically deploy capital to expand and advance our pipeline, and the financial terms of the agreement allow us to maintain a multi-year cash runway to fund our ongoing development efforts and deliver data from multiple clinical programs. Harbour BioMed is a global clinical-stage biotech company with experienced therapeutic innovation capabilities and a network of partnerships, and we look forward to realizing the full potential of this exciting program.”

Under the agreement, Cullinan Oncology will pay Harbour BioMed an upfront license fee of \$25 million at closing for the exclusive right to develop and commercialize CLN-418/HBM7008 in the U.S. Harbour BioMed will be eligible to receive up to \$148M in development and regulatory milestones plus up to an additional \$415M in sales-based milestones as well as tiered royalties up to high teens on potential U.S. commercial sales.

“This agreement is another validation from a leading global biotech company on our technology platforms and innovation capabilities. We believe that Cullinan Oncology is the ideal partner to continue the development of CLN-418/HBM7008, which we believe has first-in-class potential to treat a wide range of solid-tumor cancers. They have a seasoned clinical development team, strong capabilities in oncology drug development, and the robust infrastructure necessary to move it forward,” said Dr. Jingsong Wang, Founder, Chairman and CEO of Harbour BioMed. “We look forward to working with Nadim and his team to advance this program forward.”

Cullinan Oncology Conference Call Information

Cullinan Oncology will host a conference call on Tuesday, February 14 at 8 a.m. ET. Investors and the general public are invited to listen to a live webcast of the call. A link to join the call and to find related materials will be available at: investors.cullinanoncology.com/events

About CLN-418/HBM7008

CLN-418/HBM7008 is the only B7H4 x 4-1BB bispecific immune activator in clinical studies. Both B7H4 and 4-1BB have been targets of high interest and both have been evaluated clinically. Their distinct biology and mechanisms of action provide strong rationale to combine them as a bispecific antibody.

B7H4 is an attractive tumor associated antigen (TAA) highly expressed on multiple tumor types, including triple negative breast cancer, ovarian cancer, and lung cancer, while expression on normal tissue is low. A coinhibitory immune checkpoint with PD-L1 in the B7 family, B7H4 has minimal overlap with PD-L1 expression. Targeting B7H4 has the potential to address tumor types for which PD-L1-based immunotherapies have exhibited limited efficacy.

4-1BB is a key costimulatory molecule for both T- and NK-cell engagement and is being studied in multiple clinical programs. However, safety concerns such as hepatic toxicity remain despite the biological validation of the 4-1BB pathway. Conditional activation of 4-1BB in the tumor microenvironment that is dependent on B7H4 expression presents a novel approach to harness the potential of both targets. CLN-418/HBM7008, with strict TAA crosslinking dependent T-cell activation, can potentially translate to better safety and a more favorable therapeutic window.

The ongoing Phase 1 trial ([NCT05306444](#)) is an open-label, multicenter study being conducted at U.S. and Australian sites evaluating the safety, tolerability, pharmacokinetics and anti-tumor activity of CLN-418/HBM7008 administered intravenously in patients with advanced solid tumors. The study, which is expected to enroll up to 108 subjects, aims to identify a maximum tolerated dose and a recommended Phase 2 dose of CLN-418/HBM7008. Initial clinical data from this study could be available in 2024.

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](#).

About Harbour BioMed

Harbour BioMed (HKEX: 02142) is a global biopharmaceutical company committed to the discovery, development and commercialization of novel antibody therapeutics focusing on oncology and immunology. Harbour BioMed is building its robust portfolio and differentiated pipeline through internal R&D capability, collaborations with co-discovery and co-development partners and select acquisitions. Harbour BioMed's proprietary antibody technology platforms Harbour Mice[®] generate fully human monoclonal antibodies in two heavy and two light chain (H2L2) format, as well as heavy chain only (HCAb) format. Building upon the HCAb antibodies, the HCAb-based immune cell engagers (HBICE[®]) are capable of delivering tumor killing effects unachievable by traditional combination therapies. Integrating Harbour Mice[®], HBICE[®] with single B cell cloning platform, its antibody discovery engine is highly unique and efficient for development of next generation therapeutic antibodies. For more information, please visit www.harbourbiomed.com, and follow us on [LinkedIn](#).

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 of, and plans relating to, the license agreement between Cullinan and Harbour BioMed, including anticipated milestone payments under the license agreement; the therapeutic potential of CLN-418; our expectations regarding our use of capital; 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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