
**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 22, 2021

CULLINAN MANAGEMENT, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-39856
(Commission
File Number)

81-387991
(I.R.S. Employer
Identification No.)

Cullinan Management, 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:

- 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 | Trade 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 February 22, 2021, Cullinan Management, Inc. issued a press release, a copy of which is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, 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 a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|--|
| 99.1 | <u>Press Release issued by Cullinan Management, Inc., dated February 22, 2021, furnished herewith.</u> |

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.

Date: February 22, 2021

Cullinan Management, Inc.

By: /s/Owen Hughes

Owen Hughes

President and Chief Executive Officer



Cullinan Management, Inc. Announces Business Update

February 22, 2021

- Enrollment expansion in CLN-081 NSCLC EGFRex20ins Phase 1/2a trial
- Cullinan withdraws IND application for CLN-049 in Relapsed/Refractory AML
- CLN-619 IND submission planned for the second quarter of 2021
- Cullinan to present at SVB Leerink Conference February 26, 2021

Cambridge, MA, February 22, 2021 – Cullinan Management, Inc. (Nasdaq: CGEM) (“Cullinan”), a biopharmaceutical company focused on developing a diversified pipeline of targeted oncology and immuno-oncology therapies, today announces the following business updates:

Portfolio Overview and Updates:

- **Cullinan Pearl**
Based on pre-specified efficacy criteria, Cullinan recently initiated Phase 2a Dose Expansion at the 100 mg BID dosing level in the ongoing Phase 1/2a study evaluating CLN-081 in adult NSCLC patients with EGFRex20ins mutations. This expansion will enable enrollment of up to 36 patients, inclusive of 13 previously enrolled patients, at this dosing level. Cullinan is contemplating additional expansion cohorts and intends to provide updated safety and efficacy data in mid-2021.
- **Cullinan Florentine**
In January 2021, Cullinan submitted an IND to the U.S. Food and Drug Administration (FDA) for a Phase 1/2a clinical trial evaluating CLN-049, a bispecific antibody targeting FLT3 and CD3, in relapsed or refractory AML patients. The FDA subsequently provided feedback, including a request to consider alternative trial designs that would enable the collection of exploratory pharmacokinetic and pharmacodynamic data before dose escalation. Based on this information, Cullinan elected to withdraw the IND to determine the most efficient path forward.
- **Cullinan MICA**
Cullinan is completing the production of GMP drug product to support an IND submission and subsequent clinical trial for its investigational product CLN-619, a monoclonal antibody designed to stimulate natural killer (NK) and T cell responses by engaging a unique target, MICA/B. Consistent with prior guidance, Cullinan intends to submit an IND in the second quarter of 2021.

SVB Leerink Global Healthcare Conference Event Details:

Chief Executive Officer, Owen Hughes, will provide a company overview and update at the 10th Annual SVB Leerink Global Healthcare Conference.

- Event: **10th Annual SVB Leerink Global Healthcare Conference**
- Location: **Virtual**
- Date: **Friday, February 26, 2021**
- Time: **4:20 PM ET/1:20PM PT**

Members of the Cullinan management team will also host investor meetings during the SVB Leerink Global Healthcare Conference.

A webcast of the SVB Leerink presentation will be available in the Investors section of the Cullinan website at

<https://www.cullinanoncology.com/>.

About CLN-081

CLN-081 is an orally available, irreversible EGFR inhibitor that is designed to selectively target cells expressing mutant EGFR variants, including EGFR exon 20 insertion mutations, with relative sparing of cells expressing wild type EGFR. CLN-081 is currently in a Phase 1/2a dose escalation and expansion trial evaluating oral, twice-daily administration of various doses in patients with NSCLC harboring EGFRex20ins mutations who have had at least one prior treatment with platinum-based chemotherapy or another approved standard therapy. CLN-081 is being developed in Cullinan Pearl, a Cullinan subsidiary.

About CLN-049

CLN-049 is a humanized bispecific antibody targeting FLT3 on target leukemic cells and CD3 on T cells, triggering cancer cell lysis via T cell cytolytic mechanisms. FLT3 is expressed frequently on AML cells and leukemic blasts but minimally on healthy blood cells, unlike other tumor surface antigens such as CD33 and CD123. CLN-049 is being developed in Cullinan Florentine, a Cullinan subsidiary.

About CLN-619

CLN-619 is MICA/B-targeted, humanized IgG1 monoclonal antibody that Cullinan intends to develop in patients with advanced solid tumors. MICA/B are stress-induced ligands that innate and adaptive immune cell populations recognize via the NKG2D receptor. To evade potential cytotoxic destruction by NK cells and T cells, tumors shed MICA/B from the cell surface. CLN-619 is designed to promote an antitumor response through multiple mechanisms of action, including shielding the proteolytic cleavage sites of MICA/B on cancer cells. CLN-619 is being developed in Cullinan MICA, a Cullinan subsidiary.

About Cullinan Management

Cullinan Management is a biopharmaceutical company focused on developing a diversified pipeline of targeted oncology and immuno-oncology therapies. The Company's strategy is to build a pipeline of 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.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact, including those related to our development plans for our therapeutic candidates, including the timing thereof, should be considered forward-looking statements. These forward-looking statements are based on management's current expectations. These statements involve 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 results of regulatory submissions, including our ability to agree with the FDA on an acceptable trial design for CLN-049; success of our clinical trials and preclinical studies; risks related to manufacturing, supply and distribution of our therapeutic candidates; 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, or SEC, including under the caption "Risk Factors" in our Prospectus dated January 7, 2021 filed with the SEC on January 11, 2021 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. 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.

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