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): September 17, 2024

CULLINAN THERAPEUTICS, 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 7.01 Regulation FD Disclosure.

On September 17, 2024, Cullinan Therapeutics, Inc. (the "Company") issued a press release related to the announcement that the Company received Human Research Ethics Committee ("HREC") approval in Australia to initiate its global Phase 1 clinical trial to evaluate its CD19xCD3 bispecific T cell engager, CLN-978, for the treatment of systemic lupus erythematosus ("SLE"). 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.

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 September 17, 2024, the Company announced it received HREC approval in Australia to initiate its global Phase 1 clinical trial to evaluate CLN-978, the Company's CD19xCD3 bispecific T cell engager, for the treatment of SLE. CLN-978 is a novel CD19 bispecific T cell engager designed to deliver T cell directed potency with off-the-shelf access and convenient dosing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	**Description**
99.1	Press release issued by Cullinan Therapeutics, Inc. on September 17, 2024, 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 THERAPEUTICS, INC.

Date: September 17, 2024

By: /s/ Mary Kay Fenton
Mary Kay Fenton
Chief Financial Officer

Exhibit 99.1

Cullinan Therapeutics Receives Approval to Initiate its Global Phase 1 Clinical Trial of CLN-978 for the Treatment of Systemic Lupus Erythematosus

Phase 1 clinical trial is designed to assess the safety, pharmacokinetics and initial clinical activity of CLN-978 for patients with systemic lupus erythematosus

The trial will be conducted in multiple sites in Australia as well as other countries around the world

CAMBRIDGE, Mass., September 17, 2024 (GLOBE NEWSWIRE) -- Cullinan Therapeutics, Inc. (Nasdaq: CGEM), a biopharmaceutical company focused on developing modality-agnostic targeted therapies, today received Human Research Ethics Committee (HREC) approval in Australia to initiate its global Phase 1 clinical trial to evaluate CLN-978, its CD19xCD3 bispecific T cell engager, for the treatment of systemic lupus erythematosus (SLE).

SLE affects approximately 430,000 individuals globally.[1] Currently available treatments do not routinely induce treatment-free remission, with most patients requiring lifelong immune suppression to treat symptoms without modifying the course of disease. CLN-978 is a novel CD19 bispecific T cell engager designed to deliver T cell-directed potency with off-the-shelf access and convenient dosing.

“We are pleased to receive this first approval to initiate our global study of CLN-978 in SLE in Australia,” said Jeffrey Jones, MD, MBA, Chief Medical Officer, Cullinan Therapeutics. “We have been focused on rapidly executing our global clinical development strategy for autoimmune diseases, and today’s approval is an important step to treat patients around the world living with SLE. Our investigational candidate, CLN-978, combines the optimal target (CD19) and modality (T cell engager) for a highly differentiated, potentially best-in-class program. We look forward to working with all our sites, investigators, and patients as we continue to expeditiously progress development of CLN-978 in Australia and beyond.”

On September 16, Cullinan Therapeutics announced the submission of an Investigational New Drug Application to the U.S. Food and Drug Administration for this study.

About CLN-978
CLN-978 is a novel, highly potent, half-life extended CD19xCD3 bispecific T cell engager construct. CLN-978 potently triggers redirected lysis of CD19-expressing target cells *in vitro* and *in vivo*. CLN-978 is engineered to achieve very high affinity binding to CD19 to efficiently target B cells expressing very low CD19 levels. A human serum albumin (HSA)-binding domain

increases the serum half-life of CLN-978 and, with subcutaneous delivery, permits more patient-friendly dosing and potentially reduced toxicity. CLN-978 contains two single-chain variable fragments, one binding with very high affinity to the CD19 target and the other binding to CD3 on T cells, and a single-domain antibody binding to HSA. CLN-978 was developed by an internal Cullinan team and is a wholly owned asset. CLN-978 has the potential to offer a convenient, off-the-shelf therapeutic option for patients with autoimmune diseases such as SLE and rheumatoid arthritis.

About Systemic Lupus Erythematosus (SLE)
SLE is a chronic, heterogeneous autoimmune disease in which the immune system attacks a patient's own tissues. The most common manifestations of SLE include skin rashes, arthritis, swelling in the feet, and around the eyes, extreme fatigue, and low fevers. Lupus nephritis (LN) is a kidney disease and the most common severe manifestation of SLE. Approximately 40% of patients with SLE develop LN, which has a 10-year 30% mortality rate. SLE is more prevalent in women, people of color, and women of childbearing age. SLE affects approximately 430,000 individuals globally.[1] Currently available treatments do not routinely induce treatment-free remission, and most patients require lifelong immune suppression that treats symptoms without modifying the course of disease.

About Cullinan Therapeutics
Cullinan Therapeutics, Inc. (Nasdaq: CGEM) is a biopharmaceutical company dedicated to creating new standards of care for patients. Cullinan has strategically built a diversified portfolio of clinical-stage assets that inhibit key drivers of disease or harness the immune system to eliminate diseased cells in both autoimmune diseases and cancer. Cullinan's portfolio encompasses a wide range of modalities, each with the potential to be best and/or first in class. Anchored in a deep understanding of oncology, immunology, and translational medicine, we create differentiated ideas, identify the most appropriate targets, and select the optimal modality to develop transformative therapeutics across a wide variety of autoimmune and cancer indications. We push conventional boundaries from candidate selection to differentiated therapeutic, applying rigorous go/no go criteria at each stage of development to fast-track only the most promising molecules to the clinic and, ultimately, commercialization. With deep scientific expertise, our teams exercise creativity and urgency to deliver on our promise to bring new therapeutic solutions to patients. Learn more about Cullinan at https://cullinantherapeutics.com/, and follow us on LinkedIn and X.

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 the company's beliefs and expectations regarding: our preclinical and clinical developments plans and timelines, the clinical and

therapeutic potential of our product candidates, the strategy of our product candidates, and our research and development activities. The words “believe,” “continue,” “could,” “estimate,” “expect,” “intends,” “may,” “plan,” “potential,” “project,” “pursue,” “will,” 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, including the IND that we filed for CLN-978; the risk that any INDs or other global regulatory submissions we may file with the United States Food and Drug Administration or other global regulatory agencies are not cleared on our expected timelines, or at all; the success of our clinical trials and preclinical studies; the risks related to our ability to protect and maintain our intellectual property position; the 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 the 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 the company 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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[1] GlobalData estimates. Includes U.S., EU5 (United Kingdom, Germany, France, Spain, Italy), Japan, Australia.