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): November 08, 2026

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 November 8, 2026, Cullinan Therapeutics, Inc. (the "Company") issued a press release announcing clinical data from the ongoing Phase 1b/2a clinical trial in velinotamig in patients with active, refractory, moderate-to-severe systemic lupus erythematosus ("SLE") being conducted by Chongqing Genrix Biopharmaceutical Co., Ltd. ("Genrix") in China. The Company holds a global (ex-Greater China), all-indication, exclusive license to develop velinotamig from Genrix. 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 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 filing.

Item 8.01 Other Events.

On November 8, 2026, clinical data was presented from the ongoing Phase 1b/2a clinical trial in velinotamig in patients with active, refractory, moderate-to-severe SLE being conducted by Genrix in China at the American College of Rheumatology Convergence 2026.

As of the September 8, 2026 data cutoff, 12 patients had been treated across three multi-dose cohorts. Velinotamig demonstrated a favorable safety profile, with no dose-limiting toxicities, no immune effector cell-associated neurotoxicity ("ICANS"), and no Grade 3 or higher cytokine release syndrome ("CRS"). CRS occurred in two patients and was limited to Grade 1 or Grade 2 events that resolved with standard management. No Grade 2 events were observed after modifications to the step-up dosing regimen.

Among the first nine patients with at least four weeks of follow-up, clinical activity was observed across measures of disease activity, serologic markers, and renal function. Eight of nine evaluable patients achieved a clinically meaningful reduction of at least four points in SLEDAI-2K. Among seven evaluable patients with urine protein excretion greater than 500 mg/24 hours at baseline, five experienced rapid and marked reductions in proteinuria, and four of these patients achieved a complete renal response as demonstrated by proteinuria levels below 500 mg/24 hours, within 24 weeks. Reductions in anti-double-stranded DNA antibodies and blood IgG, improvement in complement C3, and depletion of CD19-positive B cells were also observed.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Any statements in this Current Report on Form 8-K that are not historical facts may be considered "forward-looking statements," including statements regarding the safety data and observed efficacy from the ongoing Phase 1b/2a clinical trial in velinotamig in patients with active, refractory, moderate-to-severe SLE being conducted by Genrix in China and the clinical and therapeutic potential of velinotamig. The clinical trial referenced in this Current Report on Form 8-K is ongoing, and the data described are interim, subject to change, and based on data available as of a specified date. As patient enrollment continues and additional follow-up data is obtained, the reported safety profile and other clinical outcomes may change materially. There can be no assurance that the interim results will be predictive of final clinical trial results or that additional data will confirm or support these observations. Forward-looking statements are typically, but not always, identified by the use of words such as "estimate," "expect," and other similar terminology. 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 future results, performance or achievements expressed or implied by the forward-looking statements. Such risks and uncertainties include, but are not limited to, uncertainty regarding the timing and results of clinical trial data and regulatory submissions, the risk that any INDs, NDAs or other global regulatory submissions the Company may file with the United States Food and Drug Administration or other global regulatory agencies are not cleared or approved on the Company's expected timelines, or at all, the success of the Company's clinical trials and preclinical studies, the risks related to the Company's ability to protect and maintain the Company's intellectual property position, the risks related to manufacturing, supply, and distribution of the Company's product candidates, the risk that any one or more of the Company's 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 trials will not be predictive of future results in connection with future studies or clinical trials, the effect of changes in global economic conditions, including uncertainties related to international trade policies, tariffs and supply chain dynamics on the Company's business and operations, and the success of any collaboration, partnership, license or similar agreements, along with the risks detailed in the Company's recent filings on Forms 10-K and 10-Q with the Securities and Exchange Commission. While the Company may elect to update such forward-looking statements at some point in the future, the Company 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. 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.

Exhibit No.	Description
99.1	Press release issued by Cullinan Therapeutics, Inc. on November 8, 2026, 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: November 9, 2026

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

Exhibit 99.1

Velinotamig, a BCMAxCD3 T Cell Engager, Achieves Complete Renal Responses and Significantly Reduces Disease Activity in Systemic Lupus Erythematosus in Data Presented at ACR Convergence 2026

Clinically meaningful improvement in disease activity among 8 of 9 evaluable patients, including rapid and marked reductions in proteinuria with complete renal responses

Deep and sustained reduction in pathogenic autoantibodies and IgG reduction underscore potential in plasma-cell driven diseases

Favorable safety profile in patients with refractory SLE

CAMBRIDGE, Mass., Nov. 8, 2026 (GLOBE NEWSWIRE) -- **Cullinan Therapeutics, Inc.** (Nasdaq: CGEM), a clinical-stage biopharmaceutical company accelerating potential first- or best-in-class, disease-modifying T cell engagers in autoimmune diseases and cancer, today announced clinical data from the ongoing Genrix Bio Phase 1b/2a study of velinotamig (GR1803) in patients with active, refractory, moderate-to-severe systemic lupus erythematosus (SLE). The results will be presented at the American College of Rheumatology (ACR) Convergence 2026 on November 8 in Poster #0272, “Initial Results of Velinotamig (GR1803, BCMAxCD3 TCE) Therapy in Patients with Refractory Systemic Lupus Erythematosus: a Phase 1b/2a Study.”

As of the September 8, 2026 data cutoff, 12 patients had been treated across three multi-dose cohorts. Velinotamig demonstrated a favorable safety profile, with no dose-limiting toxicities, no immune effector cell-associated neurotoxicity (ICANS), and no Grade 3 or higher cytokine release syndrome (CRS). CRS occurred in two patients and was limited to Grade 1 or 2 events that resolved with standard management. No Grade 2 events were observed after modifications to the step-up dosing regimen.

Among the first nine patients with at least four weeks of follow-up, clinical activity was observed across measures of disease activity, serologic markers, and renal function. Eight of nine evaluable patients achieved a clinically meaningful reduction of at least four points in SLEDAI-2K. Among seven evaluable patients with urine protein excretion greater than 500 mg/24 hours at baseline, five experienced rapid and marked reductions in proteinuria, and four of these patients achieved a complete renal response as demonstrated by proteinuria levels below 500 mg/24 hours, within 24 weeks. Reductions in anti-double-stranded DNA antibodies and blood IgG, improvement in complement C3, and depletion of CD19-positive B cells were also observed.

“These compelling early findings demonstrate consistent and meaningful clinical, serological, and pharmacodynamic evidence in most treated patients, further validating the therapeutic potential of velinotamig as a short-duration BCMA-directed therapy,” said Jeffrey Jones, MD, MBA, Chief Medical Officer of Cullinan Therapeutics. “Combined with the favorable safety profile observed to date, these data reinforce our confidence in the global development plan for velinotamig, including our initial focus on autoimmune cytopenias, where pathogenic autoantibody-producing plasma cells play a central role in disease pathogenesis. Our unique and complementary clinical stage BCMA- and CD19-directed T cell engager portfolio positions us to address the diverse biology of autoimmune diseases, with the goal of bringing differentiated and tailored treatment options to more patients across a broad range of conditions.”

About the Genrix Bio Phase 1b/2a Velinotamig Study

The open-label, multicenter, dose-escalation Phase 1b/2a study (NCT07348055) is evaluating the safety, pharmacokinetics, pharmacodynamics, and preliminary efficacy of velinotamig in patients with active, refractory, moderate-to-severe SLE despite at least three months of standard-of-care therapy. Patients receive four intravenous doses on Days 1, 4, 8, and 29, with follow-up for up to 48 weeks. Key assessments include adverse events, CRS, ICANS, DLTs, SLEDAI-2K, 24-hour proteinuria, estimated glomerular filtration rate, anti-double-stranded DNA antibodies, complement C3/C4, and B cell depletion.

About Velinotamig (CLN-803, GR1803)

Velinotamig is a BCMAxCD3 T cell engager designed to redirect cytotoxic T cells to target BCMA-expressing cells, including pathogenic, autoantibody-producing plasma cells. Velinotamig is engineered with high-affinity binding to BCMA and lower-affinity binding to CD3, with the goal of enhancing target-cell depletion while minimizing nonspecific T cell activation and associated cytokine-related toxicity. By targeting BCMA-expressing cells, velinotamig has the potential to address autoimmune diseases driven by pathogenic autoantibodies.

Cullinan holds a global (ex-Greater China), all-indication, exclusive license to velinotamig from Genrix Bio. Genrix Bio is evaluating velinotamig in a Phase 1b/2a clinical trial in patients with refractory SLE in China (NCT07348055). Cullinan Therapeutics is also evaluating subcutaneously administered velinotamig in a global Phase 1b/2a study in patients with relapsing and refractory immune thrombocytopenia and warm autoimmune hemolytic anemia (NCT07738822).

About Systemic Lupus Erythematosus (SLE)

Systemic lupus erythematosus (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, 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.[1,2] The prevalence of SLE in the US is estimated at 160,000 to 320,000 cases and SLE affects approximately 3.4 million individuals globally.[3,4] SLE is more prevalent in women and people of color.[5] It occurs most often in people between the ages of 15 and 45 years but can occur in childhood or later in life as well.[6] Currently available treatments can reduce the signs and symptoms of SLE; however, they do not routinely induce treatment-free remission, and most patients require lifelong immune suppression that treats symptoms without modifying the course of disease.[7-9]

About Cullinan Therapeutics

Cullinan Therapeutics, Inc. (Nasdaq: CGEM) is a biopharmaceutical company developing potential first- or best-in-class, disease-modifying T cell engagers for autoimmune diseases and cancer. Cullinan pursues promising therapeutic targets while leveraging core expertise in T cell engagers, which are established in oncology and are now advancing into autoimmune diseases. With a clinical-stage pipeline built on a rigorous scientific approach and purposeful innovation, Cullinan is advancing its mission to deliver new standards of care for patients. Learn more about Cullinan at https://cullinantherapeutics.com/, and follow Cullinan 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 clinical development plan and timeline for velinotamig, the clinical and therapeutic potential of velinotamig, our plans regarding future data presentations, our beliefs regarding the broader potential of our BCMA- and CD 19-directed T cell engager portfolio in the treatment of autoimmune diseases, and other statements that are not historical facts. The clinical trial referenced in this press release is ongoing, and the data described are interim, subject to change, and based on data available as of a specified date. As patient enrollment continues and additional follow-up data is obtained, the reported safety profile and other clinical outcomes may change materially. There can be no assurance that the interim results will be predictive of final clinical trial results or that additional data will confirm or support these observations. 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; the risk that any INDs, NDAs or other global regulatory submissions we may file with the FDA or other global regulatory agencies are not cleared or approved 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; the effect of changes in global economic conditions, including uncertainties related to international trade policies, tariffs and supply chain dynamics on our business and operations; 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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