Cullinan Therapeutics Provides Corporate Update and Highlights Anticipated 2026 Milestones

January 8, 2026

Data readouts planned for CLN-978 across all three autoimmune indications in 2026, including single dose and repeat dosing data

Company to complete monotherapy expansion cohorts to determine recommended Phase 2 dose for CLN-049 pivotal registrational study and initiate combination study in frontline AML in Q4 2026

Zipalertinib rolling NDA submission expected to be complete in Q1 2026 and full enrollment of REZILIENT3 frontline study expected in H1 2026

Preliminary cash and investments of $439.0 million as of December 31, 2025; Runway into 2029

CAMBRIDGE, Mass., Jan. 08, 2026 (GLOBE NEWSWIRE) -- Cullinan Therapeutics, Inc. (Nasdaq: CGEM; "Cullinan"), a clinical-stage biopharmaceutical company accelerating potential first- or best-in-class, high-impact therapies in autoimmune diseases and cancer, today provided a corporate update and shared anticipated business highlights for 2026.

"We have built strong momentum with CLN-978 and are pleased to share that we have completed multiple dose cohorts in our OUTRACE RA and OUTRACE SLE studies, and we have initiated dosing in our Sjögren's disease study. This significant progress positions us to deliver the first company sponsored data with a CD19 T cell engager in autoimmune diseases. Throughout 2026, we will deliver data across all three indications, including important repeat dosing data in rheumatoid arthritis," said Nadim Ahmed, President and CEO of Cullinan Therapeutics.

"Our CLN-049 program continues to advance following the presentation of compelling efficacy and favorable safety data at ASH 2025, which we believe enables an accelerated approval pathway. We plan to complete dose expansion in relapsed/refractory AML and *TP53*m AML to rapidly determine a recommended Phase 2 dose, while also initiating a frontline combination study this year. Additionally, 2026 marks a pivotal milestone for zipalertinib, as Taiho completes the rolling NDA submission in the beginning of the year, and completes enrollment in the frontline study REZILIENT3 in the first half of 2026. In summary, we are focused on generating multiple catalysts for our two high-priority T cell engager programs, CLN-978 and CLN-049, positioning us for a transformative year ahead."

Portfolio Highlights and Anticipated 2026 Milestones

Immunology

- **CLN-978 (CD19xCD3 bispecific T cell engager):** Rheumatoid arthritis (RA), systemic lupus erythematosus (SLE), and Sjögren's disease (SjD)

- *OUTRACE RA*
    - Dose escalation is ongoing, and patients are currently being enrolled to the 30-microgram dose cohort. The 10- and 20-microgram dose cohorts are complete with no dose-limiting toxicities observed.
    - In Q2 2026, the Company plans to share initial data from the single target dose escalation portion of the study with a focus on safety and B cell depletion in peripheral blood and tissue, additional biomarker data, and preliminary clinical activity data.
    - In Q3 2026, the Company plans to share initial repeat dosing data, including B cell depletion in peripheral blood and tissue, additional biomarker data, and preliminary clinical activity data.
- *OUTRACE SLE*
    - Dose escalation is ongoing, and patients are currently being enrolled in the 30-microgram dose cohort. The 10- and 20-microgram dose cohorts are complete with no dose-limiting toxicities observed.
    - In Q2 2026, the Company plans to share initial data from Part A (single target dose escalation) with a focus on

safety and B cell depletion in peripheral blood, additional biomarker data, and preliminary clinical activity data.

- *OUTRACE SjD*
    - The Company has initiated patient dosing, and enrollment is ongoing in the 10-microgram dose cohort.
    - In Q4 2026, the Company plans to share initial data from Part A (single target dose escalation) with a focus on safety and B cell depletion in peripheral blood and tissue, additional biomarker data, and preliminary clinical activity data.

- **Velinotamig (BCMAxCD3 bispecific T cell engager):** Autoimmune diseases
    - In December 2025, Genrix Bio initiated a Phase 1 study in China in patients with autoimmune diseases, and initial clinical data from the study will be shared in Q4 2026. Cullinan intends to use the data generated to accelerate global clinical development of the program. Following the completion of the Genrix Bio Phase 1 study, Cullinan will conduct all further development of velinotamig in autoimmune diseases.

Oncology

- **CLN-049 (FLT3xCD3 bispecific T cell engager):** Acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS)
    - In December 2025, CLN-049 received Fast Track designation for the treatment of relapsed/refractory AML from the U.S. FDA and, in an oral presentation at the 2025 ASH Annual Meeting, the Company shared compelling clinical data in a heavily pretreated all-comer population of patients with relapsed/refractory AML. The Company plans to share an update from the dose escalation portion of the study in H2 2026.
    - In Q2 2026, the Company expects to initiate monotherapy dose expansion cohorts in patients with relapsed/refractory AML and *TP53*m AML. In Q4 2026, the Company expects to complete enrollment for dose expansion to determine the recommended Phase 2 dose (RP2D) for an expected single arm pivotal registrational trial.
    - In Q4 2026, the Company plans to initiate a Phase 1/2 combination study in frontline AML.
    - Enrollment also continues in a parallel Phase 1 study in patients with AML and measurable residual disease (MRD) immediately following induction therapy.

- **Zipalertinib (EGFR ex20ins inhibitor), collaboration with Taiho Oncology:** EGFR ex20ins NSCLC
    - In November 2025, Taiho initiated a rolling submission of an NDA seeking accelerated approval of zipalertinib for the treatment of patients with relapsed EGFR ex20ins NSCLC. Taiho expects completion of the NDA submission in Q1 2026.
    - Taiho expects to complete enrollment of the pivotal study REZILIENT3 in 1L EGFR ex20ins NSCLC in H1 2026.
    - Cullinan is eligible to receive up to $130 million in payments for U.S. regulatory milestones and a 50/50 profit share in the U.S.

Cash Position and Cash Runway
Unaudited preliminary cash, cash equivalents, short- and long-term investments, and interest receivable were $439.0 million as of December 31, 2025. Consistent with prior guidance, Cullinan expects its cash resources to provide runway into 2029 under its current operating plan.

The Company expects to report its fourth quarter and full-year 2025 financial results in late February 2026 which will contain additional information required for a more complete understanding of the Company's financial position and results of operations as of and for the year ended December 31, 2025.

About Cullinan Therapeutics
Cullinan Therapeutics, Inc. (Nasdaq: CGEM) is a biopharmaceutical company developing potential first- or best-in-class,

high-impact therapies 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 preclinical and clinical developments plans and timelines for our product candidates, the clinical and therapeutic potential of our product candidates, the strategy of our product candidates, our research and development activities, our preliminary estimates of cash, cash equivalents, short- and long-term investments, and interest receivable as of December 31, 2025, our cash runway, and other statements that are not historical facts. 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: the preliminary cash position reported herein reflects information available to us only at this time and may differ from our actual cash position as of December 31, 2025, including in connection with the completion of our financial statement closing procedures; 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 United States Food and Drug Administration 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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