Cullinan Therapeutics Provides Corporate Update and Reports Fourth Quarter and Full Year 2025 Financial Results

March 10, 2026

Initial clinical data for CLN-978 in SLE and RA confirmed for Q2 2026; repeat dosing data in RA confirmed for Q3 2026

Zipalertinib rolling NDA submission completed; enrollment of REZILIENT3 frontline study completed with top-line results available by year-end 2026

Cash and investments of $439.0 million as of December 31, 2025; runway into 2029

CAMBRIDGE, Mass., March 10, 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 an update on recent and anticipated business highlights and announced its financial results for the fourth quarter and full year ended December 31, 2025.

"Cullinan Therapeutics is poised to deliver multiple value-driving catalysts across our programs throughout 2026. Strong enrollment momentum for CLN-978 positions us to deliver the first company-sponsored data for a potential best-in-class CD19 T cell engager in autoimmune diseases in the second quarter, followed by important additional data updates throughout the year. CLN-978 is the ideal therapy for immune reset, with the optimal combination of target, CD19, and modality, T cell engager, together with the convenience of subcutaneous administration. This program has the potential to transform the treatment landscape in autoimmune diseases and deliver a compelling commercial opportunity," said Nadim Ahmed, President and CEO of Cullinan Therapeutics.

"We are also pleased to begin the year with strong momentum in our oncology portfolio. With our partner, Taiho, we have completed the second line rolling NDA submission for zipalertinib and have fully enrolled the frontline study, REZILIENT3, both important milestones as zipalertinib moves closer to being available for patients. Finally, after sharing compelling clinical data at ASH 2025 and with U.S. FDA Fast Track Designation, we expect to rapidly advance CLN-049 to registrational development in AML."

Portfolio Highlights and 2026 Milestones

Immunology

- **CLN-978 (CD19xCD3 bispecific T cell engager):** Systemic Lupus Erythematosus (SLE), Rheumatoid arthritis (RA), and Sjögren's disease (SjD)
- *OUTRACE SLE*
    - 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, as well as other biomarker data and preliminary clinical activity data.
- *OUTRACE RA*
    - 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, as well as other 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, as well as other biomarker data and preliminary clinical activity data.
- *OUTRACE SjD*
    - 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, as well as other biomarker data and preliminary clinical activity data.

- **Velinotamig (BCMAxCD3 bispecific T cell engager):** Autoimmune diseases
    - Genrix Bio is enrolling a Phase 1 study in China in patients with autoimmune diseases, initially in patients with SLE, followed by future planned expansion into other indications and initial clinical data from the study are expected to be shared in Q4 2026. Cullinan intends to use the data generated to accelerate global clinical development. Following 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)
    - The Company plans to share an update from the dose escalation portion of the Phase 1 study in patients with relapsed/refractory AML or MDS 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 February, Taiho completed the rolling NDA submission to the U.S. FDA seeking accelerated approval of zipalertinib for the treatment of patients with locally advanced or metastatic EGFR ex20ins NSCLC who have previously received platinum-based systemic chemotherapy.
    - In February, Taiho completed enrollment of the pivotal study REZILIENT3 in 1L EGFR ex20ins NSCLC. Taiho expects to obtain top-line results by the end of 2026.
    - Cullinan is eligible to receive $30 million and up to $100 million upon 2L and 1L U.S. regulatory approvals, respectively, and a 50/50 profit share in the U.S. moving forward.

Fourth Quarter and Full Year 2025 Financial Results

- **Cash Position:** Cash, cash equivalents, short- and long-term investments, and interest receivable were $439.0 million as of December 31, 2025. Cullinan expects its cash resources to provide runway into 2029 under its current operating plan.
- **R&D Expenses:** Research and development expenses were $42.9 million for the fourth quarter of 2025, compared to $40.5 million for the same period in 2024, and $187.4 million for the full year 2025, compared to $142.9 million for the full year 2024.
- **G&A Expenses:** General and administrative expenses were $12.3 million for the fourth quarter of 2025, compared to $14.6 million for the same period in 2024, and $54.2 million for the full year 2025, compared to $54.0 million for the full year 2024.
- **Net Loss:** Net loss attributable to Cullinan was $50.7 million for the fourth quarter of 2025, compared to $47.6 million for the same period in 2024, and $219.9 million for the full year 2025, compared to $167.4 million for the full year 2024.

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 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: 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.

Cullinan Therapeutics, Inc.
Selected Condensed Consolidated Balance Sheet Data
(unaudited)
(in thousands)

	December 31, 2025	December 31, 2024
Cash, cash equivalents, investments, and interest receivable	$ 438,960	$ 606,917
Total assets	$ 448,374	$ 621,824
Total current liabilities	$ 37,741	$ 30,647
Total liabilities	$ 39,644	$ 31,496
Total stockholders' equity	$ 408,730	$ 590,328

Cullinan Therapeutics, Inc.
Consolidated Statements of Operations
(unaudited)
(in thousands, except per share amounts)

	Three Months Ended		Twelve Months Ended	
	December 31, 2025	December 31, 2024	December 31, 2025	December 31, 2024
Operating expenses:				
Research and development	$ 42,945	$ 40,492	$ 187,402	$ 142,903
General and administrative	12,314	14,556	54,246	54,016
Total operating expenses	55,259	55,048	241,648	196,919
Loss from operations	(55,259)	(55,048)	(241,648)	(196,919)

Other income (expense):				
Interest income	4,615	7,512	22,212	29,660
Other income (expense), net	(69)	6	(443)	(199)
Net loss before income taxes	(50,713)	(47,530)	(219,879)	(167,458)
Income tax expense (benefit)	—	117	—	117
Net loss	(50,713)	(47,647)	(219,879)	(167,575)
Net loss attributable to noncontrolling interests	—	—	—	(192)
Net loss attributable to Cullinan	$ (50,713)	$ (47,647)	$ (219,879)	$ (167,383)
Basic and diluted net loss per share attributable to Cullinan:				
Common stock	$ (0.77)	$ (0.73)	$ (3.36)	$ (2.78)
Preferred stock	$ (7.73)	$ (7.32)	$ (33.57)	$ (27.78)
Weighted-average shares used in computing basic and diluted net loss per share attributable to Cullinan:				
Common stock	59,201	58,580	59,050	53,771
Preferred stock	640	648	645	648

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