Cullinan Therapeutics Provides Corporate Update and Reports First Quarter 2026 Financial Results

May 7, 2026

Initial clinical data in SLE and RA for CLN-978, a CD19 T cell engager, to be presented at the EULAR 2026 Congress in June; multi-dose regimen data in RA expected in Q3 2026

Zipalertinib NDA for relapsed EGFR ex20ins NSCLC accepted by U.S. FDA; PDUFA target action date of February 27, 2027

Cash and investments of $393.3 million as of March 31, 2026; runway into 2029

CAMBRIDGE, Mass., May 07, 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 first quarter ended March 31, 2026.

"T cell engagers have the potential to transform outcomes for people living with autoimmune diseases and cancer, and emerging clinical data underscore their promise as a compelling therapeutic modality. We look forward to sharing initial clinical data for CLN-978 and velinotamig throughout 2026. CD19 and BCMA are now well-validated autoimmune targets, and by addressing both, we aim to comprehensively treat more diseases and redefine standards of care for more patients with these two clinical-stage programs. Similarly, the early success of CLN-049 in AML further reinforces the remarkable promise of T cell engagers in many high unmet need disease settings across immunology and oncology," said Nadim Ahmed, President and CEO of Cullinan Therapeutics.

"Further, with our partner Taiho, we announced FDA acceptance of our first NDA submission, representing a significant milestone for Cullinan Therapeutics and bringing zipalertinib meaningfully closer to being available for patients, with a PDUFA date of February 27, 2027. With multiple upcoming catalysts and milestones across the pipeline through 2026 and beyond, the company is well-positioned for continued momentum and value creation."

Portfolio Highlights and 2026 Milestones

Immunology

- **CLN-978 (CD19xCD3 T cell engager):** treatment-refractory moderate to severe systemic lupus erythematosus (SLE), difficult-to-treat rheumatoid arthritis (RA), and treatment-refractory moderate to severe Sjögren's disease (SjD)
- *OUTRACE SLE*
    - In June, the Company will 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. The initial data will be presented in a poster session at the EULAR 2026 Congress on June 6, 2026.
- *OUTRACE RA*
    - In June, the Company will 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. The initial data will be presented in a poster session at the EULAR 2026 Congress on June 6, 2026.
    - In Q3 2026, the Company plans to share initial multi-dose regimen 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 T cell engager):** treatment-refractory autoimmune diseases
    - Genrix Bio is enrolling a Phase 1 study in China in patients with autoimmune diseases, starting with moderate to severe SLE and to be followed by planned expansion into other indications. Initial multi-dose regimen data from the dose escalation phase in patients with SLE are expected to be shared in Q4 2026. Cullinan intends to use the data generated to accelerate global clinical development.

Oncology

- **CLN-049 (FLT3xCD3 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. Dose level expansion continues in order to determine the recommended Phase 2 dose (RP2D) by Q4 2026 for a potential single-arm pivotal registrational trial.
    - In Q4 2026, the Company plans to initiate a Phase 1/2 combination study in patients with previously untreated AML.
    - Enrollment 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 April, the U.S. FDA accepted an NDA for zipalertinib for the treatment of patients with locally advanced or metastatic EGFR ex20ins NSCLC whose disease has progressed on or after platinum-based chemotherapy, with or without amivantamab. The Prescription Drug User Fee Act (PDUFA) target action date is February 27, 2027.
    - 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.

First Quarter 2026 Financial Results

- **Cash Position:** Cash, cash equivalents, short- and long-term investments, and interest receivable were $393.3 million as of March 31, 2026. Cullinan expects its cash resources to provide runway into 2029 under its current operating plan.
- **R&D Expenses:** Research and development expenses were $42.1 million for the first quarter of 2026, compared to $41.5 million for the same period in 2025.
- **G&A Expenses:** General and administrative expenses were $11.6 million for the first quarter of 2026, compared to $13.5 million for the same period in 2025.
- **Net Loss:** Net loss was $49.7 million for the first quarter of 2026, compared to $48.5 million for the same period in 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 clinical development 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 plans regarding future data presentations, 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)

	March 31, 2026	December 31, 2025
Cash, cash equivalents, investments, and interest receivable	$ 393,282	$ 438,960
Total assets	$ 402,984	$ 448,374
Total current liabilities	$ 35,154	$ 37,741
Total liabilities	$ 36,812	$ 39,644
Total stockholders’ equity	$ 366,172	$ 408,730

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

	Three Months Ended March 31,	
	2026	2025
Operating expenses:		
Research and development	$ 42,123	$ 41,459
General and administrative	11,574	13,537
Total operating expenses	53,697	54,996
Loss from operations	(53,697)	(54,996)
Other income (expense):		
Interest income	4,098	6,580
Other income (expense), net	(62)	(85)
Net loss	$ (49,661)	$ (48,501)
Basic and diluted net loss per share:		
Common stock	$ (0.75)	$ (0.74)
Preferred stock	$ (7.52)	$ (7.42)
Weighted-average shares used in computing net loss per share:		
Common stock	60,462	58,905
Preferred stock	555	648

Contacts:

Investors
Nick Smith
+1 401.241.3516
nsmith@cullinantx.com

Media
Rose Weldon
+1 215.801.7644
rweldon@cullinantx.com