



Cullinan Therapeutics Provides Corporate Update and Reports First Quarter 2025 Financial Results

May 8, 2025

Company received approval from European Medicines Agency (EMA) for CLN-978; Phase 1 study in active, difficult-to-treat rheumatoid arthritis to initiate in Q2 2025

CLN-978 expands into Sjögren's disease; Phase 1 study in active, moderate to severe patients to initiate in the U.S. in Q2 2025

Zipalertinib REZILIENT1 results to be shared in oral presentation at 2025 ASCO Annual Meeting

CAMBRIDGE, Mass., May 08, 2025 (GLOBE NEWSWIRE) -- [Cullinan Therapeutics, Inc.](#) (Nasdaq: CGEM; "Cullinan"), a biopharmaceutical company focused on developing modality-agnostic targeted therapies, today reported recent and anticipated business highlights and announced its financial results for the first quarter ended March 31, 2025.

"As a leader in T cell engager development for autoimmune diseases, we continue to rapidly advance our global clinical development of CLN-978 in several autoimmune diseases and across multiple geographies. With an extensive global network of clinical investigators, CLN-978 is now in active clinical development in systemic lupus erythematosus (SLE), rheumatoid arthritis and Sjögren's disease and we expect to deliver initial clinical data in SLE by the end of the year," said Nadim Ahmed, Chief Executive Officer of Cullinan Therapeutics.

"In parallel, we continue to advance and refine our oncology programs. We recently announced that the pivotal Phase 2b portion of the REZILIENT1 study of zipalertinib met the primary endpoint of overall response rate. Together with our partner Taiho, we will share the results in an oral presentation at the 2025 ASCO Annual Meeting. For CLN-619, our MICA/B antibody, we are narrowing the scope of the program, which will allow for reallocation of resources. With \$567.4 million in cash and investments and runway into 2028, we have the resources required to maintain our leadership position in autoimmune diseases and deliver meaningful value-driving catalysts across both our immunology and oncology programs."

Portfolio Highlights

Immunology

- **CLN-978 (CD19xCD3 T cell engager):** Systemic lupus erythematosus, rheumatoid arthritis, and Sjögren's disease
 - The global Phase 1 study in patients with moderate to severe SLE is ongoing in the United States, Europe, and Australia, and the Company plans to share initial clinical data in Q4 2025.
 - In April 2025, the Company received approval from EMA to initiate a Phase 1 study in patients with active, difficult-to-treat rheumatoid arthritis. The Company expects to initiate the study at FAU Erlangen-Nuremberg in Germany and Università Cattolica del Sacro Cuore in Italy in Q2 2025.
 - In April 2025, the Company announced plans to initiate a Phase 1 study in patients with active, moderate to severe Sjögren's disease in the U.S. in Q2 2025.

Oncology

- **CLN-619 (Anti-MICA/MICB monoclonal antibody):** NSCLC and multiple myeloma
 - Following a review of the data from the disease-specific expansion cohorts for endometrial and cervical cancers, the Company has discontinued further development of CLN-619 in patients with gynecological cancers as preliminary results did not meet the internal threshold for advancement.
 - Cullinan will continue enrolling to go/no-go decisions the ongoing expansion cohorts in patients with NSCLC and the ongoing Phase 1 study in patients with relapsed/refractory multiple myeloma.
- **Zipalertinib (EGFR ex20ins inhibitor), collaboration with Taiho Oncology:** EGFR ex20ins NSCLC
 - In January 2025, Cullinan announced that the pivotal Phase 2b portion of REZILIENT1 met the primary endpoint of overall response rate in patients with EGFR ex20ins NSCLC who have received prior therapy. The results will be

presented during an oral abstract session at the 2025 ASCO Annual Meeting on June 1, 2025.

- Pending discussions with the U.S. Food and Drug Administration, Taiho plans to submit an NDA in relapsed/refractory EGFR ex20ins NSCLC in the second half of 2025. Taiho continues enrollment of the pivotal study REZILIENT3 in 1L EGFR ex20ins NSCLC.

- **CLN-049 (FLT3xCD3 T cell-engaging bispecific antibody):** Acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS)
 - Enrollment continues in the ongoing Phase 1 study in patients with relapsed/refractory AML or MDS, and in the ongoing Phase 1 study in patients with measurable minimal residual disease in AML.
- **CLN-617 (IL-2 and IL-12 cytokine fusion protein):** Solid tumors
 - Enrollment continues in the ongoing Phase 1 study in patients with advanced solid tumors.

First Quarter 2025 Financial Results

- **Cash Position:** Cash, cash equivalents, short- and long-term investments, and interest receivable were \$567.4 million as of March 31, 2025. Cullinan continues to expect its cash resources to provide runway into 2028 based on its current operating plan.
- **R&D Expenses:** Research and development expenses were \$41.5 million for the first quarter of 2025, compared to \$30.6 million for the same period in 2024.
- **G&A Expenses:** General and administrative expenses were \$13.5 million for the first quarter of 2025, compared to \$12.3 million for the same period in 2024.
- **Net Loss:** Net loss attributable to Cullinan was \$48.5 million for the first quarter of 2025, compared to \$37.1 million for the same period in 2024.

About Cullinan Therapeutics

[Cullinan Therapeutics, Inc.](https://cullinantherapeutics.com/) (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 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 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)

	<u>March 31, 2025</u>	<u>December 31, 2024</u>
Cash, cash equivalents, investments, and interest receivable	\$ 567,403	\$ 606,917
Total assets	\$ 579,681	\$ 621,824
Total current liabilities	\$ 27,349	\$ 30,647
Total liabilities	\$ 27,842	\$ 31,496
Total stockholders' equity	\$ 551,839	\$ 590,328

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

	<u>Three Months Ended March 31,</u>	
	<u>2025</u>	<u>2024</u>
Operating expenses:		
Research and development	\$ 41,459	\$ 30,646
General and administrative	13,537	12,343
Total operating expenses	<u>54,996</u>	<u>42,989</u>
Loss from operations	<u>(54,996)</u>	<u>(42,989)</u>
Other income (expense):		
Interest income	6,580	5,693
Other income (expense), net	<u>(85)</u>	<u>(44)</u>
Net loss	<u>(48,501)</u>	<u>(37,340)</u>
Net loss attributable to noncontrolling interests	<u>—</u>	<u>(192)</u>
Net loss attributable to Cullinan	<u>\$ (48,501)</u>	<u>\$ (37,148)</u>
Basic and diluted net loss per share attributable to Cullinan:		
Common stock	\$ (0.74)	\$ (0.75)
Preferred stock	\$ (7.42)	\$ (7.51)
Weighted-average shares used in computing net loss per share attributable to Cullinan:		
Common stock	58,905	43,011
Preferred stock	648	648

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