



## Cullinan Therapeutics Provides Corporate Update and Reports Third Quarter 2025 Financial Results

November 6, 2025

*Promising Phase 1 clinical data for CLN-049, a FLT3xCD3 bispecific T cell engager, demonstrating ~30% CRc rate in heavily pretreated, all-comer population of patients with relapsed/refractory AML to be presented in oral presentation at ASH 2025*

*Company to share initial data for CLN-978, a CD19xCD3 bispecific T cell engager, in both SLE and RA in first half of 2026*

*Based on review of emerging clinical data, CLN-619 and CLN-617 programs discontinued*

*Cash and investments of \$475.5 million as of September 30, 2025; Runway into 2029*

CAMBRIDGE, Mass., Nov. 06, 2025 (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 third quarter ended September 30, 2025.

"Cullinan is strategically focusing resources and development efforts on select, high-conviction clinical stage programs. We are well-positioned to further concentrate resources on CLN-978, a CD19xCD3 bispecific T cell engager, and we plan to share initial clinical data in autoimmune diseases in the first half of 2026. We are also particularly encouraged by the emerging efficacy profile of CLN-049, our FLT3xCD3 bispecific T cell engager, and we look forward to unveiling important clinical data in an oral presentation at the upcoming 2025 ASH Annual Meeting in December. We believe the differentiated mechanism of CLN-049 supports its potential to address a broad population of AML patients regardless of mutational status, including those with poor prognostic features," said Nadim Ahmed, Chief Executive Officer of Cullinan Therapeutics.

"Additionally, following a positive pre-NDA meeting with the FDA in October, our partner Taiho plans to initiate a rolling submission of an NDA for zipalertinib in relapsed EGFR ex20ins NSCLC by year-end and expects to complete enrollment of the frontline study REZILIENT3 in the first half of 2026. Finally, after reviewing emerging clinical data, we have decided not to pursue further development of CLN-619 and CLN-617. Notably, our core pipeline is now focused on T cell engagers applied to well-validated targets with transformative potential in immunology and oncology. This focused pipeline extends our cash runway into 2029 and provides us ample financial resources to deliver meaningful value-driving catalysts across our programs in 2026 and beyond."

### Portfolio Highlights

#### Immunology

- **CLN-978 (CD19xCD3 bispecific T cell engager):** Systemic lupus erythematosus (SLE), rheumatoid arthritis (RA), and Sjögren's disease (SjD).
  - The Phase 1 OUTRACE Program is enrolling and treating patients across the OUTRACE SLE, OUTRACE RA and OUTRACE SjD Studies. The Company plans to share initial safety and B cell depletion data in SLE and RA in the first half of 2026.
  - The Company was issued a key composition of matter patent by the United States Patent and Trademark Office, which is expected to extend patent protection until at least 2042, excluding possible patent term extension.
- **Velinotamig (BCMAxCD3 bispecific T cell engager):** Autoimmune diseases
  - Genrix Bio, from whom Cullinan licensed velinotamig in June 2025, plans to initiate a Phase 1 study in China in patients with autoimmune diseases by the end of 2025. 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

- **Zipalertinib (EGFR ex20ins inhibitor), collaboration with Taiho Oncology:** EGFR ex20ins NSCLC
  - Following a positive Type B pre-NDA meeting with the U.S. Food and Drug Administration in October, Taiho plans to initiate a rolling submission of an NDA in relapsed EGFR ex20ins NSCLC by the end of 2025. Taiho expects to complete enrollment of the pivotal study REZILIENT3 in 1L EGFR ex20ins NSCLC in the first half of 2026.
  - The Company shared updated efficacy and safety data demonstrating responses in patients previously treated with amivantamab during a mini oral abstract session at the IASLC 2025 WCLC.
  - Taiho shared initial data from the REZILIENT2 cohort demonstrating the clinical activity of zipalertinib in patients with uncommon EGFR mutations during a mini oral abstract session at the IASLC 2025 WCLC.
  - Taiho also shared initial data from the REZILIENT2 cohort demonstrating intracranial responses with zipalertinib in patients with active brain metastases at the ESMO Congress 2025.
- **CLN-049 (FLT3xCD3 bispecific T cell engager):** Acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS)
  - Enrollment continues in the Phase 1 study in patients with relapsed/refractory AML or MDS. The Company recently shared clinical data in a published ASH abstract and updated results will be shared in an oral presentation at the 2025 ASH Annual Meeting on December 8, 2025. CLN-049 demonstrated promising anti-leukemic activity, including a ~30% CRc rate at clinically active target doses, in a heavily pretreated population of patients, regardless of FLT3 mutational status.
  - Enrollment also continues in a parallel Phase 1 study in patients with AML and measurable residual disease (MRD) immediately following induction therapy.

## Third Quarter 2025 Financial Results

- **Cash Position:** Cash, cash equivalents, short- and long-term investments, and interest receivable were \$475.5 million as of September 30, 2025. Cullinan expects its cash resources to provide runway into 2029 under its new operating plan.
- **R&D Expenses:** Research and development expenses were \$42.0 million for the third quarter of 2025, compared to \$35.5 million for the same period in 2024.
- **G&A Expenses:** General and administrative expenses were \$13.6 million for the third quarter of 2025, compared to \$13.3 million for the same period in 2024.
- **Net Loss:** Net loss attributable to Cullinan was \$50.6 million for the third quarter of 2025, compared to \$40.6 million for the same period in 2024.

## About Cullinan Therapeutics

[Cullinan Therapeutics, Inc.](https://cullinantherapeutics.com/) (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 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 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 impacts of governmental legislation and regulations, including adverse effects from the U.S. government shutdown; 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)

	<b>September 30, 2025</b>	<b>December 31, 2024</b>
Cash, cash equivalents, investments, and interest receivable	\$ 475,498	\$ 606,917
Total assets	\$ 484,126	\$ 621,824
Total current liabilities	\$ 32,757	\$ 30,647
Total liabilities	\$ 32,757	\$ 31,496
Total stockholders' equity	\$ 451,369	\$ 590,328

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

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2025</b>	<b>2024</b>	<b>2025</b>	<b>2024</b>
Operating expenses:				
Research and development	\$ 41,968	\$ 35,506	\$ 144,457	\$ 102,411
General and administrative	13,627	13,349	41,932	39,460
Total operating expenses	55,595	48,855	186,389	141,871
Loss from operations	(55,595)	(48,855)	(186,389)	(141,871)
Other income (expense):				
Interest income	5,093	8,384	17,597	22,148
Other income (expense), net	(108)	(89)	(374)	(205)

Net loss	(50,610)	(40,560)	(169,166)	(119,928)
Net loss attributable to noncontrolling interests	—	—	—	(192)
Net loss attributable to Cullinan	<u>\$ (50,610)</u>	<u>\$ (40,560)</u>	<u>\$ (169,166)</u>	<u>\$ (119,736)</u>

Basic and diluted net loss per share attributable to Cullinan:

Common stock	\$ (0.77)	\$ (0.63)	\$ (2.58)	\$ (2.04)
Preferred stock	\$ (7.72)	\$ (6.26)	\$ (25.84)	\$ (20.42)

Weighted-average shares used in computing net loss per share attributable to Cullinan:

Common stock	59,075	58,337	58,999	52,157
Preferred stock	648	648	648	648

**Contacts:**

**Investors**

Nick Smith

+1 401.241.3516

[nsmith@cullinantx.com](mailto:nsmith@cullinantx.com)

**Media**

Rose Weldon

+1 215.801.7644

[rweldon@cullinantx.com](mailto:rweldon@cullinantx.com)