Cullinan Therapeutics Provides Corporate Update and Reports Third Quarter 2024 Financial Results

November 7, 2024

Global Phase 1 study of CLN-978 in systemic lupus erythematosus (SLE) cleared to initiate in U.S. and Australia; initial clinical data expected in Q4 2025

CLN-619 on-track for initial expansion cohort data in endometrial and cervical cancers in Q2 2025

Zipalertinib pivotal Phase 2b study enrollment completed ahead of schedule; results expected mid-year 2025

CAMBRIDGE, Mass., Nov. 07, 2024 (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 third quarter ended September 30, 2024.

"We are making meaningful progress in executing our strategic plans for CLN-978 in autoimmune diseases while simultaneously advancing our oncology pipeline," said Nadim Ahmed, Chief Executive Officer of Cullinan Therapeutics. "We have secured clearance from the U.S. Food and Drug Administration (FDA) for our IND application and Human Research Ethics Committee (HREC) approval in Australia to initiate our global Phase 1 study for CLN-978 in moderate to severe SLE. These important regulatory clearances position us to share initial clinical data for CLN-978 in the fourth quarter of 2025. We also continue to make significant progress in advancing our oncology portfolio, with data from two of our key programs expected in 2025. For CLN-619, we remain on track to share initial expansion data for endometrial and cervical cancers in the second quarter of 2025. We also completed enrollment of the pivotal Phase 2b study of zipalertinib ahead of schedule, and we plan to provide the results at mid-year 2025."

Portfolio Highlights

Immunology

- **CLN-978 (CD19xCD3 T cell engager):** Systemic lupus erythematosus and rheumatoid arthritis
    - The company obtained health authority approvals to initiate its global Phase 1 study in moderate to severe SLE, securing U.S. FDA clearance of its IND application and HREC approval in Australia. Cullinan plans to share initial clinical data for SLE in the fourth quarter of 2025. The company also continues to engage with other global health authorities to expand the planned country and site footprint.
    - The company plans to initiate a sponsored clinical trial in rheumatoid arthritis (RA) in the second quarter of 2025. The trial will be designed and executed in collaboration with FAU Erlangen-Nuremberg in Germany and Università Cattolica del Sacro Cuore, Rome in Italy.
    - Cullinan is presenting preclinical data at the upcoming American College of Rheumatology (ACR) Convergence 2024, taking place in Washington, D.C. from November 14-19, 2024.

Oncology

- **CLN-619 (Anti-MICA/MICB monoclonal antibody)**: Solid tumors and hematological malignancies
    - In September, Cullinan dosed the first patient in a Phase 1 study of CLN-619 in patients with relapsed/refractory multiple myeloma.
    - New biomarker and translational data from the monotherapy dose escalation portion of the Phase 1 study in solid tumors will be presented at the Society for Immunotherapy of Cancer (SITC) in November.
    - The company continues enrollment of disease-specific expansion cohorts of its Phase 1 study in solid tumors, enrolling cervical, endometrial and non-small cell lung cancer (NSCLC) patients. Cullinan remains on track to report initial data in endometrial and cervical cancers in the second quarter of 2025.
    - Notably, the company was issued a key composition of matter patent by the United States Patent and Trademark Office, which is expected to extend protection until at least 2041, excluding possible patent term extension.
- **Zipalertinib (EGFR ex20ins inhibitor), collaboration with Taiho Oncology:** EGFR ex20ins NSCLC
    - At the European Society for Medical Oncology (ESMO) Congress in September, Cullinan presented positive REZILIENT1 results in patients with EGFR ex20ins NSCLC who have progressed on or after prior amivantamab treatment. Zipalertinib demonstrated a consistent objective response rate of approximately 40% and a manageable safety profile.
    - In September, Cullinan successfully completed enrollment of the pivotal Phase 2b study ahead of schedule, which was originally planned for the end of this year. Cullinan plans to share the results of the pivotal Phase 2b study at mid-year 2025. Taiho continues enrollment of the pivotal study REZILIENT3 in 1L EGFR ex20ins NSCLC.

- **CLN-049 (FLT3xCD3 T cell-engaging bispecific antibody):** AML and MDS
  - Following the clinical update in Q2 2024 and discontinuation of subcutaneous administration, enrollment continues with IV administration in the ongoing Phase 1 study in patients with relapsed/refractory AML and MDS.

- **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.

Corporate Updates

- In the third quarter, the company added two rheumatology and immunology experts to its Scientific Advisory Board (SAB): Dr. Ricardo Grieshaber-Bouyer and Dr. Chaim Putterman. Dr. Grieshaber-Bouyer and Dr. Putterman's expertise will further strengthen the company's Scientific Advisory Board.
  - Dr. Grieshaber-Bouyer is head of the clinical trial unit at FAU Erlangen-Nurnberg Rheumatology and Immunology Department and cares for patients with rheumatic and immune-mediated diseases, in particular in the context of emerging therapies such as T cell redirecting therapies.
  - Dr. Putterman is Professor Emeritus of the Division of Rheumatology at Albert Einstein College of Medicine and Montefiore Medical Center, where his research focuses on mechanisms of autoimmunity, pathogenesis of kidney and neuropsychiatric disease in SLE, novel therapies for lupus, and SLE biomarkers.

Third Quarter 2024 Financial Results

- **Cash Position:** Cash, cash equivalents, short- and long-term investments, and interest receivable were $639.0 million as of September 30, 2024. 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 $35.5 million for the third quarter of 2024, compared to $33.8 million for the same period in 2023.
- **G&A Expenses:** General and administrative expenses were $13.3 million for the third quarter of 2024, compared to $11.0 million for the same period in 2023.
- **Net loss:** Net loss was $40.6 million ($0.69 per common share) for the third quarter of 2024, compared to $39.2 million ($0.91 per common share) for the same period in 2023.

About Cullinan Therapeutics

Cullinan Therapeutics, Inc. (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 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; 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)

	September 30, 2024	December 31, 2023
Cash, cash equivalents, investments, and interest receivable	$ 638,996	$ 468,264
Total assets	$ 653,254	$ 484,182
Total current liabilities	$ 24,204	$ 28,137
Total liabilities	$ 25,392	$ 30,287
Total stockholders' equity	$ 627,862	$ 453,895

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

	Three Months Ended		Nine Months Ended	
	September 30, 2024	September 30, 2023	September 30, 2024	September 30, 2023
Operating expenses:				
Research and development	$ 35,506	$ 33,821	$ 102,411	$ 113,308
General and administrative	13,349	10,982	39,460	31,856
Total operating expenses	48,855	44,803	141,871	145,164
Impairment of long-lived assets	—	(440)	—	(440)
Loss from operations	(48,855)	(45,243)	(141,871)	(145,604)
Other income (expense):				
Interest income	8,384	5,880	22,148	15,710
Other income (expense), net	(89)	180	(205)	356
Net loss	(40,560)	(39,183)	(119,928)	(129,538)
Net loss attributable to noncontrolling interests	—	—	(192)	(179)
Net loss attributable to common stockholders of Cullinan	$ (40,560)	$ (39,183)	$ (119,736)	$ (129,359)
Net loss per share attributable to common stockholders of Cullinan:				
Basic and diluted	$ (0.69)	$ (0.91)	$ (2.30)	$ (3.15)
Weighted-average shares used in computing net loss per share attributable to common stockholders of Cullinan:				
Basic and diluted	58,337	42,734	52,157	41,130

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