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

August 8, 2024

Investigational New Drug (IND) application for CLN-978 in systemic lupus erythematosus (SLE) remains on track to be filed in third quarter of 2024

Company to pursue rheumatoid arthritis (RA) as second autoimmune indication for CLN-978 development

CLN-619 combination therapy data presented at ASCO demonstrated objective responses in oncogenic driver mutation NSCLC, which is typically unresponsive to checkpoint inhibition

Company appoints Mary Thistle to its Board of Directors

CAMBRIDGE, Mass., Aug. 08, 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 second quarter ended June 30, 2024.

"We are keenly focused on executing on the strategic plans we made during the first half of 2024, including our expansion into autoimmune diseases and continued advancement of our oncology pipeline, each facilitated by our recent oversubscribed financing," said Nadim Ahmed, Chief Executive Officer of Cullinan Therapeutics. "During the second half of 2024, we will advance CLN-978 toward a first global clinical study in systemic lupus erythematosus (SLE) and remain on track to file an investigational new drug (IND) application in the third quarter of this year. We are committed to exploring the broad potential of CLN-978 across autoimmune diseases and will pursue rheumatoid arthritis (RA) as our next indication, where there is both significant unmet patient need and clinical validation for CD19 T cell engagers. We are excited to collaborate with FAU Erlangen-Nuremberg and Università Cattolica del Sacro Cuore, Rome to conduct a clinical trial of CLN-978 in patients with RA. Both are pioneering centers of excellence in the field of T cell redirecting therapies for autoimmune diseases and the first to demonstrate the potential of a CD19 T cell engager in RA. Finally, to focus our resources on our most promising programs, we will discontinue development of CLN-418 based on initial clinical observations."

"At FAU, we are excited about the prospect of a clinical trial of a new T cell engager in RA," said Dr. Ricardo Grieshaber-Bouyer, M.D., Ph.D., Professor of Clinical Systems Immunology and Head of the Clinical Trials Unit at FAU Erlangen-Nuremberg, "There is a significant unmet need in treating patients with RA who are refractory to currently available treatments. Our team at Erlangen has already demonstrated that a T cell engager targeting CD19 has potential to dramatically alter the course of disease in these patients, and we look forward to furthering our initial groundbreaking work in this area with CLN-978, which could potentially offer significant benefit to patients with convenient, off-the-shelf subcutaneous administration and a favorable safety profile."

Portfolio Highlights

Immunology

- **CLN-978 (CD19xCD3 T cell engager):** Systemic lupus erythematosus and rheumatoid arthritis
  - Cullinan remains on-track to submit an IND application for the global SLE study to the U.S. Food and Drug Administration in the third quarter of 2024.
  - The company plans to explore CLN-978 in rheumatoid arthritis as its second autoimmune indication and will collaborate with FAU Erlangen-Nuremberg in Germany and Università Cattolica del Sacro Cuore, Rome to conduct a company sponsored clinical trial in that indication.

Oncology

- **CLN-619 (Anti-MICA/MICB monoclonal antibody)**: Solid tumors and hematological malignancies
  - Cullinan presented initial data from the combination dose escalation module, as well as an update on the monotherapy dose escalation, during a poster session at the 2024 ASCO Annual Meeting on June 1, 2024.
  - The combination therapy data demonstrated objective responses in patients with non-small cell lung cancer (NSCLC) with oncogenic mutations, which is typically unresponsive to checkpoint inhibitors. The monotherapy data demonstrated durability of clinical benefit with longer follow-up.
  - Based on the observed data, the company announced additional disease expansion cohorts for both monotherapy and in combination with pembrolizumab in NSCLC as well as in combination with chemotherapy in platinum resistant ovarian cancer.
  - Cullinan remains on track to report initial data from disease-specific dose expansion cohorts in endometrial and cervical cancers in the first half of 2025.

- **Zipalertinib (EGFR ex20ins inhibitor), collaboration with Taiho Oncology:** EGFR ex20ins NSCLC
    - In June, Cullinan announced positive initial data from the pivotal Phase 2b portion of the REZILIENT1 study in patients with EGFR ex20ins NSCLC who have progressed after prior chemotherapy as well as the exon 20 targeted therapy amivantamab. The results in this emerging patient population showed similar efficacy and safety for zipalertinib as seen in patients progressing after prior chemotherapy alone.
    - An update to these initial REZILIENT1 results in patients with EGFR ex20ins NSCLC who have progressed after both prior chemotherapy and amivantamab will be presented in a mini oral presentation at the European Society for Medical Oncology (ESMO) meeting in September.
    - Cullinan expects to complete enrollment in the pivotal Phase 2b portion of REZILIENT1 by year-end 2024.

- **CLN-049 (FLT3xCD3 T cell-engaging bispecific antibody):** AML and MDS
    - Following a review of the data from the Phase 1 study of CLN-049, Cullinan is reporting that in the ongoing Phase 1 study in patients with relapsed/refractory AML and MDS, dose-limiting injection site reactions were observed during dose escalation with subcutaneous administration. Based on these findings, together with observations of preliminary clinical activity, dose escalation is now continuing in the study with IV administration.

- **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.

- **CLN-418 (B7H4x4-1BB bispecific immune activator):** Solid tumors
    - Following a review of the data from the Phase 1 study of CLN-418, Cullinan plans to discontinue development and has notified Harbour BioMed of termination of the license agreement. In connection with the termination, Cullinan will return development and commercial rights to Harbour BioMed.

Corporate Updates

- In April, the Company completed an oversubscribed private placement of common stock grossing $280 million. The financing included new and existing leading life sciences institutional investors.

- In August, the Company added experienced biotech executive Mary Thistle to its Board of Directors. Ms. Thistle brings thirty years of operational and business development expertise, including experience in autoimmune diseases, that will add significant value to Cullinan's growth strategy.

Second Quarter 2024 Financial Results

- **Cash Position:** Cash, cash equivalents, investments, and interest receivable were $664.9 million as of June 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 (R&D) expenses were $36.3 million for the second quarter of 2024, compared to $27.4 million for the second quarter of 2023. R&D expenses for the second quarter of 2024 and 2023 included $3.9 million and $3.2 million, respectively, of equity-based compensation expenses. The increase in R&D expenses, excluding equity-based compensation, was primarily related to increases in clinical costs, chemistry, manufacturing and controls costs, and preclinical costs, along with increases in personnel costs relating to additional headcount.

  R&D expenses were $66.9 million for the first six months of 2024, compared to $79.5 million for the first six months of 2023. R&D expenses for the first six months of 2024 and 2023 included $7.0 million and $6.3 million, respectively, of equity-based compensation expenses. The decrease in R&D expenses, excluding equity-based compensation, was primarily due to the one-time upfront in-licensing fee for CLN-418 in 2023, partially offset by increases in clinical and preclinical costs, and increased personnel costs relating to additional headcount.

- **G&A Expenses:** General and administrative (G&A) expenses were $13.8 million for the second quarter of 2024, compared to $10.2 million for the second quarter of 2023. G&A expenses in the second quarter of 2024 and 2023 included $6.7 million and $4.7 million, respectively, of equity-based compensation expenses. The increase in G&A expenses, excluding equity-based compensation, was primarily driven by increased personnel costs relating to additional headcount.

  G&A expenses were $26.1 million for the first six months of 2024, compared to $20.9 million for the first six months of 2023. G&A expenses in the first six months of 2024 and 2023 included $11.8 million and $8.9 million, respectively, of equity-based compensation expenses. The increase in G&A expenses, excluding equity-based compensation, was primarily driven by increased personnel costs relating to additional headcount.

- **Net Loss:** Net loss (before items attributable to noncontrolling interest) for the second quarter of 2024 was $42.0 million, compared with net loss of $32.2 million for the second quarter of 2023. Net losses resulted from the expenses described above, partially offset by interest income of $8.1 million and $5.3 million in the second quarter of 2024 and 2023, respectively.

  Net loss (before items attributable to noncontrolling interest) for the first six months of 2024 was $79.4 million, compared with net loss of $90.4 million for the six months of 2023. Net losses resulted from the expenses described above, partially offset by interest income of $13.8 million and $9.8 million in the first six months of 2024 and 2023, respectively.

- **Shares Outstanding:** As of July 31, 2024, Cullinan had 57,976,641 shares of common stock outstanding, plus pre-funded warrants outstanding that are convertible into 315,790 shares of common stock, and non-voting preferred stock outstanding that is convertible into 6,475,000 shares of common stock.

About Cullinan Therapeutics

Cullinan Therapeutics, Inc. (Nasdaq: CGEM) is a biopharmaceutical company dedicated to creating new standards of care for patients. We have 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. Our 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 our Company at www.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, the clinical and therapeutic potential of our product candidates, the strategy of our product candidates, our research and development activities and our cash runway. The words "believe," "continue," "expect," "plan," "potential," "pursue," 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, including the IND that we intend to file for CLN-978; the risk that any INDs we may file are not cleared by the United States Food and Drug Administration or are not cleared on our expected timelines, or at all; success of our clinical trials and preclinical studies; risks related to our ability to protect and maintain our intellectual property position; 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 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)

	June 30, 2024	December 31, 2023
Cash, cash equivalents, investments, and interest receivable	$ 664,943	$ 468,264
Total assets	$ 681,216	$ 484,182
Total current liabilities	$ 23,476	$ 28,137
Total liabilities	$ 24,995	$ 30,287
Total stockholders' equity	$ 656,221	$ 453,895

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

	Three Months Ended		Six Months Ended	
	June 30, 2024	June 30, 2023	June 30, 2024	June 30, 2023
Operating expenses:				

Research and development	$ 36,259	$ 27,391	$ 66,905	$ 79,487
General and administrative	13,768	10,214	26,111	20,874
Total operating expenses	50,027	37,605	93,016	100,361
Loss from operations	(50,027)	(37,605)	(93,016)	(100,361)
Other income (expense):				
Interest income	8,071	5,322	13,764	9,830
Other income (expense), net	(72)	69	(116)	176
Net loss	(42,028)	(32,214)	(79,368)	(90,355)
Net loss attributable to noncontrolling interests	—	—	(192)	(179)
Net loss attributable to common stockholders of Cullinan	$ (42,028)	$ (32,214)	$ (79,176)	$ (90,176)
Net loss per share attributable to common stockholders of Cullinan:				
Basic and diluted	$ (0.75)	$ (0.82)	$ (1.61)	$ (2.24)
Weighted-average shares used in computing net loss per share attributable to common stockholders of Cullinan:				
Basic and diluted	55,052	39,952	49,031	40,315

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