Cullinan Oncology Provides Corporate Update and Reports Fourth Quarter and Full Year 2023 Financial Results

March 14, 2024

Cullinan remains on track to report additional solid tumor dose escalation data for CLN-619 in the second quarter of 2024 and recently received FDA clearance for an IND to evaluate CLN-619 in relapsed/refractory multiple myeloma

The company is exploring development of its CD19xCD3 T cell engager CLN-978 in autoimmune disorders

Cash and investments of $468.3 million as of December 31, 2023 continues to provide runway into the second half of 2026

CAMBRIDGE, Mass., March 14, 2024 (GLOBE NEWSWIRE) -- Cullinan Oncology, Inc. (Nasdaq: CGEM; "Cullinan"), a biopharmaceutical company focused on developing modality-agnostic targeted oncology therapies, today reported on recent and upcoming business highlights and announced its financial results for the fourth quarter and full year ended December 31, 2023. The company also announced that Chief Financial Officer Jeff Trigilio will depart the company effective March 29. Following his departure, Jeff has agreed to support the company through a transition period.

"With the remarkable progress we made in 2023, we are positioned for an exciting, data-rich 2024," said Nadim Ahmed, Chief Executive Officer of Cullinan Oncology, "We are on track to present clinical data across multiple programs, starting first with our lead unpartnered program, CLN-619. We plan to present initial data assessing CLN-619 in combination with checkpoint inhibitor therapy, along with updated data from the monotherapy dose escalation module, at a major medical meeting in the second quarter. We are exploring development of CLN-978, our next generation CD19xCD3 T cell engager, for the treatment of autoimmune diseases, where we believe it has significant potential as a potent, off-the-shelf, patient-friendly alternative to CAR T cell therapy. We continue to advance a broad zipalertinib development program in collaboration with Taiho, and we are on track to complete enrollment in the pivotal Phase 2b portion of the REZILIENT1 study by the end of the year. Lastly, we thank Jeff Trigilio for playing an important role in transitioning the company from an early-stage private biotechnology company to a public company with a diversified and deep pipeline and we wish him the best in his future endeavors."

Portfolio Highlights

- **CLN-619 (Anti-MICA/MICB monoclonal antibody)**: Solid tumors and hematological malignancies
  - Enrollment continues in the ongoing Phase 1 study evaluating CLN-619 as both monotherapy and in combination with checkpoint inhibitor therapy for patients with advanced solid tumors. Accrual to the dose escalation phase of the combination module has been completed. Recruitment continues in the monotherapy disease specific expansion cohorts for patients with endometrial and cervical cancers. Cullinan also continues to evaluate potential additional disease specific expansion cohorts.
  - Cullinan remains on track to report initial data from the combination dose escalation module as well as an update on the monotherapy dose escalation module at a medical conference in the second quarter of 2024.
  - Cullinan also remains on track to report initial data from disease specific dose expansion cohorts in the first half of 2025.
  - Cullinan recently received FDA clearance for an IND for CLN-619 in multiple myeloma.
- **CLN-978 (CD19xCD3 T cell engager):** B-NHL, autoimmune disorders
  - In August 2023, Cullinan dosed the first patient in our Phase 1 clinical trial of CLN-978 in patients with relapsed/refractory B cell non-Hodgkin lymphoma. Based on emerging clinical data and case series from academic and industry groups supporting the efficacy of CD19 directed CAR T cell therapy in multiple autoimmune diseases and our belief that CLN-978 may address the limitations of CAR T cell therapy, Cullinan is exploring development of CLN-978 in autoimmune diseases.
  - CLN-978 incorporates several design features to address the limitations of other approaches, specifically: 1) an albumin binding, half-life extending domain that allows for weekly dosing; 2) high-affinity binding to CD19, enabling elimination of B cells with very low CD19 expression; and 3) subcutaneous administration, which can potentially reduce cytokine release and allow for better tolerability and convenience.
  - Cullinan's non-human primate data show that subcutaneous administration of CLN-978 achieved profound B cell depletion in the periphery and in tissues such as lymph nodes and spleen. Moreover, subcutaneous administration of CLN-978 in non-human primates was better tolerated and led to markedly decreased cytokine induction compared to intravenous administration. Finally, in vitro studies showed CLN-978 could eliminate B cells expressing extremely low levels of CD19.
- **Zipalertinib (EGFR ex20ins inhibitor), collaboration with Taiho Oncology:** EGFR ex20ins NSCLC
  - Cullinan expects to complete enrollment in the pivotal Phase 2b portion of the REZILIENT1 study in patients with EGFR ex20ins NSCLC who have progressed after prior systemic therapy, with or without exon 20 targeted therapy, by year-end 2024.
- **CLN-049 (FLT3xCD3 T cell-engaging bispecific antibody):** AML and MDS
  - Cullinan expects to provide a clinical data update from the ongoing Phase 1 multi-ascending dose study in r/r AML and MDS patients in the second half of 2024.
- **CLN-418 (B7H4x4-1BB bispecific immune activator):** Solid tumors
  - Cullinan expects to provide a clinical data update from the ongoing Phase 1 dose escalation study in patients with advanced solid tumors in the second half of 2024.
- **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.

Fourth Quarter 2023 Financial Results

- **Cash Position:** Cash, cash equivalents, investments, and interest receivable were $468.3 million as of December 31, 2023. Cullinan expects its cash resources to provide runway into the second half of 2026 based on its current operating plan.
- **R&D Expenses:** Research and development (R&D) expenses were $34.8 million for the fourth quarter of 2023, compared to $33.8 million for the third quarter of 2023. R&D expenses for the fourth and third quarters of 2023 included $2.7 million and $3.2 million of equity-based compensation expenses, respectively. The increase in R&D expenses was primarily related to increases in clinical costs, partially offset by decreases in CMC costs.
- **G&A Expenses:** General and administrative (G&A) expenses were $10.6 million for the fourth quarter of 2023, compared to $11.0 million for the third quarter of 2023. G&A expenses in the fourth and third quarters of 2023 included $4.9 million and $4.5 million of equity-based compensation expenses, respectively. The decrease in G&A expenses was primarily driven by decreases in legal and professional fees.
- **Net Loss:** Net loss (before items attributable to noncontrolling interest) for the fourth quarter of 2023 was $25.6 million, compared with net loss of $39.2 million for the third quarter of 2023. Net losses included the items described above, partially offset by interest income of $5.9 million in each of the fourth and third quarter of 2023 and a $14.1 million income tax benefit related to a 2022 return-to-provision adjustment and 2023 federal R&D tax credits that can be carried back to 2022 that were recorded in the fourth quarter of 2023.

Full Year 2023 Financial Results

- **R&D Expenses:** R&D expenses were $148.2 million for 2023, compared to $91.9 million for 2022. R&D expenses for 2023 and 2022 included $12.2 million and $11.0 million of equity-based compensation expenses, respectively. The increase in R&D expenses for 2023 compared to 2022 was primarily due to a one-time upfront payment related to in-licensing CLN-418 in 2023, higher personnel costs due to increased headcount and expansion of operations to support our research and development activities, and higher equity-compensation costs, partially offset by decreased of lower preclinical costs.
- **G&A Expenses:** G&A expenses were $42.5 million for 2023, compared to $40.2 million for 2022. G&A expenses for 2023 and 2022 included $18.3 million and $16.9 million of equity-based compensation expenses, respectively. The increase in G&A expenses was primarily due to an increase in personnel costs, higher equity-based compensation costs, and higher occupancy and other costs to support our expanded operations, partially offset by one-time costs related to the sale of Cullinan Pearl in 2022 that did not recur in 2023, and lower legal and other professional service fees.
- **Net Loss:** Net loss (before items attributable to noncontrolling interest) for 2023 was $155.1 million, compared with net income of $109.2 million for 2022. Net losses in 2023 and net income in 2022 included the items described above, partially offset by interest income of $21.6 million and $6.6 million for 2023 and 2022, respectively, and a $14.1 million income tax benefit related to a 2022 return-to-provision adjustment and 2023 federal R&D tax credits that can be carried back to 2022 that were recorded in 2023.
- **Shares Outstanding:** As of March 1, 2024, Cullinan had 43,065,645 shares of common stock outstanding plus 647,500 shares of non-voting preferred stock outstanding, each of which is convertible into 10 shares of common stock.

About Cullinan Oncology

Cullinan Oncology, Inc. (Nasdaq: CGEM) is a biopharmaceutical company dedicated to creating new standards of care for patients with cancer. We innovate without borders to find the most promising clinic-ready cancer therapies, whether from our own discovery efforts or through exceptional engagement with our academic and industry partners. Anchored in a deep understanding of immuno-oncology and translational cancer medicine, we leverage our scientific excellence in small molecules and biologics to create differentiated ideas, identify unique targets, and select the optimal modality to develop transformative therapeutics across cancer indications. Powered by our novel research model, we push conventional boundaries from candidate selection to cancer therapeutic, applying rigorous early experimentation to fast-track only the most promising assets to the clinic and ultimately commercialization. As a result, our diversified pipeline is strategically built with assets that activate the immune system or inhibit key oncogenic drivers across a wide range of modalities, each with the potential to be the best or first in their class.

Our people possess deep scientific expertise, seek innovation openly, and exercise creativity and urgency to deliver on our promise to bring new therapeutic solutions to patients with cancer. Learn more about our Company at www.cullinanoncology.com, and follow us on LinkedIn and Twitter.

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 Cullinan's beliefs and expectations regarding our preclinical and clinical development plans and timelines, clinical trial designs, clinical and therapeutic potential, and strategy of our product candidates; our ability to evaluate strategic opportunities to accelerate development timelines; our ability to optimize the impact of our collaborations and license agreements with external parties; our ability to continue our growth; our expectations regarding our cash runway and use of capital; and our plans regarding future data presentations. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "hope," "intend," "may," "plan," "potential," "predict," "project," "target," "should," "would," 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; 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 Cullinan 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 Oncology, Inc.
Condensed Consolidated Balance Sheets
(unaudited)
(in thousands)

	December 31, 2023	December 31, 2022
Cash, cash equivalents, investments, and interest receivable	$ 468,264	$ 550,118
Total assets	$ 484,182	$ 561,117
Total current liabilities	$ 28,137	$ 22,498
Total liabilities	$ 30,287	$ 26,088
Total stockholders' equity	$ 453,895	$ 535,029
Total liabilities and stockholders' equity	$ 484,182	$ 561,117

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

	Three Months Ended		Twelve Months Ended	
	December 31, 2023	September 30, 2023	December 31, 2023	December 31, 2022
Operating expenses:				
Research and development	$ 34,848	$ 33,821	$ 148,156	$ 91,948
General and administrative	10,637	10,982	42,493	40,189
Total operating expenses	45,485	44,803	190,649	132,137
Impairment of long-lived assets	—	(440)	(440)	-
Gain on sale of Cullinan Pearl	—	—	—	276,785
Income (loss) from operations	(45,485)	(45,243)	(191,089)	144,648
Other income (expense):				
Interest income	5,917	5,880	21,627	6,611
Other income (expense), net	(117)	180	239	57
Net income (loss) before income taxes	(39,685)	(39,183)	(169,223)	151,316
Income tax expense (benefit)	(14,122)	—	(14,122)	42,121
Net income (loss)	(25,563)	(39,183)	(155,101)	109,195
Net loss attributable to noncontrolling interests	(1,760)	—	(1,939)	(2,019)
Net income (loss) attributable to common stockholders of Cullinan	$ (23,803)	$ (39,183)	$ (153,162)	$ 111,214
Net income (loss) per share attributable to common stockholders of Cullinan:				
Basic	$ (0.54)	$ (0.91)	$ (3.69)	$ 2.46
Diluted	$ (0.54)	$ (0.91)	$ (3.69)	$ 2.38
Weighted-average shares used in computing net income (loss) per share attributable to common stockholders of Cullinan:				
Basic	42,794	42,734	41,550	45,164
Diluted	42,794	42,734	41,550	46,640

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