Cullinan Oncology Provides Corporate Update and Reports Second Quarter 2022 Financial Results

August 10, 2022

Completed agreement for strategic collaboration to jointly develop and commercialize CLN-081 with Taiho Pharmaceutical

Presented updated Phase 1/2a data for CLN-081 at the 100mg BID dose showing median duration of response greater than 21 months and median progression-free survival of 12 months at the American Society for Clinical Oncology (ASCO) Annual Meeting

Cash and investments of $656 million[1] as of June 30, 2022 expected to provide runway through 2026.

CAMBRIDGE, Mass., Aug. 10, 2022 (GLOBE NEWSWIRE) -- Cullinan Oncology, Inc. (Nasdaq: CGEM), a biopharmaceutical company focused on developing a diversified pipeline of targeted therapeutic candidates across multiple modalities for patients with cancer, today reported on recent and upcoming business highlights and announced its financial results for the second quarter ended June 30, 2022.

“In the second quarter of 2022, Cullinan Oncology demonstrated significant portfolio advancement, including the closing of our agreement with Taiho Pharmaceutical for CLN-081, an oral presentation for CLN-081 at the American Society of Clinical Oncology (ASCO) 2022 Annual Meeting, and continued progression of our pipeline of potential first-in-class and best-in-class oncology assets. These achievements demonstrate our commitment to creating new standards of care for patients with unmet need,” said Nadim Ahmed, Chief Executive Officer of Cullinan Oncology.

“We are pleased with the continued strengthening of CLN-081’s clinical profile,” Ahmed continued. “Updated data released at ASCO highlighted a high response rate, favorable safety and tolerability, and improving durability of response from the ongoing Phase 1/2a study for patients with EGFR exon 20 insertion mutation non-small-cell lung cancer. Financially, the closing of the Taiho transaction for CLN-081 has extended our cash runway through 2026, giving us the financial flexibility to accelerate and expand the development of our diverse pipeline as well as obtain promising new oncology assets. Looking ahead, we continue to advance our earlier-stage programs, including CLN-619 and CLN-049, with initial Phase 1 data readouts expected by mid-2023, as well as CLN-617 and CLN-978, for which we anticipate IND filings in the first half of next year.”

Portfolio Highlights

- **CLN-081:** In June, Cullinan Oncology completed its strategic agreement with Taiho Pharmaceutical Co., Ltd. (Taiho Pharmaceutical) pursuant to which Cullinan Oncology received a $275 million upfront payment and is eligible to receive an additional $130 million tied to EGFR exon 20 non-small-cell lung cancer regulatory milestones in exchange for selling its equity interest in Cullinan Pearl, which holds worldwide rights to CLN-081 outside of Japan and Greater China. Additionally, Cullinan Oncology entered into an agreement with Taiho Oncology, Inc. (Taiho Oncology), a subsidiary of Taiho Pharmaceutical, to jointly develop and commercialize CLN-081 in the U.S. Pursuant to the co-development agreement, Cullinan Oncology and Taiho Oncology will share equally in the development expenses and future potential U.S. profits and losses for CLN-081.
- Also in June, Cullinan Oncology presented updated data from its ongoing Phase 1/2a clinical study of CLN-081 in an oral presentation at the ASCO 2022 Annual Meeting. The updated data showed a median duration of response greater than 21 months, median progression free survival of 12 months and a confirmed overall response rate of 41% among 39 patients treated at the 100 mg BID dose, along with a continued favorable safety and tolerability profile. In collaboration with its partner, Taiho Oncology, Cullinan Oncology intends to initiate a pivotal study for CLN-081 in the second half of 2022 under the co-development agreement.
- **CLN-049:** Cullinan Oncology continued dosing patients in its first-in-human clinical trial evaluating CLN-049 in patients with relapsed/refractory acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS). Initial clinical data are expected by mid-2023. CLN-049 is a FLT3/CD3-bispecific T cell-engaging antibody in an IgG format for the treatment of AML and MDS. CLN-049 targets the extracellular domain of FLT3, regardless of mutant or wild type FLT3 status.
- **CLN-619:** Cullinan Oncology continued dosing subjects in its first-in-human clinical trial evaluating CLN-619 alone and in combination with pembrolizumab in patients with advanced tumors. Initial clinical data are expected by mid-2023. CLN-619 is a first-in-class monoclonal antibody with broad therapeutic potential across multiple cancer indications. CLN-619 stabilizes expression of MICA/MICB on the tumor cell surface to promote an antitumor response via activation of both natural killer (NK) cells and certain T cells.
- **Preclinical Portfolio:**
  - Cullinan Oncology remains on track for Investigational New Drug (IND) submissions in the first half of 2023 for its two most advanced preclinical programs:
    - CLN-617, a cytokine fusion protein uniquely combining IL-12 and IL-2 with a collagen binding domain designed for retention in the tumor microenvironment (TME) following intratumoral injection, and
    - CLN-978, a novel CD19/CD3-bispecific construct with extended serum half-life and high potency against target cells expressing low levels of CD19.
  - Cullinan Oncology continues to progress its additional 3 preclinical programs, including Jade, Opal, and the HPK1 degrader collaboration with Icahn Mount Sinai.

Second Quarter 2022 Financial Results

- **Cash Position:** Cash and investments were $656 million as of June 30, 2022. During the second quarter of 2022, we received cash proceeds of $270 million from the sale of Cullinan Pearl. The remaining $5 million of the $275 million upfront payment was held in escrow as of June 30 and is expected to be released in the third quarter of 2022. Based on current operating plans, the Company expects that its cash and investments will be sufficient to fund operations through 2026.
- **R&D Expenses:** Research and development (R&D) expenses were $26.4 million for the second quarter of 2022, compared to $24.5 million for the first quarter of 2022. R&D expenses for the second and first quarters of 2022 included $4.4 million and $2.6 million of equity-based compensation expenses, respectively. The increase in R&D expenses is primarily related to expanded clinical activities for CLN-049 and CLN-619 and IND-enabling activities for CLN-617, which were partially offset by a decrease in chemistry, manufacturing, and control activities for CLN-081.
- **G&A Expenses:** General and administrative (G&A) expenses were $10.7 million for the second quarter of 2022, compared to $8.1 million for the first quarter of 2022. G&A expenses in the second and first quarters of 2022 included $4.2 million and $3.8 million of equity-based compensation expenses, respectively. Nonrecurring expenses related to the Cullinan Pearl transaction were $1.7 million in the second quarter and $0.3 million in the first quarter.
- **Gain on sale of Cullinan Pearl:** The Company recognized a gain on the sale of Cullinan Pearl of $276.8 million, which includes the upfront payment of $275 million, as well as the impact of net liabilities transferred to Taiho. As of June 30, 2022, the Company also recognized an income tax liability related to this gain of $46.5 million. The Company estimates the net income tax liability will be reduced to approximately $41 million based on our utilization of net operating losses we anticipate incurring during the remainder of 2022. We expect to make estimated tax payments in an amount equal to 75% of our tax liability in the third quarter of 2022 and the remainder in the fourth quarter of 2022.
- **Net Income:** The Company generated net income (before items attributable to noncontrolling interest) of $174.1 million for the second quarter of 2022 compared to a net loss of $12.9 million for the first quarter of 2022.

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 receipt of escrowed funds related to our transaction with Taiho Pharmaceutical; and our expectations regarding our use of capital. 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 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; risks related to the impact of COVID-19 affecting countries or regions in which we have operations or do business, including potential negative impacts on our employees, customers, supply chain and production as well as global economies and financial markets; 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

(in thousands)

	June 30, 2022	March 31, 2022
	(unaudited)	*(unaudited)*
Cash, cash equivalents, investments, and interest receivable	$ 655,623	$ 410,063
Total assets	**$ 667,249**	**$ 437,463**
Total current liabilities	$ 62,035	$ 17,257
Total liabilities	$ 62,631	$ 17,993
Total stockholders' equity	$ 604,618	$ 419,470
Total liabilities and stockholders' equity	**$ 667,249**	**$ 437,463**

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

	Three Months Ended		Six Months Ended June 30,	
	June 30, 2022	March 31, 2022	2022	2021
	(unaudited)	*(unaudited)*	*(unaudited)*	*(unaudited)*
License revenue	$ —	$ —	$ —	$ 18,943
Operating expenses:				
Research and development	26,411	24,536	50,947	24,193
General and administrative	10,695	8,121	18,816	9,982
Total operating expenses	37,106	32,657	69,763	34,175
Gain on sale of Cullinan Pearl	276,785	—	276,785	—
Income (loss) from operations	239,679	(32,657)	207,022	(15,232)
Other income (expense):				
Interest income	697	197	894	222
Other income (expense), net	(241)	-	(241)	(10)
Net income (loss) before income taxes	240,135	(32,460)	207,675	(15,020)
Income tax expense (benefit)	66,070	(19,568)	46,502	—
Net income (loss)	174,065	(12,892)	161,173	(15,020)
Net income (loss) attributable to noncontrolling interests	(833)	(794)	(1,627)	686
Net income (loss) attributable to common stockholders of Cullinan	$ 174,898	$ (12,098)	$ 162,800	$ (15,706)
Earnings (net loss) per share:				
Basic	$ 3.90	$ (0.27)	$ 3.65	$ (0.37)
Diluted	$ 3.77	$ (0.27)	$ 3.51	$ (0.37)
Weighted-average shares used in computing earnings (net loss) per share:				
Basic	44,873	44,432	44,654	42,713
Diluted	46,381	44,432	46,389	42,713

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[1] Includes cash, cash equivalents, investments, and interest receivable.