Curis Provides Second Quarter 2023 Business Update

Removal of partial clinical hold – enrolling patients at confirmed RP2D in the TakeAim Leukemia Study

Enrolling patients in the TakeAim Lymphoma Study in combination with ibrutinib

Strong balance sheet with $77.4 million in cash and investments; cash runway into 2025

Management to host conference call today at 4:30 p.m. ET

LEXINGTON, Mass., Aug. 3, 2023 /PRNewswire/ -- Curis, Inc. (NASDAQ: CRIS), a biotechnology company focused on the development of emavusertib, an orally available, small molecule IRAK4 inhibitor for the treatment of hematologic malignancies, today reported its business update and financial results for the second quarter ended June 30, 2023.

"We are very pleased with our progress this quarter, as we were able to work with the FDA to remove the partial clinical hold on the TakeAim Leukemia study a quarter ahead of schedule. In that process, we also gained alignment with FDA in confirming 300 mg BID as the RP2D for monotherapy, which we believe is the optimal monotherapy dose. We appreciate the strong support of our clinical investigators during our discussions with FDA and we are excited to expand patient enrollment in the TakeAim Leukemia study at the RP2D," said James Dentzer, President and CEO of Curis.

Second Quarter 2023 and Recent Operational Highlights

Precision Oncology, Emavusertib (IRAK4 Inhibitor)

TakeAim Leukemia

In July, the Company announced that the U.S. Food and Drug Administration (FDA) removed the partial clinical hold on the TakeAim Leukemia Phase 1/2 study of emavusertib. Further, the recommended phase 2 dose (RP2D) for emavusertib as a monotherapy has been confirmed at 300 mg BID in patients with Acute Myelogenous Leukemia (AML) or Myelodysplastic Syndromes (MDS).
The Company is currently enrolling relapsed or refractory (R/R) AML patients with FLT3 mutation or a spliceosome mutation (U2AF1 or SF3B1 mutation) who have received ≤ 2 prior lines of treatment in the monotherapy study.
The Company is also planning a combination study of emavusertib with azacitidine and venetoclax to treat AML patients in the front-line setting.

TakeAim Lymphoma

The Company is focusing its lymphoma clinical development efforts on Primary CNS lymphoma (PCNSL), a rare form of extranodal non-Hodgkin lymphoma for which there are limited treatment options. The Company is currently enrolling pCNSL patients in its TakeAim Lymphoma study in which patients are being treated with a combination of emavusertib and ibrutinib.

Upcoming Milestones

We expect updated clinical data in both the monotherapy and combination studies in 2024.

Corporate

In July 2023, the Company completed a registered direct offering with net proceeds of approximately $13.8 million.

First Quarter 2023 Financial Results

For the second quarter of 2023, Curis reported a net loss of $12.0 million or $0.12 per share on both a basic and diluted basis as compared to $15.9 million or $0.17 per share on both a basic and diluted basis, for the same period in 2022. Curis reported a net loss of $23.5 million or $0.24 per share on both a basic and diluted basis, for the six months ended June 30, 2023 as compared to a net loss of $32.0 million or $0.35 per share on both a basic and diluted basis for the same period in 2022.

Revenues for the first quarter of 2023 were $2.2 million as compared to $2.4 million for the same period in 2022. Revenues for both periods consist of royalty revenues from Genentech's and Roche's sales of Erivedge®. Revenues for the six months ended June 30, 2023 and 2022 were both $4.5 million.

Research and development expenses were $10.0 million for the second quarter of 2023, as compared to $12.3 million for the same period in 2022. The decrease was primarily attributable to lower employee related costs due to a reduction in headcount. Research and development expenses were $19.2 million for the six months ended June 30, 2023, as compared to $23.8 million for the same period in 2022.

General and administrative expenses were $4.2 million for the second quarter of 2023, as compared to $5.1 million for the same period in 2022. The decrease was mainly attributable to lower employee related costs due to a reduction in headcount. General and administrative expenses were $9.0 million for the six months ended June 30, 2023, as compared to $10.8 million for the same period in 2022.

Other income, net was $0.2 million for the second quarter of 2023, as compared to other expense, net of $0.9 million for the same period in 2022. Other income (expense), net primarily consisted of interest income partially offset by expense related to future royalty payments. Other income, net was $0.2 million for the six months ended June 30, 2023 compared to other expense, net $1.9 million for the same period in 2022.

Including the impact of the July Registered Direct offering, Curis's cash, cash equivalents and investments totaled $77.4 million, and the Company had approximately 117.7 million shares of common stock outstanding. Curis expects its existing cash, cash equivalents and investments should enable it to maintain its planned operations into 2025.

Conference Call Information

Curis management will host a conference call today, August 3, 2023, at 4:30 p.m. ET, to discuss the business update and these financial results.

To access the live conference call, please dial 1-888-346-6389 from the United States or 1-412-317-5252 from other locations, shortly before 4:30 p.m. ET. The conference call can also be accessed on the Curis website in the Investors section.

About Curis, Inc.

Curis is a biotechnology company focused on the development of emavusertib, an orally available, small molecule IRAK4 inhibitor for the treatment of hematologic malignancies. In 2015, Curis entered into a collaboration with Aurigene in the areas of immuno-oncology and precision oncology. As part of this collaboration, Curis has exclusive licenses to oral small molecule antagonists of immune checkpoints including the VISTA/PDL1 antagonist CA-170, and the TIM3/PDL1 antagonist CA-327, as well as the IRAK4 kinase inhibitor, emavusertib (CA-4948). Emavusertib is currently undergoing testing in the Phase 1/2 TakeAim Lymphoma study in patients with hematologic malignancies, such as non-Hodgkin's lymphoma and other B cell malignancies both as a monotherapy and in combination with the BTK inhibitor ibrutinib, and the Phase 1/2 TakeAim Leukemia study in patients with acute myeloid leukemia and myelodysplastic syndrome, for which it has received Orphan Drug Designation from the U.S. Food and Drug Administration. In addition, Curis is engaged in a collaboration with ImmuNext for development of CI-8993, a monoclonal anti-VISTA antibody. Curis is also party to a collaboration with Genentech, a member of the Roche Group, under which Genentech and Roche are commercializing Erivedge® for the treatment of advanced basal cell carcinoma. For more information, visit Curis's website at www.curis.com.

Cautionary Note Regarding Forward-Looking Statements:

This press release contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, including, without limitation, any statements with respect to Curis's plans, strategies and objectives, cash runway, statements concerning product research, development, clinical trials and studies and commercialization plans, timelines, anticipated results or the therapeutic potential of drug candidates including any statements regarding the initiation, progression, expansion, use, safety, efficacy, dosage and potential benefits of emavusertib in clinical trials as a monotherapy and/or as a combination therapy, the progression, use and potential benefits of CI-8993, Curis's plans and timelines to provide preliminary, interim and/or additional data from its ongoing or planned clinical trials, its ability to further patient enrollment in its TakeAim Leukemia and TakeAim Lymphoma studies, any statements concerning Curis's expectations regarding its interactions with the FDA, statements with respect to mutations or potential biomarkers, and statements of assumptions underlying any of the foregoing. Forward-looking statements may contain the words "believes," "expects," "anticipates," "plans," "intends," "seeks," "estimates," "assumes," "predicts," "projects," "targets," "will," "may," "would," "could," "should," "continue," "potential," "focus," "strategy," "mission," or similar expressions. These forward-looking statements are not guarantees of future performance and involve risks, uncertainties, assumptions and other important factors that may cause actual results to be materially different from those indicated by such forward-looking statements. For example, the FDA may take further regulatory action with regard to Curis's clinical trials. Curis may experience adverse results, delays and/or failures in its drug development programs and may not be able to successfully advance the development of its drug candidates in the time frames it projects, if at all. Curis's drug candidates may cause unexpected toxicities, fail to demonstrate sufficient safety and efficacy in clinical studies and/or may never achieve the requisite regulatory approvals needed for commercialization. Favorable results seen in preclinical studies and early clinical trials of Curis's drug candidates may not be replicated in later trials. There can be no guarantee that the collaboration agreements with Aurigene and ImmuNext will continue for their full terms, or the CRADA with NCI, that Curis or its collaborators will each maintain the financial and other resources necessary to continue financing its portion of the research, development and commercialization costs, or that the parties will successfully discover, develop or commercialize drug candidates under the collaboration. Regulatory authorities may determine to delay or restrict Genentech's and/or Roche's ability to continue to commercialize Erivedge in basal cell carcinoma. Competing drugs may be developed that are superior to Erivedge. In connection with its agreement with Oberland Capital, Curis faces risks relating to the transfer and encumbrance of certain royalty and royalty-related payments on commercial sales of Erivedge, including the risk that, in the event of a default by

Curis or its wholly-owned subsidiary, Curis could lose all retained rights to future royalty and royalty-related payments, Curis could be required to repurchase such future royalty and royalty-related payments at a price that is a multiple of the payments it has received, and its ability to enter into future arrangements may be inhibited, all of which could have a material adverse effect on its business, financial condition and stock price. Curis will require substantial additional capital to fund its business. If it is not able to obtain sufficient funding, it will be forced to delay, reduce in scope or eliminate some of its research and development programs, including related clinical trials and operating expenses, potentially delaying the time to market for, or preventing the marketing of, any of its product candidates, which could adversely affect its business prospects and its ability to continue operations, and would have a negative impact on its financial condition and its ability to pursue its business strategies. Curis faces substantial competition. Curis and its collaborators face the risk of potential adverse decisions made by the FDA and other regulatory authorities, investigational review boards, and publication review bodies. Curis may not obtain or maintain necessary patent protection and could become involved in expensive and time-consuming patent litigation and interference proceedings. Unstable market and economic conditions, natural disasters, public health crises, political crises and other events outside of Curis's control could significantly disrupt its operations or the operations of third parties on which Curis depends and could adversely impact Curis's operating results and its ability to raise capital. Other important factors that may cause or contribute to actual results being materially different from those indicated by forward-looking statements include the factors set forth under the captions "Risk Factor Summary" and "Risk Factors" in our most recent Form 10-K and Form 10-Q, and the factors that are discussed in other filings that we periodically make with the Securities and Exchange Commission. In addition, any forward-looking statements represent the views of Curis only as of today and should not be relied upon as representing Curis's views as of any subsequent date. Curis disclaims any intention or obligation to update any of the forward-looking statements after the date of this press release whether as a result of new information, future events or otherwise, except as may be required by law.

CURIS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(UNAUDITED)
(In thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenues, net:	$ 2,197	$ 2,393	$ 4,494	$ 4,450
Costs and expenses:				
Cost of royalty revenues	74	42	98	124
Research and development	10,012	12,323	19,152	23,758
General and administrative	4,249	5,089	9,009	10,762
Total costs and expenses	14,335	17,454	28,259	34,644
Loss from operations	(12,138)	(15,061)	(23,765)	(30,194)
Other income (expense), net	177	(879)	245	(1,855)
Net loss	$ (11,961)	$ (15,940)	$ (23,520)	$ (32,049)
Net loss per common share (basic and diluted)	$ (0.12)	$ (0.17)	$ (0.24)	$ (0.35)
Weighted average common shares (basic and diluted)	96,685,924	91,650,950	96,649,934	91,648,175

CURIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)
(In thousands)

	June 30, 2023	December 31, 2022
ASSETS		
Cash, cash equivalents and investments	$ 63,487	$ 85,623
Restricted cash	635	635
Accounts receivable	2,386	2,975
Prepaid expenses and other assets	4,517	5,543
Property and equipment, net	561	689
Operating lease right-of-use asset	3,740	4,401

Goodwill	8,982	8,982
Total assets	$ 84,308	$ 108,848

LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued liabilities and other liabilities	$ 8,462	$ 8,872
Operating lease liability	3,384	3,941
Liability related to the sale of future royalties, net	46,238	49,483
Total liabilities	58,084	62,296
Total stockholders' equity	26,224	46,552
Total liabilities and stockholders' equity	$ 84,308	$ 108,848

SOURCE Curis, Inc.

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