Curis Provides First Quarter 2023 Business Update

Company expects to discuss lifting of partial clinical hold on emavusertib with FDA in Q3

Curis strengthens executive team with appointment of industry veteran Jonathan Zung, Ph.D. as Chief Development Officer

Strong balance sheet with $71.8 million in cash and investments; cash runway into 2025

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

LEXINGTON, Mass., May 4, 2023 /PRNewswire/ -- Curis, Inc. (NASDAQ: CRIS), a biotechnology company focused on the development of innovative therapeutics for the treatment of cancer, today reported its business update and financial results for the first quarter ended March 31, 2023.

"I am pleased with our progress in the TakeAim leukemia study. We enrolled the additional patients requested by FDA ahead of schedule in the first quarter – which is indicative of both the clear unmet need in leukemia and the excitement among the clinical community for this novel agent. We are on track to collect data from these patients in the second quarter and discuss these data with the FDA in the third quarter of this year. I am also pleased to announce the expansion of the Curis Executive Team with the addition of Jonathan Zung, Ph.D. as our Chief Development Officer. Dr. Zung is a well-respected leader in the industry and brings a wealth of experience from senior roles across the industry, most recently at Evelo. We look forward to his contributions toward our mission at Curis," said James Dentzer, President and CEO of Curis.

"I am excited to be joining the Curis team during this critical time, as the company advances its first-in-class IRAK4 inhibitor, emavusertib. In biotech, it is rare to find a novel target with such broad therapeutic potential in that exciting period between the initial demonstration of clear single agent activity and the final stage of clinical development. I look forward to working with the Curis team on the clinical development of emavusertib and helping to establish it as a cornerstone therapy in hematologic malignancies," said Dr. Zung.

First Quarter 2023 and Recent Operational Highlights

Appointed new CDO

Dr. Zung was appointed as Chief Development Officer of Curis on May 1, 2023. Prior to joining Curis, he served as CDO of Evelo Biosciences, where he was responsible for the operational design and execution of Evelo's clinical programs. Dr. Zung held previous leadership roles at WCG, Covance, UCB, Bristol Myers Squibb, and Pfizer. He also serves on the advisory board of Saama Technologies. He received his Ph.D. in analytical chemistry from Emory University.

Upcoming Milestones

- Curis completed the enrollment of 9 additional patients at the 200mg BID dose level requested by FDA, is collecting data on those patients in the second quarter, and expects to discuss those data with FDA in the third quarter of 2023. Discussions with the FDA are expected to determine the recommended Phase 2 dose and resolution of the partial clinical hold on emavusertib development in leukemia.

First Quarter 2023 Financial Results

For the first quarter of 2023, Curis reported a net loss of $11.6 million or $0.12 per share on both a basic and diluted basis as compared to $16.1 million or $0.18 per share on both a basic and diluted basis, for the same period in 2022.

Revenues for the first quarter of 2023 were $2.3 million as compared to $2.1 million for the same period in 2022. Revenues for both periods consist of royalty revenues from Genentech's and Roche's sales of Erivedge®.

Research and development expenses were $9.1 million for the first quarter of 2023, as compared to $11.4 million for the same period in 2022. The decrease is primarily attributable to the timing of manufacturing costs and lower employee related costs due to a reduction in headcount.

General and administrative expenses were $4.8 million for the first quarter of 2023, as compared to $5.7 million for the same period in 2022. The decrease was mainly attributable to lower employee related costs due to a reduction in headcount.

Other income, net was $0.1 million for the first quarter of 2023, as compared to other expense, net of $1.0

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.

As of March 31, 2023, Curis's cash, cash equivalents and investments totaled $71.8 million, and the Company had approximately 96.6 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, May 4, 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 innovative therapeutics for the treatment of cancer. 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 trial in patients with hematologic malignancies, such as non-Hodgkin's lymphoma and other B cell malignancies, both as a monotherapy and in combination with BTK inhibitor ibrutinib, and the Phase 1/2 TakeAim Leukemia trial 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. The FDA has placed a partial clinical hold on the TakeAim Leukemia trial during which no new patients will be enrolled in the monotherapy expansion phase (Phase 2a) or the combination phase (Phase 1b) of emavusertib with azacitidine or venetoclax. 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 resume and further patient enrollment in its TakeAim Lymphoma trial and in the monotherapy dose escalation phase (Phase 1a) of the TakeAim Leukemia trial, its ability to resolve the remaining partial clinical hold on the monotherapy expansion phase (Phase 2a) and the combination therapy phase (Phase 1b) of the TakeAim Leukemia study, 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 not remove the remaining partial clinical hold on the monotherapy expansion phase (Phase 2a) and the combination therapy phase (Phase 1b) of the TakeAim Leukemia trial or may take further regulatory action with regard to such trial. 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 (BCC). 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 fourth parties on which Curis depends and could adversely impact Curis's operating results and its ability to raise capital. For example, the periodic COVID-19 resurgence may result in closures of third-party facilities, impact enrollment in clinical trials or impact sales of Erivedge by Genentech and/or Roche. 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 ("SEC"). 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 March 31,	
	2023	**2022**
Revenues, net:	$ 2,297	$ 2,057
Costs and expenses:		
Cost of royalty revenues	24	82
Research and development	9,140	11,435
General and administrative	4,760	5,673
Total costs and expenses	13,924	17,190
Loss from operations	(11,627)	(15,133)
Other income (expense), net:	68	(976)
Net loss	$ (11,559)	$ (16,109)
Net loss per common share (basic and diluted)	$ (0.12)	$ (0.18)
Weighted average common shares (basic and diluted)	96,613,544	91,645,369

CURIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)

(In thousands)

	March 31, 2023	December 31, 2022
ASSETS		
Cash, cash equivalents and investments	$ 71,759	$ 85,623
Restricted cash	635	635
Accounts receivable	2,314	2,975
Property and equipment, net	625	689
Operating lease right-of-use asset	4,076	4,401
Goodwill	8,982	8,982
Prepaid expenses and other assets	6,153	5,543
Total assets	$ 94,544	$ 108,848
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued liabilities and other liabilities	$ 6,888	$ 8,872
Operating lease liability	3,673	3,941
Liability related to the sale of future royalties, net	47,393	49,483
Total liabilities	57,954	62,296
Total stockholders' equity	36,590	46,552
Total liabilities and stockholders' equity	$ 94,544	$ 108,848

SOURCE Curis, Inc.

For further information: For further information: Investor Relations, Stephanie Ascher, Stern Investor Relations, Inc., (212) 362-1200, stephanie.ascher@sternir.com

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