Curis Provides Fourth Quarter 2023 Business Update

Emavusertib data presented at ASH showed 3 of 5 patients achieved CR in R/R PCNSL

Expansion of clinical sites in US and Europe in progress

Cash runway into 2025

Management to host conference call today at 8:30 a.m. ET

LEXINGTON, Mass., Feb. 8, 2024 /PRNewswire/ -- Curis, Inc. (NASDAQ: CRIS), a biotechnology company focused on the development of emavusertib (CA-4948), an orally available, small molecule IRAK4 inhibitor, today reported its business update and financial results for the quarter ended December 31, 2023.

Operational Highlights

In December at the 65th American Society of Hematology Annual Meeting and Exposition (ASH), the Company presented data from both the TakeAim Lymphoma and TakeAim Leukemia studies. A summary of key findings of the data that were presented from the on-going studies are as follows:

- TakeAim Lymphoma – data for patients with primary CNS lymphoma (PCNSL) who had failed prior BTKi therapy showed 3 of 5 evaluable patients achieved Complete Response (CR).
- TakeAim Leukemia – data for patients with relapsed/refractory (R/R) AML with a FLT3 mutation who received < 3 prior lines of treatment showed 2 of 3 patients achieved CR and the 3rd patient achieved Morphological Leukemia Free State (MLFS).

In addition to the presentations at ASH, Curis announced in December that it had entered into an agreement for an Investigator-Initiated Trial to study the combination of emavusertib and pembrolizumab in patients with metastatic melanoma. In this study, Curis will be responsible for the supply of emavusertib and Merck will be responsible for the supply of pembrolizumab and clinical study costs.

"The R/R PCNSL data presented at ASH highlight the potential of emavusertib in combination with ibrutinib to address a critical unmet need, for a patient population with no approved treatments, and achieve CR in patients who have failed prior BTKi therapy. The R/R AML FLT3 data highlight emavusertib's potential to provide targeted anti-cancer activity as a monotherapy. We have also begun working with clinical investigators to initiate a Phase 1 clinical study of emavusertib as an add-on agent to the combination of azacitidine and venetoclax in the front-line setting. Finally, the study evaluating emavusertib and pembrolizumab in metastatic melanoma will explore the potential of emavusertib and IRAK4 inhibition in solid tumors," said James Dentzer, President and Chief Executive Officer of Curis. "We are encouraged by the reaction of the clinical community to the data released at ASH and are working to open additional clinical sites in the US and Europe for both the TakeAim Leukemia and Lymphoma studies."

Upcoming Milestones

- TakeAim Leukemia – updated clinical data from the on-going monotherapy study in the first half of 2024.
- TakeAim Lymphoma – updated clinical data from the on-going combination study of emavusertib with ibrutinib in the second half of 2024.
- Curis expects initial clinical data from the recently initiated triplet combination study of emavusertib with azacitidine and venetoclax to treat AML patients in the second half of 2024.

Fourth Quarter 2023 Financial Results

For the year ended December 31, 2023, Curis reported a net loss of $47.4 million, or $8.96 per share on both a basic and diluted basis, as compared to a net loss of $56.7 million, or $12.14 per share on both a basic and diluted basis in 2022. For the fourth quarter of 2023, Curis reported a net loss of $11.7 million or $2.03 per share on both a basic and diluted basis as compared to a net loss of $11.3 million or $2.35 per share on both a basic and diluted basis for the same period in 2022.

Revenues, net for the year ended December 31, 2023, were $10.0 million as compared to $10.2 million for the same period in 2022. Revenues for both periods comprise primarily royalty revenues related to Genentech and Roche's net sales of Erivedge®. Revenues for the fourth quarters of 2023 and 2022 were $2.7 million and $2.9 million, respectively.

Cost of royalties, which relate to third-party university patent licensors in connection with Genentech and Roche's Erivedge net sales, for the year ended December 31, 2023, were $0.2 million compared to $0.3 million for the same period in 2022. Cost of royalties for the fourth quarters of 2023 and 2022 were $0.1 million for both periods.

Research and development expenses were $39.5 million for the year ended December 31, 2023, as compared to $43.3 million for the same period in 2022. The decrease was primarily attributable to lower employee-related costs due to reduced headcount. Research and development expenses were $10.0 million and $8.7 million for the fourth quarters of 2023 and 2022, respectively.

General and administrative expenses were $18.6 million for the year ended December 31, 2023, as compared to $19.6 million for the same period in 2022. The decrease was primarily attributable to lower employee-related costs due to reduced headcount. General and administrative expenses were $4.9 million and $4.3 million for the fourth quarters of 2023 and 2022, respectively.

Other income, net was $0.9 million for the year ended December 31, 2023, as compared to other expense, net of $3.7 million for the same period in 2022. The increase was attributable to an increase in interest income and a decrease in the non-cash expense related to the sale of future royalties. Other income, net was $0.5 million for the fourth quarter of 2023 as compared to other expense, net of $1.1 million for the same period in 2022.

As of December 31, 2023, Curis's cash, cash equivalents and investments totaled $56.3 million, and the Company had approximately 5.9 million shares of common stock outstanding. Curis expects its existing cash, cash equivalents and investments should enable its planned operations into 2025.

Conference Call Information

Curis management will host a conference call today, February 8, 2024, at 8:30 a.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 8:30 a.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. Emavusertib is currently undergoing testing in the Phase 1/2 TakeAim Lymphoma study in patients with relapsed/refractory primary central nervous system lymphoma (PCNSL) in combination with the BTK inhibitor ibrutinib, as a monotherapy in the Phase 1/2 TakeAim Leukemia study in patients with relapsed/refractory acute myeloid leukemia (AML) and relapsed/refractory high risk myelodysplastic syndrome (hrMDS), for which it has received Orphan Drug Designation from the U.S. Food and Drug Administration and as a frontline combination therapy with azacitidine and venetoclax in patents with AML. Curis, through its 2015 collaboration with Aurigene, has the exclusive license to emavusertib (CA-4948). Curis licensed its rights to Erivedge® to Genentech, a member of the Roche Group, under which they 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, commercialization plans, timelines, anticipated results or the therapeutic potential of emavusertib, 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, its 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 Lymphoma and TakeAim Leukemia studies as well as initiate and enroll patients in its AML triplet 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. 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. Curis depends heavily on the success of emavusertib and any delays in the development of emavusertib could have a material adverse effect on its business. There can be no guarantee that the collaboration agreement with Aurigene will continue for its full term, 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. Based on its available cash resources, it does not have sufficient cash on hand to support current operations within the next 12 months from the date of this press release. If it is not able to obtain sufficient funding, it will be forced to delay, reduce in scope or eliminate its development of emavusertib, including related clinical trials and operating expenses, potentially delaying the time to market for, or preventing the marketing of, emavusertib, 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 December 31,		Twelve Months Ended December 31,	
	2023	2022	2023	2022
Revenues, net	2,696	2,887	10,023	10,162
Operating expenses:				
Cost of royalties	54	71	212	257
Research and development	9,964	8,706	39,496	43,277
General and administrative	4,877	4,330	18,647	19,648
Total operating expenses	14,895	13,107	58,355	63,182
Loss from operations	(12,199)	(10,220)	(48,332)	(53,020)
Total other income (expense)	487	(1,109)	919	(3,652)
Net loss	$ (11,712)	$ (11,329)	$ (47,413)	$ (56,672)
Net loss per common share (basic and diluted)	$ (2.03)	$ (2.35)	$ (8.96)	$ (12.14)
Weighted average common shares (basic and diluted)	5,772,201	4,821,283	5,293,294	4,669,626

CURIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)
(In thousands)

	December 31, 2023	December 31, 2022
ASSETS		
Cash, cash equivalents and investments	$ 56,334	$ 85,623
Restricted cash	544	635

Accounts receivable		2,794		2,975
Prepaid expenses and other assets		5,138		5,543
Property and equipment, net		434		689
Operating lease right-of-use asset		3,056		4,401
Goodwill		8,982		8,982
Total assets	$	77,282	$	108,848
LIABILITIES AND STOCKHOLDERS' EQUITY				
Accounts payable and accrued liabilities	$	12,212	$	8,872
Operating lease liability		2,794		3,941
Liability related to the sale of future royalties, net		42,606		49,483
Total liabilities		57,612		62,296
Total stockholders' equity		19,670		46,552
Total liabilities and stockholders' equity	$	77,282	$	108,848

SOURCE Curis, Inc.

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https://investors.curis.com/2024-02-08-Curis-Provides-Fourth-Quarter-2023-Business-Update