Curis Provides First Quarter 2024 Business Update

Management to host conference call today at8:30 a.m. ET

LEXINGTON, Mass., May 7, 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 first quarter ended March 31, 2024.

Operational Highlights

The Company will release a topline update of clinical data from the ongoing TakeAim Leukemia study of emavusertib monotherapy in patients with relapsed or refractory (R/R) Acute Myeloid Leukemia (AML), including separate readouts for the FLT3 mutation (mFLT3) and Splicing Factor mutation (mSF) cohorts, on Tuesday, May 14, 2024, in connection with the publication of accepted abstracts for the 2024 European Hematology Association (EHA) Conference.

"We are very pleased to have several opportunities to present additional patient data in R/R AML patients with a targeted mutation (mFLT3 or mSF), as well as progress updates for our R/R PCNSL and AML frontline triplet studies, at these prestigious oncology meetings," said James Dentzer, President and CEO of Curis.

Upcoming Presentations

At the upcoming ASCO and EHA conferences, Curis will update its current dataset of 5 targeted patients with R/R AML (3 mFLT3, 3 mSF – including 1 patient with both a FLT3 and SF mutation who is included in both populations). The clinical update will include data for 25 new patients, bringing the total to 30 targeted patients with R/R AML treated with emavusertib as a monotherapy. The mutation status for the 30 patients is: 12 mFLT3, 20 mSF – including 2 patients with both a FLT3 and SF mutation who are included in both populations.

The following abstracts have been accepted for poster presentation at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago (May 31 - June 4):

TakeAim Leukemia

Preliminary safety, efficacy and molecular characterization of emavusertib (CA-4948) in patients with relapsed/refractory (R/R) acute myeloid leukemia (AML) with FLT3 mutation (FLT3m).
Predictive biomarkers of response to the IRAK4/FLT3 inhibitor emavusertib in hematological malignancies.

TakeAim Lymphoma

Emavusertib (CA-4948) in combination with ibrutinib in patients with relapsed/refractory primary central nervous system lymphoma (R/R PCNSL).

AML Triplet

A phase 1 single-arm, open-label study of emavusertib (CA-4948) in combination with azacitidine and venetoclax in patients (pts) with acute myeloid leukemia (AML) in complete response (CR) with measurable residual disease (MRD).

The following abstract has been accepted for poster presentation at the 2024 European Hematology Association (EHA) Hybrid Conference in Madrid (June 13 - 16):

TakeAim Leukemia

Preliminary safety, efficacy and molecular characterization relapsed/refractory acute myeloid leukemia patients with a FLT3 mutation treated with single agent emavusertib (CA-4948).

Upcoming Milestones

TakeAim Leukemia – updated clinical data from the on-going combination study of emavusertib monotherapy in patients with R/R AML in mid-year 2024 (at ASCO and EHA later this quarter).
TakeAim Lymphoma – updated clinical data from the on-going combination study of emavusertib with ibrutinib in patients with R/R PCNSL in late 2024.
Initial safety data from the frontline triplet combination study of emavusertib with azacitidine and venetoclax in patients with AML in late 2024.

First Quarter 2024 Financial Results

For the first quarter of 2024, Curis reported a net loss of $11.9 million or $2.05 per share on both a basic and diluted basis as compared to $11.6 million or $2.39 per share on both a basic and diluted basis, for the same period in 2023.

Revenues for the first quarter of 2024 were $2.1 million as compared to $2.3 million for the same period in 2023. Revenues for both periods consist of royalty revenues from Genentech/Roche's sales of Erivedge®.

Research and development expenses were $9.6 million for the first quarter of 2024, as compared to $9.1 million for the same period in 2023. The increase was primarily attributable to higher employee-related costs.

General and administrative expenses were $4.9 million for the first quarter of 2024, as compared to $4.8 million for the same period in 2023.

Other income, net was $0.6 million for the first quarter of 2024, as compared to $0.1 million for the same period in 2023. The increase was primarily attributable to a decrease in the non-cash expense related to the sale of future royalties.

Curis's cash, cash equivalents and investments totaled $40.7 million as of March 31, 2024, and the Company had approximately 5.9 million shares of common stock outstanding. Curis expects its existing cash, cash equivalents and investments will enable its planned operations into 2025.

Conference Call Information

Curis management will host a conference call today, May 7, 2024, at 8:30 a.m. ET, to discuss the business update and these financial results.

To access the live conference call, please dial 800-836-8184 from the United States or 1-646-357-8785 from other locations, or login to https://app.webinar.net/0aEy7XK4DOY 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) with either a FLT3 mutation or a splicing factor mutation (U2AF1 or SF3B2), and as a frontline combination therapy with azacitidine and venetoclax in patents with AML. Emavusertib has received Orphan Drug Designation from the U.S. Food and Drug Administration for the treatment of AML and MDS. 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 March 31,	
	2024	**2023**
Revenues, net	$ 2,086	$ 2,297
Operating expenses:		
Cost of royalties	47	24
Research and development	9,617	9,140
General and administrative	4,891	4,760
Total operating expenses	14,555	13,924
Loss from operations	(12,469)	(11,627)
Total other income	593	68
Net loss	$ (11,876)	$ (11,559)
Net loss per common share (basic and diluted)	$ (2.05)	$ (2.39)
Weighted average common shares (basic and diluted)	5,783,585	4,830,763

CURIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)
(In thousands)

	March 31, 2024	**December 31, 2023**
ASSETS		
Cash, cash equivalents and investments	$ 40,720	$ 56,334

Restricted cash	544	544
Accounts receivable	2,154	2,794
Prepaid expenses and other assets	6,550	5,138
Property and equipment, net	370	434
Operating lease right-of-use asset	2,704	3,056
Goodwill	8,982	8,982
Total assets	$ 62,024	$ 77,282

LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable and accrued liabilities	$ 9,954	$ 12,212
Operating lease liability	2,486	2,794
Liability related to the sale of future royalties, net	40,122	42,606
Total liabilities	52,562	57,612
Total stockholders' equity	9,462	19,670
Total liabilities and stockholders' equity	$ 62,024	$ 77,282

SOURCE Curis, Inc.

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