Curis Provides First Quarter 2025 Business Update

Curis strengthens executive team with the appointment of industry veteran Dr.Ahmed Hamdy as Chief Medical Officer

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

LEXINGTON, Mass., May 6, 2025 /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, 2025.

"I am pleased to announce the expansion of the Curis Executive Team with the addition of DrAhmed Hamdy as our Chief Medical Officer. Dr. Hamdy is a well-known and respected leader in the industry and brings a wealth of experience as CMO of Pharmacyclics, CMO and CEO of Acerta, and CEO of Vincerx. We look forward to his contributions to Curis."

"Also, as we announced at the end of March, we have made exciting progress with both the FDA and EMA on the potential for accelerated approval of emavusertib in R/R PCNSL. We are currently enrolling patients in the TakeAim Lymphoma study to enable accelerated approval filings in both the EU and US. We expect to provide additional data for both BTK-naïve and BTK-experienced patients from the TakeAim Lymphoma study at ASH later this year," said James Dentzer, President and CEO of Curis.

"Curis has made great progress developing IRAK4 as a novel oncology target and emavusertib as the first-in-class IRAK4 inhibitor. I am excited to be joining the Curis team at this critical time of advancement toward regulatory filing in PCNSL in the US and EU and expansion beyond PCNSL into additional indications in NHL, AML, and solid tumors. Given my experience developing both ibrutinib and acalabrutinib, I have a special appreciation for the potential of emavusertib in combination with BTK inhibition in NHL, and the importance of targeting IRAK4 and the toll-like receptor pathway in NHL, AML and solid tumors. I look forward to working with the Curis Team to bring this novel therapy to patients," said Dr. Hamdy.

Operational Highlights

TakeAim Lymphoma

- Successfully concluded meetings with both the U.S. Food and Drug Administration (FDA) and the Committee for Medicinal Products for Human Use of the European Medicines Agency (EMA) on the suitability of using the ongoing TakeAim Lymphoma study (NCT 03328078) to support a potential accelerated approval path in PCNSL.
- Announced emavusertib had been granted Orphan Drug Designation for PCNSL in both the U.S. and Europe.
- Provided data update for 27 patients enrolled in the ongoing TakeAim Lymphoma study in relapsed/refractory (R/R) PCNSL, 20 BTK-experienced patients and 7 BTK-naïve patients.

Ema-Ven-Aza Triplet Study in Frontline AML

- Announced successful completion of the first dosing cohort and the commencement of dosing in the second cohort. Enrollment is currently ongoing.

Corporate

- Completed a registered direct offering and concurrent private placement with net proceeds of approximately $8.8 million.

First Quarter 2025 Financial Results

For the first quarter of 2025, Curis reported a net loss of $10.6 million or $1.25 per share on both a basic and diluted basis as compared to $11.9 million or $2.05 per share on both a basic and diluted basis for the same period in 2024.

Revenues for the first quarter of 2025 were $2.4 million, as compared to $2.1 million for the same period in 2024. Revenues for both periods consist of royalty revenues from Genentech/Roche's sales of Erivedge®.

Research and development expenses were $8.5 million for the first quarter of 2025, as compared to $9.6 million for the same period in 2024. The decrease was primarily attributable to lower employee related costs.

General and administrative expenses were $4.0 million for the first quarter of 2025, as compared to $4.9 million for the same period in 2024. The decrease was primarily attributable to lower employee related and professional, legal and consulting costs.

Other expense, net was $0.5 million for the first quarter of 2025, as compared to other income, net of $0.6 million for the same period in 2024. The decrease was primarily attributable to an increase in the expense related to the sale of future royalties and a decrease in interest income.

Curis's cash and cash equivalents totaled $20.3 million as of March 31, 2025, and the Company had approximately 10.5 million shares of common stock outstanding. Curis expects its existing cash and cash equivalents will enable its planned operations into the fourth quarter of 2025.

Conference Call Information

Curis management will host a conference call today, May 6, 2025, at 8:30 a.m. ET, to discuss the business update and these financial results.

To access the live conference call, please dial 1-800-836-8184 from the United States or 1-646-357-8785 from other locations, or login here shortly before 8:30 a.m. ET. The conference call can also be accessed on the Curis website at the Events and Presentations section of the Investors page.

About Curis, Inc.

Curis is a biotechnology company focused on the development of emavusertib, an orally available, small molecule IRAK4 inhibitor. Emavusertib is currently being evaluated in the TakeAim Lymphoma Phase 1/2 study (CA-4948-101) in patients with relapsed/refractory primary central nervous system lymphoma (PCNSL) in combination with the BTK inhibitor ibrutinib, as a monotherapy in the TakeAim Leukemia Phase 1/2 study (CA-4948-102) in patients with relapsed/refractory acute myeloid leukemia (AML) and relapsed/refractory high risk myelodysplastic syndrome (hrMDS), and as a frontline combination therapy with venetoclax and azacitidine in patents with AML (CA-4948-104). Emavusertib has received Orphan Drug Designation from the U.S. Food and Drug Administration for the treatment of PCNSL, AML and MDS and from the European Commission for the treatment of PCNSL. 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, expectations and anticipated benefits of Dr. Hamdy's experience and services; statements concerning the regulatory guidance on potential Conditional Marketing Authorization (CMA) from the EMA and potential NDA for Accelerated Approval from the FDA for emavusertib in the treatment of PCNSL, and Curis's expectations with respect to regulatory objectives; Curis's expectations with respect to enrollment of BTKi naïve and BTKi experienced populations in the TakeAim Lymphoma study; statements regarding updated PCNSL data and the timing of such data from the TakeAim Lymphoma study, the potential use thereof for regulatory submissions to support CMA and/or Accelerated Approval, and the therapeutic potential and tolerability of emavusertib in patients with PCNSL; statements concerning research, development, clinical trials and commercialization plans, timelines, anticipated results, use, safety, efficacy, rates and duration of responses, mutations or potential biomarkers, and potential benefits of emavusertib as a monotherapy and/or as a combination therapy; statements regarding Curis's anticipated cash runway; 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," "likelihood", "continue," "potential," "opportunity," "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. Notably, Curis may not achieve its project timeline to fully enroll patients and submit regulatory filings for emavusertib within the next 18-24 months, and the safety and efficacy data results from the TakeAim Lymphoma study of emavusertib in PCNSL may not be sufficient for Curis to successfully achieve conditional marketing authorization from the EMA or accelerated approval from the FDA for emavusertib. Favorable results seen in preclinical studies and early clinical trials of Curis's drug candidates may not be replicated in later trials. Curis is dependent 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. Curis will require substantial additional funding in the immediate term to fund the development of emavusertib through regulatory approval and commercialization, and to support its continued operations. If it is not able to obtain sufficient funding, it will be forced to delay, reduce in scope or eliminate the development 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, EMA 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 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,	
	2025	**2024**
Revenues, net	$ 2,380	$ 2,086
Operating expenses:		
Cost of royalties	14	47
Research and development	8,539	9,617
General and administrative	3,984	4,891
Total operating expenses	12,537	14,555
Loss from operations	(10,157)	(12,469)
Total other income (expense)	(459)	593
Net loss	$ (10,616)	$ (11,876)
Net loss per common share (basic and diluted)	$ (1.25)	$ (2.05)
Weighted average common shares (basic and diluted)	8,493,886	5,783,585

CURIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)
(In thousands)

	March 31, 2025	***December 31, 2024***
ASSETS		
Cash, cash equivalents and investments	$ 20,282	$ 19,997
Restricted cash	544	544
Accounts receivable	2,315	3,349
Prepaid expenses and other assets	4,174	4,999
Property and equipment, net	172	231
Operating lease right-of-use asset	2,857	3,163
Goodwill	8,982	8,982

Total assets	$	39,326	$	41,265

LIABILITIES AND STOCKHOLDERS' EQUITY				
Accounts payable and accrued liabilities	$	11,582	$	10,135
Operating lease liability		2,639		2,954
Liability related to the sale of future royalties, net		31,712		34,174
Total liabilities		45,933		47,263
Total stockholders' equity		(6,607)		(5,998)
Total liabilities and stockholders' equity	$	39,326	$	41,265

SOURCE Curis, Inc.

For further information: Investor Relations: IR@curis.com

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https://investors.curis.com/2025-05-06-Curis-Provides-First-Quarter-2025-Business-Update