Investor Relations - Curis

Curis Provides Second Quarter 2024 Financial and Operating Update

EC Grants ODD to emavusertib in PCNSL

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

LEXINGTON, Mass., Aug. 1, 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 financial and operating results for the second quarter ended June 30, 2024.

Operational Highlights

TakeAim Lymphoma

In July 2024, emavusertib was granted Orphan Drug Designation (ODD) by the European Commission (EC) for the treatment of patients with primary central nervous system lymphoma (PCNSL). To qualify for ODD in the European Union, among several requirements, emavusertib must be intended for the treatment, prevention or diagnosis of a disease that is life-threatening or chronically debilitating and the prevalence of the condition must be fewer than 5 in 10,000 across the EU.

"We are extremely pleased that emavusertib has been granted ODD in the EU for the treatment of PCNSL. The designation is significant for the development of emavusertib in the EU and shows the high unmet need for this patient population," said Jonathan Zung, Chief Development Officer.

In addition to the EC ODD designation, Curis continues to progress the clinical development of emavusertib and expects to have initial data for 15-20 patients with R/R PCNSL by late 2024.

"We are pleased with our progress in the TakeAim Lymphoma study and look forward to providing updated data at the ASH conference in December. As we continue the expansion of clinical sites in our PCNSL study, we have initiated discussions with health authorities to align on a registrational development path for emavusertib in PCNSL. We are excited to take this next step in advancing a novel treatment for patients with PCNSL," said James Dentzer, President and Chief Executive Officer.

TakeAim Leukemia

In May 2024, Curis released data for 25 new patients in the Relapsed/Refractory (R/R) FLT3 mutation (FLT3m) and U2AF1/SF3B1 Splicing Factor mutation (SFm) cohorts who had received fewer than 3 lines of prior therapy and were treated with emavusertib as monotherapy at the Recommended Phase 2 Dose (RP2D) of 300 mg BID. 12 R/R AML patients with FLT3m were treated with emavusertib. Preliminary data show 6 objective responses in 11 response-evaluable patients: 3 complete remission (CR), 1 CR with partial hematologic recovery (CRh) and 2 morphologic leukemia-free state (MLFS) with on-treatment duration range of 46-324 days. 4 patients were ongoing at the data-cutoff, including 1 CRh and 1 MLFS. 20 R/R AML patients with SFm were treated with emavusertib. Preliminary data show 4 of 18 response-evaluable patients in this population have achieved objective response (CR/CRh/MLFS). 8 of 20 patients were ongoing at the data-cutoff, including 1 MLFS. 2 patients were not response-evaluable.

Upcoming Presentations

On September 26, 2024, Curis will be hosting the 3rd Annual Symposium on IRAK-4 in cancer. The symposium will be hosted by Dr. Eric S. Winer and Dr. Grzegorz S. Nowakowski and will focus on IRAK-4 and the promise of IRAK-4 inhibition in both hematologic malignancies and solid tumors.

Upcoming Milestones

- TakeAim Lymphoma – updated clinical data from the on-going combination study of emavusertib with ibrutinib in patients with R/R PCNSL in late 2024.
- TakeAim Leukemia – updated clinical data from the on-going monotherapy study of emavusertib in patients with R/R AML with a FLT3 or SFm 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.

Second Quarter 2024 Financial Results

For the second quarter of 2024, Curis reported a net loss of$11.8 million or $2.03 per share on both a basic and diluted basis as compared to $12.0 million or $2.47 per share on both a basic and diluted basis, for the same period in 2023. Curis reported a net loss of $23.7 million or $4.08 per share on both a basic and diluted basis, for the six months endedJune 30, 2024 as compared to a net loss of $23.5 million or $4.87 per share on both a basic and diluted basis for the same period in 2023.

Revenues for the second quarter of 2024 were $2.5 million as compared to $2.2 million for the same period in 2023. Revenues were $4.6 million for the six months ended June 30, 2024 as compared to $4.5 million for the same period in 2023. Revenues consist of royalty revenues from Genentech/Roche's sales of Erivedge®.

Research and development expenses were $10.3 million for the second quarter of 2024, as compared to $10.0 million for the same period in 2023. The increase was primarily attributable to higher employee related costs, partially offset by a decrease in consulting costs. Research and development expenses were $19.9 million for the six months ended June 30, 2024, as compared to $19.2 million for the same period in 2023.

General and administrative expenses were $4.8 million for the second quarter of 2024, as compared to $4.2 million for the same period in 2023. The increase was primarily attributable to higher employee related costs. General and administrative expenses were $9.7 million for the six months ended June 30, 2024, as compared to $9.0 million for the same period in 2023.

Other income was $0.7 million for the second quarter of 2024, as compared to $0.2 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. Other income, net was $1.3 million for the six months ended June 30, 2024 compared to $0.2 million for the same period in 2023.

Curis's cash, cash equivalents and investments totaled $28.4 million as of June 30, 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 the first quarter of 2025.

Conference Call and Webcast Information

Curis management will host a conference call and webcast today, August 1, 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, to access the webcast login to https://app.webinar.net/KNq2AB6AXGy shortly before 8:30 a.m. ET. The webcast can also be accessed via 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 (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 Phase 1/2 TakeAim Leukemia study (CA-4948-102) 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 (CA-4948-104). Emavusertib has received Orphan Drug Designation from the U.S. Food and Drug Administration for the treatment of 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, any statements with respect to Curis's plans, strategies and objectives, cash runway, clinical development timelines and commercialization plans, 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 and enroll patients in its AML triplet study, any statements concerning Curis's interactions with the FDA and/or health authorities on the potential development path for emavusertib in PCNSL or the potential benefits of having received orphan drug designation from the EC for emavusertib in PCNSL, 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 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. 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 June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenues, net	$ 2,546	$ 2,197	$ 4,632	$ 4,494
Operating expenses:				
Cost of royalties	12	74	59	98
Research and development	10,254	10,012	19,871	19,152
General and administrative	4,792	4,249	9,683	9,009
Total operating expenses	15,058	14,335	29,613	28,259
Loss from operations	(12,512)	(12,138)	(24,981)	(23,765)
Total other income	709	177	1,302	245
Net loss	$ (11,803)	$ (11,961)	$ (23,679)	$ (23,520)
Net loss per common share (basic and diluted)	$ (2.03)	$ (2.47)	$ (4.08)	$ (4.87)
Weighted average common shares (basic and diluted)	5,818,416	4,834,381	5,801,000	4,832,582

CURIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)
(In thousands)

	June 30, 2024	*December 31, 2023*
ASSETS		

Cash, cash equivalents and investments	$ 28,360	$ 56,334
Restricted cash	544	544
Accounts receivable	2,546	2,794
Prepaid expenses and other assets	5,921	5,138
Property and equipment, net	308	434
Operating lease right-of-use asset	3,752	3,056
Goodwill	8,982	8,982
Total assets	$ 50,413	$ 77,282

LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Accounts payable and accrued liabilities	$ 9,190	$ 12,212
Operating lease liability	3,558	2,794
Liability related to the sale of future royalties, net	38,359	42,606
Total liabilities	51,107	57,612
Total stockholders' equity (deficit)	(694)	19,670
Total liabilities and stockholders' equity (deficit)	$ 50,413	$ 77,282

SOURCE Curis, Inc.

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

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