Curis Provides Third Quarter 2024 Business Update

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

LEXINGTON, Mass., Nov. 14, 2024 /PRNewswire/ -- Curis, Inc. ("Curis") (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 September 30, 2024.

"We continue to make excellent progress across our clinical programs. We are especially excited about the recent R/R PCNSL data released in September which continue to demonstrate the activity of emavusertib in combination with ibrutinib in salvage-line patients and that the CR/CRu responses appear to be durable," said James Dentzer, Curis Chief Executive Officer. "We are also excited to present additional clinical data in our TakeAim Leukemia study next month at ASH. We believe the positive momentum as we finish the year sets us up well for 2025."

Third Quarter 2024 and Recent Operational Highlights

Emavusertib (IRAK4 Inhibitor)

TakeAim Lymphoma

In September, at the 3rd Annual IRAK4 Symposium in Cancer, the Company released preliminary efficacy data in 10 response-evaluable patients who had progressed on treatment with a BTKi. The data showed 3 complete responses (CR), 1 unconfirmed complete response (CRu) and 2 partial responses (PR). The duration of response for 3 of the 4 patients with a CR/CRu was greater than 6 months.
The Company is actively engaged in discussions with regulatory authorities to gain alignment on the registrational path in PCNSL.

TakeAim Leukemia

The Company will have both an oral presentation and a poster presentation at the 66th American Society of Hematology (ASH) annual meeting in December.

Oral Presentation:

Session Name: 616. Acute Myeloid Leukemias: Investigational Drug and Cellular Therapies: New Treatment Approaches for AML
Session Date: Monday, December 9, 2024
Presentation Time: 11:30 AM
Room: Manchester Grand Hyatt San Diego, Grand Hall B
Publication Number: 737
Title: Preliminary Safety, Efficacy, and Molecular Characterization of Emavusertib (CA-4948) in Relapsed/Refractory Acute Myeloid Leukemia Patients

Poster:

Session Name: 637. Myelodysplastic Syndromes: Clinical and Epidemiological: Poster II
Session Date: Sunday, December 8, 2024
Presentation Time: 6:00 PM - 8:00 PM
Location: San Diego Convention Center, Halls G-H
Publication Number: 3225
Title: Preliminary Safety, Efficacy and Molecular Characterization in Patients with Higher-Risk Myelodysplastic Syndrome Treated with Single Agent Emavusertib (CA-4948)

Corporate

In October 2024, Curis completed a registered direct offering and concurrent private placement of unregistered warrants ("October 2024 Offerings") with net proceeds of approximately $10.8 million.

Third Quarter 2024 Financial Results

For the third quarter of 2024, Curis reported a net loss of $10.1 million or $1.70 per share on both a basic and diluted basis as compared to $12.2 million or $2.13 per share on both a basic and diluted basis, for the same period in 2023. Curis reported a net loss of $33.8 million or $5.77 per share on both a basic and diluted basis, for the nine months ended September 30, 2024 as compared to a net loss of $35.7 million or $6.96 per share on both a basic and diluted basis for the same period in 2023.

Revenues for the third quarter of 2024 were $2.9 million as compared to $2.8 million for the same period in 2023. Revenues for both periods consist of royalty revenues from Genentech and Roche's sales of Erivedge®. Revenues for the nine months ended September 30, 2024 and 2023 were $7.6 million and $7.3 million, respectively.

Research and development expenses were $9.7 million for the third quarter of 2024, as compared to $10.4 million for the same period in 2023. The decrease was primarily attributable to lower consulting and employee related costs. Research and development expenses were $29.6 million for the nine months ended September 30, 2024, as compared to $29.5 million for the same period in 2023.

General and administrative expenses were $3.8 million for the third quarter of 2024, as compared to $4.8 million for the same period in 2023. The decrease was primarily attributable to lower legal and employee related costs. General and administrative expenses were $13.4 million for the nine months ended September 30, 2024, as compared to $13.8 million for the same period in 2023.

Other income, net was $0.5 million for the third 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 $1.8 million for the nine months ended September 30, 2024, as compared to $0.4 million for the same period in 2023.

Including the impact of the October 2024 Offerings, Curis's cash and cash equivalents totaled $31.6 million, and the Company had approximately 8.5 million shares of common stock outstanding. Curis expects its existing cash and cash equivalents will enable its planned operations into mid-2025.

Conference Call Information

Curis management will host a conference call today, November 14, 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/jG81a9Deb0V 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 cash runway, plans, strategies and objectives; statements concerning research, development, clinical trials and commercialization plans, timelines, anticipated results or the therapeutic potential of emavusertib including the progression, expansion, use, safety, efficacy, rates and duration of responses, mutations or potential biomarkers, and potential benefits of emavusertib in clinical trials as a monotherapy and/or as a combination therapy; statements regarding Curis's plans and timelines to provide preliminary, interim and/or additional data from its ongoing or planned clinical trials; any statements concerning Curis's expectations regarding its 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; 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 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 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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenues, net	$ 2,931	$ 2,833	$ 7,563	$ 7,327
Operating expenses:				
Cost of royalties	22	60	81	158
Research and development	9,723	10,380	29,594	29,532
General and administrative	3,753	4,761	13,436	13,770
Total operating expenses	13,498	15,201	43,111	43,460
Loss from operations	(10,567)	(12,368)	(35,548)	(36,133)
Total other income	475	187	1,777	432
Net loss	$ (10,092)	$ (12,181)	$ (33,771)	$ (35,701)
Net loss per common share (basic and diluted)	$ (1.70)	$ (2.13)	$ (5.77)	$ (6.96)
Weighted average common shares (basic and diluted)	5,940,924	5,720,789	5,847,982	5,131,904

CURIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)
(In thousands)

September 30, 2024	December 31, 2023

ASSETS		
Cash, cash equivalents and investments	$ 20,854	$ 56,334
Restricted cash	544	544
Accounts receivable	2,978	2,794
Prepaid expenses and other assets	5,408	5,138
Property and equipment, net	246	434
Operating lease right-of-use asset	3,461	3,056
Goodwill	8,982	8,982
Total assets	$ 42,473	$ 77,282
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable and accrued liabilities	$ 11,959	$ 12,212
Operating lease liability	3,260	2,794
Liability related to the sale of future royalties, net	35,989	42,606
Total liabilities	51,208	57,612
Total stockholders' equity (deficit)	(8,735)	19,670
Total liabilities and stockholders' equity (deficit)	$ 42,473	$ 77,282

SOURCE Curis, Inc.

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

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https://investors.curis.com/2024-11-14-Curis-Provides-Third-Quarter-2024-Business-Update