Investor Relations - Curis

Curis Provides Fourth Quarter 2022 Business Update

Curis completes enrollment of the 9 additional patients requested by FDA ahead of schedule in its TakeAim Leukemia study

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

LEXINGTON, Mass., March 13, 2023 /PRNewswire/ -- Curis, Inc. (NASDAQ: CRIS), a biotechnology company focused on the development of innovative therapeutics for the treatment of cancer, today reported its business update and financial results for the fourth quarter ended December 31, 2022.

As announced in November, the Company has concentrated its resources to focus on the development of emavusertib. As a result of these efforts, the Company has completed the re-opening of its clinical sites and completed enrollment of the 9 additional patients at the 200mg BID dose level requested by FDA in discussions related to the resolution of the partial clinical hold on the Company's TakeAim Leukemia study. The Company expects to collect data from these patients in Q2 and request a Q3 meeting to discuss these data with FDA.

"We are pleased to announce that we have completed enrollment of the 9 additional patients requested by FDA ahead of schedule. This is an important step towards resolving the partial clinical hold in the TakeAim Leukemia study. We also look forward to discussions with FDA on the determination of the Recommended Phase 2 Dose (RP2D), as we work with our clinical investigators to develop potential pivotal study designs for emavusertib," said James Dentzer, President and Chief Executive Officer of Curis.

Fourth Quarter 2022 and Recent Operational Highlights

Precision Oncology, Emavusertib (IRAK4 Inhibitor)

In December at the 64th Annual ASH Meeting and Exposition, the Company presented positive updated clinical data from the ongoing open label Phase 1a dose escalation study of emavusertib (CA-4948), a novel, small molecule IRAK-4 inhibitor, as a monotherapy in patients with relapsed or refractory (R/R) acute myeloid leukemia (AML) or high-risk myelodysplastic syndromes (hrMDS) in both targeted and non-targeted populations. Key findings in the data in targeted AML and hrMDS patient monotherapy populations included:

AML Patients with a FLT3 mutation had a CR rate of 29% (2 of 7 patients);
AML Patients with a spliceosome mutation had a CR/CRh rate of 22% (2 of 9 patients);
MDS Patients with a spliceosome mutation had an ORR of 45% (5 of 11 patients), with all 5 responses achieving a marrow Complete Remission (mCR).
CR: Complete Remission
CRh: Complete Remission with Partial Hematologic Recovery
ORR: Objective Response Rate

Upcoming Milestones

The Company expects to include data from the 9 additional patients in discussions with FDA in Q3 that it hopes will facilitate the determination of RP2D and resolution of the partial clinical hold.

Fourth Quarter 2022 Financial Results

For the year ended December 31, 2022, Curis reported a net loss of $56.7 million, or $0.61 per share on both a basic and diluted basis, as compared to a net loss of $45.4 million, or $0.50 per share on both a basic and diluted basis in 2021. For the fourth quarter of 2022, Curis reported a net loss of $11.3 million or $0.12 per share on both a basic and diluted basis as compared to a net loss of $13.6 million or $0.15 per share on both a basic and diluted basis, for the same period in 2021.

Revenues, net for the year ended December 31, 2022, were $10.2 million as compared to $10.6 million for the same period in 2021. Revenues for both periods comprise primarily royalty revenues recorded on Genentech and Roche's net sales of Erivedge®. Revenues for the fourth quarters of 2022 and 2021 were $2.9 million and $3.1 million, respectively.

Costs 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, 2022, were $0.3 million compared to $0.5 million for the same period in 2021. Cost of royalties for the fourth quarters of 2022 and 2021 were $0.1 million and $0.2 million, respectively.

Research and development expenses were $43.3 million for the year ended December 31, 2022, as compared to $34.9 million for the same period in 2020. The increase is mainly a result of increased employee-related costs of $7.4 million due to an increase in headcount. Research and development expenses were $8.7 million and $10.8 million for the fourth quarters of 2022 and 2021, respectively.

General and administrative expenses were $19.6 million for the year ended December 31, 2022, as compared to $17.3 million for the same period in 2021. The increase is mainly a result of increased employee-related costs of $1.4 million due to an increase in headcount and facility related costs of $0.8 million. General and administrative expenses were $4.3 million and $4.8 million for the fourth quarters of 2022 and 2021, respectively.

Other expense, net was $3.7 million for the year ended December 31, 2022, as compared to $3.4 million for the same period in 2021. Other expense, net was $1.1 million for the fourth quarters of 2022 and 2021, respectively. Other expense, net for the year ended December 31, 2022 primarily consisted of expense related to future royalty payments partially offset by interest income. Other expense, net for the year ended December 31, 2021 primarily consisted of imputed interest expense related to future royalty payments partially offset by a gain recognized upon the forgiveness of a PPP loan.

As of December 31, 2022, Curis's cash, cash equivalents and investments totaled $85.6 million, and the Company had approximately 96.6 million shares of common stock outstanding. Curis expects its existing cash, cash equivalents and investments should enable it to maintain its planned operations into 2025.

Conference Call Information

Curis management will host a conference call today, March 13, 2023, 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 innovative therapeutics for the treatment of cancer. In 2015, Curis entered into a collaboration with Aurigene in the areas of immuno-oncology and precision oncology. As part of this collaboration, Curis has exclusive licenses to oral small molecule antagonists of immune checkpoints including the VISTA/PDL1 antagonist CA-170, and the TIM3/PDL1 antagonist CA-327, as well as the IRAK4 kinase inhibitor, emavusertib (CA-4948). Emavusertib is currently undergoing testing in the Phase 1/2 TakeAim Lymphoma trial in patients with hematologic malignancies, such as non-Hodgkin's lymphoma and other B cell malignancies, both as a monotherapy and in combination with BTK inhibitor ibrutinib, and the Phase 1/2 TakeAim Leukemia trial in patients with acute myeloid leukemia and myelodysplastic syndrome, for which it has received Orphan Drug Designation from the U.S. Food and Drug Administration. The FDA has placed a partial clinical hold on the TakeAim Leukemia trial during which no new patients will be enrolled in the monotherapy expansion phase (Phase 2a) or the combination phase (Phase 1b) of emavusertib with azacitidine or venetoclax. In addition, Curis is engaged in a collaboration with ImmuNext for development of CI-8993, a monoclonal anti-VISTA antibody, which is currently undergoing testing in a Phase 1 trial in patients with solid tumors. Curis is also party to a collaboration with Genentech, a member of the Roche Group, under which Genentech and Roche 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 and commercialization plans, timelines, anticipated results or the therapeutic potential of drug candidates including 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, the progression, use and potential benefits of CI-8993, Curis's plans and timelines to provide preliminary, interim and/or additional data from its ongoing or planned clinical trials, its ability to resume and further patient enrollment in its TakeAim Lymphoma trial and in the monotherapy dose escalation phase (Phase 1a) of the TakeAim Leukemia trial, its ability to resolve the remaining partial clinical hold on the monotherapy expansion phase (Phase 2a) and the combination therapy phase (Phase 1b) of the TakeAim Leukemia 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. For example, the FDA may not remove the remaining partial clinical hold on the monotherapy expansion phase (Phase 2a) and the combination therapy phase (Phase 1b) of the TakeAim Leukemia trial or may take further regulatory action with regard to such trial. 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. There can be no guarantee that the collaboration agreements with Aurigene and ImmuNext will continue for their full terms, 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 (BCC). 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. If it is not able to obtain sufficient funding, it will be forced to delay, reduce in scope or eliminate some of its research and development programs, including related clinical trials and operating expenses, potentially delaying the time to market for, or preventing the marketing of, any of its product candidates, 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 fourth parties on which Curis depends and could adversely impact Curis's operating results and its ability to raise capital. For example, the periodic COVID-19 resurgence may result in closures of fourth-party facilities, impact enrollment in clinical trials or impact sales of Erivedge by Genentech and/or Roche. 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 ("SEC"). 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,	
	2022	2021	2022	2021
Revenues, net:				
Royalties	$ 2,901	$ 3,156	$ 10,278	$ 10,749
Other revenue	—	—	—	1
Contra revenue, net	(14)	(21)	(116)	(101)
Total revenues, net	2,887	3,135	10,162	10,649
Costs and expenses:				

Cost of royalty revenues	71	157	257	533
Research and development	8,706	10,772	43,277	34,884
General and administrative	4,330	4,773	19,648	17,297
Total costs and expenses	13,107	15,702	63,182	52,714
Loss from operations	(10,220)	(12,567)	(53,020)	(42,065)
Other expense, net:	(1,109)	(1,053)	(3,652)	(3,371)
Net loss	$ (11,329)	$ (13,620)	$ (56,672)	$ (45,436)
Net loss per common share (basic and diluted)	$ (0.12)	$ (0.15)	$ (0.61)	$ (0.50)
Weighted average common shares (basic and diluted)	96,425,650	91,618,770	93,392,515	91,569,154

CURIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)
(In thousands)

	December 31, 2022	***December 31, 2021***
ASSETS		
Cash, cash equivalents and investments	$ 85,623	$ 139,848
Restricted cash	635	726
Accounts receivable	2,975	3,224
Property and equipment, net	689	505
Operating lease right-of-use asset	4,401	5,749
Goodwill	8,982	8,982
Prepaid expenses and other assets	5,543	3,267
Total assets	$ 108,848	$ 162,301
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued liabilities and other liabilities	$ 8,872	$ 12,756
Operating lease liability	3,941	5,040
Liability related to the sale of future royalties, net	49,483	53,798
Total liabilities	62,296	71,594
Total stockholders' equity	46,552	90,707
Total liabilities and stockholders' equity	$ 108,848	$ 162,301

SOURCE Curis, Inc.

For further information: ir@curis.com

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