Curis Provides Third Quarter 2022 Business Update

Data from additional patients in the TakeAim Leukemia trial of emavusertib to be presented during ASH 2022

Curis focuses its resources to drive the development of emavusertib

Cash runway extended into 2025

Management to host conference call today at 4:30 p.m. ET

LEXINGTON, Mass., Nov. 9, 2022 /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 third quarter ended September 30, 2022.

The Company plans to release updated data from its TakeAim Leukemia Phase 1/2 trial of emavusertib in relapsed or refractory (R/R) acute myeloid leukemia (AML) and high-risk myelodysplastic syndromes (hrMDS) during the upcoming 64th annual meeting of the American Society of Hematology (ASH) in New Orleans on December 10-13, 2022. The release includes data for 11 additional evaluable AML/hrMDS patients treated with monotherapy (total to date 24) in targeted populations (patients with U2AF1, SF3B1 or FLT3 mutations), as well as 5 AML/hrMDS patients treated with the combination of emavusertib and venetoclax.

To further advance the development of emavusertib based on these data, the Company is concentrating its resources to focus on and accelerate emavusertib. Resources will be reallocated to the emavusertib programs and resources dedicated to all other pipeline programs will be reduced. Deprioritization of other programs will enable a reduction of approximately 30% of the Company's workforce and is expected to extend the Company's cash runway into 2025.

"We believe emavusertib's potential to address an area of high unmet need in R/R AML and R/R hrMDS sets it apart. To that end, we are dedicating the resources of the company to prioritize the acceleration of its regulatory path," said James Dentzer, President and Chief Executive Officer of Curis. "While we continue to believe in our entire pipeline, we recognize the unique potential of emavusertib and are fortunate that our existing cash will allow us to extend our runway into 2025 to advance its development," continued Mr. Dentzer.

Third Quarter 2022 and Recent Operational Highlights

Precision Oncology, Emavusertib (IRAK4 Inhibitor)

The Company announced in August that, after review of the comprehensive data packages submitted by the Company, the FDA has allowed enrollment to resume in the TakeAim Lymphoma study and in the monotherapy dose finding phase (Phase 1a) of the TakeAim Leukemia study.

Curis held the first annual IRAK4 in Cancer symposium virtually on October 7, 2022 where leaders from academia and industry gathered to present their cutting edge research on IRAK4, its biology and the role it could play as a target for therapeutic intervention.

Upcoming Milestones

The Company plans to report monotherapy and combination data from the TakeAim Leukemia studies during ASH 2022.

Third Quarter 2022 Financial Results

For the third quarter of 2022, Curis reported a net loss of $13.3 million or $0.14 per share on both a basic and diluted basis, as compared to a net loss of $11.1 million, or $0.12 per share on both a basic and diluted basis for the same period in 2021. Curis reported a net loss of $45.3 million or $0.49 per share on both a basic and diluted basis, for the nine months ended September 30, 2022 as compared to a net loss of $31.8 million, or $0.35 per share on both a basic and diluted basis for the same period in 2021.

Revenues, net for the third quarter of 2022 and 2021 were $2.8 million and $3.0 million, respectively. Revenues, net for the nine months ended September 30, 2022 were $7.3 million as compared to $7.5 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®.

Operating expenses for the third quarter of 2022 were $15.4 million, as compared to $13.1 million for the same period in 2021. Operating expenses for the nine months ended September 30, 2022 were $50.1 million, as compared to $37.0 million for the same period in 2021, and comprised the following:

Cost of Royalty Revenues. Cost of royalty revenues, which represents amounts due to third-party university patent licensors in connection with Genentech and Roche's Erivedge net sales, were $0.1 million for the third quarter of 2022 and $0.2 million for the same period in 2021. Cost of royalty revenues for the nine months ended September 30, 2022 were $0.2 million, as compared to $0.4 million for the same period in 2021.

Research and Development Expenses. Research and development expenses were $10.8 million for the third quarter of 2022 as compared to $8.6 million for the same period in 2021. The increase in research and development expenses for the quarter is primarily attributable to increased personnel and consulting costs, partially offset by decreased manufacturing and clinical development costs. Research and development expenses were $34.6 million for the nine months ended September 30, 2022 as compared to $24.1 million for the same period in 2021.

General and Administrative Expenses. General and administrative expenses were $4.6 million for the third quarter of 2022, as compared to $4.3 million for the same period in 2021. The increase in general and administrative expenses was driven primarily by the timing of costs. General and administrative expenses were $15.3 million for the nine months ended September 30, 2022, as

compared to $12.5 million for the same period in 2021.

Other Expense. For the third quarter of 2022 and 2021, total other expense was $0.7 million and $1.0 million, respectively. Other expense primarily consisted of imputed interest expense related to future royalty payments partially offset by interest income. Other expense was $2.5 million for the nine months ended September 30, 2022, as compared to $2.3 million for the same period in 2021.

As of September 30, 2022, Curis's cash, cash equivalents and investments totaled $98.7 million, and the Company had approximately 96.4 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, November 9, 2022, at 4:30 p.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 4:30 p.m. ET. The conference call can also be accessed on the Curis website at 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, and current study participants benefiting from treatment may continue to be treated with emavusertib at doses of 300mg BID or lower. 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 develop or commercialize Erivedge in basal cell carcinoma (BCC). Erivedge may not demonstrate sufficient or any activity to merit its further development in disease indications other than 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 third parties on which Curis depends and could adversely impact Curis's operating results and its ability to raise capital. For example, the COVID-19 pandemic may result in closures of third-party facilities, impact enrollment in clinical trials or impact sales of Erivedge by Genentech and/or Roche. The extent to which the COVID-19 pandemic may impact Curis's business or operating results is uncertain. 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 September 30,		Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Revenues, net:				
Royalties	$ 2,843	$ 3,058	$ 7,377	$ 7,593
Other revenue	—	—	—	1
Contra revenue, net	(18)	(19)	(102)	(80)
Total revenues, net	2,825	3,039	7,275	7,514
Costs and expenses:				
Cost of royalty revenues	62	151	186	376
Research and development	10,813	8,602	34,571	24,112
General and administrative	4,556	4,334	15,318	12,524
Total costs and expenses	15,431	13,087	50,075	37,012
Loss from operations	(12,606)	(10,048)	(42,800)	(29,498)
Other expense:				
Interest income	335	54	577	158
Imputed interest expense related to the sale of future royalties	(1,023)	(1,057)	(3,120)	(3,366)
Other income (expense), net	—	—	—	890
Total other expense	(688)	(1,003)	(2,543)	(2,318)
Net loss	$ (13,294)	$ (11,051)	$ (45,343)	$ (31,816)
Net loss per common share (basic and diluted)	$ (0.14)	$ (0.12)	$ (0.49)	$ (0.35)
Weighted average common shares (basic and diluted)	93,791,178	91,601,362	92,370,359	91,552,433

CURIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)
(In thousands)

	September 30, 2022	***December 31, 2021***
ASSETS		
Cash, cash equivalents and investments	$ 98,689	$ 139,848
Restricted cash	635	726
Accounts receivable	2,886	3,224
Property and equipment, net	780	505
Operating lease right-of-use asset	4,718	5,749
Goodwill	8,982	8,982
Prepaid expenses and other assets	6,164	3,267
Total assets	$ 122,854	$ 162,301
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued liabilities and other liabilities	$ 12,639	$ 12,756
Operating lease liability	4,201	5,040
Liability related to the sale of future royalties, net	50,269	53,798
Total liabilities	67,109	71,594

Total stockholders' equity	55,745	90,707
Total liabilities and stockholders' equity	$ 122,854	$ 162,301

SOURCE Curis, Inc.

For further information: ir@curis.com

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https://investors.curis.com/2022-11-09-Curis-Provides-Third-Quarter-2022-Business-Update