Curis Reports Second Quarter 2022 Financial Results and Business Update

Presented encouraging clinical data for the combination of emavusertib plus ibrutinib showing tumor reduction in 8 of 9 evaluable patients and the potential for overcoming ibrutinib resistance at the 2022 American Society of Clinical Oncology Annual Meeting (ASCO)

Appointed Industry Veteran Diantha Duvall as Chief Financial Officer

Strong balance sheet with $107.2 million in cash and investments as of June 30, 2022; cash runway into 2024

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

LEXINGTON, Mass., Aug. 4, 2022 /PRNewswire/ -- Curis, Inc. (NASDAQ: CRIS), a biotechnology company focused on the development of innovative therapeutics for the treatment of cancer, today reported its financial results for the second quarter ended June 30, 2022 and provided business updates.

"This quarter, we issued the noteworthy first release of data from the TakeAim Lymphoma trial's combination arm that examined emavusertib combined with ibrutinib in B cell malignancies. This data showed tumor reduction in 8 of 9 evaluable patients, and the potential to help patients experiencing ibrutinib resistance. We look forward to continuing the advancement of our first-in-class, small molecule IRAK4 inhibitor in nine distinct patient populations across acute myeloid leukemia (AML), myelodysplastic syndromes (MDS) and B cell cancers. On the administrative front, I am also pleased to announce the appointment of Diantha Duvall as our new Chief Financial Officer. Diantha brings a wealth of experience from senior roles at Merck, Biogen, Bioverativ, Genocea and PricewaterhouseCoopers. We look forward to her contributions to the Curis mission," said James Dentzer, President and Chief Executive Officer of Curis.

"I am excited to join Curis at this critical time for the company," said Ms. Duvall. "I found Curis to be particularly compelling due to its novel, targeted approach and pipeline of first-in-class cancer therapeutics with significant potential in areas of unmet need. I look forward to supporting the Curis team's mission to develop innovative and differentiated therapeutics that improve the lives of cancer patients."

Second Quarter 2022 and Recent Operational Highlights

Precision oncology, emavusertib (IRAK4 Inhibitor; Aurigene collaboration):

The company presented the first preliminary dataset from the combination arm in the TakeAim Lymphoma study at ASCO and at the European Hematology Association (EHA) Hybrid Congress which examined the use of emavusertib plus ibrutinib in patients with relapsed or refractory (R/R) hematologic malignancies, such as non-Hodgkin's lymphoma and other B cell malignancies. The presentation included clinical data on 13 patients who received the combination, 9 of whom had post-baseline response assessments and were evaluable for response.
Key findings in patients treated with the combination included:

- The combination appeared to be well tolerated
- No dose-limiting toxicities (DLTs) at 200mg of emavusertib; 2 DLTs observed at 300mg (stomatitis and syncope)
- 8 of 9 evaluable patients experienced reduction in tumor burden, including:
  - 2 complete responses (CR) (primary CNS lymphoma and mantle cell lymphoma)
  - 2 partial responses (PR) (chronic lymphocytic leukemia and mantle cell lymphoma)
  - One of the CRs was in a patient who had received prior treatment with ibrutinib, suggesting the combination may be able to overcome ibrutinib resistance

The company presented data from the TakeAim Leukemia study at ASCO and EHA during the second quarter. The data showed encouraging rates of response in three separate targeted patient populations, namely those with: spliceosome-mutated R/R AML, spliceosome-mutated R/R MDS, and FLT3-mutated R/R AML. In addition, emavusertib was well-tolerated across multiple dose levels.
The company also presented novel findings from its work involving potential biomarker development for use with emavusertib studies which described the previously unrecognized localization of IRAK4 in the nucleus of cancer cells. The localization of IRAK4 in the nucleus is being explored as a potential biomarker.
Curis's collaborators also presented data on their work with emavusertib. Two of these were in solid tumor indications: one in gastric cancer by Dr. Kian-Huat Lim's team at Washington University School of Medicine, and the second by Dr. Duane Mitchell's team at the University of Florida, which investigated emavusertib in melanoma brain metastasis. The third presentation by the Company's collaborators was also from Dr.

Duane Mitchell's team, and this work was in the treatment of patients with primary CNS lymphoma. The company is working closely with the FDA to resolve the partial clinical holds on enrollment for the emavusertib studies.

Appointed new CFO:

Curis appointed Diantha Duvall Chief Financial Officer effective August 5, 2022. Ms. Duvall joins the company from Genocea, where she served as the CFO since 2019. Prior to that, she held senior finance roles at Bioverativ, Biogen and Merck, where her roles spanned commercial finance, venture investment, business development, joint ventures, alliances, technical accounting and controls. She received a bachelor's degree in Economics and Public Policy from Colby College and masters' degrees in both Accounting and Business Administration from Northeastern University. She is also a Certified Public Accountant licensed in the state of Massachusetts. Ms. Duvall succeeds Bill Steinkrauss, who as previously announced is resigning from the company on August 5, 2022, to pursue an entrepreneurial opportunity in consulting. Mr. Steinkrauss will continue to work with the company as a consultant as needed through the end of 2022 to ensure a smooth transition.

Upcoming Planned Milestones for the remainder of 2022

Report data from the TakeAim Leukemia study

- We plan to present an update with additional monotherapy data
- We plan to present initial data for the study of emavusertib in combination with azacitadine or venetoclax

Report data from the CI-8993 (VISTA checkpoint inhibitor) study

- We plan to present an update with additional monotherapy data

Annual VISTA symposium planned for September 23, 2022
Annual IRAK4 symposium planned for October 7, 2022

Second Quarter 2022 Financial Results

For the second quarter of 2022, Curis reported a net loss of $15.9 million or $0.17 per share on both a basic and diluted basis, as compared to a net loss of $10.8 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 $32.0 million or $0.35 per share on both a basic and diluted basis, for the six months ended June 30, 2022 as compared to a net loss of $20.8 million, or $0.23 per share on both a basic and diluted basis for the same period in 2021.

Revenues for the second quarter of 2022 and 2021 were $2.4 million and $2.3 million, respectively. Revenues for the six months ended June 30, 2022 and June 30, 2021 were $4.5 million. Revenues for both periods comprise primarily royalty revenues recorded on Genentech and Roche's net sales of Erivedge®.

Operating expenses for the second quarter of 2022 were $17.5 million, as compared to $12.9 million for the same period in 2021. Operating expenses for the six months ended June 30, 2022 were $34.6 million, as compared to $23.9 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 less than $0.1 million for the second quarter of 2022 and $0.1 million for the same period in 2021. Cost of royalty revenues for the six months ended June 30, 2022 were $0.1 million, as compared to $0.2 million for the same period in 2021.

Research and Development Expenses. Research and development expenses were $12.3 million for the second quarter of 2022 as compared to $8.8 million for the same period in 2021. The increase in direct research and development expenses for the quarter is primarily attributable to increased consulting services. Additionally, personnel related costs increased by $2.5 million and stock compensation increased $0.4 million, primarily as a result of additional headcount. Research and development expenses were $23.8 million for the six months ended June 30, 2022 as compared to $15.5 million for the same period in 2021.

General and Administrative Expenses. General and administrative expenses were $5.1 million for the second quarter of 2022, as compared to $4.1 million for the same period in 2021. The increase in general and administrative expenses was driven primarily by higher costs for personnel, stock-based compensation, and insurance costs. General and administrative expenses were $10.8 million for the six months ended June 30, 2022, as compared to $8.2 million for the same period in 2021.

Other Expense, Net. For the second quarter of 2022 and 2021, total other expense was $0.9 million and $0.2

million, respectively. Net other expense primarily consisted of imputed interest expense related to future royalty payments, partially offset in the second quarter of 2021 by a gain of $0.9 million related to extinguishment of debt. Net other expense was $1.9 million for the six months ended June 30, 2022, as compared to $1.3 million for the same period in 2021.

As of June 30, 2022, Curis's cash, cash equivalents and investments totaled $107.2 million, and there were approximately 91.8 million shares of common stock outstanding. Curis expects that its existing cash, cash equivalents and investments should enable it to maintain its planned operations into 2024.

Conference Call Information

Curis management will host a conference call today, August 4, 2022, at 4:30 p.m. ET, to discuss these financial results, as well as provide a corporate update.

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 www.curis.com 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 and TakeAim Lymphoma trials during which no new patients will be enrolled, 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, objectives or financial results; 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, efficacy, dosage and potential benefits of CA-4948 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, any statements concerning Curis's expectations regarding its interactions with the FDA or its ability to resolve the partial clinical hold of the TakeAim Leukemia study or the partial clinical hold of the TakeAim Lymphoma study, and 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 partial clinical hold on the Phase 1/2 TakeAim Leukemia trial or the partial clinical hold on the Phase 1/2 TakeAim Lymphoma trial, or may take further regulatory action with regard to such trials; 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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Revenues, net:				
Royalties	$2,474	$2,348	$4,534	$4,535
Other revenue	—	1	—	1
Contra revenue, net	(81)	(63)	(84)	(61)
Total revenues, net	2,393	2,286	4,450	4,475
Costs and expenses:				
Cost of royalty revenues	42	116	124	225
Research and development	12,323	8,753	23,758	15,510
General and administrative	5,089	4,067	10,762	8,190
Total costs and expenses	17,454	12,936	34,644	23,925
Loss from operations	(15,061)	(10,650)	(30,194)	(19,450)
Other expense:				
Interest income	162	58	242	104
Imputed interest expense related to the sale of future royalties	(1,041)	(1,136)	(2,097)	(2,309)
Other income (expense), net	—	890	—	890
Total other expense	(879)	(188)	(1,855)	(1,315)

Net loss	$(15,940)	$(10,838)	$(32,049)	$(20,765)
Net loss per common share (basic and diluted)	$(0.17)	$(0.12)	$(0.35)	$(0.23)
Weighted average common shares (basic and diluted)	91,650,950	91,547,390	91,648,175	91,527,563

CURIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)
(In thousands)

	June 30, 2022	*December 31, 2021*
ASSETS		
Cash, cash equivalents and investments	$ 107,200	$ 139,848
Restricted cash	635	726
Accounts receivable	2,395	3,224
Property and equipment, net	789	505
Operating lease right-of-use asset	5,032	5,749
Goodwill	8,982	8,982
Prepaid expenses and other assets	3,801	3,267
Total assets	$ 128,834	$ 162,301
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued liabilities and other liabilities	$ 11,086	$ 12,756
Operating lease liability	4,455	5,040
Liability related to the sale of future royalties, net	51,248	53,798
Total liabilities	66,789	71,594
Total stockholders' equity	62,045	90,707
Total liabilities and stockholders' equity	$ 128,834	$ 162,301

SOURCE Curis, Inc.

For further information: For further information: Craig West, VP, Investor Relations & Corporate Communications, Curis, Inc., 617-503-6507, cwest@curis.com

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