Curis Reports Second Quarter 2020 Financial Results

- Clinical data expected in CA-4948 NHL and AML/MDS trials by year-end -
- Initiation of Phase 1 trial of CA-4948 in combination with ibrutinib in NHL expected in second half of 2020 -
- Initiation of Phase 1a/1b trial of anti-VISTA monoclonal antibody, CI-8993, in advanced refractory solid tumors, expected in the second half of 2020 -
- Management to host conference call today at 4:30 p.m. ET -

LEXINGTON, Mass., Aug. 4, 2020 /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, 2020.

"Our recent accomplishments represent meaningful progress for Curis, as we advanced our clinical pipeline and achieved key financial objectives. These recent developments set us up for near-term data readouts, which we expect will provide durable momentum into 2021," said James Dentzer, President and Chief Executive Officer of Curis. "In addition to advancing the ongoing Phase 1 study of our first-in-class IRAK4 inhibitor, CA-4948, in patients with non-Hodgkin's lymphoma (NHL), we initiated a new Phase 1 study of CA-4948 in patients with relapsed or refractory (R/R) acute myeloid leukemia (AML) and high-risk myelodysplastic syndromes (MDS). We are particularly excited about this study, as AML and high-risk MDS are driven, in over half of patients, by the long isoform of IRAK4, which CA-4948 directly targets. Today, I am pleased to announce our plans to initiate a study of CA-4948 before the end of the year, which will evaluate CA-4948 in combination with ibrutinib, a BTK inhibitor, in patients with NHL, including those with MYD88 altered disease."

Mr. Dentzer continued, "For our VISTA program, we received clearance from the U.S. Food and Drug Administration (FDA) on our Investigational New Drug (IND) application for CI-8993 to initiate a Phase 1a/1b dose-escalation study in patients with solid tumors. We look forward to building on our pipeline-wide progress and expect to report data on all three clinical studies, CA-4948 in NHL, CA-4948 in AML/MDS, and CI-8993 in solid tumors, by year-end."

Second Quarter 2020 and Recent Operational Highlights

Precision oncology, CA-4948 (IRAK4 Inhibitor; Aurigene collaboration):

Curis is evaluating CA-4948 in an ongoing Phase 1 dose-escalation study for the treatment of patients with R/R NHL, including patients with diffuse large B-cell lymphoma (DLBCL), Waldenström's macroglobulinemia (WM) and oncogenic MYD88 mutations. As a result of COVID-19 pandemic, enrollment in this trial has been slower than expected and the timeline of this clinical trial has been delayed. The Company expects to report updated efficacy data and the recommended Phase 2 dose for CA-4948 by the end of 2020.
In July 2020, Curis announced the dosing of the first patient in its open-label, Phase 1 dose-escalation study of CA-4948 in patients with R/R AML and high-risk MDS, including patients with spliceosome mutations that drive expression of the long isoform of IRAK4 (IRAK4-L). The primary objective of the study is to determine the maximum tolerated dose and recommended Phase 2 dose of CA-4948 based on safety and tolerability, dose-limiting toxicities (DLTs), and pharmacokinetic and pharmacodynamic findings. A minimum of three patients will be enrolled at each dose level, starting with 200 mg BID, which was determined to be safe, capable of achieving relevant levels of drug exposure, and demonstrated signs of biologic activity and clinical efficacy in a separate, ongoing Phase 1 study. Curis expects to provide initial data from this study by the end of 2020.
Today, Curis announced that it will initiate a Phase 1 study evaluating CA-4948 in combination with ibrutinib, a BTK inhibitor, in the second half of 2020. In preclinical models, CA-4948 has demonstrated anti-cancer activity that is highly synergistic with BTK inhibition.

Immuno-oncology, CI-8993 (anti-VISTA antibody; ImmuNext collaboration):

In June 2020, Curis announced that the FDA cleared its IND application for CI-8993, a first-in-class monoclonal antiVISTA antibody. Curis expects to initiate a Phase 1a/1b study of CI-8993 in patients with relapsed / refractory solid tumors in the second half of 2020.

Precision oncology, fimepinostat (HDAC/PI3K inhibitor):

Fimepinostat has previously been shown to induce durable single-agent responses in difficult-to-treat lymphomas, including MYC-driven and double-hit disease. Curis is collaborating with DarwinHealth on ongoing analytical research to characterize biomarkers and tumor subtype alignments, which may help guide future clinical development opportunities with fimepinostat.

Corporate:

In June 2020, Curis completed a $17.5 million registered direct offering with fundamental healthcare investors extending its cash runway into the first half of 2021.

Upcoming 2020 Planned Milestones

- Declare the recommended Phase 2 dose for CA-4948 in the ongoing lymphoma Phase 1 study and report updated efficacy data from the study by year-end 2020.
- Report initial data from the Phase 1 study of CA-4948 in patients with AML/MDS, including patients with spliceosome mutations that encode oncogenic IRAK4-L, by year-end 2020.
- Initiate Phase 1 study of CA-4948 in combination with ibrutinib in the second half of 2020.
- Initiate Phase 1a/1b dose escalation study of CI-8993 in patients with relapsed / refractory solid tumors in the second half of 2020.
- Report initial safety data from Phase 1a/1b dose escalation study of CI-8993 in patients with relapsed / refractory solid tumors by year-end 2020.

Second Quarter 2020 Financial Results

For the second quarter of 2020, Curis reported a net loss of $6.7 million, or $0.17 per share on both a basic and diluted basis, as compared to a net loss of $7.2 million, or $0.22 per share on both a basic and diluted basis, for the same period in 2019. Curis reported a net loss of $16.4 million, or $0.44 per share on both a basic and diluted basis, for the six months ended June 30, 2020, as compared to a net loss of $17.1 million, or $0.52 per share on both a basic and diluted basis, for the same period in 2019.

Revenues for the second quarter of 2020 were $2.4 million, as compared to $2.1 million for the same period in 2019. Revenues for the six months ended June 30, 2020 were $5.1 million, as compared to $3.9 million for the same period in 2019. 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 2020 were $7.8 million, as compared to $8.2 million for the same period in 2019. Operating expenses for the six months ended June 30, 2020 were $19.0 million, as compared to $15.6 million for the same period in 2019, and comprised the following:

Costs of Royalty Revenues. Costs of royalty revenues, primarily amounts due to third-party university patent licensors in connection with Genentech and Roche's Erivedge net sales, were stable at $0.1 million for the second quarter of 2020, as compared to $0.1 million for the same period in 2019. Cost of royalty revenues for the six months ended June 30, 2020 were also stable at $0.2 million, as compared to $0.2 million for the same period in 2019.

Research and Development Expenses. Research and development expenses were $5.3 million for the second quarter of 2020, as compared to $5.6 million for the same period in 2019. The decrease in research and development expenses for the quarter is primarily attributable to reduced clinical trial costs related to CA-170 and fimepinostat. Research and development expenses were $12.8 million for the six months ended June 30, 2020 as compared to $9.7 million for the same period in 2019.

General and Administrative Expenses. General and administrative expenses were $2.4 million for the second quarter of 2020, as compared to $2.5 million for the same period in 2019. The decrease was driven primarily by lower stock-based compensation costs as well as lower legal and professional services fees, partially offset by higher occupancy costs. General and administrative expenses were $6.0 million for the six months ended June 30, 2020, as compared to $5.7 million for the same period in 2019.

Other expense, net. Net other expense was $1.3 million for the second quarter of 2020, as compared to $1.1 million for the same period in 2019. Net other expense for the second quarter 2020 primarily consisted of imputed interest expense related to future royalty payments. Net other expense was $2.5 million for the six months ended June 30, 2020, as compared to $5.4 million for the same period in 2019.

As of June 30, 2020, Curis' cash, cash equivalents, marketable securities and investments totaled $23.6 million and there were approximately 50.6 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 the first half of 2021. This forecast does not include potential proceeds from the Company's stock purchase agreement with Aspire Capital or the Company's at-the-market facility with JonesTrading.

Conference Call Information

Curis management will host a conference call today, August 4, 2020, 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, CA-4948. CA-4948 is currently undergoing testing in a Phase 1 trial in patients with non-Hodgkin lymphoma and in a Phase 1 trial in patients with acute myeloid leukemia and myelodysplastic syndromes. In addition, Curis is engaged in a collaboration with ImmuNext for development of CI-8993, a monoclonal anti-VISTA antibody, which is planned to be tested in a Phase 1a/1b 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' website at www.curis.com.

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 statements regarding the Company's planned prioritization of resources, the timing and reporting of potential data, its plans to declare the recommended Phase 2 dose for CA-4948 in the ongoing lymphoma Phase 1 study, its plans to initiate a combination study with CA-4948, its plans to initiate a Phase 1a/1b trial of CI-8993 in the second half of 2020, the impacts of the COVID-19 pandemic and the measures implemented in response thereto, the period in which Curis expects that its existing cash, cash equivalents and investments will enable it to fund its operations, its ability to access financing under its purchase agreement with Aspire or under its at-the-market sales agreement with JonesTrading, statements with respect to the plans, strategies and objectives of management for future operations, and the Company's expectations regarding the potential therapeutic benefit of its proprietary drug candidates. Forward-looking statements may contain the words "believes," "expects," "anticipates," "plans," "intends," "seeks," "estimates," "assumes," "will," "may," "could" 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, 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, 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 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. 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 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. If it is unable to continue as a going concern, it may have to liquidate its assets and may receive less than the value at which those assets are carried on its audited financial statements, and it is likely that investors will lose all or a part of their investment. Curis faces substantial competition. Curis also faces risks relating to 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 Curis's ongoing or planned 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. 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 caption "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,*	
	2020	***2019***	***2020***	***2019***
Revenues, net:				
Royalties	$ 2,446	$ 2,142	$ 4,961	$ 4,279
Other revenue	—	—	211	—
Contra revenue, net	(86)	(48)	(104)	(418)
Total revenues, net:	2,360	2,094	5,068	3,861
Costs and expenses:				
Costs of royalties	122	89	247	197
Research and development	5,282	5,620	12,754	9,694
General and administrative	2,386	2,526	5,980	5,669
Total costs and expenses	7,790	8,235	18,981	15,560
Net loss from operations	(5,430)	(6,141)	(13,913)	(11,699)
Loss on debt extinguishment	—	—	—	(3,495)
Interest income	5	235	55	343
Imputed interest expense related to the sale of future royalties	(1,284)	(1,287)	(2,581)	(1,417)
Interest expense	—	—	—	(791)
Other income (expense), net	1	(20)	22	(38)
Total other expense	(1,278)	(1,072)	(2,504)	(5,398)
Net loss	(6,708)	(7,213)	(16,417)	(17,097)
Basic and diluted net loss per common share	$ (0.17)	$ (0.22)	$ (0.44)	$ (0.52)
Basic and diluted weighted average common shares outstanding	39,517,045	33,154,566	36,985,117	33,158,222

CURIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)
(In thousands)

	June 30, 2020	***December 31, 2019***
ASSETS		
Cash, cash equivalents and investments	$ 23,622	$ 20,543
Restricted cash	969	969
Accounts receivable	2,486	3,244
Property and equipment, net	737	154
Operating lease right-of-use asset	7,149	149
Goodwill	8,982	8,982
Prepaid expenses and other assets	1,005	1,066
Total assets	$ 44,950	$ 35,107

LIABILITIES AND STOCKHOLDERS' DEFICIT		
Accounts payable and accrued liabilities	$ 7,054	$ 6,375
Operating lease liability	7,197	166
Debt obligations	890	—
Liability related to the sale of future royalties, net	60,189	62,477
Total liabilities	75,330	69,018
Total stockholders' deficit	(30,380)	(33,911)
Total liabilities and stockholders' deficit	$ 44,950	$ 35,107

SOURCE Curis, Inc.

For further information: Investor Relations: Michael Horowicz, Stern Investor Relations, Inc., (212) 362-1200, Michael.Horowicz@sternir.com

---

https://investors.curis.com/2020-08-04-Curis-Reports-Second-Quarter-2020-Financial-Results