Curis Reports Third Quarter 2017 Financial Results

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

LEXINGTON, Mass., Nov. 07, 2017 (GLOBE NEWSWIRE) -- Curis, Inc. (NASDAQ:CRIS), a biotechnology company focused on the development and commercialization of innovative and effective drug candidates for the treatment of human cancers, reported today its financial results for the third quarter ended September 30, 2017.

"We are pleased to announce the acceptance of our Investigational New Drug (IND) application for CA-4948, an inhibitor of IRAK4 kinase, which we expect to enter the clinic soon for the treatment of lymphomas with specific mutations," said Ali Fattaey, President and CEO. "In addition, we are continuing to enroll patients in the Phase 1 trial of CA-170, an oral, small molecule, dual immune checkpoint inhibitor, to determine the recommended dose and most promising areas of future development for this molecule. We look forward to presenting additional preliminary data from the ongoing Phase 1 trial at the upcoming 2017 Society for Immunotherapy of Cancer (SITC) Meeting. In our CUDC-907 program, we expect to present data supporting its clinical benefit in patients with MYC-altered DLBCL at the upcoming American Society of Hematology (ASH) conference in December, and are planning for our discussions regarding these results with the FDA. And, on the financial front, our recently completed offering of common stock in September provides us operating capital to support these programs well into 2019."

Third Quarter 2017 Financial Results

Curis reported a net loss of $15.5 million, or $0.11 per share, on both a basic and diluted basis for the third quarter of 2017, as compared to a net loss of $28.3 million, or $0.21 per share, on both a basic and diluted basis for the same period in 2016. Curis reported a net loss of $45.3 million, or $0.31 per share, on both a basic and diluted basis for the nine months ended September 30, 2017, as compared to a net loss of $49.1 million, or $0.38 per share on both a basic and diluted basis for the same period in 2016. The net loss for the prior year period includes a non-cash in-process research and development charge of $18.0 million related to the amendment of Curis's license agreement with Aurigene.

Revenues for the third quarter of 2017 were $2.4 million, as compared to $1.8 million for the same period in 2016. Revenues for the nine months ended September 30, 2017 were $6.6 million, as compared to $5.2 million for the same period in 2016. Revenues for both periods comprise primarily royalty revenues recorded on Genentech and Roche's net sales of Erivedge®.

Operating expenses were $16.9 million for the third quarter of 2017, as compared to $29.5 million for the same period in 2016.

Operating expenses for the nine months ended September 30, 2017 were $49.3 million, as compared to $52.4 million for the same period in 2016, and comprised the following:

Costs of Royalty Revenues. Costs of royalty revenues, primarily relates to amounts due to third-party university patent licensors in connection with Genentech and Roche's Erivedge net sales, were $0.1 million for both the third quarter of 2017 and 2016. Cost of royalty revenues for the nine months ended September 30, 2017 and 2016 were $0.3 million for both periods.

In-Process Research and Development Expense. No in-process research and development expenses were recorded for the nine months ended September 30, 2017 as compared to $18.0 million recorded during the third quarter of 2016 associated with the issuance of 10,208,333 shares of Curis common stock to Aurigene

as consideration for the rights granted under the terms of the September 2016 amendment to our collaboration agreement.

Research and Development Expenses. Research and development expenses were $13.4 million for the third quarter of 2017, as compared to $6.8 million for the same period in 2016. The increase was primarily due to a payment to Aurigene of $3.8 million for an exclusivity option in September 2017 and increased direct spending related to clinical activities of CA-170 and increased employee-related expenses primarily due to additional headcount. Research and development expenses were $38.2 million for the nine months ended September 30, 2017 as compared to $22.4 million for the same period in 2016.

General and Administrative Expenses. General and administrative expenses were $3.4 million for the third quarter of 2017 as compared to $4.7 million for the same period in 2016. The decrease in general and administrative expenses was driven primarily by a one-time stock-based compensation modification expense incurred in 2016 and lower legal, professional, consulting and other administrative expenses. General and administrative expenses were $10.8 million for the nine months ended September 30, 2017, as compared to $11.7 million for the same period in prior 2016.

Other expense, net was $1.0 million for the third quarter of 2017, as compared to $0.6 million for the same period in 2016. Other expense, net primarily consisted of interest expense related to Curis Royalty's (a wholly owned subsidiary of Curis) debt obligations. Other expense, net was $2.7 million and $1.8 million for the nine months ended September 30, 2017 and 2016, respectively.

As of September 30, 2017, Curis's cash, cash equivalents, marketable securities and investments totaled $69.2 million and there were approximately 164.0 million shares of common stock outstanding. On a fully-diluted basis, which includes 17.0 million options, there were 181.0 million shares outstanding.

Immuno-oncology (CA-170: PD-L1 / VISTA antagonist program; Aurigene collaboration):

In September 2017, Curis presented preliminary data from the dose escalation stage of the CA-170 Phase 1 trial at the European Society for Medical Oncology (ESMO) 2017 Congress.

Following evidence in Phase 1 of tumor shrinkage, multiple patients remaining on CA-170 treatment for extended periods, and compelling signals for biomarkers of immune modulation in patient blood and tumor samples, Curis's partner Aurigene announced a decision to fund a jointly-designed Phase 2 study at sites in India.

Precision oncology (CA-4948, IRAK4 inhibitor program):

Curis announces U.S. FDA acceptance of the IND to test CA-4948 in a Phase 1 trial in patients with hematologic malignancies, and in particular those with MYD88 gene mutations. A Phase 1 trial is expected to begin in the fourth quarter of 2017.

Precision oncology (CUDC-907: MYC-altered DLBCL program):

In August 2017, Curis reported data from the interim analysis of the Phase 2 trial of CUDC-907 in patients with MYC-altered diffuse large B-cell lymphoma (DLBCL). The company is preparing for discussions with the FDA regarding these results.

CA-327 (an orally bioavailable inhibitor of PDL1 and TIM3 immune checkpoints):

Curis expects to file an IND in the first half of 2018.

Upcoming Activities

Curis expects that it will make presentations at the following conferences through December 2017:

An oral presentation on preliminary data from the ongoing Phase 1 trial of CA-170 at the Society for Immunotherapy of Cancer (SITC) 32nd Annual Meeting (Nov. 8-12, 2017) in Oxon Hill, Maryland

Poster presentation on oral small molecule combination therapy targeting PD-L1, VISTA and Tim-3 checkpoints at the Society for Immunotherapy of Cancer (SITC) 32nd Annual Meeting (Nov. 8-12, 2017) in Oxon Hill, Maryland

Presentation as part of an analyst-moderated fireside chat at the Cowen IO NEXT Summit (Nov. 10, 2017) in Oxon Hill, Maryland

CUDC-907 poster presentation at the 59th American Society of Hematology (ASH) Annual Meeting and Exposition (Dec. 9-12, 2017) in Atlanta

Overview of Company's pipeline at the Guggenheim Securities Healthcare Conference (Dec. 13, 2017) in Boston

Conference Call Information

Curis management will host a conference call today, Nov. 7, 2017, at 8:30 a.m. EST to discuss these financial results and provide a corporate update.

To access the live conference call, please dial (877) 868-1829 from the United States or (253) 237-1135 from other locations shortly before 8:30 a.m. EST. The conference ID number is 6198027. The conference call can also be accessed on the Curis website at www.curis.com in the Investors section.

About Curis

Curis is a biotechnology company focused on the development and commercialization of innovative and effective drug candidates for the treatment of human cancers, including CUDC-907, which is being investigated in clinical studies in patients with lymphomas and solid tumors. Curis is also engaged in a broad 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 the PD1 and VISTA pathways, including PDL1/VISTA antagonist CA-170, and oral small molecule antagonists of the PD1 and TIM3 pathways, including PDL1/TIM3 antagonist CA-327, as well as to molecules designed to inhibit the IRAK4 kinase, including CA-4948. CA-170 is currently undergoing testing in a Phase 1 trial in patients with advanced solid tumors and lymphomas. 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 Private Securities Litigation Reform Act of 1995, including without limitation statements regarding any expectations of revenue, expenses, earnings or losses from operations, or other financial results, statements with respect to the plans, strategies and objectives of management for future operations, the potential for the Company's proprietary drug candidates, including CUDC-907, the potential advantages and benefits of small molecule checkpoint antagonists, the Company's plans and expectations for the collaboration with Aurigene, including its plans to

discover and develop multiple first-in-class oral, small molecule checkpoint antagonists for the treatment of patients with cancer, and the Company's plans to advance its development programs, including the timing of IND filings, the start of the Phase 1 trial for CA-4948, and the Company's plans for CUDC-907. Forward-looking statements may contain the words "believes," "expects," "anticipates," "plans," "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 agreement with Aurigene will continue for its full term, that Curis or Aurigene 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. Curis faces risks relating to its wholly-owned subsidiary's royalty-collateralized loan transaction, including the risk that it may not receive sufficient levels of royalty revenue from sales of Erivedge to satisfy the debt obligation or may otherwise lose its rights to royalties and royalty-related payments as a result of a foreclosure of the loan. Curis will require substantial additional capital to fund its business and such capital may not be available on reasonable terms, or at all. 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 and unplanned expenses may adversely affect Curis's financial conditions and its ability to access the substantial additional capital needed to fund the growth of its business. Important factors that may cause or contribute to such differences 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 September 30,		Nine months ended September 30,	
	2017	2016	2017	2016
Revenues:				

Royalties	$ 2,412	$ 1,817	$ 6,706	$ 5,403
Research and development, net	32	(58)	(70)	(238)
Total revenues:	2,444	1,759	6,636	5,165
Operating expenses:				
Costs of royalty revenues	124	94	331	278
Research and development	13,382	6,781	38,177	22,431
In-process research and development	-	17,989	-	17,989
General and administrative	3,409	4,684	10,760	11,743
Total operating expenses	16,915	29,548	49,268	52,441
Net loss from operations	(14,471)	(27,789)	(42,632)	(47,276)
Other (expense) income	-	-	(104)	-
Interest income	123	101	331	325
Interest expense	(1,109)	(657)	(2,884)	(2,126)
Total other expense, net	(986)	(556)	(2,657)	(1,801)
Net loss	(15,457)	(28,345)	(45,289)	(49,077)
Basic and diluted net loss per common share	$ (0.11)	$ (0.21)	$ (0.31)	$ (0.38)
Basic and diluted weighted average common shares outstanding	146,514,196	132,065,947	144,120,718	130,122,698

CURIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)
(In thousands)

	September 30, 2017	December 31, 2016
ASSETS		
Cash, cash equivalents and investments	$ 69,231	$ 44,485
Investments — restricted	153	153
Accounts receivable	2,456	2,459
Property and equipment, net	384	413
Goodwill	8,982	8,982

Prepaid expenses and other assets	1,162	1,260
Total assets	$ 82,368	$ 57,752
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	$ 9,047	$ 8,626
Debt obligations, net	42,874	19,860
Total liabilities	51,921	28,486
Total stockholders' equity	30,447	29,266
Total liabilities and stockholders' equity	$ 82,368	$ 57,752

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