Curis Reports Third Quarter 2016 Financial Results

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

LEXINGTON, Mass., Nov. 03, 2016 (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, today reported its financial results for the third quarter ended September 30, 2016.

"We are pleased with our progress this quarter, and remain focused on patient enrollment within our two clinical programs. CA-170's Phase 1 trial is progressing rapidly through the dose escalation stage with no limiting adverse safety effects," said Ali Fattaey, Ph.D., Curis's CEO. "Additionally, we continue to enroll at multiple centers in the Phase 2 trial of CUDC-907 in patients with relapsed/refractory DLBCL. Our goal is to assess CUDC-907's efficacy in patients with MYC-altered DLBCL and we expect to use this information for discussion with the FDA in 2017."

Dr. Fattaey continued, "Our collaboration with Aurigene continues to progress well. In September, we completed a $24.5M financing with Aurigene. In October, we licensed a second immuno-oncology program, designating CA-327 as an oral small molecule development candidate targeting PDL1 and TIM3. We expect to file an IND for CA-327 in 2017."

Third Quarter 2016 Financial Results

Curis reported a net loss of $28.3 million, or $(0.21) per share on both a basic and diluted basis for the third quarter of 2016, as compared to a net loss of $5.5 million, or $(0.04) per share on both a basic and diluted basis for the same period in 2015. Curis reported a net loss of $49.1 million or $(0.38) per share on both basic and diluted basis for the nine months ended September 30, 2016, as compared to a net loss of $45.5 million, or $(0.37) per share on both basic and diluted basis for the same period in 2015. The net loss for the three and nine months ended September 30, 2016 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. The net loss for the nine months ended September 30, 2015 includes a non-cash in-process research and development charge of $24.3 million related to Curis's license agreement with Aurigene.

Revenues for the third quarter of 2016 were $1.8 million, as compared to $2.0 million for the same period in 2015. Revenues for both periods comprise primarily royalty revenues recorded on Genentech and Roche's net sales of Erivedge®. Revenues for the nine months ended September 30, 2016 were $5.2 million, as compared to $5.8 million for the same period in 2015.

Operating expenses were $29.5 million for the third quarter of 2016, as compared to $6.9 million for the same period in 2015.

Operating expenses for the nine months ended September 30, 2016 were $52.4 million, as compared to $49.0 million for the same period in 2015, 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 $0.1 million for both the third quarter of 2016 and 2015. Cost of royalty revenues for the nine months ended September 30, 2016 and 2015 were $0.3 million for both periods.

In-Process Research and Development Expense. In-process research and development expense was $18.0 million for the third quarter of 2016, as compared to $24.3 million for the same period in 2015. These charges are associated with the stock issuances of 10,208,333 and 17,120,131 shares of Curis common stock to Aurigene, respectively. These shares were issued as consideration for the rights granted under the terms of the September 2016 amendment to the collaboration agreement and partial consideration for the rights granted under the terms of the January 2015 collaboration agreement, respectively.

Research and Development Expenses. Research and development expenses were $6.8 million for the third quarter of 2016, as compared to $4.0 million for the same period in 2015. The increase was primarily due to increased direct spending related to clinical activities of CUDC-907 and programs under the Aurigene collaboration over the prior year period. Employee-related expenses increased over the prior year period primarily due to additional headcount to support the multiple programs. Research and development expenses were $22.4 million for the nine months ended September 30, 2016 as compared to $14.7 million for the same period in 2015.

General and Administrative Expenses. General and administrative expenses were $4.7 million for the third quarter of 2016 as compared to $2.8 million for the same period in 2015. The increase in general and administrative expenses was driven primarily by higher personnel costs and stock-based compensation expense due to increased headcount and an increase in legal service costs. General and administrative expenses were $11.7 million for the nine months ended September 30, 2016, as compared to $9.7 million for the same period in prior 2015.

Other expense, net was $0.6 million for the third quarter of 2016, as compared to $0.7 million for the same period in 2015. Other expense, net primarily consisted of interest expense related to the loan made by BioPharma-II (an investment fund managed by Pharmakon Advisors) to Curis Royalty (a wholly owned subsidiary of Curis). Other expense, net was $1.8 million and $2.3 million for the nine months ended September 30, 2016 and 2015, respectively.

As of September 30, 2016, Curis's cash, cash equivalents, marketable securities and investments totaled $53.4 million and there were approximately 140.0 million shares of common stock outstanding.

Recent Operational Highlights

Curis - Aurigene collaboration:

In October, 2016 Curis licensed the second oral small molecule immuno-oncology development candidate under the collaboration. This program is focused on the development of oral, small molecule antagonists that target two distinct checkpoint pathways: the programmed death-1 (PD1) and T-cell immunoglobulin and mucin domain containing protein-3 (TIM3) pathways. Curis has designated CA-327 that targets programmed death ligand-1 (PDL1) and TIM3 as the development candidate.

In September, 2016 Curis's collaboration Aurigene Discovery Technologies Ltd. invested in Curis at a premium by acquiring 10.2 million shares of Curis's common stock in lieu of receiving up to $24.5 million of milestone and other payments from Curis that may become due under the companies' 2015 collaboration agreement.

Upcoming Activities

Curis expects that it will make presentations at the following conferences through December 2016:

Presentation of preclinical results from CA-170 and CA-327 at the SITC conference
Presentation of preclinical results from combination of CUDC-907 with other treatments at the ASH annual conference

Conference Call Information

Curis management will host a conference call today, November 3, 2016, at 8:30 a.m. EDT, to discuss these financial results, as well as 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. EDT. The conference ID number is 6507701. 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 and commercialization of innovative and effective drug candidates for the treatment of human cancers. The Company's clinical drug candidates include CUDC-907, which is being investigated in a Phase 2 trial in patients with Diffuse Large B Cell Lymphoma, or DLBCL, and in a separate Phase 1 trial in patients with solid tumors. As part of a broad collaboration with Aurigene, Curis has an exclusive license to CA-170, an oral small molecule PDL1/VISTA antagonist that is currently being investigated in a Phase 1 trial in patients with solid tumors or lymphoma. Curis also has an exclusive license to 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. 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, and are further developing Erivedge in other diseases including idiopathic pulmonary fibrosis and myelofibrosis. For more information, visit Curis' 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 the potential advantages and benefits of small molecule checkpoint inhibitors and 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 inhibitors for the treatment of patients with cancer. 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 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,*	
	2016	*2015*	*2016*	*2015*
Revenues:				
Royalties	$ 1,817	$ 2,293	$ 5,403	$ 5,998
Research and development, net	(58)	(248)	(238)	(212)
Total revenues:	1,759	2,045	5,165	5,786
Operating expenses:				
Costs of royalty revenues	94	116	278	303
Research and development	6,781	4,001	22,431	14,658
In-process research and development	17,989	0	17,989	24,348
General and administrative	4,684	2,772	11,743	9,712
Total operating expenses	29,548	6,889	52,441	49,021
Net loss from operations	(27,789)	(4,844)	(47,276)	(43,235)
Interest income	101	128	325	252
Interest expense	(657)	(827)	(2,126)	(2,537)
Other expense, net	(556)	(699)	(1,801)	(2,285)
Net loss	(28,345)	(5,543)	(49,077)	(45,520)
Basic and diluted net loss per common share	$ (0.21)	$ (0.04)	$ (0.38)	$ (0.37)
Basic and diluted weighted average common shares outstanding	132,065,947	128,392,413	130,122,698	121,634,415

CURIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)
(In thousands)

	September 30, 2016	*December 31, 2015*
ASSETS		
Cash, cash equivalents and investments	$ 53,355	$ 82,191
Investments — restricted	153	153
Accounts receivable	1,857	2,106
Property and equipment, net	406	278
Goodwill	8,982	8,982
Other assets	1,440	1,255
Total assets	$ 66,193	$ 94,965
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	$ 7,421	$ 6,290
Debt obligations, net	20,902	24,165
Total liabilities	28,323	30,455
Total stockholders' equity	37,870	64,510
Total liabilities and stockholders' equity	$ 66,193	$ 94,965

For More Information:
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