Curis Reports First Quarter 2016 Financial Results

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

LEXINGTON, Mass., May 09, 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 first quarter ended March 31, 2016.

"We are pleased with the initiation of the Phase 2 study with CUDC-907 earlier this year in patients with relapsed/refractory Diffuse Large B Cell Lymphoma (DLBCL) that harbor MYC alterations," said Ali Fattaey, Ph.D., Curis's President and CEO. "At the recent AACR annual conference, we presented preclinical data, which provide further evidence for CUDC-907's effect on downregulating MYC and its anti-tumor activity in multiple lymphoma and solid tumor models with alterations in MYC oncogene."

Dr. Fattaey continued, "All IND enabling studies with CA-170 have been completed, and we remain on track to initiate a Phase 1 study in cancer patients in the first half of 2016 with CA-170 as our first oral immuno-oncology drug candidate. Additionally, preclinical development of small molecule leads that target PD-L1 and TIM3 in our second immuno-oncology program is progressing well and these candidates further underscore the potential of this discovery platform to generate multiple oral small molecule drug candidates that can modulate independent immune checkpoint targets."

First Quarter 2016 Financial Results

Curis reported a net loss of $9.4 million, or ($0.07) per share, on both a basic and diluted basis for the first quarter of 2016, as compared to a net loss of $31.8 million, or ($0.30) per share, on both a basic and diluted basis for the same period in 2015. The net loss for the prior year period includes a non-cash in-process research and development charge of $24.3 million related to Curis's license agreement with Aurigene.

Revenues were $1.7 million for each of the first quarters of 2016 and 2015. Revenues for both periods are comprised primarily of royalty revenues recorded on Genentech and Roche's net sales of Erivedge®.

Operating expenses were $10.5 million for the first quarter of 2016, as compared to $32.7 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 $89,000 for the first quarter of 2016, up from $84,000 during the first quarter of 2015.

In-Process Research and Development Expense. No in-process research and development expenses were recorded for the three months ended March 31, 2016 as compared to $24.3 million recorded during the first quarter of 2015 associated with the issuance of 17,120,131 shares of Curis common stock to Aurigene as partial consideration for the rights granted under the terms of our January 2015 collaboration agreement.

Research and Development Expenses. Research and development expenses were $6.8 million for the first quarter of 2016, as compared to $4.7 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.

General and Administrative Expenses. General and administrative expenses remained unchanged at $3.5 million for first quarter of 2016 and $3.5 million for the same period in 2015.

Other expense was $635,000 for the first quarter of 2016, as compared to $827,000 for the same period in 2015. Other expense primarily consisted of $740,000 and $867,000 in interest expense for the quarters ended March 31, 2016 and 2015, respectively, related to the loan made by BioPharma-II (an investment fund managed by Pharmakon Advisors) to Curis Royalty (a wholly-owned subsidiary of Curis).

As of March 31, 2016, Curis's cash, cash equivalents, marketable securities and investments totaled $73.1 million and there were approximately 129.0 million shares of common stock outstanding.

Recent Operational Highlights

Precision oncology (HDAC / PI3K inhibitor program):

In April 2016, preclinical data were presented for CUDC-907 at the Annual Meeting of American Association of Cancer Research (AACR) in New Orleans. The presentation included data for CUDC-907's anti-tumor activity in multiple *in vitro* and *in vivo* MYC-altered disease models, including lymphomas and solid tumors, and the molecule's effect on downregulating MYC levels.

In January 2016, Curis initiated an open label Phase 2 study to evaluate the efficacy and safety of CUDC-907 with and without rituximab in patients with relapsed/refractory MYC-altered DLBCL.

Immuno-oncology (PD-L1 / VISTA antagonist program):

In April 2016, preclinical data were presented for CA-170, a small molecule, orally available antagonist of PD-L1 and VISTA

at the Annual AACR meeting in New Orleans. The data presented included the pharmacologic and safety profile of CA-170 to support its progression into human clinical trials.

Immuno-oncology (PD-L1 / TIM-3 antagonist program):

In April 2016, preclinical data were presented from the orally available, small molecule PD-L1/TIM-3 immune checkpoint antagonist program. Results from *in vitro* studies with AUPM-327, a representative molecule from the PD-L1/TIM-3 program showed that AUPM-327 can selectively rescue T cell functions that are inhibited by PD-L1 or TIM-3 checkpoint proteins, but does not modulate the effects of other regulators such as VISTA, CTLA4, LAG-3, or CD-28, demonstrating its selectivity. Additionally, daily oral administration of the PD-L1/TIM-3 antagonist resulted in anti-tumor activity in multiple syngeneic tumor models including melanoma and colon cancer.

Precision oncology (IRAK4 inhibitor program):

In April 2016, preclinical data were presented for CA-4948, the oral IRAK4 inhibitor at the Annual AACR meeting in New Orleans. The presentations outlined CA-4948's detailed pharmacologic and biologic profile as well as data on its metabolism, pharmacokinetics properties and *in vitro* toxicity profile. CA-4948 demonstrated potent anti-tumor activity in two *in vivo* models of MYD88 mutant- DLBCL disease and anti-inflammatory effects in a rodent model of inflammation suggesting the potential use of an IRAK4 inhibitor in both cancer and inflammatory diseases.

Erivedge:

Roche initiated patient enrollment in a Phase 1 clinical study to evaluate the safety and efficacy of Erivedge in combination with ruxolitinib for the treatment of patients with intermediate- or high-risk myelofibrosis.
Roche initiated patient enrollment in a study of Erivedge in combination with pirfenidone in patients with idiopathic pulmonary fibrosis (IPF). The study is designed as a single arm, multicenter Phase 1b study to evaluate the safety and tolerability of Erivedge in combination with pirfenidone in participants with IPF currently being treated with pirfenidone.

Upcoming Activities

Curis expects that it will make presentations at the following scientific and investor conferences through June 2016:

American Society of Clinical Oncology (ASCO) 2016 Annual Meeting on June 3-7 in Chicago
Jefferies Healthcare Conference on June 7-10 in New York City
21st Congress of the European Hematology Association on June 9-12 in Copenhagen, Denmark

Our partner, Roche/Genentech expect to present data on Erivedge at ASCO 2016 Annual Meeting in Chicago from June 3-7.

Conference Call Information

Curis management will host a conference call today, May 9, 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 89164069. 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 cancers, including its lead development candidate, CUDC-907, that 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 PD-1 pathway/VISTA, including PD-L1/VISTA antagonist CA-170, as well as to oral small 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'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: the Company's plan to initiate a Phase 1 study in the first half of 2016 for CA-170 and the Company's expectations regarding the potential of the Aurigene discovery platform to generate multiple oral small drug candidates. 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, 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. 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. 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 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. Curis also faces other important risks relating to its business, operations, financial condition and future prospects that are discussed in its Annual Report on Form 10-K for the period ended December 31, 2015 and other filings that it periodically makes with the Securities and Exchange Commission.

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)

	Three months ended March 31,	
	2016	*2015*
Revenues:		
Royalties	$ 1,743,747	$ 1,671,070
Research and development, net	(17,759)	(12,738)
Total revenues	1,725,988	1,658,332
Operating expenses:		
Cost of royalty revenues	88,773	84,092
In-process research and development	—	24,347,815
Research and development	6,828,064	4,718,972
General and administrative	3,616,085	3,529,002
Total operating expenses	10,532,922	32,679,881
Loss from operations	(8,806,934)	(31,021,549)
Other expense, net	(634,563)	(826,674)
Net loss	$ (9,441,497)	$ (31,848,223)
Basic and diluted net loss per common share	$ (0.07)	$ (0.30)
Basic and diluted weighted average common shares outstanding	129,019,984	107,934,493

CURIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(UNAUDITED)

	March 31, 2016	*December 31, 2015*
ASSETS		
Cash, cash equivalents and investments	$ 73,123,116	$ 82,191,012
Investments — restricted	152,610	152,610
Accounts receivable	1,746,515	2,106,031
Property and equipment, net	383,578	277,714
Goodwill	8,982,000	8,982,000
Other assets	931,370	1,255,772
Total assets	$ 85,319,189	$ 94,965,139
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	6,472,336	6,290,154
Debt obligations, net	22,904,384	24,164,507
Total liabilities	29,376,720	30,454,661
Total stockholders' equity	55,942,469	64,510,478
Total liabilities and stockholders' equity	$ 85,319,189	$ 94,965,139

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