Curis Reports Fourth Quarter and Year-End 2015 Financial Results

LEXINGTON, Mass., Feb. 29, 2016 (GLOBE NEWSWIRE) -- Curis, Inc. (NASDAQ:CRIS), a biotechnology company focused on the development and commercialization of innovative drug candidates for the treatment of human cancers, today reported its financial results for the fourth quarter and year ended December 31, 2015.

"2015 has been a year of significant milestones for Curis," said Ali Fattaey, Ph.D., Curis' President and CEO. "During the fourth quarter, we presented data from the Phase 1 trial of CUDC-907 at the American Society of Hematology's annual meeting, including notable results from heavily pre-treated patients with DLBCL who experienced complete or partial responses, particularly in those with alterations of the MYC oncogene in their cancers. Based on these promising early results, in January we initiated a Phase 2 study to evaluate the efficacy of CUDC-907 in patients with relapsed/refractory DLBCL that harbor MYC alterations. There is a high unmet need for effective therapies for these patients due to their poor prognosis and a lack of optimal therapeutic options."

Dr. Fattaey continued, "We are making considerable progress with our pipeline and are on-track to file an IND application and initiate a Phase 1 clinical trial in cancer patients for CA-170, our first oral immuno-oncology drug candidate within the first half of 2016. We also expect to file an IND application for CA-4948, our IRAK4 inhibitor drug candidate, during the second half of 2016."

Full Year and Fourth Quarter 2015 Financial Results

For the year ended December 31, 2015, Curis reported a net loss of $59.0 million, or ($0.48) per basic and fully diluted share, as compared to a net loss of $18.7 million or ($0.22) per basic and fully diluted share in 2014. The 2015 net loss includes a one-time charge for in-process research and development expense of $24.3 million 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 the parties' January 2015 collaboration agreement. For the fourth quarter of 2015, Curis reported a net loss of $13.5 million, or ($0.10) per basic and fully diluted share, as compared to a net loss of $5.7 million or ($0.07) per basic and fully diluted share for the same period in 2014.

Revenues for the year ended December 31, 2015 were $7.9 million as compared to $9.8 million for the same period in 2014. Substantially all of the Company's revenues in 2015 and 2014 were recorded under Curis' collaboration with Genentech. The decrease in revenues for the year ended December 31, 2015 was primarily due to a decrease in license fee revenues associated with a $3 million milestone payment earned during the year ending 2014. This decrease was partially offset by an increase in royalty revenues, which were $8.0 million and $6.8 million for the years ending 2015 and 2014, respectively.

Revenues for the fourth quarters of 2015 and 2014 were $2.1 million and $2.0 million, respectively, and were comprised almost entirely of Erivedge royalty revenues.

Operating expenses were $64.4 million for the year ended December 31, 2015, as compared to $25.7 million for the same period in 2014. Operating expenses for the fourth quarter of 2015 were $15.3 million, as compared to $6.8 million for the same period in 2014.

Costs of royalty revenues. Cost of royalty revenues, which are comprised of amounts due to third-party university patent licensors in connection with Genentech/Roche's Erivedge net sales, were $406,000 for the year ended December 31, 2015, as compared to $340,000 for 2014. Cost of royalty revenues were $103,000 and $93,000 for the fourth quarters of 2015 and 2014, respectively.

In-process research and development expenses. The Company recorded a one-time charge for in-process research and development expense of $24.3 million during the year ended December 31, 2015 associated with the issuance of common stock to Aurigene.

Research and development expenses. Research and development expenses were $26.7 million for the year ended December 31, 2015 as compared to $13.7 million for 2014. The increase was primarily due to increases in spending on the Company's CUDC-907 clinical development program, and preclinical programs under its collaboration with Aurigene. These increases were partially offset by decreases in spending on the Company's other programs, including CUDC-427.

Research and development expenses were $12.0 million for the fourth quarter of 2015, as compared to $3.5 million for the same period in 2014. The Company incurred $6 million in milestone payments under the Aurigene collaboration during the fourth quarter of 2015.

General and administrative expenses. General and administrative expenses were $12.9 million for the year ended December 31, 2015 as compared to $11.7 million in 2014, and $3.2 million for each of the fourth quarters of 2015 and 2014. The increase in annual expense was primarily due to increased spending on legal costs, consulting and professional services and stock-based compensation.

Other expense was $2.5 million for the year ended 2015 and $2.9 million for the year ended 2014, and is primarily comprised of interest expense associated with the loan made by BioPharma-II to Curis Royalty, a wholly-owned subsidiary of Curis. Other expense was $215,000 for the fourth quarter of 2015, as compared to $878,000 for the fourth quarter of 2014. Interest expense was $788,000 and $914,000 for the fourth quarters of 2015 and 2014, respectively.

As of December 31, 2015, Curis' cash, cash equivalents, marketable securities and investments totaled $82.2 million and there were approximately 129.0 million shares of common stock outstanding.

Financial Guidance

Curis expects to end 2016 with cash, cash equivalents and investments of $27 to 34 million, excluding any potential future payments from existing or new collaborators.

Curis expects that 2016 research and development expenses will be $40 to $45 million and that general and administrative expenses will be $12 to $14 million. These expense expectations include approximately $1 million and $2.5 million of estimated 2016 stock-based compensation

expense in research and development and general and administrative expense, respectively, based on stock awards that are currently outstanding.

Recent Operational Highlights

CUDC-907 (oral, dual inhibitor of HDAC and PI3K enzymes):

In December 2015, Curis presented data from the Phase 1 trial of CUDC-907 at the American Society of Hematology's Annual Meeting in Orlando, FL. The data demonstrated that monotherapy treatment with CUDC-907 resulted in complete (n=3) and partial responses (n=5) in heavily pretreated patients with relapsed/ refractory diffuse large B cell lymphoma (DLBCL), including those with cancers harboring alterations of the MYC oncogene, a poor performing sub-group of lymphomas for which there are no approved targeted therapies.

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

Aurigene Collaboration (Immuno-Oncology):

In October 2015, Curis exercised its option to exclusively license a first-in-class oral, small molecule antagonist of immune checkpoint proteins and designated it CA-170. The molecule targets PD-L1 and VISTA, two negative regulators of immune activation. The toxicology studies required to support the investigational new drug (IND) application for CA-170 have been completed and Curis expects to file the IND application and initiate its Phase 1 clinical development in the first half of 2016.

In November 2015, Curis' collaborator Aurigene presented preclinical data from the CA-170 program at the 2015 AACR-NCI-EORTC Molecular Targets and Cancer Therapeutics Conference in Boston, MA. The presentation included data from *in vitro* functional studies as well as studies with isolated human T cells that demonstrated that short exposures to CA-170 are adequate to rescue and sustain activation of T cells functions in culture. In addition, daily oral administration of CA-170 resulted in anti-tumor activity in multiple syngeneic tumor models including melanoma and colon cancer, whereas no activity was observed in immune-deficient SCID-Beige mice, suggesting that the anti-cancer effects of CA-170 were mediated via activation of immune responses to these cancers.

In October 2015, Curis also selected a third program for potential further development under the collaboration, which is the second preclinical program within the immuno-oncology field and which is focused on orally available small molecules targeting PD-L1 and TIM-3 immune checkpoints. TIM-3 is an independent inhibitory checkpoint that is co-expressed with PD-1 on highly exhausted cytotoxic T cells in tumor tissues and is also expressed on certain regulatory T cells. The Company has not yet exercised its option to license this program.

Aurigene Collaboration (IRAK4 Inhibitor):

In October 2015, Curis exercised its option to exclusively license a program of orally available small molecule inhibitors of IRAK4 kinase, a serine/threonine kinase involved in innate immune responses as well as in certain hematologic cancers. The Company has since designated the development candidate as CA-4948 and expects to file an IND application for this molecule during 2016.

In November 2015, Curis' collaborator Aurigene presented preclinical data from the IRAK4 program at the 2015 AACR-NCI-EORTC Molecular Targets and Cancer Therapeutics Conference in Boston, MA. This presentation included data from chemically distinct series of small molecule compounds with potent IRAK4 inhibitory activity in biochemical assays as well as in *in vivo* preclinical models, including MYD88 mutant DLBCL xenograft tumor models as well as a model of inflammatory disease.

Erivedge:

During the fourth quarter of 2015, Roche initiated a clinical study to evaluate the efficacy and safety of Erivedge in combination with ruxolitinib for the treatment of patients with intermediate- or high-risk myelofibrosis.

In January 2016, Roche initiated 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 investor and scientific conferences through April 2016:

Cowen and Company 36th Annual Health Care Conference on March 7-9 in Boston, MA
ROTH Capital Growth Conference on March 13-16 in Los Angeles, CA
Jefferies 2016 Immuno-Oncology Summit on April 7-8 in Boston, MA
American Association for Cancer Research (AACR) Annual Meeting on April 16-20 in New Orleans, LA

Conference Call Information

Curis management will host a conference call today, February 29, 2016, at 8:30 a.m. EST, to discuss Curis' financial results for the quarter as well as provide a corporate update.

To access the live conference call, please dial (877) 868-1829 from the U.S. or (253) 237-1135 from other locations, shortly before 8:30 a.m. EST. The conference ID number is 46140545. 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 drug candidates for the treatment of cancers, including its lead development candidate, CUDC-907, that is being investigated in two 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. Curis is also party to a collaboration with Genentech, a member of the Roche Group, under which Genentech and Roche are developing and commercializing Erivedge® for the treatment of advanced basal cell carcinoma, and are further developing Erivedge in other diseases including IPF 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 Company's plan to file an IND application for CA-170 and to initiate a Phase 1 study during the first half of 2016; the Company's plan to file an IND application for CA-4948 during the second half 2016; the Company's intent to advance CUDC-907 in clinical development; and its expectations as to 2016 year end cash and cash equivalents, research and development expenses and general and administrative expenses. 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 faces a number of risks inherent in the research and development of novel drugs to treat cancer and may not be able to successfully advance the development of its drug candidates in the time frames it projects, if at all. Curis may experience adverse results, delays and/or failures in its drug development programs. Curis' 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' 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 Quarterly Report on Form 10-Q for the period ended September 30, 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' 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 December 31,		*Year ended December 31,*	
	2015	*2014*	*2015*	*2014*
Revenues:				
Royalties	$ 2,033,428	$ 1,861,569	$ 8,030,942	$ 6,757,023
License fees	—	—	—	3,000,000
Research and development, net	59,176	131,130	(152,535)	86,458
Total revenues:	2,092,604	1,992,699	7,878,407	9,843,481
Operating expenses:				
Cost of royalty revenues	102,547	93,298	405,756	339,578
In-process research and development	—	—	24,347,815	—
Research and development	12,041,353	3,479,127	26,699,370	13,659,398
General and administrative	3,194,864	3,231,362	12,906,334	11,706,754
Total operating expenses	15,338,764	6,803,787	64,359,275	25,705,730
Net loss from operations	(13,246,160)	(4,811,088)	(56,480,868)	(15,862,249)
Interest and other income	573,162	35,983	824,854	165,103
Interest expense	(787,992)	(913,765)	(3,325,016)	(3,748,374)
Change in fair value of warrant liability	—	—	—	716,786
Other expense, net	(214,830)	(877,782)	(2,500,162)	(2,866,485)

Net loss	$ (13,460,990)	$ (5,688,870)	$ (58,981,030)	$(18,728,734)
Basic and diluted net loss per common share	$ (0.10)	$ (0.07)	$ (0.48)	$ (0.22)
Basic and diluted weighted average common shares outstanding	128,501,098	86,010,499	123,365,195	85,974,535

CURIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(UNAUDITED)

	December 31, 2015	*December 31, 2014*
ASSETS		
Cash, cash equivalents and investments	$ 82,191,012	$ 50,538,961
Investments — restricted	152,610	166,487
Accounts receivable	2,106,031	1,960,995
Property and equipment, net	277,714	407,738
Goodwill	8,982,000	8,982,000
Other assets	1,255,772	557,388
Total assets	$ 94,965,139	$ 62,613,569
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	6,290,154	4,530,900
Debt obligations, net	24,164,507	28,299,043
Total liabilities	30,454,661	32,829,943
Total stockholders' equity	64,510,478	29,783,626
Total liabilities and stockholders' equity	$ 94,965,139	$ 62,613,569

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https://investors.curis.com/Curis-Reports-Fourth-Quarter-and-Year-End-2015-Financial-Results