Curis Reports Third Quarter 2015 Financial Results

Management to Host Conference Call Today at 8:30 a.m. EST

LEXINGTON, Mass., Nov. 9, 2015 (GLOBE NEWSWIRE) -- Curis, Inc. (NASDAQ:CRIS), a biotechnology company focused on the development and commercialization of innovative drug candidates for the treatment of cancers, today reported its financial results for the third quarter ended September 30, 2015.

"We are excited to have recently exercised two options under our collaboration with Aurigene to obtain exclusive licenses to the PD-L1/VISTA and IRAK4 programs," said Ali Fattaey, Ph.D., Curis' President and CEO. "Aurigene scientists presented compelling preclinical data for each program this weekend at the AACR-NCI-EORTC International Conference, and our internal team is working diligently with Aurigene to advance both programs into clinical development. During the first half of 2016, we expect to file an IND and initiate Phase 1 clinical testing of the PD-L1/VISTA inhibitor, CA-170, and also expect to file an IND for development of the IRAK4 inhibitor."

Dr. Fattaey continued, "We have also been working to advance CUDC-907 into the next stage of clinical development. We expect to provide additional data from the ongoing Phase 1 trial, as well as details of the planned Phase 2 study at the ASH annual meeting later this year."

Third Quarter and Nine Months ended September 30, 2015 Financial Results

Curis reported a net loss of $5.5 million, or ($0.04) per share on both a basic and fully diluted basis for the third quarter of 2015, as compared to a net loss of $5.6 million, or ($0.06) per share on both a basic and fully diluted basis for the third quarter of 2014. Curis reported a net loss of $45.5 million, or ($0.37) per share on both a basic and fully diluted basis for the nine months ended September 30, 2015, as compared to a net loss of $13.0 million, or ($0.15) per share on both a basic and fully diluted basis for the nine months ended September 30, 2014. The net loss for the first nine months of 2015 includes an in-process research and development charge of $24.3 million related to Curis' collaboration agreement with Aurigene.

Revenues for the third quarter of 2015 were $2.0 million, as compared to $1.8 million for the same period in 2014. The increase in revenues was primarily due to an increase in royalty revenues recorded on Genentech/Roche's net sales of Erivedge, which increased to $2.3 million during the third quarter of 2015, as compared to $1.8 million during the same period in 2014.

Revenues for the nine months ended September 30, 2015, were $5.8 million, as compared to $7.9 million for the same period in 2014. The decrease was primarily related to a $3.0 million milestone payment that Curis received in 2014 related to its Genentech collaboration. Curis did not receive any such payments from Genentech during the nine months ended September 30, 2015. Offsetting this decrease, royalty revenues recognized from Genentech and Roche's net sales of Erivedge increased $1.1 million to $6.0 million during the nine months ended September 30, 2015 as compared to $4.9 million during the same period in 2014, a 23% increase over the prior year period.

Operating expenses for the third quarter of 2015 were $6.9 million, as compared to $6.5 million for the same period in 2014. Operating expenses for the nine months ended September 30, 2015 were $49.0 million, as compared to $18.9 million for the same period in 2014 and were comprised of the following:

Costs of royalty revenues. Costs 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 $116,000 and $89,000 during the third quarters of 2015 and 2014, respectively. Costs of royalty revenues for the nine months ended September 30, 2015 were $303,000, as compared to $246,000 for the same period in 2014.

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 nine months ended September 30, 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 the parties' January 2015 collaboration agreement.

Research and development expenses. Research and development expenses were $4.0 million for the third quarter of 2015, as compared to $3.7 million for the same period in 2014. The increase in research and development expenses was primarily due to increased spending on CUDC-907 and preclinical programs under the Company's collaboration with Aurigene. The Company incurred expenses of $2.8 million and $2.1 million on CUDC-907 for the quarters ended September 30, 2015 and 2014, respectively, related to its ongoing Phase 1 studies of this molecule. The Company recorded costs of $700,000 on the Company's preclinical research programs under the Aurigene collaboration for the three months ended September 30, 2015. Offsetting these increases, spending on CUDC-427 and other programs decreased by $1 million during the three months ended September 30, 2015 as compared to the prior year period. Research and development expenses were $14.7 million for the nine months ended September 30, 2015 as compared to $10.2 million for the same period in 2014.

General and administrative expenses. General and administrative expenses were $2.8 million for the third quarter of 2015, as compared to $2.7 million for the same period in 2014. Increased spending on consulting and professional services and stock-based compensation were offset by decreases in legal spending. General and administrative expenses were $9.7 million for the nine months ended September 30, 2015 as compared to $8.5 million for the same period in 2014.

Other expense was $699,000 for the third quarter of 2015, as compared to $827,000 for the same period in 2014. Other expense primarily consisted of $827,000 and $934,000 in interest expense for the quarters ended September 30, 2015 and 2014, respectively, related to the loan made by BioPharma-II to Curis Royalty, a wholly-owned subsidiary of Curis. Other expense was $2.3 million and $2.0 million for the nine month periods ended September 30, 2015 and 2014, respectively.

As of September 30, 2015, Curis' cash, cash equivalents, marketable securities and investments totaled $93.5 million, and there were approximately 128.4 million shares of common stock outstanding.

Recent Operational Highlights

Aurigene Collaboration:

In October 2015, Curis exercised its option to exclusively license a first-in-class oral, small molecule antagonist designated as CA-170 that targets PD-L1 and VISTA, two negative checkpoint regulators of immune activation. CA-170 was selected from the broad PD-L1 antagonist program that the companies have been engaged in since the collaboration was established in January 2015. Curis also 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.
Curis selected another preclinical program within the immuno-oncology collaboration with Aurigene that is focused on evaluating small molecule antagonists with dual PD-L1 and T-cell immunoglobulin and mucin domain containing protein-3 (TIM-3) targeting properties.
In November, Curis presented data at the 2015 AACR-NCI-EORTC Molecular Targets and Cancer Therapeutics Conference in Boston, Massachusetts for the PD-L1/VISTA and IRAK4 programs.

Erivedge:

In November, Roche disclosed its intent to initiate a clinical study to examine the effectiveness of Erivedge in combination with ruxolitinib in participants with intermediate- or high-risk myelofibrosis. Myelofibrosis is a serious bone marrow disorder that disrupts the body's normal production of blood cells. The result is extensive scarring in bone marrow, leading to anemia, weakness, fatigue, and often, an enlarged spleen and liver.

A Phase 1b portion of the study will assess the safety of Erivedge plus ruxolitinib combined therapy. After getting confirmation about the safety and toxicity of this combination, a randomized, controlled portion of the study may begin. The primary endpoints relate to reduction in spleen volume and overall response rate. Details of the study have been posted on clinicaltrials.gov.

Upcoming Activities

Curis expects to present at the following conferences through February 2016:

American Society of Hematology (ASH) Annual Meeting in Orlando, Florida: December 5-8, 2015
Oppenheimer 26th Annual Healthcare Conference in New York City: December 8-9, 2015
BIO CEO Investor Conference 2016: February 8-9, 2016
2016 RBC Capital Markets' Healthcare Conference in New York City: February 23-24, 2016

Conference Call Information

Curis management will host a conference call today, November 9, 2015, 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 66760275. 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, an oral dual HDAC and PI3K inhibitor 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. 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 expected benefits of the Company's collaboration with Aurigene and the planned areas of development thereunder; 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 an IRAK4 inhibitor during the first half of 2016; the Company's plans to advance its PD-L1/VISTA and IRAK4 programs into clinical development; the Company's intent to advance CUDC-907 in clinical development; and its plans to provide additional data from the ongoing Phase 1 trial of CUDC-907, as well as details of the planned Phase 2 study at a medical meeting later this year. 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. Genentech and Roche may experience delays or failures in the manufacture of Erivedge. Erivedge's benefit/risk profile may not be widely accepted by the medical community or third-party payors for the treatment of advanced BCC, in which case revenues from sales of Erivedge could be adversely affected. Regulatory authorities may determine to delay or restrict Genentech's and/or Roche's ability to continue to develop or commercialize Erivedge. 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 capital 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 June 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 September 30,		*Nine months ended September 30,*	
	2015	*2014*	*2015*	*2014*
Revenues:				
Royalties	$2,292,608	$1,783,271	$5,997,514	$4,895,454
License fees	—	—	—	3,000,000
Research and development, net	(247,641)	(18,407)	(211,711)	(44,672)
Total revenues:	2,044,967	1,764,864	5,785,803	7,850,782
Operating expenses:				
Costs of royalty revenues	116,145	89,295	303,209	246,280
In-process research and development	—	—	24,347,815	—
Research and development	4,001,069	3,705,365	14,658,017	10,180,271
General and administrative	2,771,496	2,723,235	9,711,470	8,475,392
Total operating expenses	6,888,710	6,517,895	49,020,511	18,901,943
Net loss from operations	(4,843,743)	(4,753,031)	(43,234,708)	(11,051,161)
Interest income	127,329	38,881	251,692	129,120
Interest expense	(826,710)	(933,903)	(2,537,024)	(2,834,609)
Change in fair value of warrant liability	—	67,910	—	716,786
Other expense, net	(699,381)	(827,112)	(2,285,332)	(1,988,703)
Net loss	$(5,543,124)	$(5,580,143)	$(45,520,040)	$(13,039,864)
Basic and diluted net loss per common share	$(0.04)	$(0.06)	$(0.37)	$(0.15)
Basic and diluted weighted average common shares outstanding	128,392,413	86,004,857	121,634,415	85,962,415

CURIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)

	September 30, 2015	*December 31, 2014*
ASSETS		
Cash, cash equivalents and investments	$93,470,393	$50,538,961
Investments - restricted	152,610	166,487
Accounts receivable	2,318,202	1,960,995
Property and equipment, net	315,470	407,738
Goodwill	8,982,000	8,982,000
Other assets	874,201	557,388
Total assets	$106,112,876	$62,613,569
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	4,591,532	4,530,900
Debt obligations, net	25,528,530	28,299,043
Total liabilities	30,120,062	32,829,943
Total stockholders' equity	75,992,814	29,783,626
Total liabilities and stockholders' equity	$106,112,876	$62,613,569

CONTACT: For More Information:

Mani Mohindru, Ph.D.

Senior Vice President,

Corporate Strategy and Investor Relations

Curis, Inc.

617-503-6605

mmohindru@curis.com

Michael P. Gray

Chief Financial and Chief Business Officer

Curis, Inc.

617-503-6632

mgray@curis.com

---

https://investors.curis.com/Curis-Reports-Third-Quarter-2015-Financial-Results