Curis Reports Fourth Quarter and Year-End 2013 Financial Results

Management to Host Conference Call Today at 9:00 a.m. EST

LEXINGTON, Mass., Feb. 20, 2014 (GLOBE NEWSWIRE) -- Curis, Inc. (Nasdaq:CRIS), an oncology-focused company developing novel, targeted drug candidates for the treatment of human cancers, today reported its financial results for the fourth quarter and year ended December 31, 2013.

"Over the last several months, we have continued to focus on advancing our proprietary assets, including our ongoing Phase 1 clinical study of the dual HDAC and PI3K inhibitor, CUDC-907," commented Ali Fattaey, Ph.D., President and Chief Operating Officer of Curis. "Enrollment in CUDC-907's Phase 1 study in patients with relapsed/refractory lymphoma and multiple myeloma is progressing well at all three trial sites. We have also compiled the FDA-requested information in response to the partial clinical hold on CUDC-427. We have submitted our analysis of CUDC-427 clinical data and an amended protocol to the FDA. After we receive feedback on our response, we expect to continue to provide updates on the status of both of our proprietary programs and ongoing development plans."

"We are also pleased with the progress of our partnered assets, including initiation of new clinical studies during the fourth quarter of 2013 for both Erivedge and Debio 0932," said Dan Passeri, Curis' Chief Executive Officer. "In addition, Genentech/Roche's commercial efforts for Erivedge have resulted in significant year-over-year increases in our royalty revenue."

Full Year and Fourth Quarter 2013 Financial Results

For the year ended December 31, 2013, Curis reported a net loss of $12.3 million, or ($0.15) per basic and fully diluted share, as compared to a net loss of $16.4 million or ($0.21) per basic and fully diluted share in 2012. For the fourth quarter of 2013, Curis reported a net loss of $4.2 million, or ($0.05) per basic and fully diluted share, as compared to a net loss of $12.4 million or ($0.15) per basic and fully diluted share for the same period in 2012. The fourth quarter and full year 2012 net loss included a one-time expense of $9.5 million relating to an up-front payment and technology transfer costs associated with the Company's November 2012 CUDC-427 license agreement with Genentech.

Revenues for the year ended December 31, 2013 were $15.0 million as compared to $17.0 million in 2012. Substantially all of the Company's revenues in 2012 and 2013 were recorded under Curis' collaboration with Genentech. This decrease in revenues was primarily due to a decrease of $4.0 million in license revenues offset by an increase in royalty revenues earned from Genentech/Roche's net sales of Erivedge during 2013, which increased to $3.9 million for the year ended December 31, 2013, as compared to $1.5 million in 2012. Revenues for the fourth quarter of 2013 were $1.5 million, which were primarily comprised of $1.4 million Erivedge royalty revenues. Revenues for the prior year period were $1.7 million, including $1.0 million in milestones earned under Curis' agreement with The Leukemia and Lymphoma Society and $560,000 of Erivedge-related royalty revenues.

Operating expenses were $24.4 million for the year ended December 31, 2013, as compared to $35.6 million in 2012. Operating expenses for the fourth quarter of 2013 were $6.0 million, as compared to $15.1 million for the same period in 2012.

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 $198,000 for the year ended December 31, 2013, as compared to $176,000 in 2012. Cost of royalty revenues were $70,000 and $28,000 during the fourth quarters of 2013 and 2012, respectively.

Research and development expenses were $12.9 million for the year ended December 31, 2013 as compared to $15.5 million in 2012. Curis decreased spending related to CUDC-101 and discovery research by $6.2 million during the year ended December 31, 2013. The Company shifted the focus of its internal resources to the clinical development of CUDC-907 and CUDC-427, resulting in increased spending of $5.4 million related to these programs year-over-year. During the year ended December 31, 2013, the Company incurred $500,000 in sublicense expenses related to its obligations to university licensors as compared to $2.1 million in 2012. Research and development expenses were $3.0 million for the fourth quarter of 2013, as compared to $2.7 million for the same period in 2012.

In-process research and development expense of $9.5 million was recorded for the fourth quarter and year ended December 31, 2012 as a result of up-front payments related to the Company's in-license of CUDC-427 from Genentech. The Company did not record in-process research and development expense in 2013.

General and administrative expenses were $11.3 million for the year ended December 31, 2013 as compared to $10.4 million in 2012 and $3.0 million for the fourth quarter of 2013, as compared to $2.9 million for the same period in 2012. The increases were primarily due to increased expenses for personnel and professional services offset by decreases in stock-based compensation.

Other expense was $2.9 million for the year ended December 31, 2013 as compared to other income of $2.2 million in 2012. The increase in other expense was primarily the result of $3.8 million in interest expense and amortization of debt issuance costs related to the loan made by BioPharma II to Curis Royalty, a wholly-owned subsidiary of Curis, offset in part by decreases in the fair value of a warrant liability. Other income was $285,000 for the fourth quarter of 2013, as compared to other income of $1.1 million for the same period in 2012.

As of December 31, 2013, Curis' cash, cash equivalents, marketable securities and investments totaled $68.9 million and there were approximately 85.9 million shares of common stock outstanding. Curis management expects that its existing capital resources are adequate to fund its current and planned operations well into the first half of 2016.

As of September 30, 2013, Curis had recorded liabilities related to the loan made by BioPharma II to Curis Royalty of $30,896,000, which consisted of $30,582,000 in long- and short-term debt, net and accrued interest of $314,000. During the quarter ended December 31, 2013, Curis recorded interest and amortization of certain debt issuance costs totaling $972,000 and Curis Royalty made a payment on December 2, 2013 to BioPharma II of $1.0 million, resulting in debt-related liabilities of $30,854,000 as of December 31, 2013, which consisted of $30,555,000 in long- and short-term debt, net and accrued interest of $299,000.

Recent Operational Highlights

CUDC-907:

Curis presented interim data from the ongoing Phase 1 clinical study of CUDC-907 at the 55th Annual Meeting of the American Society of Hematology (ASH) in New Orleans in December 2013. The Company currently anticipates completion of the dose escalation phase and determination of a recommended dose for future studies by mid-2014. During the second half of 2014, Curis expects to begin enrollment in expansion cohorts where CUDC-907 is planned to be tested in patients with specific hematological malignancies.

CUDC-427:

In November 2013, Curis received written notification from the United States Food and Drug Administration (FDA) that its Phase 1 study of CUDC-427 had been placed on partial clinical hold following the report of death of a patient who progressed to liver failure approximately one month following the discontinuation of CUDC-427 dosing. As a result, new patients may not be enrolled in the study until Curis provides the FDA with requested additional data and analyses of patients treated with CUDC-427, along with a protocol amendment that is accepted by the FDA. In February 2014, Curis submitted the response and amended protocol to the FDA. If the partial clinical hold is lifted by FDA, Curis expects to re-start enrollment in the monotherapy study and also initiate a Phase 1b/2 study in HER-2 negative advanced breast cancer patients where CUDC-427 will be administered in combination with capecitabine.

Upcoming Activities

Curis expects that it will make presentations at the following investor and scientific conferences through April 2014:

2014 RBC Capital Markets Global Healthcare Conference on February 25-26, 2014 in New York City
Cowen and Company 34th Annual Health Care Conference on March 3-5, 2014 in Boston
ROTH Capital Partners 26th Annual Conference on March 10-12, 2014 in Dana Point, CA
American Association for Cancer Research (AACR) Annual Meeting 2014 on April 5-9, 2014 in San Diego
Needham & Co. Annual Healthcare Conference in New York City on April 8-9, 2014

Conference Call Information

Curis management will host a conference call today, February 20, 2014, at 9:00 a.m. ET, 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 U.S. or (253) 237-1135 from other locations, shortly before 9:00 a.m. ET. The conference ID number is 63234866. The conference call can also be accessed on the Curis website at www.curis.com in the Investors section. A replay will be available approximately two hours after the completion of the call through 12:00 p.m. ET, Saturday, March 1, 2014. To access the replay, please dial (855) 859-2056 from the United States or (404) 537-3406 from other locations and reference conference ID number 63234866.

About Curis, Inc.

Curis is an oncology-focused drug development company seeking to develop novel drug candidates for the treatment of human cancers. Erivedge is the first and only FDA-approved medicine for the treatment of advanced BCC and is being commercialized and developed by Roche and Genentech, a member of the Roche Group, under a collaboration agreement between Curis and Genentech. Curis is also seeking to further the development of its pipeline of proprietary targeted cancer drug candidates, including CUDC-907, a dual HDAC and PI3K inhibitor, and CUDC-427, a small molecule antagonist of IAP proteins,. 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: any expressed or implied statements about the efficacy, safety and potential benefits of its drug candidates, including CUDC-907 and CUDC-427; its plans and timing for conducting ongoing and planned clinical studies with CUDC-907;any expectations regarding the partial clinical hold on CUDC-427 and future development of CUDC-427; expectations regarding growth in Erivedge sales; and its estimates with respect to its cash and cash equivalent balances and research and development and general and administrative expenses at year end. 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 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 any of its programs, including CUDC-907 and CUDC-427, in the time frames it projects, if at all. The FDA may not lift the clinical hold and allow Curis to pursue further development of CUDC-427, and even if the FDA lifts the clinical hold, or if the FDA or other

regulatory agencies continue to express safety concerns even after the hold is lifted, future preclinical or clinical studies involving CUDC-427 may be more burdensome or include additional preclinical or clinical endpoints that are difficult to meet. Genentech and Roche may not obtain additional regulatory approvals for Erivedge abroad. 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 Erivedge 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 and its collaborators may experience adverse results, delays and/or failures in their drug development programs. Curis and its collaborators' drug candidates may cause unexpected toxicities, fail to demonstrate sufficient safety and efficacy in clinical trials and/or may never achieve the requisite regulatory approval needed for commercialization. Curis will require substantial additional capital to fund its business and such capital may not be available on reasonable terms, or at all. Curis may not obtain or maintain necessary patent protection and could become involved in expensive and time consuming patent litigation and interference proceedings. Curis faces substantial competition. Unstable market and economic conditions 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 September 30, 2013 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.

CURIS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(UNAUDITED)

	Three months ended December 31,		*Year ended December 31,*	
	2013	*2012*	*2013*	*2012*
Revenues:				
Royalties	$1,392,191	$559,870	$3,942,136	$1,529,644
License fees	--	--	10,000,000	14,000,000
Research and development	131,946	1,126,536	1,059,896	1,442,347
Total revenues:	1,524,137	1,686,406	15,002,032	16,971,991
Operating expenses:				
Cost of royalty revenues	70,297	27,993	197,796	176,482
Research and development	2,960,987	2,707,400	12,926,834	15,492,302
In-process research and development	--	9,500,000	--	9,500,000
General and administrative	2,976,070	2,883,498	11,293,811	10,423,014
Total operating expenses	6,007,354	15,118,891	24,418,441	35,591,798
Net loss from operations	(4,483,217)	(13,432,485)	(9,416,409)	(18,619,807)
Interest income	47,065	62,713	164,650	149,937
Interest expense	(971,559)	(204,167)	(3,841,646)	(204,167)
Change in fair value of warrant liability	1,209,679	1,202,751	771,393	2,257,130
Other income (expense), net	285,185	1,061,297	(2,905,603)	2,202,900
Net loss	($4,198,032)	($12,371,188)	($12,322,012)	($16,416,907)
Basic and diluted net loss per common share	($0.05)	($0.15)	($0.15)	($0.21)
Basic and diluted weighted average common shares outstanding	85,741,278	79,971,888	82,339,493	79,059,153

CURIS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)

	December 31, 2013	*December 31, 2012*
ASSETS		
Cash, cash equivalents and investments	$68,906,307	$58,701,423
Investments - restricted	180,364	194,282
Accounts receivable	1,477,188	908,064
Property and equipment, net	445,655	434,168
Goodwill	8,982,000	8,982,000
Other assets	599,294	548,412
Total assets	$80,590,808	$69,768,349
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	4,145,077	4,173,747
Debt, net	30,555,360	29,838,925
Warrant liability	716,786	1,488,179
Total liabilities	35,417,223	35,500,851
Total stockholders' equity	45,173,585	34,267,498
Total liabilities and stockholders' equity	$80,590,808	$69,768,349

CONTACT: For More Information:

Mani Mohindru, Ph.D.

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
