Curis Reports Second Quarter 2013 Financial Results

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

LEXINGTON, Mass., Aug. 5, 2013 (GLOBE NEWSWIRE) -- Curis, Inc. (Nasdaq:CRIS), an oncology-focused drug development company seeking to develop novel drug candidates for the treatment of human cancers, today reported its financial results for the second quarter ended June 30, 2013.

"The second quarter and recent weeks have been highlighted by significant advances within our proprietary programs, including the recent initiation of the first of three planned clinical trials with our IAP antagonist, CUDC-427," said Ali Fattaey, President and Chief Operating Officer of Curis. "We plan to initiate the second trial in HER2 negative breast cancer patients in combination with capecitabine and a third trial in patients with certain aggressive and indolent lymphomas, including MALT lymphomas, which are often associated with genetic aberrations of the molecular targets of CUDC-427."

Dr. Fattaey continued, "We are also encouraged with the progress of our ongoing Phase 1 clinical study of dual targeted PI3K and HDAC inhibitor, CUDC-907. We continue to enroll patients and expect to report interim data from this study later this year."

"In addition to our efforts on Curis' proprietary programs, our collaborator Genentech/Roche continues to successfully advance its global commercialization strategy for Erivedge®, with recent regulatory approvals in the European Union and Australia, among others," said Dan Passeri, Chief Executive Officer of Curis. "We are also highly encouraged with Erivedge's sales growth, with Roche reporting a net sales increase of approximately 22% in the second quarter versus the previous quarter. We expect continued growth in the U.S. market and anticipate Roche's commercial launch in additional markets in the coming months."

Second Quarter 2013 Financial Results

Curis reported a net loss of $1.3 million, or ($0.02) per share on both a basic and fully diluted basis for the second quarter of 2013, as compared to a net loss of $2.9 million or ($0.04) per share on both a basic and fully diluted basis for the same period in 2012. Curis reported a net loss of $6.3 million, or ($0.08) per share on both a basic and fully diluted basis for the six months ended June 30, 2013, as compared to a net loss of $661,000 or ($0.01) per share on both a basic and fully diluted basis for the same period in 2012.

Revenues for the second quarter of 2013 were $5.4 million, as compared to $4.4 million for the same period in 2012. This increase in revenues is primarily the result of an increase in royalties received from Genentech/Roche's net sales of Erivedge during the second quarter of 2013. Royalty revenues recorded on net sales of Erivedge increased to $805,000 for the second quarter of 2013 as compared to $253,000 during the same period in 2012. In addition to the increase in royalty revenue, Curis received a $550,000 milestone payment from the Leukemia and Lymphoma Society (LLS) related to the achievement of certain clinical objectives in its ongoing Phase 1 clinical study of CUDC-907.

Revenues for the six months ended June 30, 2013 were $6.3 million, as compared to $14.7 million for the same period in 2012. The decrease in revenues for the six-month period is primarily related to a non-recurring $10 million milestone payment that the Company received from Genentech upon the U.S. Food and Drug Administration (FDA) approval of Erivedge in the first quarter of 2012.

Operating expenses for the second quarter of 2013 were $6.1 million, as compared to $6.8 million for the same period in 2012.

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 $40,000 and $13,000 during the second quarters of 2013 and 2012, respectively, representing 5% of Erivedge royalties earned during the periods.

Research and development expenses were $3.2 million for the second quarter of 2013 as compared to $4.5 million for the same period in 2012. Curis incurred $200,000 in research and development expenses during the second quarter of 2013 related to the marketing approval of Erivedge in Australia in May 2013 as compared to $650,000 in research and development expenses during the same period in 2012 related to sublicense fees paid to university licensors in connection with regulatory filings in Australia. Curis also decreased its spending on CUDC-101 and discovery research to $370,000 during the second quarter of 2013 from $2.2 million during the same period in 2012 as the Company continued to focus its capital resources on the development of CUDC-907 and CUDC-427. During the second quarter of 2013, the Company spent $1.2 million on CUDC-427, which was licensed from Genentech in November 2012.

General and administrative expenses were $2.9 million for the second quarter of 2013 as compared to $2.3 million for the same period in 2012. The increase was primarily due to increased expenses for personnel, legal services and professional services.

Operating expenses for the six months ended June 30, 2013 were $11.3 million, as compared to $14.9 million for the same period in 2012. Research and development expenses were $5.8 million for the six months ended June 30, 2013 as compared to $9.7 million for the same period in 2012. General and administrative expenses were $5.5 million for the six months ended June 30, 2013 as compared to $5.1 million for the same period in 2012.

Other expense was $588,000 for the second quarter of 2013 as compared to $460,000 for the same period in 2012. The increase in other expense is primarily the result of $958,000 in interest expense and amortization of debt issuance costs related to the debt transaction between BioPharma II and Curis Royalty, a wholly-owned subsidiary of the Company. Interest expense was partially offset by $333,000 in other income recorded as a result of a decrease in the fair value of a warrant liability during the second quarter of 2013. Other expense during the prior year period primarily represents the change in the fair value of this warrant liability. Other expense was $1.2 million for the six months ended June 30, 2013 as compared to $434,000 for the same period in 2012.

As of June 30, 2013, Curis' cash, cash equivalents, marketable securities and investments totaled $57.1 million and there were approximately 81.7 million shares of common stock outstanding.

In December 2012, Curis Royalty entered into a debt transaction with BioPharma II pursuant to which BioPharma II loaned Curis Royalty $30 million at an annual interest rate of 12.25%. The loan is secured with the Erivedge royalty and royalty-related payments that arise under the collaboration agreement with Genentech, all of which payment rights were transferred and assigned to Curis Royalty by Curis at the time of the loan transaction. In addition, pursuant to the terms of the loan, certain of the royalty and royalty-related payments received by Curis Royalty are used to pay down the loan, subject to specified caps. For 2013, Curis Royalty is required to pay BioPharma II up to $1 million per quarter of the royalty revenues that it receives from Genentech/Roche. The loan constitutes an obligation of Curis Royalty and is intended to be non-recourse to the Company.

As of March 31, 2013, the Company had recorded liabilities related to the loan of $30,395,000, which consisted of $30,137,000 in long- and short-term debt, net and accrued interest of $258,000. During the quarter ended June 30, 2013, the Company recorded interest and amortization of certain debt issuance costs totaling $945,000 and made a payment on May 31, 2013 to BioPharma II of $631,000, resulting in debt-related liabilities of $30,709,000 as of June 30, 2013, which consisted of $30,397,000 in long- and short-term debt, net and accrued interest of $312,000.

2013 Financial Guidance

The Company currently anticipates that it will end 2013 with cash, cash equivalents and investments of $49 million to $54 million, which includes the $6 million milestone payment that Curis earned in July 2013 related to the conditional approval of Erivedge in the European Union. This projected estimate excludes potential future milestone and royalty payments from existing or new collaborators, including royalty revenues related to net sales of Erivedge. The Company expects that all or substantially all royalty revenues earned by Curis Royalty in 2013 will be used to service the loan from BioPharma II.

Curis expects that 2013 research and development expenses will be in the range of $11 million to $15 million. This expense expectation includes approximately $800,000 to $900,000 in stock-based compensation expense in research and development for options that were outstanding at June 30, 2013.

Recent Operational Highlights

CUDC-427:

Curis initiated the first of three planned clinical studies of CUDC-427. A Phase 1 dose-escalation study using a continuous, twice-daily oral dosing regimen in patients with advanced and refractory solid tumors or lymphomas was initiated in July 2013 and will include an expansion cohort, which is expected to primarily include patients with ovarian and fallopian tube cancers. This trial builds on the single agent clinical results reported by Genentech in the initial Phase 1 trial of intermittently dosed CUDC-427 (previously GDC-0917), where a complete response was observed in a patient with ovarian cancer.
Phase 1 data for CUDC-427 in patients with refractory cancers was presented during an oral session at the American Society of Clinical Oncology's (ASCO) Annual Meeting on June 2, 2013.

CUDC-907:

Curis announced the issuance of U.S. Patent No. 8,461,157, which along with another related patent issued in February 2013 (U.S. Patent No. 8,367,663) is expected to significantly enhance the intellectual property portfolio for the Company's proprietary compounds that target PI3K and HDAC enzymes within a single molecule including CUDC-907, for the treatment of certain human diseases.

Erivedge:

The European Commission granted conditional approval to Erivedge for the treatment of adult patients with symptomatic metastatic basal cell carcinoma (BCC) or locally advanced BCC inappropriate for surgery or radiotherapy. This regulatory decision is applicable to all 28 member states of the European Union. Erivedge is being commercialized and developed by Genentech/Roche under a collaboration agreement between Curis and Genentech. Curis earned a $6 million milestone payment from Genentech/Roche upon the conditional approval of Erivedge.
Erivedge was approved for marketing registration by Australia's Therapeutic Goods Administration (TGA) for the treatment of adult patients with metastatic BCC, or with locally advanced BCC where surgery and/or radiation therapy are not appropriate. Curis earned a $4 million milestone payment from Genentech/Roche for this approval.

Corporate:

Curis appointed Mani Mohindru, Ph.D. as Vice President of Corporate Strategy and Investor Relations.

Upcoming Activities

Curis expects to present at the following investor conferences through October 2013:

Wedbush Securities Life Sciences Management Access Conference on August 13-14, 2013 in New York City
Robert W. Baird & Co. 2013 Health Care Conference, September 10-11, 2013 in New York City
Stifel Nicolaus Weisel Healthcare Conference 2013 on September 11-12, 2013 in Boston
BioCentury Annual NewsMakers in the Biotech Industry Conference on September 27, 2013 in New York City
Curis Research and Development Day on October 3, 2013 in New York City
Brean Capital 2013 Life Sciences Summit on October 7, 2013 in New York City

Conference Call Information

Dan Passeri, Chief Executive Officer of Curis, will host a conference call today, August 5, 2013, at 9:00 a.m. ET, 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 9:00 a.m. ET. The conference ID number is 18745848. 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, Monday, August 12, 2013. 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 18745848.

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-427, a small molecule antagonist of IAP proteins, and CUDC-907, a dual PI3K and HDAC inhibitor. 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 clinical development plans and timelines, its expectations regarding growth in Erivedge sales and successful commercialization in additional markets, and the expected benefit of patent issuances. 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, 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 March 31, 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 June 30,		*Six months ended June 30,*	
	2013	*2012*	*2013*	*2012*
Revenues:				
Royalties	$ 805,312	$ 252,750	$1,469,712	$ 523,372
License Fees	4,000,000	4,000,000	4,000,000	14,000,000
Research and development	599,065	98,824	806,100	184,454
Total revenues:	5,404,377	4,351,574	6,275,812	14,707,826
Operating expenses:				
Costs of revenues	40,265	12,637	73,485	126,168
Research and development	3,166,639	4,500,456	5,795,096	9,742,405
General and administrative	2,903,669	2,264,586	5,470,791	5,065,663

Total operating expenses	6,110,573	6,777,679	11,339,372	14,934,236
Net loss from operations	(706,196)	(2,426,105)	(5,063,560)	(226,410)
Interest income	36,949	34,994	78,561	53,095
Interest expense	(957,742)	—	(1,905,544)	—
Change in fair value of warrant liability	333,141	(495,341)	634,401	(487,400)
Other expense, net	(587,652)	(460,347)	(1,192,582)	(434,305)
Net loss	$ (1,293,848)	$ (2,886,452)	$ (6,256,142)	$ (660,715)
Basic and diluted net loss per common share	$ (0.02)	$ (0.04)	$ (0.08)	$ (0.01)
Basic and diluted weighted average common shares outstanding	81,128,475	79,052,517	80,615,412	78,304,441

CURIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(UNAUDITED)

	June 30, 2013	*December 31, 2012*
ASSETS		
Cash, cash equivalents and investments	$ 57,133,947	$ 58,701,423
Investments — restricted	180,364	194,282
Accounts receivable	863,187	908,064
Property and equipment, net	500,891	434,168
Goodwill	8,982,000	8,982,000
Other assets	543,307	548,412
Total assets	$ 68,203,696	$ 69,768,349
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	4,196,565	4,173,747
Debt, net	30,396,713	29,838,925
Warrant liability	853,778	1,488,179
Total liabilities	35,447,056	35,500,851
Total stockholders' equity	32,756,640	34,267,498
Total liabilities and stockholders' equity	$ 68,203,696	$ 69,768,349

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