Curis Reports Second Quarter 2014 Financial Results

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

LEXINGTON, Mass., Aug. 7, 2014 (GLOBE NEWSWIRE) -- Curis, Inc. (Nasdaq:CRIS), an oncology-focused biotechnology company developing novel drug candidates for the treatment of human cancers, today reported its financial results for the second quarter ended June 30, 2014.

"We have continued to advance our internal programs in recent months. Dosing of patients with solid tumors or lymphomas was re-initiated in the Phase 1 study evaluating CUDC-427, our IAP antagonist. In addition dose escalation continues in multiple schedules in the Phase 1 study of our dual HDAC and PI3K inhibitor, CUDC-907, in patients with lymphoma or multiple myeloma," said Ali Fattaey, Ph.D., President and Chief Executive Officer of Curis. "We expect that the second half of this year will yield important insights into these drug candidates, as we anticipate not only to identify the recommended doses for each, but also to initiate the expansion phases of both studies during this period. In addition, an expansion arm of the CUDC-907 study will likely begin enrolling patients with hormone-receptor positive breast cancer in the coming months."

"We are pleased to report Erivedge® royalty revenues of $1.8 million for the second quarter, representing an increase of over 40% as compared to our first quarter 2014 royalty revenue. We are encouraged that Erivedge access continues to grow for patients with advanced basal cell carcinoma," said Michael Gray, Curis' Chief Financial and Chief Business Officer. "We believe that Roche's decision to file an Investigational New Drug (IND) application to study Erivedge in idiopathic pulmonary fibrosis (IPF), its first investment in a study of Erivedge in a non-oncology disease setting, has the potential to further increase the value of Erivedge. This filing also resulted in a $3 million milestone payment to Curis."

Second Quarter and First Half 2014 Financial Results

Curis reported a net loss of $1.9 million, or ($0.02) per share on both a basic and fully diluted basis for the second quarter of 2014, as compared to a net loss of $1.3 million or ($0.02) per share on both a basic and fully diluted basis for the same period in 2013. Curis reported a net loss of $7.5 million, or ($0.09) per share on both a basic and fully diluted basis for the six months ended June 30, 2014, as compared to a net loss of $6.3 million or ($0.08) per share on both a basic and fully diluted basis for the same period in 2013.

Revenues for the second quarter of 2014 were $4.8 million, as compared to $5.4 million for the same period in 2013. The decrease in revenues was primarily due to a $1 million decrease in license revenue due to $3 million and $4 million milestone payments Curis earned from Genentech/Roche upon achievement by Genentech/Roche of certain development objectives during the second quarters of 2014 and 2013, respectively. During the second quarter of 2013, Curis also received a $550,000 milestone payment from the Leukemia and Lymphoma Society (LLS) related to Curis' achievement of certain clinical objectives in its ongoing Phase 1 clinical study of CUDC-907 and no such amounts were received during the second quarter of 2014. Offsetting these decreases, royalty revenues recorded on Genentech/Roche's net sales of Erivedge increased to $1.8 million in the second quarter of 2014 as compared to $805,000 during the same period in 2013.

Revenues for the six months ended June 30, 2014 were $6.1 million, as compared to $6.3 million for the same period in 2013.

Operating expenses for the second quarter of 2014 were $6.3 million, as compared to $6.1 million for the same period in 2013. Operating expenses for the six months ended June 30, 2014 were $12.4 million, as compared to $11.3 million for the same period in 2013.

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 $92,000 and $40,000 during the second quarters of 2014 and 2013, respectively. Costs of royalty revenues for the six months ended June 30, 2014 were $157,000, as compared to $73,000 for the same period in 2013.

Research and development expenses were $3.3 million for the second quarter of 2014 as compared to $3.2 million for the same period in 2013. The increase in research and development expense was primarily due to increased spending on CUDC-907 and CUDC-427. The Company incurred expenses of $2.7 million and $2.3 million on these programs for the quarters ended June 30, 2014 and 2013, respectively. Offsetting these increases, stock-based compensation decreased by $200,000 from the prior year period. Research and development expenses were $6.5 million for the six months ended June 30, 2014 as compared to $5.8 million for the same period in 2013.

General and administrative expenses were consistent at $2.9 million for the second quarters of 2014 and 2013, respectively. Increased personnel and professional service costs were offset by decreased legal costs. General and administrative expenses were $5.8 million for the six months ended June 30, 2014 as compared to $5.5 million for the same period in 2013.

Other expense, comprised primarily of interest expense related to the loan made by BioPharma II to Curis Royalty, a wholly-owned subsidiary of Curis, was $351,000 for the second quarter of 2014 compared to $588,000 for the same period in 2013. The decrease in other expense is the result of an increase of $224,000 in other income based on the decrease in the fair value of warrant liability during the second quarter of 2014, as compared to the second quarter of 2013. Other expense was $1.2 million for the each of the six month periods ended June 30, 2014 and 2013, respectively.

As of June 30, 2014, Curis' cash, cash equivalents, marketable securities and investments totaled $59 million, which excludes the $3 million milestone payment Curis received in July 2014, and there were approximately 86 million shares of common stock outstanding.

2014 Financial Guidance

The Company currently anticipates that it will end 2014 with cash, cash equivalents and investments of $47 million to $50 million, which includes the $3 million milestone payment that Curis received in July 2014. This projected estimate excludes potential future milestone and royalty payments from existing or new collaborators, including royalty revenues related to net sales of Erivedge. Curis Royalty is required to pay BioPharma II up to $2 million per quarter of the royalty revenues that it receives from Genentech/Roche in 2014 according to the terms of the Erivedge royalty-secured debt transaction, but would retain royalty revenues that exceed this amount, if any.

Curis expects that 2014 research and development expenses will be $14 to $17 million, including an estimated $700,000 in stock-based compensation expense.

Recent Operational Highlights

CUDC-427:

Curis re-initiated dosing in the single-agent Phase 1 trial of CUDC-427 in patients with advanced and/or refractory solid tumors or lymphoma. The primary objective of the monotherapy study under the amended protocol is to determine the safety and recommended Phase 2 dose for CUDC-427 when administered orally once daily for two weeks, followed by a one week rest period in 21-day cycles until disease progression or study discontinuation. The study is designed to enroll patients in consecutive, escalating cohorts at dose levels of 100, 200 and 300 mg per day. In addition to safety and tolerability measures, the amended protocol includes expansion cohorts intended to enroll patients with specific cancers.

Erivedge:

Curis' partner, Genentech/Roche, filed an IND application with the U.S. Food and Drug Administration (FDA) to initiate a multicenter, Phase 2 clinical study of Erivedge in patients with IPF, a chronic, debilitating lung disease with a high unmet medical need. Currently, there is no cure for IPF and life expectancy for most people is approximately 3 to 5 years after diagnosis. Respiratory failure is the most common cause of death due to IPF. In the U.S., there are an estimated 128,000 people with IPF and there are 40,000 deaths attributed to the disease. The IND filing triggered a $3 million milestone payment to Curis.

Corporate:

Curis appointed Ali Fattaey, Ph.D. as President and Chief Executive Officer and as a member of its Board of Directors. Dr. Fattaey previously served as the Company's President and Chief Operating Officer. He succeeded Dan Passeri, who resigned from his position of Chief Executive Officer and assumed the role of Vice Chairman of Curis' Board of Directors. Mr. Passeri also serves as a strategic advisor to Curis.

Upcoming Activities

Curis expects to present at the following investor conferences through November 2014:

Robert W. Baird & Co. 2014 Health Care Conference, September 3-4, 2014 in New York City

Rodman and Renshaw 16th Annual Global Investment Conference, September 8-10, 2014 in New York City

BIO Investor Forum, October 7-8, 2014 in San Francisco

Stifel 2014 Healthcare Conference on November 18-19, 2014 in New York City

Conference Call Information

Curis management will host a conference call today, August 7, 2014, at 9:00 a.m. EDT, 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. EDT. The conference ID number is 73498877. The conference call can also be accessed on the Curis website at www.curis.com in the Investors section.

About Curis, Inc.

Curis is an oncology-focused biotechnology company developing novel drug candidates for the treatment of human cancers. Curis' pipeline of drug candidates includes CUDC-907, a dual histone deacetylase (HDAC) and phosphoinositide 3-kinase (PI3K) inhibitor, and CUDC-427, a small molecule antagonist of IAP proteins. Curis is also engaged in a collaboration with Genentech, a member of the Roche Group, under which Genentech and Roche are developing and commercializing Erivedge®, the first and only FDA-approved medicine for the treatment of advanced basal cell carcinoma. Curis partner Debiopharm is studying HSP90 inhibitor Debio 0932 in patients with advanced lung cancer. 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 and reading out data from ongoing and planned clinical trials with CUDC-907 and CUDC-427; its expectations regarding growth in Erivedge sales; and its financial guidance with respect to year end cash. 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. 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, 2014 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 June 30,		*Six months ended June 30,*	
	2014	*2013*	*2014*	*2013*
Revenues:				
Royalties	$ 1,823,935	$ 805,312	$ 3,112,183	$ 1,469,712
License fees	3,000,000	4,000,000	3,000,000	4,000,000
Research and development, net	(22,650)	599,065	(26,265)	806,100
Total revenues:	4,801,285	5,404,377	6,085,918	6,275,812
Operating expenses:				
Costs of revenues	91,837	40,265	156,985	73,485
Research and development	3,328,976	3,166,639	6,474,906	5,795,096
General and administrative	2,925,259	2,903,669	5,752,157	5,470,791
Total operating expenses	6,346,072	6,110,573	12,384,048	11,339,372
Net loss from operations	(1,544,787)	(706,196)	(6,298,130)	(5,063,560)
Interest income	41,479	36,949	90,239	78,561
Interest expense	(949,730)	(957,742)	(1,900,706)	(1,905,544)
Change in fair value of warrant liability	557,253	333,141	648,876	634,401
Other expense, net	(350,998)	(587,652)	(1,161,591)	(1,192,582)
Net loss	$ (1,895,785)	$ (1,293,848)	$ (7,459,721)	$ (6,256,142)
Basic and diluted net loss per common share	$ (0.02)	$ (0.02)	$ (0.09)	$ (0.08)
Basic and diluted weighted average common shares outstanding	85,963,836	81,128,475	85,940,842	80,615,412

CONDENSED CONSOLIDATED BALANCE SHEETS
(UNAUDITED)

	June 30, 2014	*December 31, 2013*
ASSETS		
Cash, cash equivalents and investments	$ 59,028,019	$ 68,906,307
Investments - restricted	166,487	180,364
Accounts receivable	4,843,412	1,477,188
Property and equipment, net	439,357	445,655
Goodwill	8,982,000	8,982,000
Other assets	441,687	599,294
Total assets	$ 73,900,962	$ 80,590,808
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	4,549,960	4,145,077
Warrant liability	67,910	716,786
Debt obligations, net	29,870,735	30,555,360
Total liabilities	34,488,605	35,417,223
Total stockholders' equity	39,412,357	45,173,585
Total liabilities and stockholders' equity	$ 73,900,962	$ 80,590,808

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