Curis Reports First Quarter 2014 Financial Results

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

LEXINGTON, Mass., May 8, 2014 (GLOBE NEWSWIRE) -- Curis, Inc. (Nasdaq:CRIS), an oncology-focused drug development company developing novel drug candidates for the treatment of human cancers, today reported its financial results for the first quarter ended March 31, 2014.

"We continue to make progress with our proprietary assets, including patient enrollment into the first-in-human Phase 1 trial of our dual HDAC and PI3K inhibitor, CUDC-907," commented Ali Fattaey, Ph.D., President and Chief Operating Officer of Curis. "In the coming months, we anticipate selecting the recommended dose for the expansion stage of this trial in certain hematological malignancies, such as diffuse large B-cell lymphoma."

Dr. Fattaey continued, "Curis is on track to re-open the Phase 1 monotherapy trial of CUDC-427 in the very near term, which is expected to include patients with cancers that have a higher likelihood of genetic alterations of IAP pathway components, such as MALT lymphomas. Evaluation of CUDC-427 in combination with standard-of-care chemotherapy regimens including capecitabine is also expected to start later this year."

"Our partnered assets continue to progress well," said Dan Passeri, Curis' Chief Executive Officer. "Genentech and Roche's efforts to commercialize Erivedge® have resulted in a meaningful year-over-year increase in our royalty revenue and we continue to expect revenue growth for the remainder of 2014 as Erivedge is commercialized in various territories worldwide. In addition, Debiopharm anticipates initiating the Phase 2 portion of Debio 0932's ongoing non-small cell lung cancer trial later this year, which would trigger a milestone payment to Curis."

First Quarter 2014 Financial Results

Curis reported a net loss of $5.6 million, or ($0.06) per share, on both a basic and fully diluted basis for the first quarter of 2014, as compared to a net loss of $5.0 million, or ($0.06) per share, on both a basic and fully diluted basis for the same period in 2013.

Revenues for the first quarter of 2014 were $1.3 million, as compared to $900,000 for the same period in 2013. The increase in revenues is primarily the result of an increase in royalty revenues recorded on Genentech and Roche's net sales of Erivedge, which increased to $1.3 million for the first quarter of 2014 from $660,000 during 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 and Roche's Erivedge net sales, were $65,000 for the first quarter of 2014, up from $33,000 during the first quarter of 2013.

Operating expenses for the first quarter of 2014 were $6.0 million, as compared to $5.2 million for the same period in 2013.

Research and development expenses were $3.1 million for the first quarter of 2014, as compared to $2.6 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 $1.7 million on these programs for the quarters ended March 31, 2014 and 2013, respectively. The Company decreased its spending on its other programs by $400,000 in the first quarter of 2014 as compared to the first quarter of 2013.

General and administrative expenses were $2.8 million for the first quarter of 2014, as compared to $2.6 million for the same period in 2013. The increase was primarily due to an increase in personnel costs and stock-based compensation, offset by decreased expenses for legal and other professional services.

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 $800,000 for the first quarter of 2014 compared to $600,000 for the same period in 2013. The increase in other expense is the result of a decrease of $200,000 in other income based on the decrease in the fair value of warrant liability during the first quarter of 2014, as compared to the first quarter of 2013.

As of March 31, 2014, Curis' cash, cash equivalents and investments totaled $63.8 million and there were approximately 85.9 million shares of common stock outstanding.

2014 Financial Expectations

Curis expects to end 2014 with cash, cash equivalents and investments of $41 to $46 million, excluding potential future payments from existing or new collaborators. This also excludes any royalty revenues in 2014 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 in 2014 per the terms of the Erivedge royalty-secured debt transaction, but would retain royalty revenues that exceed this amount, if any, for use in funding Curis' operations.

Curis expects that 2014 research and development expenses will be $16 to $19 million and that general and administrative expenses will be $11 to $13 million. These expense expectations include approximately $800,000 and $2.4 million of estimated 2014 stock-based compensation expense in research and development and general and administrative expense, respectively.

Recent Operational Highlights

CUDC-907:

In April 2014, Curis announced the issuance of U.S. Patent No. 8,710,219 entitled, "Phosphoinositide 3-kinase inhibitor with a zinc binding moiety," that covers composition-of-matter for CUDC-907, Curis' dual histone deacetylase (HDAC) and phosphoinositide 3-kinase (PI3K) inhibitor. This patent, along with related patents issued in June 2013 (U.S. Patent No. 8,461,157) and February 2013 (U.S. Patent No. 8,367,663), covers a broad range of proprietary chemical entities that target HDAC and PI3K enzymes, and in some instances mammalian target of rapamycin (mTOR), within a single molecule for the treatment of certain human diseases. CUDC-907 is being investigated in a Phase 1 trial in patients with relapsed/refractory lymphoma or multiple myeloma.

In April 2014, Curis presented data from hematologic cell-based models as well as preliminary biomarker data from the ongoing Phase 1 trial of CUDC-907 at the American Association for Cancer Research (AACR) Annual Meeting entitled, "Dual function HDAC and PI3K inhibitor, CUDC-907 affects cancer cells and the tumor microenvironment in hematological malignancies." The cell line data suggest that CUDC-907 treatment results in significant reduction in the levels of CCL17 or TARC, a chemokine involved in the stimulation and proliferation of T cells required for the survival of certain malignant blood cells. Preliminary data from the ongoing Phase 1 trial showed correlative trends between patient benefit and pre-treatment plasma TARC levels as well as potential correlations between tumor response and plasma TARC level changes induced by 15 days of CUDC-907 treatment.

CUDC-427:

In April 2014, Curis presented an abstract at the AACR 2014 Annual Meeting entitled, "Post-treatment changes in levels of TNF family ligands and XIAP may predict sensitivity to IAP antagonist CUDC-427." The poster presentation included data investigating the utility of CUDC-427-induced expression of tumor necrosis factor (TNF) family members and reduction of XIAP protein levels as potential markers of CUDC-427 sensitivity.

In March 2014, the U.S. Food and Drug Administration (FDA) notified the Company that that it was safe to proceed under the Investigational New Drug (IND) application for CUDC-427 after reviewing Curis' complete response submission to the November 2013 partial clinical hold. Curis expects to re-open the monotherapy Phase 1 trial under the amended protocol shortly.

Upcoming Activities

Curis will participate in the following investor conferences through July 2014:

Jefferies 2014 Global Healthcare Conference in New York City: June 5, 2014

ROTH Healthcare Corporate Access Day in London: June 23-24, 2014

2014 BIO International Convention in San Diego: June 23-26, 2014

JMP Securities Healthcare Conference in New York: June 24-25, 2014

Janney Capital Markets Boston Healthcare 1x1 Corporate Access Day: June 26, 2014

BMO Capital Markets Biotech Corporate Access Day in Boston: July 29, 2014

Our partners, Roche/Genentech and Debiopharm expect to present data on Erivedge and Debio 0932, respectively, at the American Society of Clinical Oncology (ASCO) 2014 Annual Meeting in Chicago from May 30 to June 3, 2014.

Conference Call Information

Curis management will host a conference call today, May 8, 2014, at 9:00 a.m. EDT, 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 United States or (253) 237-1135 from other locations, shortly before 9:00 a.m. EDT. The conference ID number is 32315158. 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 5:00 p.m. EDT, Saturday, May 17, 2014. To access the replay, please call (855) 859-2056 from the United States or (404) 537-3406 from other locations and reference the conference ID number 32315158.

About Curis, Inc.

Curis is an oncology-focused drug development company seeking to develop novel drug candidates for the treatment of human cancers. Curis is seeking to further the development of its pipeline of proprietary cancer drug candidates, including CUDC-907, a dual HDAC and 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-discovered HSP90 inhibitor, Debio 0932, is being studied in patients with advanced lung and kidney cancers by partner Debiopharm. 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 trials with CUDC-907and CUDC-427; and its expectations regarding growth in Erivedge sales. 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 Annual Report on Form 10-K for the year ended December 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 March 31,	
	2014	*2013*
Revenues:		
Royalties	$ 1,288,248	$ 664,400
Research and development, net	(3,615)	207,035
Total revenues	1,284,633	871,435
Operating expenses:		
Cost of royalty revenues	65,148	33,220
Research and development	3,145,930	2,628,457
General and administrative	2,826,898	2,567,122
Total operating expenses	6,037,976	5,228,799
Loss from operations	(4,753,343)	(4,357,364)
	(810,593)	(604,930)
Other expense, net		
	$ (5,563,936)	$ (4,962,294)
Net loss		
	$ (0.06)	$ (0.06)
Basic and diluted net loss per common share		
Basic and diluted weighted average common shares outstanding	85,917,592	80,096,650

CURIS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)

	March 31, 2014	*December 31, 2013*
ASSETS		
Cash, cash equivalents and investments	$ 63,845,065	$ 68,906,307
Investments - restricted	166,487	180,364
Accounts receivable	1,368,920	1,477,188
Property and equipment, net	408,636	445,655
Goodwill	8,982,000	8,982,000
Other assets	592,865	599,294
Total assets	$ 75,363,973	$ 80,590,808
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	3,985,947	4,145,077
Warrant liability	625,163	716,786
Debt obligations, net	30,215,105	30,555,360
Total liabilities	34,826,215	35,417,223
Total stockholders' equity	40,537,758	45,173,585
Total liabilities and stockholders' equity	$ 75,363,973	$ 80,590,808

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