Curis Reports Third Quarter 2014 Financial Results and Pipeline Update

Curis Provides Summary From Dose Escalation Stage of CUDC-907 Phase 1 Study Supporting Ongoing Expansion in DLBCL Patients

Curis Expects to Regain Rights to Debio 0932; Debiopharm not Advancing Debio 0932 Into Phase 2 Portion of Lung Cancer Study

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

LEXINGTON, Mass., Nov. 10, 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 third quarter ended September 30, 2014. Curis also provided a summary of Phase 1 dose escalation data regarding the development of CUDC-907, Curis' dual histone deacetylase (HDAC) and phosphoinositide 3-kinase (PI3K) inhibitor, as well as an update on Debio 0932, an oral heat shock protein 90 (HSP90) inhibitor licensed to Debiopharm.

CUDC-907 Phase 1 study:

A total of 41 patients with relapsed/refractory lymphomas or multiple myeloma have been enrolled thus far, with 10 patients continuing to receive treatment in the dose escalation and expansion phases of the single agent, first-in-human Phase 1 clinical study of CUDC-907. The safety profile of CUDC-907 has been consistent with prior reports of diarrhea and thrombocytopenia as the most frequent adverse events, with diarrhea and hyperglycemia identified as dose limiting toxicities. Using the optimized dose and schedule of administration, adverse events have been manageable and evidence of HDAC and PI3K enzyme modulation has been observed in pharmacodynamic analysis. Among the 8 disease-evaluable patients with diffuse large B-cell lymphoma (DLBCL) treated with CUDC-907 to date, 7 have experienced tumor shrinkage, including 1 patient with a complete response, 2 with partial responses (i.e., tumor shrinkage greater than 50%), and 4 patients with tumor shrinkage ranging from 5% to 46%. Additionally, one subject with multiple myeloma continues to receive CUDC-907 monotherapy treatment for nearly 22 months. Curis recently initiated an expansion cohort to further evaluate CUDC-907 in patients with DLBCL or multiple myeloma at the recommended Phase 2 dose.

"We remain focused on the advancement of CUDC-907 and are particularly encouraged by its promising single agent anti-tumor activity in patients with DLBCL. We recently also began enrolling patients with DLBCL into the expansion phase of the study and anticipate that data from this portion of the study will guide the drug candidate's future development and regulatory path," said Ali Fattaey, Ph.D., President and Chief Executive Officer of Curis. "In addition, we were pleased that the FDA recently accepted our second IND application for a clinical study of CUDC-907 in patients with advanced solid tumors, including hormone receptor positive breast cancer, the first study of CUDC-907 outside of hematological cancers. We expect to enroll the first patient into this study before the end of this year."

CUDC-427 Phase 1 dose escalation:

Curis has completed enrollment in all consecutive, escalating dose cohorts at 100, 200 or 300 mg per day in the single-agent Phase 1 study of CUDC-427 in patients with advanced and/or refractory solid tumors or lymphoma. The primary objective of this 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. In addition to safety and tolerability measures, the study protocol includes expansion cohorts intended to enroll patients with specific cancers at the recommended Phase 2 dose.

Debio 0932:

Curis collaborator Debiopharm has decided that the Phase 1 dose escalation data from the Phase 1/2 HALO (HSP90 inhibition And Lung cancer Outcomes) study of Debio 0932 in combination with 3 different standard-of-care chemotherapy regimens in an unselected population of patients with advanced or metastatic non-small cell lung cancer were inconclusive, and has opted not to advance Debio 0932 into the Phase 2 portion of the study. No new Debio 0932-related side effects were identified and safety observations were generally consistent with the expected side effects of Debio 0932 and/or the respective chemotherapeutic regimens administered in the study. Curis expects to receive formal notice of termination of the license agreement from Debiopharm shortly and the partners are expected to enter into a transition agreement in the fourth quarter of 2014 regarding the orderly return of the program and all rights to Curis.

"We'd like to thank our colleagues at Debiopharm for the progress made to develop Debio 0932," said Dr. Fattaey. "We anticipate that we will regain the full rights to Debio 0932 in the near future after which we plan to control its future development. Based on Debio 0932's profile and our discussion with expert clinical investigators, we anticipate initiating a clinical study of Debio 0932 in patients with systemic mastocytosis, a myeloproliferative neoplasm that has a strong rationale for benefit through HSP90 inhibition. Additionally, based on its ability to cross the blood-brain-barrier in preclinical models, we are also in discussion with expert investigators interested in examining Debio 0932 for the treatment of patients with glioblastoma multiforme."

Financial Results for the Third Quarter 2014 and Nine Months ended September 30, 2014

Curis reported 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, as compared to a net loss of $1.9 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 $13.0 million, or ($0.15) per share on both a basic and fully diluted basis for the nine months ended September 30, 2014, as compared to a net loss of $8.1 million, or ($0.10) per share on both a basic and fully diluted basis for the same period in 2013.

Revenues for the third quarter of 2014 were $1.8 million, as compared to $7.2 million for the same period in 2013. The decrease in revenues was primarily due to a decrease in license fee revenue as the result of a $6 million milestone earned from Genentech, a member of the Roche Group, upon the conditional approval of Erivedge by the European Commission in July 2013. No such milestones were earned during the third quarter ended September 30, 2014. The decrease in license fee revenues was partially offset by royalty revenues recorded on Genentech/Roche's net sales of Erivedge, which increased to $1.8 million during the third quarter of 2014, as compared to $1.1 million during the same period in 2013.

Revenues for the nine months ended September 30, 2014, were $7.9 million, as compared to $13.5 million for the same period in 2013. The decrease in revenues for the nine-month period was primarily due to a decrease in license fee revenues from Genentech to $3 million from $10 million for milestone payments earned related to Erivedge in the nine-month periods ending September 30, 2014 and 2013, respectively. This decrease was partially offset by an increase in royalty revenues, which were $4.9 million and $2.5 million for the nine month periods ending September 30, 2014 and 2013, respectively. During the nine months ended September 30, 2013, Curis also recorded $650,000 in milestone payments received from The Leukemia and Lymphoma Society (LLS).

Operating expenses for the third quarter of 2014 were $6.5 million, as compared to $7.1 million for the same period in 2013. Operating expenses for the nine months ended September 30, 2014 were $18.9 million, as compared to $18.4 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 $89,000 and $54,000 during the third quarters of 2014 and 2013, respectively. Costs of royalty revenues were $246,000 and $127,000 for the nine months ended September 30, 2014 and 2013, respectively.

Research and development expenses were $3.7 million for the third quarter of 2014, as compared to $4.2 million for the same period in 2013. This decrease was primarily due to a decrease in sublicense fees of $300,000 related to third-party obligations on milestone payments we received from Genentech in the prior year period as well as a decrease of $150,000 in stock-based compensation expense. There was an increase in spending on CUDC-907 in the third quarter of 2014 related to our ongoing Phase 1 clinical study and to a lesser extent to costs associated with our efforts to open a second Phase 1 study in solid tumors. This increase was partially offset by decreased spending on CUDC-427 as compared to the prior year period.

Research and development expenses were $10.2 million for the nine months ended September 30, 2014 as compared to $10.0 million for the same period in 2013.

General and administrative expenses were $2.7 million for the third quarter of 2014, as compared to $2.8 million for the same period in 2013. General and administrative expenses were $8.5 million for the nine months ended September 30, 2014 as compared to $8.3 million for the same period in 2013. The increase was primarily due to increased expenses for personnel, consulting and professional services, and stock-based compensation offset by decreased spending on legal services.

Other expense was $827,000 for the third quarter of 2014 compared to $2 million for the same period in 2013 and is primarily comprised of interest expense associated with the loan made by BioPharma-II to Curis Royalty, a wholly-owned subsidiary of Curis, as well as expense associated with the change in fair value of a warrant liability. Interest expense was $934,000 and $965,000 for the third quarters of 2014 and 2013, respectively. The Company recorded other income of $68,000 and other expense of $1.1 million associated with the change in fair value of the warrant liability during the third quarters of 2014 and 2013, respectively. Other expense was $2.0 million for the nine months ended September 30, 2014 as compared to other expense of $3.2 million for the same period in 2013.

As of September 30, 2014, Curis' cash, cash equivalents, marketable securities and investments totaled $56.1 million and there were approximately 86.0 million shares of common stock outstanding.

Upcoming Activities

Curis expects to present at the following investor and medical conferences through December 2014:

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

Brean Capital 2014 Life Sciences Summit on November 24, 2014 in New York City

2014 Deutsche Bank BioFEST on December 1-2, 2014 in Boston

Piper Jaffray 26th Annual Health Care Conference on December 2-3, 2014 in New York City

Oppenheimer 25th Annual Healthcare Conference on December 10-11, 2014 in New York City

Conference Call Information

Curis management will host a conference call today, November 10, 2014, at 9:00 a.m. EST, to discuss Curis' financial results for the third 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. EST. The conference ID number is 13258840. 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 HDAC and PI3K inhibitor, CUDC-427, a small molecule antagonist of IAP proteins and Debio 0932, an oral HSP90 inhibitor. 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. 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: expressed and implied statements about the efficacy, safety, potential benefits and potential clinical advancement of CUDC-907 and CUDC-427; its plans and timing for initiating, conducting and presenting data from ongoing and planned clinical studies with CUDC-907 and CUDC-427, and the expected return of rights to Debio 0932 and the Company's current development plans for the compound. 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 CUDC-907, CUDC-427 and Debio 0932, 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, including CUDC-907, CUDC-427 and Debio 0932 may cause unexpected toxicities, fail to demonstrate sufficient safety and efficacy in clinical studies and/or may never achieve the requisite regulatory approval 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 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 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 June 30, 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 September 30,		Nine months ended September 30,	
	2014	2013	2014	2013
Revenues:				
Royalties	$ 1,783,271	$ 1,080,233	$ 4,895,454	$ 2,549,945
License fees	—	6,000,000	3,000,000	10,000,000
Research and development	(18,407)	121,850	(44,672)	927,950
Total revenues:	1,764,864	7,202,083	7,850,782	13,477,895
Operating expenses:				
Costs of royalty revenues	89,295	54,014	246,280	127,499
Research and development	3,705,365	4,170,751	10,180,271	9,965,847
General and administrative	2,723,235	2,846,950	8,475,392	8,317,741
Total operating expenses	6,517,895	7,071,715	18,901,943	18,411,087
Income (loss) from operations	(4,753,031)	130,368	(11,051,161)	(4,933,192)
Interest income	38,881	39,024	129,120	117,585
Interest expense	(933,903)	(964,543)	(2,834,609)	(2,870,087)

Change in fair value of warrant liability	67,910	(1,072,687)	716,786	(438,286)
Other expense, net	(827,112)	(1,998,206)	(1,988,703)	(3,190,788)
Net loss	$ (5,580,143)	$ (1,867,838)	$ (13,039,864)	$ (8,123,980)
Basic and diluted net loss per common share	$ (0.06)	$ (0.02)	$ (0.15)	$ (0.10)
Basic and diluted weighted average common shares outstanding	86,004,857	82,456,708	85,962,415	81,235,922

CURIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(UNAUDITED)

	September 30, 2014	*December 31, 2013*
ASSETS		
Cash, cash equivalents and investments	$ 56,080,622	$ 68,906,307
Investments - restricted	166,487	180,364
Accounts receivable	1,839,319	1,477,188
Property and equipment, net	407,361	445,655
Goodwill	8,982,000	8,982,000
Other assets	733,323	599,294
Total assets	$ 68,209,112	$ 80,590,808
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	4,500,551	4,145,077
Warrant liability	—	716,786
Debt obligations, net	29,061,984	30,555,360
Total liabilities	33,562,535	35,417,223
Total stockholders' equity	34,646,577	45,173,585
Total liabilities and stockholders' equity	$ 68,209,112	$ 80,590,808

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