Curis Reports Third Quarter 2012 Financial Results

Conference Call Today at 9:00 am EST

LEXINGTON, Mass., Nov. 6, 2012 (GLOBE NEWSWIRE) -- Curis, Inc. (Nasdaq:CRIS), a drug development company seeking to develop next generation targeted small molecule drug candidates for cancer treatment, today reported its financial results for the third quarter ended September 30, 2012.

"The last few months have featured important progress in our proprietary and licensed programs, including our initiation of a Phase I clinical trial of an oral formulation of CUDC-101, our recent IND filing to advance PI3K and HDAC inhibitor CUDC-907 into Phase I clinical testing and our partner Debiopharm's initiation of a Phase I/II clinical trial in non-small cell lung cancer patients of Hsp90 inhibitor Debio 0932," said Dan Passeri, Curis' President and Chief Executive Officer. "We continue to be encouraged with the U.S. commercial launch of Erivedge™ in advanced basal cell carcinoma, with average weekly demand increasing significantly from the second to third quarter and Roche recently noting an increasing awareness of Erivedge's availability. We look forward to continued growth in the U.S., as well as for potential regulatory approvals and market expansion for Erivedge in several other territories, including in Europe and Australia."

For the third quarter of 2012, Curis reported a net loss of $3.4 million, or ($0.04) per share on both a basic and fully diluted basis, as compared to a net loss of $4.2 million or ($0.05) on both a basic and fully diluted basis for the same period in 2011.

Revenues for the third quarter of 2012 were $600,000, as compared to $150,000 for the same period in 2011. The increase is the result of $450,000 in royalty revenues that Curis earned from its collaborator Genentech's U.S. net sales of Erivedge during the third quarter of 2012.

Operating expenses for the third quarter of 2012 were $5.5 million, as compared to $5.0 million for the same period in 2011.

Cost of royalty revenues was $22,000 for the third quarter of 2012, consisting of amounts paid to two university licensors, representing 5% of the royalties earned by Curis with respect to net U.S. sales of Erivedge during the third quarter of 2012.

Research and development spending was $3.0 million for the third quarters of 2012 and 2011, respectively. Spending on Curis' CUDC-907 program increased $200,000 over the prior year period primarily due to expenses associated with outside services related to formulation studies ahead of Curis' recent filing of an Investigational New Drug, or IND, application. In addition, spending related to Curis' CUDC-101 programs increased $200,000 over the prior year period due to an increase in employee-related expenses and CUDC-101 manufacturing costs. These increases were primarily offset by a decline of $450,000 in spending on the Company's other network-targeted cancer programs, when compared to the prior year period, as a result of the reallocation of resources to the CUDC-101 and CUDC-907 development programs.

General and administrative spending was $2.5 million for the third quarter of 2012 as compared to $1.9 million for the same period in 2011. The increase was primarily due to an increase in stock-based compensation of $500,000 over the prior year period as a result of an increase in the number of, and grant-date fair value of, stock options issued during 2012 compared to the prior year period. In addition, legal fees increased by $100,000 from the prior year period, primarily due to increased spending on patent costs, including fees related to foreign patent filings, and costs associated with various corporate matters.

Other income was $1.6 million for the third quarter of 2012 compared to $600,000 for the same period in 2011. The $1.0 million increase is primarily the result of a decrease in the fair value of a warrant liability established in connection with Curis' January 2010 registered direct offering.

As of September 30, 2012, Curis' cash, cash equivalents and investments totaled $41.9 million, and there were 80.0 million shares of common stock outstanding. Curis currently expects that its year end cash position will approximate $36-$38 million, excluding any royalty revenue or potential milestones that Curis could earn under its collaboration with Genentech.

Recent Developments

-- Achieved CUDC-907 Milestones under Collaboration with The Leukemia & Lymphoma Society

In October 2012, Curis achieved the first two development milestones under its agreement with The Leukemia & Lymphoma Society (LLS) for the development of CUDC-907, a first-in-class orally-administered small molecule drug candidate inhibitor of phosphatidylinositol-3-kinase (PI3K) and histone deacetylase (HDAC). These milestones include a preclinical development objective, as well as Curis' recent filing of an IND application to begin Phase I clinical testing of CUDC-907 in patients. As a result, Curis earned an aggregate of $750,000 in milestone payments under the terms of its agreement with LLS. Curis is eligible to receive up to $3.3 million in additional milestone payments under this agreement, assuming the successful achievement of further clinical development objectives.

-- Announced Dosing of First Patient in a Phase I Clinical Trial of an Oral Formulation of CUDC-101

In October 2012, Curis announced that the first patient was treated in a Phase I clinical study of an oral formulation of CUDC-101 in patients with advanced and refractory solid tumors. CUDC-101 is a first-in-class small molecule drug candidate that has been designed as an inhibitor of histone deacetylase (HDAC), epidermal growth factor receptor (EGFR) and human epidermal growth factor receptor 2 (Her2). The Phase I clinical trial is designed as a standard dose escalation study in which a tablet form of CUDC-101 will be orally administered to patients at two study centers in the U.S. The primary objectives are to determine the maximum tolerated dose (MTD) and recommended Phase 2 dose of orally administered CUDC-101 and to assess the bioavailability and pharmacokinetics of orally administered CUDC-101. The secondary objectives of this study are to assess

safety and tolerability, to evaluate biomarkers of CUDC-101 activity and to assess preliminary anti-cancer activity.

-- Announced Initiation of Phase I/II Clinical Study of HSP90 Inhibitor Debio 0932

In August 2012, Curis announced that its collaborator, Debiopharm, had begun treating patients in its HALO Hsp90 inhibition And Lung cancer Outcomes) Phase I/II clinical trial of orally-administered Heat Shock Protein 90 (Hsp90) inhibitor Debio 0932 in combination with chemotherapy regimens in patients with advanced stages of non-small cell lung cancer (NSCLC). The HALO study is a Phase I/II clinical trial of the safety and efficacy of Debio 0932 in combination with standard of care agents in first- and second-line therapy of patients with advanced NSCLC. Curis is eligible to receive its next milestone payment under its license agreement with Debiopharm if and when Debiopharm treats its fifth patient in a Phase II clinical trial. Based upon information furnished by Debiopharm, Curis currently anticipates that Phase II testing could commence in 2013.

Conference Call Information

Daniel Passeri, President and Chief Executive Officer of Curis, will host a conference call today, November 6, 2012, at 9:00 a.m. EST, to discuss Curis' financial results for the quarter and corporate developments, plans and strategies.

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 41203077. 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. EST, Monday, November 12, 2012. 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 41203077.

About Curis, Inc.

Curis is a drug development company that is committed to leveraging its innovative signaling pathway drug technologies to seek to create new targeted small molecule drug candidates for cancer. Curis is building upon its previous experiences in targeting signaling pathways, including in the Hedgehog pathway, in its effort to develop proprietary targeted cancer programs. For more information, visit Curis' website at http://www.curis.com.

The Curis, Inc. logo is available at http://www.globenewswire.com/newsroom/prs/?pkgid=11347

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 timing of regulatory filings, clinical advancement of Curis' and its collaborators' products under development, the expected continued growth of Erivedge sales in the U.S., and the potential for regulatory approvals of Erivedge in several non-U.S. territories. Forward-looking statements used in this press release 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 ultimately demonstrate to the satisfaction of the EMA, the TGA or regulatory authorities in other territories, the safety and efficacy profile of Erivedge in the treatment of advanced BCC, in which case Erivedge may not be approved for sales and marketing for the treatment of such indication in the respective territory. 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. Regulatory and administrative governmental 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 may not achieve meaningful amounts of royalty revenue from sales of Erivedge and may not achieve milestone payments from existing or new collaborators. Curis and its collaborators may experience adverse results, delays and/or failures in their drug development programs. Curis may experience difficulties with: required regulatory approvals; maintaining necessary intellectual property protections; maintaining key collaborations; and obtaining the substantial additional funding required to conduct its business. Curis may experience unplanned cash requirements, and may not receive additional anticipated payments under its collaborations, any of which would shorten the estimated period in which Curis will have cash to fund its operations, and could adversely affect its expectations with respect to 2012 operating expenses and year-end cash. Curis also faces other important risks relating to its business, operations, financial condition and future prospects generally, that are discussed in its Quarterly Report on Form 10-Q for the quarter ended June 30, 2012 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 September 30,		*Nine months ended September 30,*	
	2012	*2011*	*2012*	*2011*
Revenues	$ 577,759	$ 147,122	$ 15,285,585	$ 673,527
Operating expenses:				

Cost of revenues	22,320	--	148,489	--
Research and development	3,042,498	3,042,251	12,784,902	9,244,800
General and administrative	2,473,853	1,921,206	7,539,516	6,196,337
Total operating expenses	5,538,671	4,963,457	20,472,907	15,441,137
Net loss from operations	(4,960,912)	(4,816,335)	(5,187,322)	(14,767,610)
Other income (expense), net	1,575,908	609,780	1,141,603	(1,153,160)
Net loss	$ (3,385,004)	$ (4,206,555)	$ (4,045,719)	$ (15,920,770)
Basic and diluted net loss per common share	$ (0.04)	$ (0.05)	$ (0.05)	$ (0.21)
Basic and diluted weighted average common shares outstanding	79,639,433	76,543,074	78,752,687	76,251,709

CURIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(UNAUDITED)

	September 30, 2012	*December 31, 2011*
ASSETS		
Cash, cash equivalents and investments	$ 41,887,150	$ 37,717,575
Investments — restricted	194,282	235,914
Accounts receivable	548,392	42,067
Property and equipment, net	461,591	455,730
Goodwill	8,982,000	8,982,000
Other assets	501,047	746,779
Total assets	$ 52,574,462	$ 48,180,065
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	4,168,022	$ 3,942,940
Warrant liability	2,690,930	4,361,168
Total liabilities	6,858,952	8,304,108
Total stockholders' equity	45,715,510	39,875,957
Total liabilities and stockholders' equity	$ 52,574,462	$ 48,180,065

CONTACT: Michael P. Gray

Chief Operating and Chief Financial Officer

Curis, Inc.

617-503-6632

mgray@curis.com
