Curis Reports First Quarter 2013 Financial Results

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

LEXINGTON, Mass., April 30, 2013 (GLOBE NEWSWIRE) -- Curis, Inc. (Nasdaq:CRIS), an oncology-focused company seeking to develop next generation targeted drug candidates for cancer treatment, today reported its financial results for the first quarter ended March 31, 2013.

"This quarter was marked by the continued progress of our proprietary drug candidates, including the enrollment of the first dosing cohort for our Phase I clinical trial in advanced lymphomas and multiple myeloma patients of CUDC-907, a dual targeted PI3K and HDAC inhibitor, as well as our advancement of IAP inhibitor CUDC-427 towards initiation of a Phase II development campaign," said Ali Fattaey, President and Chief Operating Officer of Curis.

"Our collaborator Genentech/Roche has continued to successfully expand the U.S commercialization of Erivedge®, with an approximately 20% sequential sales growth in this quarter when compared to the fourth quarter of 2012. Genentech and Roche have demonstrated their commitment to make Erivedge available to patients globally, having recently secured marketing approvals in Israel, Mexico and South Korea and having received a positive opinion for the conditional marketing approval of Erivedge from the Committee for Medicinal Products for Human Use (CHMP) in Europe. We expect Erivedge marketing approvals in Europe and Australia in the coming months, and Genentech and Roche are actively pursuing approvals in several other territories," said Dan Passeri, Chief Executive Officer of Curis.

First Quarter 2013 Financial Results

Curis reported a net loss of $5.0 million, or ($0.06) per share on both a basic and fully diluted basis for the first quarter of 2013, as compared to net income of $2.2 million or $0.03 per share on both a basic and fully diluted basis for the same period in 2012.

Revenues for the first quarter of 2013 were $900,000, as compared to $10.4 million for the same period in 2012. This decrease in revenues is primarily the result of $10 million in license fee revenues received from Genentech upon FDA approval of Erivedge in the first quarter of 2012. Genentech/Roche's net sales of Erivedge during the first quarter of 2013 were $13.3 million resulting in an increase in royalty revenues recorded on net sales of Erivedge, which increased to $660,000 for the first quarter of 2013 from $270,000 during 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 and Roche's Erivedge net sales, were $30,000 and $110,000 during the first quarters of 2013 and 2012, respectively. The first quarter of 2012 included in a one-time charge of $100,000 on the first commercial sale of Erivedge.

Operating expenses for the first quarter of 2013 were $5.2 million, as compared to $8.2 million for the same period in 2012. Research and development expenses were $2.6 million for the first quarter of 2013 as compared to $5.2 million for the same period in 2012. The decrease in research and development expense was primarily due to expenses of $1.5 million that the Company incurred related to amounts due to various university licensors in connection with the FDA approval of Erivedge during the first quarter of 2012. Curis also decreased its spending on CUDC-101 and discovery research to $700,000 during the first quarter of 2013 from $2.4 million during the first quarter of 2012. The Company increased its spending on CUDC-427 by $700,000. CUDC-427 was licensed from Genentech by Curis in November 2012.

General and administrative expenses were $2.6 million for the first quarter of 2013 as compared to $2.8 million for the same period in 2012. The decrease was primarily due to decreased expenses for legal services and stock-based compensation, offset in part by an increase in other professional services and personnel costs.

Other expense was $600,000 for the first quarter of 2013 compared to other income of $30,000 for the same period in 2012. The increase in other expense is primarily the result of $900,000 in interest expense related to the Company's December 2012 $30 million royalty-secured debt transaction, partially offset by $300,000 in other income recorded based on a decrease in the fair value of a warrant liability during the first quarter of 2013.

As of March 31, 2013, Curis' cash, cash equivalents, marketable securities and investments totaled $54.2 million and there were approximately 80.2 million shares of common stock outstanding.

Recent Operational Highlights

- The CHMP of the European Medicines Agency (EMA) issued a positive recommendation for the conditional marketing approval of Erivedge for the treatment of advanced basal cell carcinoma in Europe. The European Commission, which has the authority to approve medicines for use in the European Union, generally delivers its final decision within three months of the CHMP recommendation. Curis would earn a $6 million milestone payment from Genentech/Roche upon the conditional approval of Erivedge.
- Curis appointed Kenneth Pienta, M.D. to its Board of Directors.
- Curis appointed Ali Fattaey, Ph.D. as its President and Chief Operating Officer.
- Curis treated the first patient in a Phase I clinical study of CUDC-907 in relapsed or refractory lymphoma or multiple myeloma cancer patients. To date Curis has received an aggregate of $1.1 million in funding under its agreement with The Leukemia and Lymphoma Society related to the continued development of CUDC-907.

Upcoming Activities

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

Needham & Co. 12th Annual Healthcare Conference, April 30 — May 1, 2013, in New York City
Deutsche Bank 38th Annual dbAccess Health Care Conference, May 29-30, 2013, in Boston, Massachusetts
Jefferies 2013 Global Healthcare Conference, June 3-6, 2013, in New York City
Wells Fargo Securities 2013 Health Care Conference, June 18-19, 2013, in Boston, Massachusetts
BMO Capital Markets Biotech Corporate Access Day, July 30, 2013, in Boston, Massachusetts

Conference Call Information

Daniel Passeri, Chief Executive Officer of Curis, will host a conference call today, April 30, 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 35916940. 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, Tuesday, May 7, 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 35916940.

About Curis, Inc.

Curis is an oncology-focused company seeking to develop and commercialize next generation targeted drug candidates for cancer treatment. Erivedge® is the first and only FDA-approved medicine for the treatment of advanced basal cell carcinoma 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 developing its pipeline of proprietary targeted cancer drug candidates, including CUDC-907, a dual PI3K and HDAC inhibitor; CUDC-427, a small molecule antagonist of IAP proteins; and CUDC-101, an EGFR/HER2 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 potential positioning among oncology drug development companies; expectations regarding the Company's clinical development plans and expectations regarding Erivedge® sales and regulatory approvals. 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 regulatory authorities outside the U.S. the safety and efficacy profile of Erivedge in the treatment of advanced BCC, in which case Erivedge may not be approved for 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 receive contingent payments from existing or new collaborators. Curis and its collaborators may experience adverse results, delays and/or failures in their drug development programs. Curis' drug candidates may cause unexpected toxicities and/or fail to demonstrate sufficient safety and efficacy in clinical trials and may never achieve the requisite regulatory approval needed for commercialization. Curis will require substantial additional capital to fund the research and development of its drug development programs. The proceeds of Curis' royalty-secured loan may not be sufficient to fund its near-term capital requirements for advancing programs. Curis may not obtain or maintain necessary patent protection for its programs and could become involved in expensive and time consuming patent litigation and interference proceedings. Curis faces substantial competition from other companies developing cancer therapeutics. 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, 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 March 31,	
	2013	*2012*
Operating expenses:		
Royalties	$ 664,400	$ 270,622
License Fees	--	10,000,000
Research and development	207,035	85,630
Operating expenses:	871,435	10,356,252

Operating expenses:		
Cost of royalty revenues	33,220	113,531
Research and development	2,628,457	5,241,949
General and administrative	2,567,122	2,801,077
Total operating expenses	5,228,799	8,156,557
Net loss from operations	(4,357,364)	2,199,695
Other (expense) income, net	(604,930)	26,042
Net (loss) income	$ (4,962,294)	$ 2,225,737
Basic and diluted net (loss)/income per common share	$ (0.06)	$ 0.03
Basic weighted average common shares outstanding	80,096,650	77,556,366
Diluted weighted average common shares outstanding	80,096,650	83,336,695

CURIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(UNAUDITED)

	March 31, 2013	*December 31, 2012*
ASSETS		
Cash, cash equivalents and investments	$54,189,529	$58,701,423
Investments — restricted	180,364	194,282
Accounts receivable	764,429	908,064
Property and equipment, net	434,967	434,168
Goodwill	8,982,000	8,982,000
Other assets	541,154	548,412
Total assets	$65,092,443	$69,768,349
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	3,520,348	4,173,747
Debt obligations, net	30,137,128	29,838,925
Warrant liability	1,186,919	1,488,179
Total liabilities	34,844,395	35,500,851
Total stockholders' equity	30,248,048	34,267,498
Total liabilities and stockholders' equity	$65,092,443	$69,768,349

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