Curis Reports Fourth Quarter and Year-End 2012 Financial Results

Conference Call to Discuss Results and Provide 2013 Outlook Today at 9:00 a.m. EST

LEXINGTON, Mass., Feb. 20, 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 fourth quarter and year ended December 31, 2012.

"During the last few months, we have taken key steps to strengthen Curis' position as an innovative targeted cancer drug company. This period was marked by several important achievements, including in-licensing the exclusive worldwide rights from Genentech to CUDC-427, bringing CUDC-907 into Phase I clinical testing, securing $30 million of important capital in an Erivedge® royalty-secured debt transaction to further advance our pipeline and enhancing our scientific depth and capacity by hiring Dr. Ali Fattaey as our President and Chief Operating Officer," said Dan Passeri, Chief Executive Officer.

"We believe the combination of our 2012 revenues and the completion of the $30 million Erivedge royalty-secured debt transaction have put Curis in a strong capital position to advance our lead assets further in clinical development," said Mike Gray, Curis' Chief Financial Officer. "We ended 2012 with approximately $59 million in cash, cash equivalents and investments, and we anticipate that we may earn additional revenues in 2013 related to the successful achievement of development and commercialization milestones under our partnered programs, including potential Erivedge® approvals in Europe and Australia in the first half of 2013 under our collaboration agreement with Genentech, a member of the Roche Group."

Full Year and Fourth Quarter 2012 Financial Results

For the year ended December 31, 2012, Curis reported a net loss of $16.4 million, or ($0.21) per basic and fully diluted share, as compared to a net loss of $9.9 million or ($0.13) per basic and fully diluted share for the year ended December 31, 2011. The 2012 net loss included a one-time expense of $9.5 million pursuant to the Company's November 2012 CUDC-427 license agreement with Genentech. For the fourth quarter of 2012, Curis reported a net loss of $12.4 million, or ($0.15) per share on both a basic and fully diluted basis, as compared to net income of $6.1 million or $0.08 per basic share and $0.07 per fully diluted share for the same period in 2011.

Revenues for the year ended December 31, 2012 were $17.0 million as compared to $14.8 million for the year ended December 31, 2011. Revenues for the fourth quarter of 2012 were $1.7 million, as compared to $14.1 million for the same period in 2011. Curis earned $14 million in milestone payments under its collaboration with Genentech in each of the years ended December 31, 2012 and 2011 related to the achievement of regulatory objectives for Erivedge®, which was approved for sale in the U.S. in January 2012. The increase in revenues in 2012 as compared to 2011 was primarily the result of $1.5 million in royalty revenues resulting from Genentech's net sales of Erivedge® and $1 million in milestone payments received under the Company's agreement with LLS.

Research and development expenses were $15.5 million for the year ended December 31, 2012, as compared to $13.7 million for the year ended December 31, 2011 and $2.7 million for the fourth quarter of 2012 as compared to $4.4 million for the same period in 2011. During the year ended December 31, 2012, the Company incurred $2.1 million in sublicense expenses related to its obligations to university licensors as compared to $700,000 for the prior year. In addition, stock-based compensation increased $350,000 over the prior year primarily related to the expense recognized on unvested non-employee stock options.

In-process research and development expense of $9.5 million was recorded for the year ended December 31, 2012 and the fourth quarter of 2012 as a result of up-front payments related to the Company's in-license of CUDC-427 from Genentech. The Company did not record in-process research and development expense in 2011.

General and administrative expenses were $10.4 million for the year ended December 31, 2012, as compared to $8.3 million for the year ended December 31, 2011 and $2.9 million for the fourth quarter of 2012 as compared to $2.1 million for the same period in 2011. The increase was primarily due to increases in stock-based compensation expense of $1.5 million and legal and consulting fees of $500,000.

Other income was $2.2 million for the year ended December 31, 2012, as compared to other expense of $2.7 million for the year ended December 31, 2011. Other income was $1.1 million for the fourth quarter of 2012 compared to other expense of $1.5 million for the same period in 2011. These increases are primarily the result of decreases in the fair value of a warrant liability, largely caused by a decline in the market value of the Company's common stock during the full year and fourth quarter of 2012.

As of December 31, 2012, Curis' cash, cash equivalents, marketable securities and investments totaled $58.7 million and there were approximately 80.0 million shares of common stock outstanding.

2013 Financial Expectations

Curis expects to end 2013 with cash, cash equivalents and investments of $31 to $36 million, excluding potential future milestone payments from existing or new collaborators. This also excludes any royalty revenues in 2013 related to net sales of Erivedge®. Curis is required to pay BioPharma II up to $1 million per quarter of the royalty revenues that it receives from Genentech in 2013 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 its operations.

Curis expects that 2013 research and development expenses will be $16 to $20 million and that general and administrative expenses will be $10 to $12 million. These expense expectations include approximately $800,000 and $1.9 million of stock-based compensation expense in research and development and general and administrative expense, respectively.

Potential 2013 Milestones

In 2013, Curis expects to advance its proprietary pipeline of targeted cancer therapeutics and also expects that its partners will advance their programs under development, including the potential for Genentech and Roche to successfully broaden the commercial opportunity for Erivedge.

CUDC-427:

- Principal investigators and Genentech to present full study results from its completed Phase I study in solid tumors or lymphoma at a medical meeting in mid-2013
- Curis to initiate clinical studies of CUDC-427 administered in combination with other anti-cancer agents and explore the therapeutic potential of single-agent CUDC-427 in selected population of cancer patients

CUDC-907:

- Curis to continue enrollment and provide updates on ongoing Phase I study in patients with advanced or refractory lymphomas or multiple myeloma
- Curis to evaluate CUDC-907 administered in combination with other anti-cancer agents in solid tumor clinical study

Erivedge:

- Regulatory approval decisions in advanced BCC in Europe and Australia in the first half of 2013 and decisions in other territories later in 2013
- Results of Phase II study in operable nodular BCC expected in first half of 2013
- Results from ongoing National Cancer Institute and investigator sponsored clinical studies

Debio 0932:

- Debiopharm intends to plan the initiation of a Phase I/II clinical trial with Debio 0932 in combination with everolimus in renal cell carcinoma patients
- Debiopharm to present Phase Ib clinical study results at a medical meeting in 2013
- Debiopharm to continue enrollment in Phase I/II study of Debio 0932 in advanced non-small cell lung cancer

CUDC-101:

- Curis to continue enrollment in Phase I study in locally advanced head and neck cancer patients
- Curis to pursue development of alternate oral formulations

Recent Operational Highlights

- In February 2013, Curis hired Ali Fattaey, Ph.D. as its President and Chief Operating Officer.
- In January 2013, Curis treated the first patient in a Phase I clinical study of CUDC-907 in relapsed or refractory lymphoma or multiple myeloma cancer patients. During the fourth quarter of 2012 and early 2013, Curis received an aggregate of $1.1 million under its agreement with LLS.
- In December 2012, Curis closed a $30 million Erivedge royalty-secured debt transaction. The debt is secured with certain future royalties and other royalty-related payments from net sales of Erivedge.
- In December 2012, the U.S. Patent and Trademark Office issued a patent covering a genus of compounds that includes Debio 0932, an orally-administered Heat Shock Protein 90 (HSP90) inhibitor, which is being developed by Curis' licensee Debiopharm.
- In November 2012, Curis secured the exclusive global development and commercialization rights from Genentech to antagonist of IAP proteins, CUDC-427.
- In October 2012, Curis initiated a Phase I clinical study of an oral formulation of CUDC-101. This study was subsequently terminated as sufficient drug exposure was not achieved after dosing the first cohort of patients. Curis is currently pursuing the development of alternative formulations as well as backup candidates, which may be more amenable to oral dosing.

Upcoming Activities

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

- Citi 2013 Global Healthcare Conference on February 25-27, 2013 in New York City
- 2013 RBC Capital Markets' Healthcare Conference on February 26-27, 2013 in New York City
- Cowen and Company 33rd Annual Health Care Conference on March 4-6, 2013 in Boston, Massachusetts
- Roth Capital Partners 25th Annual ROTH Growth Conference on March 18-20, 2013 in Dana Point, California
- BioCentury Future Leaders in the Biotech Industry on April 5, 2013 in New York City

12th Annual Needham Healthcare Conference on April 30 — May 1, 2013 in New York City

Conference Call Information

Daniel Passeri, Chief Executive Officer of Curis, will host a conference call today, February 20, 2013, at 9:00 a.m. EST, to discuss Curis' financial results for the quarter and year ended December 31, 2012, as well as 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 98576283. 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, Tuesday, February 26, 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 98576283.

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-427, a small molecule antagonist of IAP proteins; CUDC-907, a dual PI3K and HDAC inhibitor; and CUDC-101, an EGFR/HER2 and HDAC inhibitor. For more information, visit Curis' website at 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 expected benefits of the Company's recent financial, clinical and operational developments; the Company's potential positioning among oncology drug development companies; expectations regarding Erivedge sales; the Company's financial positioning for 2013 and beyond; the Company's expectations regarding potential milestone achievement in 2013 under both its internal and partnered drug development and commercialization programs; and the Company's 2013 financial guidance. 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, if Genentech's sales of Erivedge are lower than anticipated, the time period for repayment of the royalty-secured loan will be extended. There are also certain events of default in which the loan repayment could be accelerated, including actions by Curis' that could lead to Genentech's termination of the collaboration agreement between Curis and Genentech. 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 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 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 Quarterly Report on Form 10-Q for the quarter ended September 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 December 31,		*Year ended December 31,*	
	2012	*2011*	*2012*	*2011*
Revenues	$ 1,686,406	$ 14,089,053	$ 16,971,991	$ 14,762,580

Operating expenses:				
Cost of revenues	27,993	—	176,482	—
Research and development	2,707,400	4,447,859	15,492,302	13,692,659
In-Process research and development	9,500,000	—	9,500,000	—
General and administrative	2,883,498	2,076,087	10,423,014	8,272,424
Total operating expenses	15,118,891	6,523,946	35,591,798	21,965,083
Net loss from operations	(13,432,485)	7,565,107	(18,619,807)	(7,202,503)
Other income (expense), net	1,061,297	(1,503,232)	2,202,900	(2,656,392)
Net income (loss) income	$ (12,371,188)	$ 6,061,875	$ (16,416,907)	$ (9,858,895)
Basic net (loss)/income per common share	$ (0.15)	$ 0.08	$ (0.21)	$ (0.13)
Diluted net (loss)/income per common share	(0.15)	0.07	(0.21)	(0.13)
Basic weighted average common shares outstanding	79,971,888	76,649,034	79,059,153	76,351,856
Diluted weighted average common shares outstanding	79,971,888	81,354,223	79,059,153	76,351,856

CURIS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)

	December 31, 2012	*December 31, 2011*
ASSETS		
Cash, cash equivalents and investments	$ 58,701,423	$ 37,717,575
Investments — restricted	194,282	235,914
Accounts receivable	908,064	42,067
Property and equipment, net	434,168	455,730
Goodwill	8,982,000	8,982,000
Other assets	760,471	746,779
Total assets	$ 69,980,408	$ 48,180,065
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	$ 4,224,731	$ 3,942,940
Debt	30,000,000	—
Warrant liability	1,488,179	4,361,168
Total liabilities	35,712,910	8,304,108
Total stockholders' equity	34,267,498	39,875,957
Total liabilities and stockholders' equity	$ 69,980,408	$ 48,180,065

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