Curis Reports First Quarter 2012 Financial Results

Conference call to be Held Today at 9:00 a.m. EDT

LEXINGTON, Mass., May 8, 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 first quarter ended March 31, 2012.

"The beginning of 2012 has been a period of continued progress with both our partnered and proprietary programs, highlighted by the FDA's U.S. approval of Erivedge™ in advanced basal cell carcinoma and Roche's efforts to expand patient access to Erivedge with regulatory submissions seeking approval of Erivedge in Australia, Canada and Switzerland. These submissions are in addition to the Marketing Authorization Application that was submitted by Roche in the fourth quarter of 2011 and is currently under review by the European Medicines Agency," said Dan Passeri, Curis President and Chief Executive Officer. "We also continue to advance our proprietary programs, including our ongoing Phase I study in locally advanced head and neck cancer patients with the IV formulation of CUDC-101 and preclinical studies required to file INDs to begin Phase I clinical testing for both an oral formulation of CUDC-101 as well as our oral PI3K and HDAC inhibitor CUDC-907. We expect to file both INDs during the second half of 2012. In addition, our partner Debiopharm has advanced Hsp90 inhibitor Debio 0932 into Phase Ib testing and has indicated that it expects to initiate a Phase I/II clinical trial in non-small cell lung cancer patients during the second quarter of 2012."

For the first quarter of 2012, Curis reported net income of $2.2 million, or $0.03 per share on both a basic and fully diluted basis, as compared to net loss of $6.8 million or ($0.09) on both a basic and fully diluted basis for the same period in 2011.

Revenues for the first quarter of 2012 were $10.4 million, as compared to $100,000 for the same period in 2011. This increase is the result of $10.0 million in license fee revenues received from Genentech upon FDA approval of Erivedge and $270,000 in royalty revenues that Curis earned from Genentech's net sales of Erivedge during the first quarter of 2012.

Operating expenses for the first quarter of 2012 were $8.2 million, as compared to $5.5 million for the same period in 2011.

Cost of royalty revenues were $114,000 for the first quarter of 2012, including a one-time payment of $100,000 that Curis paid to a university licensor upon the first commercial sale of Erivedge and $14,000 paid to two university licensors, which represents 5% of the $271,000 in royalties earned by the Company with respect to Genentech's net sales of Erivedge during the first quarter of 2012.

Research and development spending was $5.2 million for the first quarter of 2012 as compared to $3.1 million for the same period in 2011. The increase of $2.1 million was primarily due to $1.5 million in expenses that the Company incurred related to various university licensors, including $1.0 million in non-cash expense representing the fair value of a one-time issuance of an aggregate of 200,000 shares of Curis' common stock to university licensors in connection with the FDA approval of Erivedge and $500,000 in sublicense fees payable to university licensors, representing 5% of the $10 million milestone payment earned by Curis during the first quarter of 2012.

Spending on Curis' CUDC-907 program also increased $200,000 primarily due to costs for IND-enabling toxicology studies. In addition, spending related to Curis' CUDC 101 programs increased $200,000 due to costs associated with its ongoing development of an oral formulation of CUDC-101, as well as the costs associated with the ongoing Phase I trial in head and neck cancers that were not incurred in the prior year period. Finally, stock-based compensation increased $200,000 to $400,000 from $200,000 in the prior year period primarily related to the expense recognized on unvested non-employee stock options that are marked-to-market at each reporting period.

General and administrative spending was $2.8 million for the first quarter of 2012 as compared to $2.4 million for the same period in 2011. This increase was primarily due to increased spending for legal services and personnel costs. Legal fees increased $200,000 from the prior year period related to spending on patent costs, including fees related to foreign patent filings, and various corporate matters. In addition, personnel costs increased $100,000 due to the accrual of cash incentive payments for executive officers under the Company's 2012 short-term incentive program. Finally, stock-based compensation increased $100,000 to $600,000 from $500,000 in the prior year period as a result of an increase in the value of stock options issued during the first quarter of 2012 as compared to the prior year period.

Other income was $30,000 for the first quarter of 2012 compared to other expense of $1.5 million for the same period in 2011. Other income and expense primarily represents the change in the fair value of a warrant liability established in connection with Curis' January 2010 registered direct offering.

As of March 31, 2012, Curis' cash, cash equivalents and marketable securities totaled $45.0 million, and there were 78.7 million shares of common stock outstanding. The Company currently anticipates that it will end 2012 with cash, cash equivalents and marketable securities of $30 to $34 million, including the $4 million milestone payment that Curis earned in May 2012 in connection with Roche's filing for the approval of Erivedge in Australia. This projection excludes royalty revenues that Curis expects to receive from Genentech on its net sales of Erivedge and any additional future milestone payments from existing or new collaborators that Curis has the potential to receive in 2012.

Recent Developments

-- FDA Approval of Erivedge, Developed under Collaboration with Genentech and Roche, as First Treatment for Advanced Basal Cell Carcinoma (BCC); Curis Earned $10 Million Milestone Payment from Genentech During the First Quarter of 2012

In January 2012, the Erivedge capsule was approved by the FDA for the treatment of adults with BCC that has spread to other parts of the body or that has come back after surgery or that their healthcare provider decides cannot be treated with surgery or radiation. Curis earned a $10 million milestone payment from Genentech as a result of the FDA's approval of Erivedge in this indication and is also entitled to receive royalties on future sales of the product. Erivedge is the first and only FDA-approved medicine for people with advanced forms of BCC, the most common skin cancer.

-- Erivedge Regulatory Submission under Review by Australia's Therapeutic Goods Administration

In May 2012, we announced that Roche had submitted an application for marketing registration for Erivedge to Australia's Therapeutic Goods Administration (TGA). The application is currently under review by the TGA for the treatment of adults with advanced basal cell carcinoma (BCC) for whom surgery is inappropriate. Curis earned a $4 million milestone payment as a result of the submission and acceptance of this application to the TGA. If Roche receives approval to commercialize Erivedge in Australia, Curis will also be entitled to receive an additional milestone payment as well as royalties on any future net sales of Erivedge in Australia.

-- *Announced Initiation of Phase Ib Expansion Study of Hsp90 Inhibitor Debio 0932*

In February 2012, Debiopharm began treating patients in a Phase Ib clinical trial of Hsp90 inhibitor Debio 0932. Debiopharm recently successfully completed a Phase Ia dose escalation study with Debio 0932 and has indicated that it expects to initiate a combination Phase I/II study in non-small cell lung cancer patients in the second quarter of 2012. Debiopharm expects to treat approximately 30 patients as part of the Phase Ib expansion study. The objectives of this study will be to further assess the safety profile, pharmacokinetics and pharmacodynamics of Debio 0932 at the recommended dose level and regimen, and to further assess anti-tumor activity in patients with advanced solid tumors, including patients with non-small cell lung cancer.

-- *Presented data on CUDC-907 at the AACR Annual Meeting 2012*

In April 2012, Curis scientists delivered a poster presentation titled, "Antitumor Activity of CUDC-907, a Dual PI3K and HDAC Inhibitor in Hematological Cancer Models" at the American Association for Cancer Research (AACR) Annual Meeting 2012 held in Chicago, Illinois. CUDC-907 is being designed to disrupt multiple points in cancer networks and the presented data demonstrated broad activity in preclinical cancer models, favorable performance compared to first-in-class PI3K and HDAC inhibitors and oral bioavailability.

Conference Call Information

Daniel Passeri, President and Chief Executive Officer of Curis, will host a conference call today, May 8, 2012, at 9:00 a.m. EDT, 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. EDT. The conference ID number is 71544098. The conference call also can 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. EDT, Tuesday, May 15, 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 71544098.

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 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 and clinical advancement of the Company's and its collaborators' products under development; and the Company's financial guidance with respect to its year end cash position for fiscal 2012. 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 European Medicines Agency or regulatory authorities in Australia, Canada and Switzerland the safety and efficacy profile of Erivedge in the treatment of advanced BCC, in which case Erivedge will not be approved for sales and marketing for the treatment of such indication in Europe, Australia, Canada or Switzerland. 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 effect 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 Annual Report on Form 10-K for the year ended December 31, 2011 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,	
	2012	*2011*
Revenues		
Research and development	$ 85,630	$ 133,538
Royalties	270,622	--
License fees	10,000,000	--
Total operating expenses	$ 10,356,252	$ 133,538
Operating expenses:		
Cost of royalty revenues	113,531	--
Research and development	5,241,949	3,058,499
General and administrative	2,801,077	2,407,349
Total operating expenses	8,156,557	5,465,848
Net income (loss) from operations	2,199,695	(5,332,310)
Other income (expense)	26,042	(1,467,841)
Net income (loss)	$ 2,225,737	$ (6,800,151)
Basic and diluted net income (loss) per common share	$ 0.03	$ (0.09)
Basic weighted average common shares outstanding	77,556,366	75,825,801
Diluted weighted average common shares outstanding	83,336,695	75,825,801

CURIS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)

	March 31, 2012	*December 31, 2011*
ASSETS		
Cash, cash equivalents and marketable securities	$ 45,039,446	$ 37,717,575
Investments — restricted	194,282	235,914
Accounts receivable	339,802	42,067
Property and equipment, net	435,858	455,730
Goodwill	8,982,000	8,982,000
Other assets	354,313	746,779
Total assets	$ 55,345,701	$ 48,180,065
LIABILITIES AND STOCKHOLDERS' EQUITY		

Accounts payable, accrued expenses and other liabilities	3,937,416	$ 3,942,940
Warrant liability	3,809,581	4,361,168
Total liabilities	7,746,997	8,304,108
Total stockholders' equity	47,598,704	39,875,957
Total liabilities and stockholders' equity	$ 55,345,701	$ 48,180,065

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