Curis Reports Fourth Quarter and Year-End 2011 Financial Results

Conference Call to be Held Today at 9:00 a.m. EST

LEXINGTON, Mass., Feb. 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 fourth quarter and fiscal year ended December 31, 2011.

"With the recent FDA approval of Erivedge as the first and only medicine for people with advanced forms of basal cell carcinoma, we have reached a critical milestone in Curis' growth as a leader in developing cancer network disruption therapeutics," said Dan Passeri, President and Chief Executive Officer. "This approval earned Curis a $10 million milestone payment that, when combined with the $14 million that Curis received during the fourth quarter under our collaboration with Genentech, significantly improves our capital position and will also provide us with long-term royalty revenues on U.S. sales. In addition, a marketing authorization application is currently under review by the European Medicines Agency, potentially increasing patient access to Erivedge."

Mr. Passeri continued, "We have also made important progress during 2011 with the other programs in our pipeline. We initiated a Phase I dose escalation study with CUDC-101 in locally advanced human papillomavirus negative (HPV-) head and neck cancer patients and concluded dosing in our Phase I expansion study in several cancer types. We have been advancing an oral formulation of CUDC-101 as well as CUDC-907, a PI3K and HDAC inhibitor, toward planned IND filings and clinical trial initiations in 2012. In addition, our licensee Debiopharm has also made important progress in the development of our Hsp90 inhibitor, Debio 0932, and is expected to present data from the recently concluded Phase I study of this molecule at a medical conference in the first half of 2012. Debiopharm also plans to treat the first patient in a Phase Ib study of Debio 0932 shortly and we expect that a Phase I/II study of Debio 0932 in lung cancer patients will be initiated in the second quarter of this year."

"We look forward to what we anticipate will be a year of continued growth and value creation of our Company in 2012, including the U.S. launch and potential European regulatory approval of Erivedge in advanced basal cell carcinoma, possible data for Erivedge in other indications, our planned advancement of CUDC-101 and CUDC-907 and Debiopharm's progression of Debio 0932."

Fourth Quarter 2011 Financial Results

For the fourth quarter of 2011, Curis reported net income of $6.1 million, or $0.08 per basic share and $0.07 per fully diluted share, as compared to a net loss of $5.6 million or ($0.07) per share on both a basic and fully diluted basis for the same period in 2010.

Revenues for the fourth quarter of 2011 were $14.1 million, as compared to $100,000 for the same period in 2010. This increase is the result of $14.0 million in license fee revenues recorded during the fourth quarter of 2011 for payments that Curis received from Genentech for the achievement of certain regulatory objectives related to Erivedge.

Operating expenses were $6.5 million for the fourth quarter of 2011, as compared to $5.7 million for the same period in 2010.

> Research and development spending was $4.4 million for the fourth quarter of 2011 as compared to $3.7 million for the same period in 2010. This increase is the result of $700,000 in sublicense fees paid by Curis to its licensors as a result of the milestone payments received by Curis from Genentech during the fourth quarter of 2011. While overall spending on other programs was unchanged from the 2010 period, spending related to CUDC-907 increased as a result of the commitment of additional resources to advance CUDC-907 through IND-enabling studies. Spending related to the Phase I expansion trial for CUDC-101 decreased as this study neared its conclusion and the last patient came off study in October 2011. This decrease was offset by increased spending related to the initiation of a Phase I trial of CUDC-101 in combination with cisplatin and radiation in HPV- locally advanced head and neck cancer patients as well as the Company's preclinical development work on an oral formulation of CUDC-101. An increase in the overall investment in CUDC-101 and CUDC-907, particularly Curis' employee costs allocated to these programs, resulted in a decrease in spending on Curis' research-stage programs.
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> General and administrative spending was $2.1 million for the fourth quarter of each of 2011 and 2010. Employee cost increases in the fourth quarter of $140,000, related primarily to expenses associated with performance-based bonuses paid to Curis' executive officers, were offset by decreases in legal, consulting and occupancy costs totaling approximately $120,000.

Other expense was $1.5 million for the fourth quarter of 2011 as compared to other income of $4,000 in 2010. This expense represents the increase in the fair value of the warrant liability incurred in connection with Curis' January 2010 registered direct offering. Other income for the fourth quarter of 2010 consisted primarily of federal tax grants totaling $500,000 that Curis was awarded pursuant to the Qualifying Therapeutic Discovery Project tax credit program implemented by the IRS under the Patient Protection and Affordable Care Act of 2010. Offsetting the grant income in the fourth quarter of 2010 was a charge of $500,000 related to the increase in the fair value of the warrant liability.

Fiscal Year 2011 Financial Results

For the year ended December 31, 2011, Curis reported a net loss of $9.9 million, or ($0.13) per basic and fully diluted share, as compared to a net loss of $4.4 million or ($0.06) per basic and fully diluted share for the year ended December 31, 2010.

Revenues for the year ended December 31, 2011 were $14.8 million as compared to $16.0 million for the same period in 2010. This decrease was the result of lower license fee revenues in 2011. In 2011, Curis recognized $14.0 million in license revenues

under the Company's Hedgehog pathway inhibitor collaboration with Genentech resulting from milestone payments tied to the achievement of certain regulatory objectives related to Erivedge. In 2010, Curis recognized $11.3 million in license fee revenue as a result of milestone payments received from Debiopharm and $4.0 million pursuant to a settlement agreement that the Company entered into with a former collaborator.

Operating expenses were $22.0 million for the year ended December 31, 2011, as compared to $21.6 million for the same period in 2010. Research and development expenses were $13.7 million in 2011, as compared to $11.4 million for the same period in 2010. General and administrative expenses were $8.3 million for the year ended December 31, 2011, as compared to $10.3 million for the same period in 2010.

Other expense was $2.7 million for the year ended December 31, 2011, as compared to other income of $1.2 million for the same period in 2010. The 2011 other expense was primarily the result of an increase in the fair value of the warrant liability incurred in connection with Curis' January 2010 registered direct offering. Other income in 2010 consisted primarily of federal tax grants totaling $500,000 and a decrease in the fair value of the warrant liability.

As of December 31, 2011, Curis' cash, cash equivalents and marketable securities totaled $37.7 million and there were 77.1 million shares of common stock outstanding.

2012 Financial Expectations

The Company expects to end 2012 with cash, cash equivalents and marketable securities of $23 to $27 million, excluding royalty revenues that we expect to receive from Genentech on its net sales of Erivedge. This expectation also excludes any future milestone payments from existing or new collaborators that Curis could receive in 2012. Curis has the potential to earn milestone payments in 2012 under its agreements with Genentech and The Leukemia & Lymphoma Society.

Curis expects that 2012 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 $2.5 million of stock-based compensation expense in research and development and general and administrative expense, respectively.

Recent Developments

-- FDA Approval of Erivedge, Developed under Collaboration with Genentech and Roche, as First Treatment for Advanced Basal Cell Carcinoma (BCC); Curis Earned $24 Million in Milestone Payments from Genentech During the Fourth Quarter of 2011 and Early 2012

In January 2012, the Erivedge capsule was approved by the FDA for the treatment of adults with a type of skin cancer, called basal cell carcinoma, 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. Erivedge is the first and only FDA-approved medicine for people with advanced forms of the most common skin cancer. It is being developed and will be commercialized by Roche and Genentech, a member of the Roche Group, under a collaboration agreement between Curis and Genentech. 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.

In December 2011, Roche submitted a Marketing Authorization Application (MAA) for Erivedge to the European Medicines Agency (EMA) and this filing is currently under review.

Curis received a total of $14 million in milestone payments from Genentech in the fourth quarter of 2011 as a result of US and EU regulatory filings relating to Erivedge.

-- Appointed Maurizio Voi, M.D., as Chief Medical and Chief Development Officer

In November 2011, Curis appointed Maurizio Voi, M.D., as Chief Medical and Chief Development Officer, responsible for the Company's development, clinical trial and regulatory affairs operations, as well as biomarker and translational medicine activities. Dr. Voi brings to Curis significant experience in targeted oncology drug development, most recently as Vice President of Clinical Development and Medical Affairs for the Oncology Business Unit at Pfizer's Global Research and Development site in New York.

-- Announced Agreement with the Leukemia & Lymphoma Society to Develop CUDC-907

In November 2011, Curis entered into an agreement with The Leukemia & Lymphoma Society (LLS), under which LLS will support Curis' ongoing development of its oral small molecule dual P13K and HDAC inhibitor, CUDC-907, for patients with B-cell lymphoma and multiple myeloma. Under the agreement, LLS will fund approximately 50% of the direct costs of the development of CUDC-907, up to $4 million. Curis expects to file an IND and start patient enrollment in a Phase Ia dose escalation clinical trial in B-cell lymphoma and multiple myeloma in the second half of 2012. If the study is successful, LLS has also agreed to support Curis' subsequent Phase Ib or Phase IIa study in one or more specific indications as well as Curis' ongoing investigation of biomarkers for CUDC-907 in these diseases.

-- Presented data on CUDC-907 at AACR-EORTC-NCI

In November 2011, Curis scientists delivered a poster presentation titled, "Anti-tumor activity of CUDC-907, a single small molecule inhibitor that targets both P13K and HDAC, in hematologic cancer models" at the 2011 AACR-EORTC-NCI International Conference on Molecular Targets and Cancer Therapeutics. CUDC-907 has been 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, February 8, 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 international locations, shortly before 9:00 a.m. EST. The conference ID number is 44997106. 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. EST, Wednesday, February 15, 2012. To access the replay, please dial (855) 859-2056 from the United States or (404) 537-3406 from international locations and reference conference ID number 44997106.

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 for the commercial availability of Erivedge in the U.S. and the potential for Erivedge to have a clinical benefit in treating advanced basal cell carcinoma and other disease indications; 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 operating results and 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 EMA 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 the EU. Genentech and Roche may experience delays or failures in the manufacture and/or commercial launch 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 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. 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 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 December 31,		*Year ended December 31,*	
	2011	*2010*	*2011*	*2010*
Revenues	$ 14,089,053	$ 100,287	$ 14,762,580	$ 15,999,565
Operating expenses:				
Research and development	4,447,859	3,651,710	13,692,659	11,372,850
General and administrative	2,076,087	2,058,936	8,272,424	10,264,459
Total operating expenses	6,523,946	5,710,646	21,965,083	21,637,309
Net income (loss) from operations	7,565,107	(5,610,359)	(7,202,503)	(5,637,744)
Other (expense) income, net	(1,503,232)	3,570	(2,656,392)	1,202,434

Net income (loss)	$ 6,061,875	$ (5,606,789)	$ (9,858,895)	$ (4,435,310)
Basic net income (loss) per common share	$ 0.08	$ (0.07)	$ (0.13)	$ (0.06)
Diluted net income (loss) per common share	$ 0.07	$ (0.07)	$ (0.13)	$ (0.06)
Basic weighted average common shares outstanding	76,649,034	75,668,337	76,351,856	74,959,158
Diluted weighted average common shares outstanding	81,354,223	75,668,337	76,351,856	74,959,158

CURIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(UNAUDITED)

	December 31, 2011	*December 31, 2010*
ASSETS		
Cash, cash equivalents and marketable securities	$ 37,717,575	$ 40,379,818
Investments — restricted	235,914	497,004
Accounts receivable	42,067	92,371
Property and equipment, net	455,730	302,721
Goodwill	8,982,000	8,982,000
Other assets	746,779	395,229
Total assets	$ 48,180,065	$ 50,649,143
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	$ 3,942,940	$ 3,526,744
Warrant liability	4,361,168	1,604,742
Total liabilities	8,304,108	5,131,486
Total stockholders' equity	39,875,957	45,517,657
Total liabilities and stockholders' equity	$ 48,180,065	$ 50,649,143

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