Curis Reports Second Quarter 2012 Financial Results

Conference Call Today at 9:00 am EDT

LEXINGTON, Mass., Aug. 2, 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 second quarter ended June 30, 2012.

"The quarter was highlighted by the continued positive U.S. commercial launch of Erivedge™ in advanced basal cell carcinoma. We are highly pleased with the increase in the number of prescriptions, and Roche's continued efforts to provide Erivedge to advanced BCC patients around the world with regulatory submissions in Europe, Australia, Canada, Israel, Mexico and Switzerland," said Dan Passeri, Curis' President and Chief Executive Officer. "In addition, we continue to focus internal resources on our ongoing Phase I clinical study in locally advanced head and neck cancer patients with our IV formulation of CUDC-101 and progressing towards planned IND filings in the second half of 2012 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. Our partner Debiopharm has advanced Hsp90 inhibitor Debio 0932 into Phase Ib testing and expects to initiate a Phase I/II clinical trial in non-small cell lung cancer patients in the near future."

For the second quarter of 2012, Curis reported a net loss of $2.9 million, or ($0.04) per share on both a basic and fully diluted basis, as compared to a net loss of $4.9 million or ($0.06) on both a basic and fully diluted basis for the same period in 2011.

Revenues for the second quarter of 2012 were $4.4 million, as compared to $400,000 for the same period in 2011. The increase is the result of $4.0 million in license fee revenues received upon Roche's filing of Erivedge for marketing registration in Australia and $250,000 in royalty revenues that Curis earned from net U.S. Erivedge sales during the second quarter of 2012.

Operating expenses for the second quarter of 2012 were $6.8 million, as compared to $5.0 million for the same period in 2011.

> Cost of royalty revenues was $13,000 for the second 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 second quarter of 2012.
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> Research and development spending was $4.5 million for the second quarter of 2012 as compared to $3.1 million for the same period in 2011, an increase of $1.4 million. Curis incurred $650,000 in research and development expenses during the second quarter of 2012 related to sublicense fees paid to university licensors in connection with regulatory filings in Australia.
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> Spending on Curis' internal programs also increased, including an increase of $600,000 on the Company's CUDC-907 program, primarily due to an increase in preclinical development costs as CUDC-907 advances towards an expected IND filing in the second half of 2012. Spending related to CUDC-101 also increased by $100,000 primarily due to costs associated with Curis' ongoing development of an oral formulation of CUDC-101 during the second quarter of 2012. Finally, stock-based compensation increased by $200,000, primarily due to expense recognized on unvested non-employee stock options that are marked-to-market at each reporting period.
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> General and administrative spending was $2.3 million for the second 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, personnel costs increased $100,000, primarily due to the accrual of cash incentive payments for executive officers under Curis' 2012 short-term incentive program.
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> Legal fees decreased by $200,000 from the prior year period, primarily due to decreased spending on patent costs, including fees related to foreign patent filings.

Other expense was $500,000 for the second quarter of 2012 compared to $300,000 for the same period in 2011. Other net 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 June 30, 2012, Curis' cash, cash equivalents and marketable securities totaled $44.7 million, and there were 79.5 million shares of common stock outstanding.

"In the second quarter, Roche recorded a slight decrease in net sales of Erivedge when compared with the net sales of the first quarter," said Mike Gray, Curis' Chief Financial Officer. "However, as Roche records net Erivedge sales based on shipments to specialty pharmacy distributors, we believe the sequential decrease in Erivedge revenues during the second quarter has resulted from an initial build-up of inventory levels at distributors following the February launch of Erivedge. Importantly, total prescriptions in the second quarter have increased several-fold from the first quarter and there has been a consistent increase in prescriptions on a monthly basis since February. We are highly encouraged by these data and the progress of the launch to date."

Recent Developments

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

In May 2012, Curis announced that Roche had submitted an application for marketing registration of Erivedge in advanced basal carcinoma 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 by the TGA. If Roche receives approval to commercialize Erivedge in Australia, Curis will be entitled to receive an additional milestone payment as well as royalties on any future net sales of Erivedge in Australia.

-- Announced Publication of Erivedge ™ Data in the New England Journal of Medicine

In June 2012, Curis announced that two publications describing Erivedge clinical data were published in *The New England Journal of Medicine*. The first publication, entitled "Efficacy and Safety of Vismodegib in Advanced Basal Cell Carcinoma," reports on the results of the Phase II ERIVANCE BCC study in 104 patients with advanced BCC conducted by Genentech. The second publication, entitled "Inhibiting the Hedgehog Pathway in Patients with Basal-Cell Nevus Syndrome," reports on results from an investigator-sponsored study evaluating the potential of Erivedge in 41 patients with basal cell nevus syndrome and surgically eligible patients with BCC.

-- Announced Publication of Clinical Research Data of CUDC-907

In June 2012, Curis announced that *Clinical Cancer Research* published an article on CUDC-907, an orally-available small molecule drug candidate that is designed to simultaneously inhibit PI3K and HDAC. The publication, entitled "Cancer network disruption by a single molecule inhibitor targeting both histone deacetylase (HDAC) activity and phosphatidylinositol 3-kinase (PI3K) signaling," was authored by several members of Curis' scientific team.

Conference Call Information

Daniel Passeri, President and Chief Executive Officer of Curis, will host a conference call today, August 2, 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 10305459. 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, Friday, August 10, 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 10305459.

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 Curis' and its collaborators' products under development. 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, the TGA or regulatory authorities in Australia, Canada, Israel, Mexico and Switzerland 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 March 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 June 30,		*Six months ended June 30,*	
	2012	*2011*	*2012*	*2011*
Revenues	$ 4,351,574	$ 392,867	$ 14,707,826	$ 526,405
Operating expenses:				
Costs of revenues	12,637	--	126,168	--
Research and development	4,500,456	3,144,050	9,742,405	6,202,549
General and administrative	2,264,586	1,867,782	5,065,663	4,275,131
Total operating expenses	6,777,679	5,011,832	14,934,236	10,477,680
Net (loss) income from operations	(2,426,105)	(4,618,965)	(226,410)	(9,951,275)
Other expense, net	(460,347)	(295,099)	(434,305)	(1,762,940)
Net (loss) income	$ (2,886,452)	$ (4,914,064)	$ (660,715)	$ (11,714,215)
Basic and diluted net loss per common share	$ (0.04)	$ (0.06)	$ (0.01)	$ (0.15)
Basic and diluted weighted average common shares outstanding	79,052,517	76,378,369	78,304,441	76,103,611

CURIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(UNAUDITED)

	June 30, 2012	*December 31, 2011*
ASSETS		
Cash, cash equivalents and marketable securities	$ 44,705,802	$ 37,717,575
Investments — restricted	194,282	235,914
Accounts receivable	318,306	42,067
Property and equipment, net	428,950	455,730
Goodwill	8,982,000	8,982,000
Other assets	400,119	746,779
Total assets	$ 55,029,459	$ 48,180,065
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	3,669,645	$ 3,942,940
Warrant liability	4,304,922	4,361,168
Total liabilities	7,974,567	8,304,108
Total stockholders' equity	47,054,892	39,875,957
Total liabilities and stockholders' equity	$ 55,029,459	$ 48,180,065

CONTACT: Michael P. Gray

Chief Operating and Chief Financial Officer

Curis, Inc.

617-503-6632

mgray@curis.com

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