Curis Reports Fourth Quarter and Year-End 2007 Financial Results

CAMBRIDGE, Mass., Feb 14, 2008 (BUSINESS WIRE) -- Curis, Inc. (NASDAQ:CRIS), a drug development company focused on developing novel targeted medicines primarily for cancer treatment, today reported its financial results for the fourth quarter and fiscal year ended December 31, 2007.

"2007 has been a year of transformation for Curis, as we have made substantial progress toward our goal of transitioning from a discovery-stage biology company to a development-stage targeted small molecule cancer company," commented Daniel Passeri, MSc., J.D., President and Chief Executive Officer of Curis. "We expect to continue to build on this momentum in 2008, as we seek to continue to grow and advance our portfolio of cancer drug candidates, with several key milestones expected throughout the year."

"We were pleased with the recent announcement by our collaborator Genentech that regression has been observed in one patient with an established metastatic basal cell tumor in its Phase I Hedgehog antagonist clinical trial. We believe that this early evidence of clinical activity is important and demonstrates possible proof of concept for this program. Additionally, we expect that Genentech will submit the Phase I data for presentation at an upcoming scientific conference," continued Mr. Passeri.

Financial Results

For the fourth quarter of 2007, Curis reported net income of $4.3 million or $0.07 per share, as compared to net income of $700,000 or $0.01 per share for the same period in the prior year.

Net revenues for the fourth quarter of 2007 were $11.5 million as compared to $6.1 million for the fourth quarter of 2006. The reasons for the increase in net revenues are detailed below:

-- Increase in license fee revenue. During the fourth quarter of 2007, license fee revenues were $11.0 million as compared to $1.1 million for the same period in 2006. The increase is primarily the result of the recognition of $10.5 million in previously deferred revenue under the June 2003 Hedgehog antagonist collaboration with Genentech. Prior to the fourth quarter of 2007, the Company could not estimate the performance period related to its ongoing joint steering committee obligation under this collaboration and therefore deferred $7.5 million in payments that Curis had received from Genentech in prior years. During the fourth quarter of 2007, as a result of changed facts and circumstances relating to the nature of the joint steering committee, including the Company's diminished role on the steering committee as the program advanced into clinical testing, the Company concluded that its joint steering committee performance obligation had become inconsequential to the agreement. Accordingly, during the fourth quarter of 2007 Curis recorded as license fee revenues the $7.5 million in previously deferred revenues as well as a $3 million cash payment received in October 2007.

-- Decrease in research and development contracts revenue. Revenue under research and development contracts was $500,000 for the fourth quarter of 2007 as compared to $2.0 million for the same period in the prior year. This decrease was primarily the result of the conclusion of sponsored research funding during the fourth quarter of 2006 and first quarter of 2007 under the ongoing Hedgehog antagonist and Wnt signaling pathway collaborations with Genentech.

-- Milestone revenue. Curis recorded $3.0 million in substantive milestone revenue during 2006 under its Hedgehog antagonist collaboration with Genentech. The Company did not record any substantive milestone revenue during the fourth quarter of 2007.

Operating expenses for the fourth quarter of 2007 were $7.7 million as compared to $5.8 million for the same period in the prior year. The primary changes in research and development and general and administrative expenses are as follows:

-- Research and Development. Research and development spending was $5.2 million for the fourth quarter of 2007 as compared to $3.6 million for the same period in the prior year. Included in the fourth quarter 2007 research and development expenses was $900,000 in license fee payments, $750,000 of which was made to a former collaborator as a result of the Company's December 2007 BMP-7 transaction with Stryker Corporation.

The Company incurred expenses of $2.6 million during the fourth quarter of 2007 related to development efforts for its lead preclinical drug candidate, CUDC-101, $1.5 million of which related to toxicology testing of the molecule in support of Curis' planned IND application filing in 2008. The Company also incurred expenses of approximately $1.1 million during the fourth quarter of 2007 to advance earlier stage candidates under the Company's targeted cancer platform. The Company incurred expenses of approximately $1.0 million on these efforts during the fourth quarter of 2006.

Offsetting the Company's increased expenses relating to its targeted cancer drug candidates was a decline in spending on all other programs of $1.5 million as funded research under most of its collaborations concluded in late 2006 or early 2007. Spending under such programs was $600,000 for the fourth quarter of 2007 as compared to $2.1 million for the prior year period.

-- General and Administrative. General and administrative spending was $2.4 million for the fourth quarter of 2007 as compared to $2.2 million for the same period in 2006. The increase in general and administrative expenses was primarily due to a $300,000 increase in legal expenses primarily related to the Company's patent portfolio and a $100,000 increase in personnel

expenses. These increases were offset by decreases of $100,000 in stock-based compensation as a result of a decline in the grant date fair value of stock options issued in 2007 as compared to 2006 as well as a decrease of $100,000 in consulting and other professional services expenses.

For the year ended December 31, 2007, the Company reported a net loss of $7.0 million or ($0.13) per share, as compared to a net loss of $8.8 million or ($0.18) per share for the prior year.

Net revenues for the year ended December 31, 2007 were $16.4 million as compared to $14.9 million for the prior year. The increase in net revenues was primarily the result of the recognition of $10.5 million in license revenue related to the June 2003 Hedgehog antagonist collaboration with Genentech, offset by decreases in research and development contract revenues and substantive milestone revenues.

Operating expenses were $24.8 million for the year ended December 31, 2007 as compared to $25.0 million for the prior year.

Research and development expenses were $14.8 million for the year ended December 31, 2007 as compared to $14.6 million for the prior year. This is the result of several offsetting variances in research and development programs, primarily related to increased efforts on CUDC-101 and other targeted cancer drug programs, offset by the reduced spending on other research programs, as funded research under most of the Company's collaborations concluded in late 2006 or early 2007. The Company spent $5.1 million during 2007 on development efforts related to CUDC-101. The Company also spent approximately $4.9 million during 2007 to advance earlier stage candidates under its targeted cancer platform, as compared to $2.1 million during 2006. Spending under other programs was $3.8 million for 2007 as compared to $11.2 million for the prior year.

General and administrative expenses were $10.0 million for the year ended December 31, 2007 as compared to $10.4 million for the prior year. This decrease is attributable to decreases in occupancy costs, professional and consulting services and stock based compensation expenses offset by increased spending related to legal services for the Company's patent portfolio.

As of December 31, 2007, the Company's cash, cash equivalents and marketable securities totaled $41.5 million and there were 63.2 million shares of common stock outstanding.

"In 2007, we strengthened our financial position through a $14.5 million private placement, and looking forward, we are actively seeking collaborative opportunities for our developing pipeline, focusing especially on our proprietary targeted cancer drug candidates," commented Michael Gray, Chief Financial Officer and Chief Operating Officer of Curis.

2008 Expected Milestones

-- Genentech's Phase II clinical trial initiation of a Hedgehog systemic antagonist under the parties' 2003 collaboration agreement in the first half of 2008.

-- File an IND application for CUDC-101, a preclinical stage inhibitor of HDAC, EGFR and Her2, during the first quarter of 2008 and begin treating patients in a Phase I clinical trial during the second quarter of 2008.

-- Select one to two additional preclinical development drug candidates from the Company's proprietary targeted cancer platform in 2008.

-- Enter into a new collaboration in 2008. The Company currently plans to pursue an Asia territory partnering strategy for CUDC-101 in order to retain proprietary development of CUDC-101 in the majority of the worldwide markets into at least early clinical testing and is also pursuing a collaboration for one or more of the earlier stage targeted cancer programs. The Company expects to announce a new collaboration for one of these programs in 2008.

Financial Guidance

The Company expects to end 2008 with cash, cash equivalents and marketable securities of $17-21 million, which excludes any potential payments from existing or new collaborators in 2008. The Company expects that the existing cash, cash equivalents and marketable securities will be sufficient to support the current operating plans into the second half of 2009.

The Company expects that 2008 research and development expenses will be $16-19 million and that general and administrative expenses will be $8-10 million. These expense projections include $500,000 to $700,000 and $1.2-1.4 million of stock-based compensation expense for research and development and general and administrative expense, respectively. Actual 2008 stock-based compensation expense may be higher since the Company may issue additional awards as part of its planned compensation programs, consistent with past practices.

Fourth Quarter and Recent Highlights

-- Genentech Updates on Hedgehog Program. During the fourth quarter of 2007 and in January 2008, Curis' collaborator Genentech publicly provided several important updates on the Phase I Hedgehog antagonist program. First, during the fourth quarter of 2007, Genentech disclosed to the Company that the initial objectives of the Phase I clinical trial had been achieved and that Genentech had initiated an expansion cohort in its ongoing Phase I clinical trial, which is enrolling additional patients in a specific cancer indication for preliminary signs of clinical response as well as the continued accumulation of Phase I safety data. As a result of the trial expansion, Curis received a $3 million cash milestone payment from Genentech. Genentech also notified Curis of its decision to progress a systemically administered Hedgehog antagonist drug candidate into Phase II clinical testing in 2008. The drug candidate is expected to be evaluated in one or more solid tumor indications.

-- Sale of BMP Assets to Stryker. In December 2007, Curis entered into a transaction with Stryker Corporation for the sale and assignment of all of the remaining BMP assets. Under this agreement, the Company received an initial payment of $1.75 million. As a result of the transaction, Stryker will assume all future costs subsequent to the December 26, 2007 effective date related

to maintenance and prosecution of the patent portfolio. The Company has deferred revenue recognition on the initial payment until it completes its performance obligations under the agreement. The Company estimates that such obligations will be fulfilled, and that it will record the up-front payment as revenue, during the first quarter of 2008. As a result of this transaction, the Company paid $750,000 in January 2008 to a former collaborator.

-- CUDC-101 Poster at AACR-NCI-EORTC. In October 2007, Curis scientists presented a poster entitled "CUDC-101, a Synthetic and Potent HDAC, EGFR and Her2 Inhibitor, Effectively Inhibits Proliferation of Cancer Cell Lines" during a poster session at the AACR-NCI-EORTC Conference on Molecular Targets and Cancer Therapeutics. This presentation included discussions of a potential mechanism of action and the anticancer properties of CUDC-101.

Conference Call

Curis management will hold a conference call today, February 14, 2008, at 9:00 A.M. EST, to discuss the progress of CUDC-101, the other targeted inhibitors that the Company is developing under the Targeted Cancer Drug Development Platform, the product development programs under collaborations, the financial results and additional corporate activities. The Company's CEO, Daniel Passeri, will host the call.

To access the live conference call, please call (866) 356-3377 from the United States or Canada or (617) 597-5392 from other locations, shortly before 9:00 A.M. EST. The conference ID number is 14512747. 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 and through 5:00 P.M. EST, Thursday, February 28, 2008. To access the replay, please call (888) 286-8010 from the United States or Canada or (617) 801-6888 from other locations and reference the conference ID number 38258302.

CURIS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(UNAUDITED)

	Three months ended December 31,		Year ended December 31,	
	2007	2006	2007	2006
Revenues:				
Gross revenues	$11,484,842	$ 6,067,883	$16,388,554	$ 16,663,364
Contra-revenues from co-development with Genentech	-	-	-	(1,727,727)
Net revenues	11,484,842	6,067,883	16,388,554	14,935,637
Operating expenses:				
Research and development	5,233,357	3,595,319	14,779,184	14,589,647
General and administrative	2,441,686	2,223,515	9,983,931	10,373,883
Amortization of intangible assets	-	-	-	27,050
Total operating expenses	7,675,043	5,818,834	24,763,115	24,990,580
Net income/(loss) from operations	3,809,799	249,049	(8,374,561)	(10,054,943)
Other income, net	482,575	431,445	1,410,318	1,225,621
Net income/(loss)	$ 4,292,374	$ 680,494	$(6,964,243)	$ (8,829,322)
Basic and diluted net income/(loss) per common share	$ 0.07	$ 0.01	$ (0.13)	$ (0.18)
Basic weighted average common shares outstanding	63,180,451	49,240,712	54,914,666	49,066,680

Diluted weighted average common shares outstanding	63,206,837	49,422,874	54,914,666	49,066,680

CURIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(UNAUDITED)

	December 31, 2007	December 31, 2006
ASSETS		
Cash, cash equivalents and marketable securities	$41,459,176	$36,656,007
Long-term investments - restricted	210,007	201,844
Accounts receivable	230,467	1,315,412
Property and equipment, net	2,577,602	4,393,604
Goodwill	8,982,000	8,982,000
Other assets	357,433	719,386
Total assets	$53,816,685	$52,268,253
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	$ 4,715,772	$ 3,504,659
Debt obligations	403,832	1,979,622
Deferred revenue	1,852,518	10,886,833
Total liabilities	6,972,122	16,371,114
Total stockholders' equity	46,844,563	35,897,139
Total liabilities and stockholders' equity	$53,816,685	$52,268,253

About Curis, Inc.

Curis is a drug development company that is committed to leveraging the innovative signaling pathway drug technologies to seek to create new medicines, primarily for cancer. In expanding the drug development efforts in the field of cancer through the Targeted Cancer Drug Development Platform, the Company is building upon the previous experiences in targeting signaling pathways in the areas of cancer, neurological disease and cardiovascular disease. For more information, visit the website at www.curis.com.

Cautionary Statement: This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including without limitation: the Company's expectation that it will advance additional preclinical development candidates in 2008; the Company's expectations regarding the potential therapeutic benefits of its clinical-stage Hedgehog antagonist and its preclinical drug candidates, including CUDC-101; its plans to enter into one or more collaborations in 2008, and its financial guidance regarding working capital and operating expenses for 2008. Forward-looking statements used in this press release may contain the words "believes", "expects", "anticipates", "plans", "seeks", "estimates", "will", "may" or similar expressions. These forward-looking statements are not guarantees of future performance and involve risks, uncertainties, assumptions and other factors that may cause the actual results to be materially different from those indicated by such forward-looking statements including, among other things:

-- adverse results, delays and/or failures in the Company's and the Company's strategic collaborators' product development programs, including without limitation adverse events, difficulties with patient enrollment and other unplanned delays in the Hedgehog pathway antagonist currently under Phase I clinical development with Genentech, and unplanned delays and/or failures in the efforts to advance CUDC-101 and the other programs under the Targeted Cancer Drug Development Platform;

-- difficulties or delays in obtaining or maintaining required regulatory approvals for products being developed by the Company and by its collaborators;

-- Curis and its collaborators' ability to obtain or maintain the patent and other proprietary intellectual property protection necessary for the development and commercialization of products based on the technologies;

-- changes in, or the inability to execute, the Company's business plan;

-- the risk that the Company does not obtain the additional funding required to conduct research and development of its product candidates;

-- unplanned cash requirements and expenditures which, among other things, could shorten the estimated period in which the Company will have cash to fund the operations and which could also adversely affect the Company's estimated operating expenses for 2008 and beyond;

-- risks relating to the Company's ability to enter into and maintain important strategic collaborations, and the risk that the current and future collaborators will not perform adequately, including such risks with respect to the current collaboration agreements with Genentech and Wyeth;

-- competitive pressures; and

-- other risk factors identified in the Quarterly Report on Form 10-Q for the Quarter ended September 30, 2007 and other filings that the Company periodically makes with the Securities and Exchange Commission.

In addition, any forward-looking statements represent the views only as of today and should not be relied upon as representing the 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.

SOURCE: Curis, Inc.

Curis, Inc.
Michael P. Gray, 617-503-6632
Chief Financial Officer and Chief Operating Officer
mgray@curis.com
