Curis Reports Fourth Quarter and Year-End 2006 Financial Results

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Feb. 14, 2007--Curis, Inc. (NASDAQ:CRIS), a drug development company focusing on signaling pathway drug technologies to create new medicines primarily for cancer, today reported its financial results for the fourth quarter and fiscal year ended December 31, 2006.

For the fourth quarter of 2006, Curis reported net income of $680,000, or $0.01 per share (on both a basic and fully diluted basis) as compared to a net loss of $1,365,000, or ($0.03) per share for the same period in the prior year.

Net revenues for the fourth quarter of 2006 were $6,068,000 as compared to $3,509,000 for the fourth quarter of 2005, an increase of $2,559,000, or 73%. The increase in net revenues was primarily due to $3,000,000 in substantive milestone revenue associated with Genentech's filing in October 2006 of an Investigational New Drug application with the FDA to initiate Phase I clinical testing of a systemically administered small molecule Hedgehog antagonist for the treatment of cancer. In addition, during the fourth quarter of 2006, Curis did not record any co-development costs under its basal cell carcinoma co-development arrangement with Genentech, which ended in August 2006. During the fourth quarter of 2005, the Company recorded $1,301,000 in co-development costs under such arrangement with Genentech, which were recorded as a reduction to revenues. These increases in net revenues in the fourth quarter of 2006 were partially offset by a $1,743,000 decrease in our research and development and license fee revenues.

Operating expenses for the fourth quarter of 2006 were $5,819,000 as compared to $5,263,000 for the fourth quarter of 2005, an increase of $556,000, or 11%. The primary changes in the Company's research and development and general and administrative expenses are as follows:

Research and development spending increased to $3,595,000 for the fourth quarter of 2006 as compared to $3,295,000 for the same period in 2005. Spending increased primarily for the Company's Targeted Drug Development Cancer Platform, which includes a series of new programs focusing on the development of multi-targeted inhibitors of validated cancer pathways. These increases were offset by decreases in spending on a majority of Curis' other research programs. In addition, we recognized an impairment charge of approximately $150,000 in the fourth quarter of 2006 related to the disposal of assets that are no longer used in operations, primarily assets used to conduct discovery research activities.

General and administrative spending was $2,224,000 for the fourth quarter of 2006 as compared to $1,949,000 for the same period in 2005, an increase of $275,000, or 14%. The increase in general and administrative expenses was principally due to an increase of $622,000 in stock-based compensation expense during the fourth quarter of 2006 as a result of the Company's adoption on January 1, 2006 of Statement of Financial Accounting Standards No. 123R, Share-Based Payments (SFAS 123R). This increase was partially offset by decreases in certain general and administrative cost categories, including a $191,000 decrease in legal costs incurred during the fourth quarter of 2006 as compared to the same period in 2005.

Other income for the fourth quarter of 2006 was $431,000 as compared to $389,000 for the same period in 2005, an increase of $42,000, or 11%.

Net loss for the year ended December 31, 2006 was $8,829,000 or ($0.18) per share as compared to $14,855,000 or ($0.31) per share for the year ended December 31, 2005.

Net revenues for the year ended December 31, 2006 were $14,936,000 as compared to $6,002,000 for 2005, an increase of $8,934,000, or 149%. The increase in net revenues was primarily due to a $5,271,000 decrease in contra-revenues recorded by the Company in 2006 as compared to 2005 under its basal cell carcinoma co-development arrangement with Genentech, which ended in August 2006. During 2006 and 2005, the Company recorded $1,728,000 and $6,999,000 in co-development costs, respectively, which were recorded as a reduction to revenues. In addition, in the fourth quarter of 2006, the Company recorded $3,000,000 in substantive milestone revenue associated with Genentech's filing of an IND with the FDA to initiate Phase I clinical testing of a systemically administered small molecule Hedgehog antagonist for the treatment of cancer.

Operating expenses for the year ended December 31, 2006 were $24,991,000 as compared to $21,870,000 for the prior year, an increase of $3,121,000, or 14%. The primary changes in our research and development and general and administrative expenses are as follows:

Research and development spending increased by $885,000, or 6%, to $14,590,000 for 2006 as compared to $13,705,000 for 2005. Spending primarily increased for our Targeted Drug Development Cancer Platform, which includes a series of new programs focusing on the development of multi-targeted inhibitors of validated cancer pathways. These increases were offset by decreases in spending on a majority of Curis' other research programs.

General and administrative spending was $10,374,000 for 2006 as compared to $8,090,000 for 2005, an increase of $2,284,000, or 28%. The increase in general and administrative expenses was principally due to an increase of $2,650,000 in stock-based compensation expense recorded during 2006 as a result of the Company's adoption on January 1, 2006 of SFAS 123R.

Other income for the year ended December 31, 2006 was $1,226,000 as compared to other income of $1,012,000 for the year ended December 31, 2005, an increase of $214,000, or 21%. The increase was principally due to a $381,000 increase in interest income, offset in part by a decrease of $112,000 in interest expense in 2006 as compared to 2005.

As of December 31, 2006, Curis' cash, cash equivalents and marketable securities were $36,656,000 and there were 49,333,854 shares of common stock outstanding.

2007 Financial Guidance

The Company expects that its existing cash, cash equivalents and marketable securities, together with contractually defined cash payments that Curis expects to receive under its collaborations, assuming such collaborations continue in accordance with their terms, will be sufficient to support its current operating plans into the second half of 2008. The Company expects to end 2007 with cash, cash equivalents and marketable securities of between $20,000,000 and $23,000,000.

The Company expects that its 2007 gross revenues from existing collaborators will be in a range of $4,000,000 to $5,000,000, excluding any future development milestones and assuming such collaborations continue in accordance with their terms. The Company expects that its 2007 research and development expenses will be between $12,500,000 and $15,000,000 and that its general and administrative expenses will be in a range of $9,900,000 to $11,200,000. These expense projections include between $500,000 and $700,000 and between $1,900,000 and $2,200,000 in stock-based compensation expense that is attributable to share-based awards outstanding at December 31, 2006, for research and development and general and administrative expense, respectively. Actual 2007 stock-based compensation expense may be higher since the Company expects to issue additional share-based awards in 2007 as part of its planned compensation programs, consistent with past practices. The amount of stock-based compensation expense allocable to Curis' 2007 share-based awards will be based on a number of factors, including the number of stock awards issued in 2007, the fair market value of the Company's common stock at the respective grant dates, and the specific terms of the stock award, and the key assumptions used in the valuation of the awards.

Recent Developments and Fourth Quarter 2006 Highlights

In January 2007, Curis announced that Genentech had treated the first patient in a Phase I clinical trial of a systemically administered Hedgehog antagonist for the treatment of cancer. The Phase I trial is designed as an open-label study of a systemic Hedgehog antagonist in patients with locally advanced or metastatic cancers that are refractory to standard therapy or for whom no standard therapies exist. The primary objectives of the Phase I trial are to evaluate the safety and tolerability of escalating doses of the Phase I molecule and to establish the maximum tolerable dose and dose limiting toxicities. The trial is expected to enroll approximately 50 patients spread across several dose-escalating cohorts. The successful completion of the Phase I trial will be dependent upon, among other things, the patient enrollment rate as well as treating the number of patients that will ultimately need to be treated to achieve the Phase I trial objectives. The Company received a $3,000,000 milestone payment from Genentech in October 2006 in connection with Genentech's IND filing for the trial.

Wyeth and Curis have been continuing to conduct screening and preclinical research on Hedgehog agonist compounds. The Company previously estimated that Wyeth may select a lead clinical candidate in early 2007, but currently expects that further preclinical testing on potential candidate compounds will be required. Wyeth has recently extended its funding of five Curis researchers through February 2008. The Company expects that these researchers will continue the Company's development efforts related to Hedgehog agonists in neurological disorders, particularly stroke.

In October 2006 the Company was issued U.S. patent 7,115,653, entitled "Small Organic Molecule Regulators of Cell Proliferation." The claims of this patent cover specific small molecule compounds that are activators, or agonists, of the Hedgehog signaling pathway, as well as pharmaceutical compositions and preparations containing specific Hedgehog agonist compounds. Curis believes that the claims of this patent provide additional depth to its existing intellectual property position surrounding Hedgehog agonist compounds.

Daniel Passeri, Curis' President and Chief Executive Officer, stated, "2006 was a challenging, yet productive, year for Curis. We began 2006 with the decision not to advance our Phase I basal cell carcinoma drug candidate into Phase II testing. Since that time, we have been working diligently toward our goal of becoming a leading drug development company focused on cell signaling pathways, particularly in developing small molecule drug candidates for cancer." Passeri continued, "We took a number of deliberate steps in 2006 designed to improve our development capacities. Most notably, we changed our business strategy to focus on developing later-stage preclinical drug development programs with a goal of ultimately advancing such programs into the clinic and to de-emphasize our earlier-stage discovery research. We also implemented our Targeted Cancer Drug Development Platform, which is aimed at producing proprietary cancer drugs that are designed to inhibit multiple validated cancer pathway targets. In order to increase our medicinal chemistry capabilities to meet the expected needs of this drug development platform, we entered into a collaborative relationship with a leading chemistry provider in Shanghai, China and are currently contracting approximately 25 to 30 chemists to advance our proprietary compounds. We anticipate that we will select our first lead clinical candidate from our drug development platform in the first half of 2007 and that we will file an IND for this clinical candidate in late 2007 or early 2008. We plan to seek a corporate collaborator for the first successfully selected drug candidate that will provide us with significant involvement in at least the early stages of clinical testing."

The Company will hold a conference call today, February 14, 2007, at 10:00 A.M. EST, to discuss its financial results and guidance, the progress of its therapeutic product development programs, and additional corporate activities. Daniel Passeri, President and Chief Executive Officer of Curis, will host the call.

To access the live conference call, please call (800) 659-2032 from the United States and Canada or (617) 614-2712 from other locations, shortly before 10:00 A.M. EST. The conference ID number is 81229487. The conference call can also be accessed on the Curis website at www.curis.com in the Investor Relations section. Replay will be available approximately two hours after the completion of the call and through 5:00 P.M. EST, Wednesday, February 28, 2007. To access the replay, please call (888) 286-8010 from the United States and Canada or (617) 801-6888 from other locations and reference the conference ID number 50926099.

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

	Three months ended December 31,		Year ended December 31,	
	2006	2005	2006	2005
Revenues:				
Research and development contracts	$ 1,962,596	$ 3,134,326	$ 9,339,191	$ 10,493,077
License fees	1,105,287	1,676,434	4,324,173	2,258,677
Substantive milestones	3,000,000	-	3,000,000	250,000
Gross revenues	6,067,883	4,810,760	16,663,364	13,001,754
Contra-revenues from co-development with Genentech	-	(1,301,316)	(1,727,727)	(6,999,308)
Net revenues	6,067,883	3,509,444	14,935,637	6,002,446
Operating expenses:				
Research and development	3,595,319	3,295,488	14,589,647	13,705,074
General and administrative	2,223,515	1,948,728	10,373,883	8,089,738
Amortization of intangible assets	-	18,768	27,050	75,072
Total operating expenses	5,818,834	5,262,984	24,990,580	21,869,884
Income (loss) from operations	249,049	(1,753,540)	(10,054,943)	(15,867,438)
Total other income, net	431,445	388,959	1,225,621	1,012,266
Net income (loss)	$ 680,494	$(1,364,581)	$ (8,829,322)	$(14,855,172)
Basic and diluted net loss per common share	$ 0.01	$ (0.03)	$ (0.18)	$ (0.31)
Basic weighted average common shares outstanding	49,240,712	48,298,273	49,066,680	48,074,181
Diluted weighted average common shares outstanding	49,433,057	48,298,273	49,066,680	48,074,181

CURIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(UNAUDITED)

	December 31, 2006	December 31, 2005

ASSETS		
Cash, cash equivalents, marketable securities	$36,656,007	$44,209,322
Long-term investments - restricted	201,844	195,998
Accounts and notes receivable	1,315,412	1,002,511
Property and equipment, net	4,393,604	5,347,639
Intangible assets, net	8,982,000	9,009,050
Other assets	719,386	1,149,733
Total assets	$52,268,253	$60,914,253
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	$3,504,659	$5,088,998
Debt and capital lease obligations, excluding convertible debt	1,979,622	3,226,712
Convertible debt	-	2,605,280
Deferred revenue	10,886,833	11,993,684
Total liabilities	16,371,114	22,914,674
Total stockholders' equity	35,897,139	37,999,579
Total liabilities and stockholders' equity	$52,268,253	$60,914,253

About Curis, Inc.

Curis is a drug development company that is committed to leveraging its innovative signaling pathway drug technologies to create new medicines, primarily for cancer. In expanding its drug development efforts in the field of cancer through its Targeted Cancer Drug Development Platform, the Company is building upon its previous experiences in targeting signaling pathways in the areas of cancer, neurological disease, hair growth regulation and cardiovascular disease. For more information, visit 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 Curis' expectations regarding: its financial guidance and outlook for 2007; its expected cash, cash equivalents and marketable securities available at the end of 2007; 2007 gross revenues, and research and development and general and administrative expenses, including the expected impact of stock-based compensation expense; its ability to select its first lead clinical candidate from the Targeted Cancer Drug Development Platform in the first half of 2007 and to file an IND for this clinical candidate in late 2007 or early 2008; the Company's plans to seek a corporate collaborator for this drug candidate that will provide Curis with significant involvement in at least the early stages of clinical testing; the expected enrollment and study outcomes for the Phase I trial of a hedgehog antagonist currently being undertaken by Genentech; the depth of its intellectual property position and the progress of its Targeted Cancer Drug Development Platform program. Forward-looking statements used in this press release may contain the words "believes", "expects", "anticipates", "plans", "seeks", "estimates" 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 Company's 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 its strategic collaborators' and licensees' product development programs, including without limitation adverse events, difficulties with patient enrollment and other unplanned delays in its Hedgehog pathway antagonist program currently under phase I clinical development with Genentech and unplanned delays and/or failures in the Company's efforts to advance its Targeted Cancer Drug Development Platform program;

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

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

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

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

-- unplanned cash requirements and expenditures which, among other things, could shorten the estimated period in which the Company will have cash to fund its operations;

-- risks relating to the Company's ability to enter into and maintain important strategic collaborations, including its ability to maintain its current collaboration agreements with Genentech, Wyeth, and Procter & Gamble as well as its license agreement with Ortho Biotech Products, which, among other things, could adversely effect the Company's estimates with respect to future revenues and expenses;

-- the risk that competitors will discover and develop signaling pathway-based or other competing therapeutics faster and more successfully than the Company and its collaborators are able to; and

-- other risk factors identified in the Company's most recent Annual Report on Form 10-K, Quarterly Report on Form 10-Q and subsequent reports periodically filed with the Securities and Exchange Commission.

In addition, any forward-looking statements represent the Company's views only as of today and should not be relied upon as representing its views as of any subsequent date. The Company 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.

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