Investor Relations - Curis

Curis Reports Second Quarter 2008 Financial Results

CAMBRIDGE, Mass.--(BUSINESS WIRE)--July 30, 2008--Curis, Inc. (NASDAQ:CRIS), a drug development company focused on 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, 2008.

"We are pleased with the progress of our programs to-date, including Genentech's recent initiation of Phase II clinical testing of GDC-0449 under our Hedgehog antagonist collaboration," said Dan Passeri, Curis' President and Chief Executive Officer. "We also continued to advance our preclinical internally-developed drug candidates during the quarter, including filing an IND application for our lead candidate, CUDC-101. We expect to treat our first patient in the CUDC-101 Phase I trial during the third quarter of 2008. In July, we announced that we selected CUDC-305, an orally available, synthetic small molecule inhibitor of heat shock protein 90, as a development candidate. Pending the successful completion of IND-enabling studies, we expect to file an IND application for CUDC-305 in mid-2009."

For the second quarter of 2008, Curis reported a net loss of $2.0 million or ($0.03) per share, as compared to a net loss of $4.0 million or ($0.08) per share for the same period in the prior year.

Revenues for the second quarter of 2008 were $3.1 million as compared to $1.2 million for the second quarter of 2007, an increase of $1.9 million, or 158%. The increase in total revenues was primarily the result of an increase in license fee revenues offset by a decrease in research funding revenues under collaborative arrangements as follows:

-- License fee revenues. During the second quarter of 2008, license fee revenues were $3.0 million as compared to $500,000 for the same period in 2007, an increase of $2.5 million. The increase was primarily the result of the receipt of a $3 million cash payment from Genentech upon its initiation of a phase II metastatic colorectal cancer trial in May 2008.

-- Research and development contracts revenues. Revenues under research and development contracts were $100,000 for the second quarter of 2008 as compared to $700,000 for the same period in the prior year, a decrease of $600,000, or 86%. This decrease was primarily the result of the conclusion of research funding under Curis' collaboration with Procter & Gamble in November 2007 and Curis' Hedgehog agonist collaboration with Wyeth in February 2008.

Operating expenses for the second quarter of 2008 were $5.3 million as compared to $5.4 million for the second quarter of 2007, a decrease of $100,000, or 2%. The primary changes in research and development and general and administrative expenses are as follows:

-- Research and development. Research and development spending was $3.2 million for the second quarter of 2008 as compared to $3.0 million for the same period in 2007, an increase of $200,000, or 7%. The increase was due to increased spending of $800,000 on the Company's targeted drug development programs, including its lead drug candidate, CUDC-101, and a second drug candidate, CUDC-305, which was selected as a development candidate in July 2008. The spending on these programs was partially offset by decreased spending on other research programs as funded research under the Company's collaborations concluded.

-- General and administrative. General and administrative spending was $2.1 million for the second quarter of 2008 as compared to $2.4 million for the same period in 2007, a decrease of $300,000, or 13%. The decrease in general and administrative expenses was primarily due to a $400,000 decrease in stock-based compensation expense.

For the six-month period ending June 30, 2008, Curis reported a net loss of $5.4 million or ($0.09) per share, as compared to a net loss of $7.5 million or ($0.15) per share for the same period in the prior year.

Revenues for the six months ended June 30, 2008 were $5.2 million as compared to $3.6 million for the same period in 2007, an increase of $1.6 million, or 44%. The increase in revenues was primarily the result of an increase in license fee revenues related to the June 2003 Hedgehog antagonist collaboration with Genentech and the sale and assignment of Curis' remaining BMP assets to Stryker Corporation, offset by a decrease in research and development contracts revenues.

Operating expenses were $11.2 million and $11.7 million for the six-month periods ended June 30, 2008 and 2007, respectively, a decrease of $500,000, or 4%. Research and development expenses were $6.7 million for the six months ended June 30, 2008 as compared to $6.3 million for the same period in the prior year, an increase of $400,000, or 6%. This increase was primarily

related to increased spending on Curis' targeted drug development programs, offset by reduced spending on other research programs. General and administrative expenses were $4.5 million for the six months ended June 30, 2008 as compared to $5.3 million for the same period in the prior year, a decrease of $800,000, or 15%. This decrease was attributable to decreases in stock based compensation, legal services related to the Company's patent portfolio and professional and consulting services offset by increased spending related to occupancy and travel costs.

As of June 30, 2008, Curis' cash, cash equivalents, marketable securities and investments totaled $33.9 million and there were 63,430,160 shares of common stock outstanding. The Company expects that its existing cash, cash equivalents and marketable securities should provide adequate capital to fund its currently-planned operations into the fourth quarter of 2009.

Second Quarter and Recent Highlights

-- Progress on clinical development of CUDC-101.

In May 2008, Curis filed an IND application for CUDC-101, Curis' lead drug candidate under internal development. CUDC-101 is designed as a first-in-class therapeutic to simultaneously inhibit three validated cancer targets: histone deacetylase (HDAC), epidermal growth factor receptor (EGFR) and human epidermal growth factor receptor 2 (Her2). In preclinical studies, CUDC-101 inhibits all three molecular targets resulting in the potent killing of a wide range of cancer cell lines that are representative of a variety of human cancer types, many of which have demonstrated resistance to various approved targeted agents.

Curis expects to treat its first patient with CUDC-101 during the third quarter of 2008. The phase I trial is designed as an open-label study of CUDC-101 in patients with advanced, refractory solid tumors. The primary objectives of the phase I trial are to evaluate the safety and tolerability of escalating doses of CUDC-101 and to establish the maximum tolerated dose and dose-limiting toxicities. Secondary objectives will assess the pharmacokinetics, efficacy and ability of CUDC-101 to inhibit HDAC, EGFR and Her2 in this patient population. Curis plans to conduct the study at two sites within the United States and expects to enroll between 18 and 40 patients across several dose-escalating cohorts. The successful completion of the phase I trial will be dependent upon, among other things, observed toxicities and whether CUDC-101 achieves the phase I trial objectives.

-- CUDC-305 selected as a development candidate.

In July 2008, Curis selected CUDC-305, an orally available, synthetic small molecule inhibitor of heat shock protein 90 (Hsp90), as a development candidate. CUDC-305 demonstrated high potency in laboratory and preclinical testing across several cancer types, with tumor regression demonstrated in mouse xenograft models of acute myelogenous leukemia (AML), brain, breast, non-small cell lung and gastric cancers. To date, the preclinical safety assessment for CUDC-305 appears favorable and Curis expects to initiate IND-enabling studies shortly. Should such further testing be favorable, Curis anticipates that it will file an IND application for CUDC-305 in mid-2009.

-- Progress on clinical development of Hedgehog antagonist GDC-0449 with collaborator Genentech.

In May 2008, Genentech initiated a phase II clinical trial of GDC-0449 in first-line metastatic colorectal cancer. The study is designed to evaluate GDC-0449 in approximately 150 patients with metastatic colorectal cancer in combination with the current standard of care as first-line therapy in a randomized, placebo-controlled, double-blind phase II trial. Patients will receive either FOLFOX or FOLFIRI chemotherapy regimens in combination with bevacizumab and will be randomized to receive GDC-0449 or placebo. The primary objective of the phase II clinical trial is progression-free survival from randomization to disease progression or death. Secondary outcome measures include the measurement of Hedgehog protein expression in archival tissue and tracking of adverse events.

Genentech has also indicated that it plans to initiate additional phase II clinical trials of GDC-0449 in advanced ovarian cancer and that it expects this trial to begin during the second half of 2008. If Genentech initiates the ovarian cancer trial as it has indicated, Genentech is obligated to make a $3 million cash payment to Curis within 30 days thereafter.

Genentech has also stated that it plans to initiate a phase II trial in advanced basal cell carcinoma during the second half of 2008.

--Data presented from Phase I study of GDC-0449 at ASCO.

On June 1, 2008, Dr. Patricia LoRusso, a phase I clinical investigator, presented select phase I clinical data of GDC-0449, including full toxicity data, at the American Society of Clinical Oncologists (ASCO) Annual Meeting. Dr. LoRusso reported that GDC-0449 demonstrated a favorable pharmacokinetic and pharmacodynamic profile with high sustained plasma concentrations and a prolonged terminal half-life of greater than seven days. No dose-limiting adverse events occurred. Gli1, a biomarker of Hedgehog signaling activity, was down modulated greater than 2-fold in skin biopsies from 11 of 14 patients analyzed.

-- Data presented from Phase I study of GDC-0449 at AACR.

In April 2008, at the American Association for Cancer Research Annual Meeting, Daniel D. Von Hoff, M.D., an investigator of the GDC-0449 phase I clinical trial, presented data from nine patients treated with GDC-0449 with locally advanced, multifocal and metastatic basal cell carcinoma. In five patients with metastatic basal cell carcinoma to the lungs, two patients had confirmed RECIST partial responses, two had ongoing stable disease and one had progressive disease. In four patients with clinically evaluable, locally advanced or multi-focal basal cell carcinoma, two patients exhibited complete response in subcutaneous masses by physical exam and two patients had improvement in skin lesions. Gli-1, a biomarker for Hedgehog signaling activity, was reduced in all evaluated patients. No significant toxicities were observed with GDC-0449 and no dose limiting toxicities were reached in the phase I clinical trial. Some patients experienced a loss of sense of taste, and there was a small amount of hair and weight loss.

Conference Call Information

Curis will hold a conference call today, July 30, 2008, at 9:00 A.M. EDT, to discuss (i) its Hedgehog antagonist program under collaboration with Genentech, (ii) CUDC-101 and other proprietary targeted cancer programs, (iii) its financial results as of and for the three- and six-month periods ended June 30, 2008, and (iv) additional corporate activities. Daniel Passeri, President and Chief Executive Officer of Curis, will host the call.

To access the live conference call, please call (866) 356-4123 from the United States or Canada or (617) 597-5393 from other locations, shortly before 9:00 A.M. EDT. The conference ID number is 42440244. The conference call can also 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. EDT, Wednesday, August 13, 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 84085781.

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

	Three months ended June 30,		Six months ended June 30,	
	2008	2007	2008	2007
Revenues	$ 3,107,810	$ 1,228,724	$ 5,175,393	$ 3,591,510
Operating expenses:				
Research and development	3,200,683	3,046,824	6,676,495	6,342,439
General and administrative	2,124,809	2,359,186	4,540,303	5,310,771
Total operating expenses	5,325,492	5,406,010	11,216,798	11,653,210
Net loss from operations	(2,217,682)	(4,177,286)	(6,041,405)	(8,061,700)
Other income, net	253,126	179,742	646,182	523,383
Net loss	$(1,964,556)	$(3,997,544)	$(5,395,223)	$(7,538,317)
Basic and diluted net loss per common share	$ (0.03)	$ (0.08)	$ (0.09)	$ (0.15)
Basic and diluted weighted average common shares outstanding	63,337,647	49,408,100	63,291,592	49,381,508

CURIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(UNAUDITED)

	June 30, 2008	December 31, 2007
ASSETS		
Cash, cash equivalents and marketable securities	$33,914,399	$41,459,176
Long-term investments - restricted	210,007	210,007
Accounts receivable	209,514	230,467
Property and equipment, net	2,117,262	2,577,602
Goodwill	8,982,000	8,982,000

Other assets	198,054	357,433
Total assets	$45,631,236	$53,816,685
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	$ 2,813,284	$ 4,715,772
Debt obligations	-	403,832
Deferred revenue	-	1,852,518
Total liabilities	2,813,284	6,972,122
Total stockholders' equity	42,817,952	46,844,563
Total liabilities and stockholders' equity	$45,631,236	$53,816,685

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 medicines, primarily for cancer. In expanding its drug development efforts in the field of cancer through its targeted cancer drug development platform, Curis is building upon its previous experiences in targeting signaling pathways for the development of next generation targeted cancer therapies. For more information, visit Curis' 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: statements regarding the development plans and timelines for GDC-0449, CUDC-101, CUDC-305 and the Company's other drug development programs; the potential clinical and therapeutic benefits of GDC-0449 and the Company's other programs under development; and the Company's estimate regarding the period in which its existing cash will fund its operations. 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:

- The Company may experience adverse results, delays and/or failures in its internal product development programs, including without limitation unplanned delays and/or failures in its ability to further advance its product candidates, CUDC-101 and CUDC-305, and any other programs under its targeted cancer drug development platform. For example, further preclinical testing of CUDC-305 may produce inconsistent, negative or inconclusive results which could cause the Company to delay or terminate its planned IND application for this compound. Moreover, the timing and completion of the phase I clinical trial of CUDC-101 may be delayed or interrupted by a number of factors including difficulties in achieving and maintaining patient enrollment, undesirable side effects and toxicities caused by the drug candidate, and the Company's failure to achieve study objectives.

- The Company's collaborator, Genentech, may experience adverse results, delays and/or failures in the Hedgehog pathway antagonist program currently under clinical development and the Company may have no control over, or foreknowledge of, the progress of this program.

- The Company may experience difficulties or delays in obtaining or maintaining required regulatory approvals for products under development both internally and through its collaborations with Genentech.

- The Company may not be able to obtain or maintain the patent and other proprietary intellectual property protection necessary for the development and commercialization of products based on its technologies.

- There may be adverse changes in the Company's ability to execute its business plan.

-- The Company may not be able to obtain the additional funding required to conduct research and development of its product candidates.

-- The Company may experience 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 and which could also adversely affect the Company's estimated operating expenses for 2008 and beyond.

-- The Company faces risks relating to its ability to enter into and maintain planned collaborations for development candidates under its targeted drug development programs, its ability to maintain its current collaboration with Genentech and the risk that any such collaborators will not perform adequately.

-- The Company may experience competitive pressures.

-- The Company also faces other risk factors identified in the Quarterly Report on Form 10-Q for the quarter ended March 31, 2008 and other filings that it 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 Company's 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.

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