Curis Reports Third Quarter 2008 Financial Results

Conference Call to be Held Today at 10:00 a.m. EDT

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Oct. 28, 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 third quarter ended September 30, 2008.

"This quarter was a productive period at Curis, as we announced significant progress with our development programs, including our initiation of a Phase I clinical trial of CUDC-101 in solid tumors and our selection of CUDC-305 as a development candidate. We expect further progress in the coming months, as Genentech has indicated that it expects to initiate a Phase II trial of GDC-0449 in ovarian cancer by the end of the year and another Phase II trial in advanced basal cell carcinoma in the first half of 2009," said Dan Passeri, Curis' President and Chief Executive Officer. "In addition to the continued development of our proprietary drug candidates, we also plan to continue to focus our efforts on seeking to establish a third-party collaboration for one or more of our targeted cancer programs. Consistent with our strategy over the past two years, we will seek to secure higher-value alliances by retaining ownership of our lead drug candidates into the later stages of preclinical testing or into the early stages of clinical development."

For the third quarter of 2008, Curis reported a net loss of $4.6 million or ($0.07) per share, as compared to a net loss of $3.7 million or ($0.06) per share for the same period in the prior year.

- Revenues for the third quarter of 2008 were $100,000 as compared to $1.3 million for the same period in the prior year, a decrease of 92%. Revenues under research and development contracts were $100,000 for the third quarter of 2008 as compared to $800,000 for the same period in the prior year. This decrease was primarily the result of the conclusion of research funding under Curis' collaboration with Procter & Gamble as of November 2007 and Curis' Hedgehog agonist collaboration with Wyeth as of February 2008. Curis did not recognize any license revenues during the third quarter of 2008 as a result of the conclusion of these collaborations as compared to $500,000 of license revenues for the same period in the prior year.

- Operating expenses for the third quarter of 2008 were $4.9 million as compared to $5.4 million for the same period in the prior year, a decrease of 9%. Research and development spending was $3.0 million for the third quarter of 2008 as compared to $3.2 million for the same period in the prior year, a decrease of 6%. The decrease is primarily attributable to decreased spending of $300,000 as a result of the conclusion of the Hedgehog agonist program under collaboration with Wyeth in early 2008. General and administrative spending was $1.9 million for the third quarter of 2008 as compared to $2.2 million for the same period in the prior year, a decrease of 14%. The decrease in general and administrative expenses was primarily due to a $200,000 decrease in personnel costs.

For the nine-month period ending September 30, 2008, Curis reported a net loss of $10.0 million or ($0.16) per share, as compared to a net loss of $11.3 million or ($0.22) per share for the same period in the prior year.

Revenues for the nine months ended September 30, 2008, were $5.3 million as compared to $4.9 million for the same period in the prior year, an increase of 8%.

Operating expenses were $16.1 million for the nine months ended September 30, 2008, as compared to $17.1 million for the same period in the prior year, a decrease of 6%. Research and development expenses were $9.7 million for the nine months ended September 30, 2008, as compared to $9.5 million for the same period in the prior year, an increase of 2%. General and administrative expenses were $6.4 million for the nine months ended September 30, 2008, as compared to $7.5 million for the same period in the prior year, a decrease of 15%.

As of September 30, 2008, Curis' cash, cash equivalents and marketable securities totaled $29.9 million, and there were 63,437,985 shares of common stock outstanding.

"We currently expect to end 2008 with between $26 and $28 million in cash. This estimate includes an expected $3 million milestone payment from Genentech upon its initiation of a Phase II trial in advanced ovarian cancer," said Mike Gray, Chief Financial and Chief Operating Officer. "We recently implemented spending reductions in various general and administrative and preclinical research areas. Spending reductions include decreases in contract medicinal chemistry and biology being performed on our preclinical research programs in China, personnel, legal and occupancy costs. After giving effect to these cost reductions, we expect that Curis will have capital to fund its currently-planned operations into the first half of 2010. If we successfully enter into a third-party collaboration that includes an upfront payment to us, then any such payments would be expected to further extend that period."

Third Quarter and Recent Highlights

-- GDC-0449 Phase I clinical trial data presented by study investigators at the 20th EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics.

In October 2008, Dr. Charles Rudin of Johns Hopkins University and a Phase I study investigator, presented a poster with an update on safety and efficacy data from the ongoing GDC-0449 Phase I trial in solid tumors and advanced BCC at the 20th EORTC-NCI- AACR Symposium on Molecular Targets and Cancer Therapeutics in Geneva, Switzerland. Earlier interim data had previously been presented at the AACR Annual Meeting in April 2008 and the ASCO Annual Meeting in June 2008.

As of the data cutoff of June 1, 2008, the open-label, multi-center, "3+3" Phase I study enrolled a total of 42 patients in two stages. Stage 1 is designed as a dose-escalation study that enrolled 20 patients in 3 cohorts (150, 270 and 540 mgs). Twenty-two additional patients were enrolled in Stage 2 of the study, which is an expanded safety cohort that is designed to collect additional safety, pharmacokinetic and pharmacodynamic data.

In this Phase I study (in Stage 1 and 2) a total of 13 patients with locally advanced or metastatic BCC received continuous once-daily dosing of GDC-0449 at 150, 270, or 540 mgs per day. As confirmed by an Independent Review Facility, two patients have experienced partial responses (PR) per the Response Evaluation Criteria in Solid Tumors (RECIST). As of the June 1, 2008 data cutoff, responses are ongoing with durations of 9.2+ and 5.6+ months. In addition, four patients have experienced PRs assessed by clinical examination, with observations of shrinkage or resolution of subcutaneous masses, re-epithelialization and/or cessation of bleeding or discharge of ulcerated tumors and/or flattening of nodular tumors. Of the remaining BCC patients enrolled, one patient experienced progressive disease as best response, four patients have stable disease and two are too early to evaluate.

No dose-limiting toxicities have been observed in the Phase I study. The most frequently observed adverse events (regardless of relationship to drug) were fatigue, dysguesia (altered taste sensation), nausea, anorexia, cough, abdominal pain, diarrhea, hyponatremia, decreased weight, back pain and decreased appetite. Two cases of drug-related grade 3 fatigue and one case of grade 3 drug-related asymptomatic hyponatremia (sodium imbalance) were reported and were reversed with temporary discontinuation of drug.

-- Initiated Phase 1 trial of CUDC-101.

In August 2008, Curis treated its first patient in a Phase I clinical trial of CUDC-101, Curis' lead drug candidate under internal development. The Phase I trial is designed as an open-label dose escalation 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 the Phase I molecule and to establish the maximum tolerated dose and dose limiting toxicities. Secondary objectives will be to assess the pharmacokinetics, efficacy and ability of CUDC-101 to inhibit histone deacetylase (HDAC), epidermal growth factor receptor (EGFR) and human epidermal growth factor receptor 2 (Her2) in this patient population. CUDC-101 is designed as a first-in-class therapeutic to simultaneously inhibit these three validated cancer targets. Curis currently estimates that this trial will be completed in mid-2009.

-- Announced progress with preclinical development program for CUDC-305.

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. Curis initiated IND-enabling studies in October 2008 and anticipates filing an IND application for CUDC-305 in mid-2009, assuming the outcome of these studies is favorable. Curis is currently seeking a potential collaboration for the continued development of this drug candidate.

--Presented CUDC-305 preclinical data at the 20th EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics.

In October 2008, Curis presented a poster entitled, "CUDC-305, a novel, synthetic Hsp90 inhibitor with unique pharmacological properties," at the 20th EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics in Geneva, Switzerland. The poster highlighted preclinical data demonstrating that CUDC-305 appears to have a strong combination of pharmacological properties that may contribute to its potent efficacy in preclinical cancer models.

Conference Call Information

Daniel Passeri, President and Chief Executive Officer of Curis will host a conference call today, October 28, 2008, at 10:00 am EDT, to discuss: Curis' financial results for the three- and nine-month periods ended September 30, 2008, and corporate developments, plans and strategies.

To access the live conference call, please call (800) 591-6945 from the United States or Canada or (617) 614-4911 from other locations, shortly before 10:00 am EDT. The conference ID number is 30630167. 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 pm EDT, Tuesday, November 11, 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 conference ID number 35904101.

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

	Three months ended		Nine months ended	

	September 30, 2008	2007	September 30, 2008	2007
Revenues	$ 86,721	1,312,202	$ 5,262,114	4,903,712
Operating expenses:				
Research and development	3,000,266	3,203,388	9,676,761	9,545,827
General and administrative	1,861,971	2,231,474	6,402,274	7,542,245
Total operating expenses	4,862,237	5,434,862	16,079,035	17,088,072
Net loss from operations	(4,775,516)	(4,122,660)	(10,816,921)	(12,184,360)
Other income, net	204,065	404,360	850,247	927,743
Net loss	$(4,571,451)	$(3,718,300)	$ (9,966,674)	$(11,256,617)
Basic and diluted net loss per common share	$ (0.07)	$ (0.06)	$ (0.16)	$ (0.22)
Basic and diluted weighted average common shares outstanding	63,435,070	57,534,767	63,339,767	52,129,126

CURIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(UNAUDITED)

	September 30, 2008	December 31, 2007
ASSETS		
Cash, cash equivalents and marketable securities	$29,929,031	$41,459,176
Long-term investments - restricted	210,007	210,007
Accounts receivable	76,217	230,467
Property and equipment, net	1,875,233	2,577,602
Goodwill	8,982,000	8,982,000
Other assets	449,802	357,433
Total assets	$41,522,290	$53,816,685
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	$ 2,752,399	$ 4,715,772
Debt obligations	-	403,832
Deferred revenue	-	1,852,518
Total liabilities	2,752,399	6,972,122
Total stockholders' equity	38,769,891	46,844,563

Total liabilities and stockholders' equity	$41,522,290	$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 targeting small molecule drug candidates for cancer. In expanding its drug development efforts in the field of cancer through its targeted cancer programs, 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 drug development programs, including without limitation unplanned delays and/or failures in its ability to further advance its drug candidates, CUDC-101 and CUDC-305, and any other of its targeted cancer programs. 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 drug candidate. 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 drug candidates 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 drug 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 cancer programs, its ability to maintain its current collaborations 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 June 30, 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.

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

SOURCE: Curis, Inc.
