Curis Reports Second Quarter 2015 Financial Results

Management to Host Conference Call Today at 8:30 a.m. EDT

LEXINGTON, Mass., Aug. 6, 2015 (GLOBE NEWSWIRE) -- Curis, Inc. (NASDAQ:CRIS), a biotechnology company focused on the development and commercialization of innovative drug candidates for the treatment of human cancers, today reported its financial results for the second quarter ended June 30, 2015.

"During the second quarter, we presented results of the Phase 1 trial of CUDC-907 at scientific conferences, where we reported clinical activity, including complete responses in heavily pre-treated patients with relapsed or refractory diffuse large B cell lymphoma (DLBCL)," said Ali Fattaey, Ph.D., Curis' President and Chief Executive Officer. "CUDC-907 appears to be well tolerated with a manageable side effect profile at the recommended dose and schedule. Enrollment of patients with relapsed or refractory DLBCL in the expansion arms of the ongoing Phase 1 study is continuing, where we are administering CUDC-907 either as monotherapy or in combination with rituximab. We are in the process of finalizing the Phase 2 study design for CUDC-907, and we expect to initiate the study later this year."

Dr. Fattaey continued, "Our partner Aurigene has made progress in advancing programs under our collaboration, and we remain on-track to file an IND application for the first immuno-oncology drug candidate later this year. We also expect to file an IND application for the lead IRAK4 inhibitor candidate and initiate its Phase 1 program during the first half of 2016."

Second Quarter and First Half 2015 Financial Results

Curis reported a net loss of $8.1 million, or ($0.06) per share on both a basic and fully diluted basis for the second quarter of 2015, as compared to a net loss of $1.9 million or ($0.02) per share on both a basic and fully diluted basis for the same period in 2014. Curis reported a net loss of $40 million, or ($0.34) per share on both a basic and fully diluted basis for the six months ended June 30, 2015, as compared to a net loss of $7.5 million or ($0.09) per share on both a basic and fully diluted basis for the same period in 2014. The net loss for the first half of 2015 includes an in-process research and development charge of $24.3 million related to Curis' license agreement with Aurigene.

Revenues for the second quarter of 2015 were $2.1 million, as compared to $4.8 million for the same period in 2014. The decrease in revenues was primarily due to a decrease in license fee revenues due to a $3 million milestone payment that Curis earned from Genentech/Roche upon achievement by Genentech/Roche of certain development objectives during the second quarter of 2014. Offsetting these decreases, royalty revenues recorded on Genentech/Roche's net sales of Erivedge increased to $2.0 million in the second quarter of 2015 as compared to $1.8 million during the same period in 2014.

Revenues for the six months ended June 30, 2015 were $3.7 million, as compared to $6.1 million for the same period in 2014.

Operating expenses for the second quarter of 2015 were $9.5 million, as compared to $6.3 million for the same period in 2014. Operating expenses for the six months ended June 30, 2015 were $42.1 million, as compared to $12.4 million for the same period in 2014 and were comprised of the following:

Costs of royalty revenues. Costs of royalty revenues, which are comprised of amounts due to third-party university patent licensors in connection with Genentech/Roche's Erivedge net sales, were $103,000 and $92,000 during the second quarters of 2015 and 2014, respectively. Costs of royalty revenues for the six months ended June 30, 2015 were $187,000, as compared to $157,000 for the same period in 2014.

In-process research and development expenses. The Company recorded a one-time charge for in-process research and development expense of $24.3 million during the first half of 2015 associated with the issuance of 17,120,131 shares of Curis common stock to Aurigene as partial consideration for the rights granted under the terms of the parties' January 2015 collaboration agreement.

Research and development expenses. Research and development expenses were $5.9 million for the second quarter of 2015 as compared to $3.3 million for the same period in 2014. The increase in research and development expense was primarily due to increased spending on CUDC-907 and preclinical programs under the Company's collaboration with Aurigene. The Company incurred expenses of $2.7 million and $1.4 million on CUDC-907 for the quarters ended June 30, 2015 and 2014, respectively, related to its ongoing Phase 1 studies. Spending of $2.5 million on the Company's preclinical research programs for the three months ended June 30, 2015 includes a $2 million milestone payment to Aurigene for selection of a third program under that collaboration and also includes costs to support planned development activities, primarily consisting of personnel costs, compared to costs of $81,000 in the prior year quarter. Offsetting these increases, spending on CUDC-427 decreased by $900,000 during the three months ended June 30, 2015 as compared to the prior year period. Research and development expenses were $10.7 million for the six months ended June 30, 2015 as compared to $6.5 million for the same period in 2014.

General and administrative expenses. General and administrative expenses were $3.4 million for the second quarter of 2015 as compared to $2.9 million for the second quarter of 2014. Increased legal costs and stock-based compensation were partially offset by decreased professional and consulting costs. General and administrative expenses were $6.9 million for the six months ended June 30, 2015 as compared to $5.8 million for the same period in 2014.

Other expense was $759,000 for the second quarter of 2015, as compared to $351,000 for the same period in 2014. Other expense primarily consisted of $843,000 and $950,000 in interest expense for the quarters ended June 30, 2015 and 2014, respectively, related to the loan made by BioPharma-II to Curis Royalty, a wholly-owned subsidiary of Curis. The Company also recorded other income of $557,000 and $649,000 during the three and six month periods ended June 30 2014, respectively, associated with the change in fair value of a warrant liability. Other expense was $1.6 million and $1.2 million for the six month periods ended June 30, 2015 and 2014, respectively.

As of June 30, 2015, Curis' cash, cash equivalents, marketable securities and investments totaled $99.2 million, and there were approximately 128.4 million shares of common stock outstanding.

2015 Financial Guidance

The Company has revised its 2015 financial guidance for research and development expenses for 2015. The Company currently expects that these expenses will be in the range of $30 to $35 million for 2015. The Company had previously estimated that these expenses would range from $37 to $42 million. As a result, the Company currently expects to end 2015 with cash, cash equivalents and investments of $72 to $77 million versus its previous estimate of $65 to $70 million.

The Company's decrease in research and development expenses is primarily the result of a decrease in estimated expenses across its development programs, including a recent re-evaluation of its clinical development plans for CUDC-427, an orally-available, small molecule antagonist of IAP proteins, as well as for its HSP90 inhibitor CUDC-305. The Company's management determined that it would preserve Curis' current resources for the continued development of CUDC-907 and drug candidates under the Company's collaboration with Aurigene.

Recent Operational Highlights

CUDC-907:

In May 2015, Curis reported data from the dose escalation (completed) and expansion (ongoing) stages of the Phase 1 study of CUDC-907 at the Annual Meeting of American Society of Clinical Oncology (ASCO) that was held in Chicago, IL. CUDC-907 demonstrated evidence of clinical activity with objective responses reported in patients with relapsed/refractory DLBCL and Hodgkin's lymphoma. Among 10 response evaluable patients with DLBCL across various cohorts, two complete responses and four partial responses were reported. One patient with Hodgkin's lymphoma experienced partial response out of a total of 12 response evaluable patients with Hodgkin's lymphoma. In addition, stable disease was observed in 25 of 44 response evaluable patients across various lymphomas and multiple myeloma.
In June 2015, Curis presented data from the Phase 1 study of CUDC-907 at the 20th Congress of the European Hematology Association (EHA), in Vienna, Austria, and the 13th International Congress on Malignant Lymphoma (ICML) in Lugano, Switzerland.

Aurigene Collaboration:

In April 2015, Aurigene presented a poster entitled "Novel IRAK4 inhibitors exhibit highly potent anti-proliferative activity in DLBCL cell lines with activating MYD88 L265P mutation" at the American Association for Cancer Research (AACR) 2015 Annual Meeting. This poster included data from multiple orally bioavailable molecules that showed potent inhibition of IRAK4 kinase activity in biochemical assays and proliferation in DLBCL cancer cell lines with MYD88 mutation. Some of these compounds were further tested in *in vivo* models and demonstrated significant anti-tumor activity in a DLBCL xenograft model with MYD88 mutation as well as disease reduction in a rat collagen-induced arthritis model, which is a model for inflammatory conditions.

Upcoming Activities

Curis expects to present at the following investor conferences through October 2015:

Robert W. Baird & Co. 2015 Health Care Conference, September 9-10, 2015 in New York City
FBR 2nd Annual Healthcare Conference, September 9, 2015 in Boston, MA
14th Annual BIO Investor Forum, October 20-21, 2015 in San Francisco

Conference Call Information

Curis management will host a conference call today, August 6, 2015, at 8:30 a.m. EDT, to discuss Curis' financial results for the quarter as well as provide a corporate update.

To access the live conference call, please dial (877) 868-1829 from the U.S. or (253) 237-1135 from other locations, shortly before 8:30 a.m. EDT. The conference ID number is 85133062. The conference call can also be accessed on the Curis website at www.curis.com in the Investors section.

About Curis, Inc.

Curis is a biotechnology company focused on the development and commercialization of innovative drug candidates for the treatment of human cancers, including its lead development candidate, CUDC-907, a dual HDAC and PI3K inhibitor that is being investigated in two clinical studies in patients with lymphomas and solid tumors. Curis is also engaged in a broad collaboration with Aurigene in the areas of immuno-oncology and precision oncology. Curis is also party to a collaboration agreement with Genentech, a member of the Roche Group, under which Genentech and Roche are developing and commercializing Erivedge®, which is approved for the treatment of advanced basal cell carcinoma. For more information, visit Curis' website at www.curis.com.

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 expected benefits of the Company's collaboration with Aurigene and the planned areas of development thereunder; the Company's plans to enroll patients with relapsed or refractory DLBCL in the expansion arms of the ongoing Phase 1 study, to finalize the Phase 2 study design for CUDC-907 and initiate the trial later this year; the Company's plan to file an IND application for the first immuno-oncology drug candidate within this year; the Company's plan to file an IND application for an IRAK4 inhibitor during the first half of 2016; expressed and implied statements about the efficacy, safety, potential benefits and potential clinical advancement of the Company's drug candidates; its plans and timing for initiating, conducting and presenting data from ongoing and planned clinical studies with its drug candidates; its projections with respect to the period in which it will have cash to fund operations; the Company's goal of achieving milestones with respect to its key programs; its expectations as to 2015 year end cash and cash equivalents and research and development expenses; and any other statements about Curis' business, plans, prospects and strategies. Forward-looking statements 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, there can be no guarantee that the collaboration agreement with Aurigene will continue for its full term, that Curis or Aurigene will maintain the financial resources necessary to continue financing its portion of research, development and commercialization costs or that the parties will successfully discover, develop or commercialize drug candidates under the collaboration. Curis faces a number of risks inherent in the research and development of novel drugs to treat cancer and may not be able to successfully advance the development of its drug candidates in the time frames it projects, if at all. Curis may experience adverse results, delays and/or failures in its drug development programs. Curis' drug candidates may cause unexpected toxicities, fail to demonstrate sufficient safety and efficacy in clinical studies and/or may never achieve the requisite regulatory approval needed for commercialization. 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, in which case revenues from sales of Erivedge could be adversely affected. Regulatory 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 faces risks relating to its wholly-owned subsidiary's Erivedge royalty-collateralized loan transaction, including the risk that it may not receive sufficient levels of royalty revenue from sales of Erivedge to satisfy the debt obligation or may otherwise lose its rights to royalties and royalty-related payments as a result of a foreclosure of the loan. Curis will require substantial additional capital to fund its business and such capital may not be available on reasonable terms, or at all. Curis faces substantial competition. Curis may not obtain or maintain necessary patent protection and could become involved in expensive and time consuming patent litigation and interference proceedings. Unstable market and economic conditions and unplanned expenses may adversely affect Curis' financial conditions and its ability to access capital to fund the growth of its business. Curis also faces other important risks relating to its business, operations, financial condition and future prospects that are discussed in its Quarterly Report on Form 10-Q for the period ended March 31, 2015 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, except as may be required by law.

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

	Three months ended June 30,		*Six months ended June 30,*	
	2015	*2014*	*2015*	*2014*
Revenues:				
Royalties	$ 2,033,836	$ 1,823,935	$ 3,704,906	$ 3,112,183
License fees	—	3,000,000	—	3,000,000
Research and development, net	48,668	(22,650)	35,930	(26,265)
Total revenues:	2,082,504	4,801,285	3,740,836	6,085,918
Operating expenses:				
Costs of royalty revenues	102,972	91,837	187,064	156,985
In-process research and development	—	—	24,347,815	—
Research and development	5,937,976	3,328,976	10,656,948	6,474,906
General and administrative	3,410,972	2,925,259	6,939,974	5,752,157
Total operating expenses	9,451,920	6,346,072	42,131,801	12,384,048
Net loss from operations	(7,369,416)	(1,544,787)	(38,390,965)	(6,298,130)
Interest income	84,092	41,479	124,363	90,239
Interest expense	(843,369)	(949,730)	(1,710,314)	(1,900,706)
Change in fair value of warrant liability	--	557,253	--	648,876
Other expense, net	(759,277)	(350,998)	(1,585,951)	(1,161,591)
Net loss	$ (8,128,693)	$ (1,895,785)	$ (39,976,916)	$ (7,459,721)
Basic and diluted net loss per common share	$ (0.06)	$ (0.02)	$ (0.34)	$ (0.09)
Basic and diluted weighted average common shares outstanding	128,351,482	85,963,836	118,199,388	85,940,842

CURIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(UNAUDITED)

	June 30, 2015	*December 31, 2014*
ASSETS		
Cash, cash equivalents and investments	$ 99,186,298	$ 50,538,961
Investments - restricted	152,610	166,487
Accounts receivable	2,093,094	1,960,995
Property and equipment, net	323,101	407,738
Goodwill	8,982,000	8,982,000
Other assets	839,116	557,388
Total assets	$ 111,576,219	$ 62,613,569
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	4,361,987	4,530,900
Debt obligations, net	26,637,231	28,299,043
Total liabilities	30,999,218	32,829,943
Total stockholders' equity	80,577,001	29,783,626
Total liabilities and stockholders' equity	$ 111,576,219	$ 62,613,569

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