Curis Reports First Quarter 2015 Financial Results

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

LEXINGTON, Mass., May 7, 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 first quarter ended March 31, 2015.

"The first quarter of 2015 was a potentially transformative period for Curis, highlighted by our entry into a broad, exclusive collaboration with Aurigene for the discovery, development and commercialization of small molecule drug candidates in the areas of immuno- and precision oncology," said Ali Fattaey, Ph.D., President and Chief Executive Officer of Curis. "This collaboration has the potential to generate a steady pipeline of novel drug candidates in the coming years. Our partner Aurigene reports that it has made significant progress in advancing the lead immuno-oncology program with molecules designed to antagonize the PD-1/ PD-L1 pathway and that it has a growing number of small molecules under investigation addressing other immune checkpoint pathways. Aurigene is also advancing compounds that are designed to inhibit the IRAK4 kinase, and we expect to exercise options to exclusively license these first two programs in the near future."

Dr. Fattaey continued, "We are pleased that the U.S. FDA recently granted Orphan Drug Designation to CUDC-907 for the treatment of diffuse-large B-cell lymphoma (DLBCL), which represents an area of significant unmet need, especially in the relapsed/refractory setting. Clinical development of CUDC-907 continues in the ongoing expansion stage of the Phase 1 hematology trial, with a focus on DLBCL. We look forward to presenting completed dose escalation and available expansion stage data from this trial at the ASCO 2015 Annual Meeting later this month. We are also planning for a registration-directed Phase 2 study in DLBCL, which could initiate later this year. This would represent an important step in our continued evolution in clinical development and towards commercialization of an increasingly robust pipeline of innovative therapeutics."

"During the first quarter of 2015, Curis successfully raised $64.6 million from a public offering of shares of common stock, significantly strengthening our capital position and providing the company with cash that is expected to fund planned operations into 2017," said Michael Gray, Chief Financial and Chief Business Officer of Curis. "Importantly, this estimated cash runway should provide us with the resources that we need as we seek to generate significant milestones across many of our programs, including advancement of CUDC-907 into a registration-directed Phase 2 study and securing early proof-of-concept clinical data with the lead PD-L1 antagonist and IRAK4 inhibitor under our collaboration with Aurigene."

First Quarter 2015 Financial Results

Curis reported a net loss of $31.8 million, or ($0.30) per share, on both a basic and fully diluted basis for the first quarter of 2015, as compared to a net loss of $5.6 million, or ($0.06) per share, on both a basic and fully diluted basis for the same period in 2014. The net loss for the current period includes an in-process research and development charge of $24.3 million related to Curis' license agreement with Aurigene.

Revenues for the first quarter of 2015 were $1.7 million, as compared to $1.3 million for the same period in 2014. Revenues for both periods are comprised solely of royalty revenues recorded on Genentech and Roche's net sales of Erivedge.

Operating expenses were $32.7 million for the first quarter of 2015, as compared to $6.0 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 and Roche's Erivedge net sales, were $84,000 for the first quarter of 2015, up from $65,000 during the first quarter of 2014.

In-Process Research and Development Expense. The Company recorded one-time in-process research and development expense of $24.3 million during the first quarter 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 $4.7 million for the first quarter of 2015, as compared to $3.1 million for the same period in 2014. The increase in research and development expense was primarily due to increased spending on CUDC-907 of $1.3 million related to outside services supporting the ongoing Phase 1 clinical trials. During the quarter ended March 31, 2015, Curis also paid Debiopharm $750,000 in connection with the termination and transition agreement entered into between the parties related to CUDC-305 (formerly Debio 0932). These increases were partially offset by decreased spending on CUDC-427.

General and Administrative Expenses. General and administrative expenses were $3.5 million for the first quarter of 2015, as compared to $2.8 million for the same period in 2014. The increase was primarily due to an increase in legal, professional and consulting costs related to the Aurigene transaction. Costs associated with the Company's intellectual property and stock-based compensation also increased as compared to the prior year period.

Other expense was $827,000 for the first quarter of 2015, as compared to $811,000 for the same period in 2014. Other expense primarily consisted of $867,000 and $951,000 in interest expense for the quarters ended March 31, 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 $91,000 associated with the change in fair value of a warrant liability during the first quarter of 2014.

As of March 31, 2015, Curis' cash, cash equivalents and investments totaled $107.2 million and there were approximately 128.3 million shares of common stock outstanding.

2015 Financial Expectations

Curis expects to end 2015 with cash, cash equivalents and investments of $65 to $70 million, excluding any potential future payments from

existing or new collaborators.

Curis expects that 2015 research and development expenses will be $37 to $42 million and that general and administrative expenses will be $12 to $14 million. These expense expectations include approximately $800,000 and $2.4 million of estimated 2015 stock-based compensation expense in research and development and general and administrative expense, respectively, based on stock awards that are currently outstanding.

Recent Operational Highlights

CUDC-907:

In April 2015, the U.S. Food and Drug Administration (FDA) granted orphan drug designation to Curis' lead proprietary drug candidate, CUDC-907, for the treatment of DLBCL. The FDA's Orphan Drug Designation program grants orphan status to drugs and biologics that are intended for use in rare diseases or disorders, defined as those that affect fewer than 200,000 people in the U.S. or that affect more than 200,000 people in the U.S. where there is no reasonable expectation that the developmental cost for the specific disease or condition will be recovered from sales in the U.S. within 7 years following approval. Orphan drug designation may qualify the sponsor for certain incentives. For example, the first product to receive FDA approval for an indication for which it has orphan designation may result in orphan drug exclusivity. This means that the FDA may not approve a market competitor for that indication for a period of 7 years, except in limited circumstances, such as demonstration of therapeutic superiority as compared to the drug granted orphan exclusivity.

Aurigene Collaboration:

In January 2015, Curis and Aurigene Discovery Technologies Limited entered into an exclusive collaboration agreement focused on immuno-oncology and selected precision oncology targets. The collaboration provides for inclusion of multiple programs, with Curis having the option to exclusively license compounds once a development candidate is nominated within each respective program. The partnership draws from each company's respective areas of expertise, with Aurigene having responsibility for conducting all discovery and preclinical activities, including IND-enabling studies and providing Phase 1 clinical trial supply, and Curis having responsibility for all clinical development, regulatory and commercialization efforts worldwide, excluding India and Russia, for each program for which it exercises an option to obtain an exclusive license. Curis expects that it will file an IND application for the first immuno-oncology molecule in 2015 and for the IRAK4 molecule in late 2015 or early 2016.
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 of proliferation in MYD88 mutant DLBCL cell lines. 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 inflammation.

CUDC-305:

In February 2015, Curis entered into a transition agreement with Debiopharm and regained all worldwide development and commercialization rights to HSP90 inhibitor Debio 0932 from Debiopharm and re-designated the molecule as CUDC-305. During the fourth quarter of 2014, Debiopharm determined that it would not advance Debio 0932 to the Phase 2 stage of the HALO, or HSP90 inhibition And Lung cancer Outcomes, study. While Curis does not plan to further investigate CUDC-305 in non-small cell lung cancer, the Company is evaluating initiating company-sponsored or investigator sponsored clinical studies of CUDC-305 in rare diseases with high unmet clinical need, including systemic mastocytosis and glioblastoma multiforme. Curis is also exploring potential partnering opportunities for this molecule.

CUDC-427:

In April 2015, Curis scientists presented two posters for IAP inhibitor CUDC-427 at the AACR 2015 Annual Meeting. The first poster, "Predictive biomarker signatures for IAP inhibitor CUDC-427," discussed data from *in vitro* and *in vivo* studies that were conducted to identify predictive gene signatures that may be associated with drug response in ovarian and breast cancers. The second poster, "IAP inhibitor CUDC-427 induces tumor regression or stasis in preclinical models of B-cell lymphoma," reported data from *in vitro* and *in vivo* studies showing CUDC-427's anti-tumor activity in multiple hematologic cancer models, including DLBCL. In a panel of human hematologic cell lines, the DLBCL cell lines were shown to be the most sensitive to CUDC-427 treatment in growth inhibition assays. Data from these DLBCL cell lines as well as *in vivo* studies in certain DLBCL xenograft and B-cell lymphoma syngeneic mouse models demonstrated the anti-tumor potential of CUDC-427 in the setting of hematologic cancer.

Corporate:

Curis sold 25,090,908 shares of its common stock in a public offering at a price of $2.75 per share, including the exercise in full by the underwriters of their option to purchase an additional 3,272,727 shares of common stock at the public offering price. Curis received net proceeds of approximately $64.6 million, after deducting underwriting discounts and commissions and estimated offering expenses.

Upcoming Activities

Curis plans to participate in the following investor conferences through July 2015:

Sachs Immuno-Oncology: BD&L and Investment Forum in Chicago: May 29, 2015
2015 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago: May 29-June 2, 2015
Jefferies 2015 Global Healthcare Conference in New York City: June 1 - 4, 2015
20th Congress of the European Hematology Association, Vienna. Austria; June 11 - 14, 2015
2015 BIO International Convention in Philadelphia: June 15-18, 2015

13th International Conference on Malignant Lymphoma, Lugano, Switzerland: June 17-20, 2015
BMO Capital Markets Biotech Corporate Access Day in Boston: July 28, 2015

Conference Call Information

Curis management will host a conference call today, May 7, 2015, at 8:30 a.m. EDT, to discuss these financial results, as well as provide a corporate update.

To access the live conference call, please dial (877) 868-1829 from the United States or (253) 237-1135 from other locations, shortly before 8:30 a.m. EDT. The conference ID number is 75846737. 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. Curis' pipeline of drug candidates includes CUDC-907, a dual HDAC and PI3K inhibitor, CUDC-427, a small molecule antagonist of IAP proteins, and CUDC-305, an oral HSP90 inhibitor. Curis is also engaged in a broad collaboration with Aurigene in the areas of immuno-oncology and precision oncology. As part of this collaboration, Curis expects to exercise options to exclusively license oral small molecules antagonists of PDL-1 and IRAK4. 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®, the first and only FDA-approved medicine 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 exercise its option on the first two programs under such collaboration and to file an IND for a development candidate, including a PD-L1 antagonist and an IRAK4 kinase inhibitor; the Company's intention to continue to build and to commercialize its pipeline of drug candidates; the Company's plans to present data from the dose escalation and expansion cohorts of the CUDC-907 Phase 1 trial and to initiate a registration-directed Phase 2 trial in 2015; 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, research and development expenses and general and administrative 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 Annual Report on Form 10-K for the period ended December 31, 2014 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 March 31,

	2015	*2014*
Revenues:		
Royalties	$1,671,070	$1,288,248
Research and development, net	(12,738)	(3,615)
Total revenues	1,658,332	1,284,633
Operating expenses:		
Cost of royalty revenues	84,092	65,148
In-process research and development	24,347,815	—
Research and development	4,718,972	3,145,930
General and administrative	3,529,002	2,826,898
Total operating expenses	32,679,881	6,037,976
Loss from operations	(31,021,549)	(4,753,343)
Other expense, net	(826,674)	(810,593)
Net loss	$(31,848,223)	$(5,563,936)
Basic and diluted net loss per common share	$(0.30)	$(0.06)
Basic and diluted weighted average common shares outstanding	107,934,493	85,917,592

CURIS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)

	March 31, 2015	*December 31, 2014*
ASSETS		
Cash, cash equivalents and investments	$107,153,326	$50,538,961
Investments - restricted	152,610	166,487
Accounts receivable	1,769,344	1,960,995
Property and equipment, net	364,005	407,738
Goodwill	8,982,000	8,982,000
Other assets	889,124	557,388
Total assets	$119,310,409	$62,613,569
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	4,315,310	4,530,900
Debt obligations, net	27,379,239	28,299,043
Total liabilities	31,694,549	32,829,943
Total stockholders' equity	87,615,860	29,783,626
Total liabilities and stockholders' equity	$119,310,409	$62,613,569

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