Curis Reports Fourth Quarter and Year-End 2014 Financial Results

LEXINGTON, Mass., Feb. 24, 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 fourth quarter and year ended December 31, 2014.

"We are excited about our recently announced, exclusive, multi-year partnership with Aurigene focused on developing small molecule drug candidates in the areas of immuno-oncology and precision oncology," said Ali Fattaey, Ph.D., President and Chief Executive Officer of Curis. "We believe that orally administered small molecule antagonists of immune checkpoint targets represent a highly differentiated strategy to stimulate the immune system for cancer therapy. Along with flexible, oral dosing, the ease of combining such small molecule therapeutics with other anti-cancer therapies may provide additional benefit for cancer patients. We expect to file INDs for at least two molecules from this collaboration later this year, including a small molecule PD-L1 antagonist and an IRAK4 kinase inhibitor. Supported by this partnership, we intend to continue building a successful business focused on commercialization of a strong pipeline of drug candidates in select territories."

Dr. Fattaey continued, "We are also encouraged by the promising single agent activity observed with CUDC-907, our dual HDAC and PI3-K inhibitor in patients with relapsed or refractory diffuse large B cell lymphoma, or DLBCL. We look forward to presenting data from the dose escalation and expansion cohorts of the Phase 1 trial as well as initiating a registration-directed Phase 2 trial later this year."

Full Year and Fourth Quarter 2014 Financial Results

For the year ended December 31, 2014, Curis reported a net loss of $18.7 million, or ($0.22) per basic and fully diluted share, as compared to a net loss of $12.3 million or ($0.15) per basic and fully diluted share in 2013. For the fourth quarter of 2014, Curis reported a net loss of $5.7 million, or ($0.07) per basic and fully diluted share, as compared to a net loss of $4.2 million or ($0.05) per basic and fully diluted share for the same period in 2013.

Revenues for the year ended December 31, 2014 were $9.8 million as compared to $15.0 million for the same period in 2013. Substantially all of the Company's revenues in 2013 and 2014 were recorded under Curis' collaboration with Genentech. The decrease in revenues for the year ended December 31, 2014 was primarily due to a decrease in license fee revenues from Genentech of $7 million when compared to the year ending 2013. This decrease was partially offset by an increase in royalty revenues, which were $6.8 million and $3.9 million for the years ending 2014 and 2013, respectively. For the year ended 2013, Curis also recorded $650,000 in research and development revenues for milestone payments received from The Leukemia and Lymphoma Society (LLS).

Revenues for the fourth quarter of 2014 were $2.0 million, which were primarily comprised of $1.9 million of Erivedge royalty revenues. Revenues for the fourth quarter of 2013 were $1.5 million, which were primarily comprised of $1.4 million of Erivedge royalty revenues.

Operating expenses were $25.7 million for the year ended December 31, 2014, as compared to $24.4 million for the same period in 2013. Operating expenses for the fourth quarter of 2014 were $6.8 million, as compared to $6.0 million for the same period in 2013.

Cost 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 $340,000 for the year ended December 31, 2014, as compared to $198,000 for 2013. Cost of royalty revenues were $93,000 and $70,000 for the fourth quarters of 2014 and 2013, respectively.

Research and development expenses were $13.7 million for the year ended December 31, 2014 as compared to $12.9 million for 2013. This increase was primarily due to increased spending on CUDC-907 of $2.7 million related to the ongoing Phase 1 clinical trial as well as initial expenses related to a second Phase 1 clinical trial in solid tumors, which began enrolling patients in the fourth quarter of 2014. The increased spending in CUDC-907 was offset by decreased spending on other development programs, including CUDC-427, and discovery research.

Research and development expenses were $3.5 million for the fourth quarter of 2014, as compared to $3.0 million for the same period in 2013.

General and administrative expenses were $11.7 million for the year ended December 31, 2014 as compared to $11.3 million in 2013, and $3.2 million for the fourth quarter of 2014, as compared to $3.0 million for the same period in 2013. The increase was primarily due to increased expenses for personnel, consulting and professional services, and stock-based compensation offset by a decreased spending in legal services.

Other expense was $2.9 million for the years ended 2014 and 2013, and is primarily comprised of interest expense associated with the loan made by BioPharma-II to Curis Royalty, a wholly-owned subsidiary of Curis, offset in part by other income associated with the change in fair value of a warrant liability. Other expense was $878,000 for the fourth quarter of 2014, as compared to other income of $285,000 for the fourth quarter of 2013. Interest expense was $914,000 and $972,000 for the fourth quarters of 2014 and 2013, respectively. The Company recorded other income of $1.2 million associated with the change in fair value of a warrant liability during the fourth quarter of 2013.

As of December 31, 2014, Curis' cash, cash equivalents, marketable securities and investments totaled $50.5 million and there were approximately 86.0 million shares of common stock outstanding. In January 2015, the Company issued 17.1 million shares of common stock to Aurigene in partial consideration for the rights granted to the Company under the collaboration agreement. Curis management expects that its existing capital resources are adequate to fund its current and planned

operations into 2016.

Recent Operational Highlights

Curis-Aurigene Collaboration:

In January 2015, Curis entered into an exclusive collaboration agreement with Aurigene Discovery Technologies Limited, Bangalore, India. The collaboration is focused on the discovery and development of orally administered small molecules in immuno-oncology and precision oncology and 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. Under the agreement, Aurigene is responsible for conducting all discovery and preclinical activities, including IND-enabling studies and providing Phase 1 clinical trial supply, and Curis is responsible for all clinical development, regulatory and commercialization efforts worldwide, excluding India and Russia, for each program for which it exercises an option to obtain a license.

The most advanced molecules under the collaboration include an orally-available small molecule antagonist of programmed death ligand-1 (PD-L1) in the immuno-oncology field and an orally-available small molecule inhibitor of Interleukin-1 receptor-associated kinase 4 (IRAK4) in the precision oncology field. Curis expects to exercise its option to obtain exclusive licenses to both programs and file IND applications for a development candidate from each in 2015.

CUDC-907:

Curis initiated expansion cohorts in the ongoing Phase 1 study that are projected to enroll up to 12 patients each with either relapsed/refractory DLBCL, multiple myeloma at the recommended dose and schedule of administration.

Curis initiated dosing with CUDC-907 in a Phase 1 clinical trial in patients with advanced or relapsed solid tumors, including hormone receptor positive (HR+)/ HER2-negative breast cancer or midline carcinoma with certain NUT gene rearrangements. This study was initiated under a second Investigational New Drug (IND) application for CUDC-907 that was accepted by the U.S. Food & Drug Administration.

Curis received Notice of Allowance of a U.S. patent that covers a broad genus of compounds that target HDAC and PI3K activities in a single chemical structure including CUDC-907. This patent, along with prior patents issued to Curis, collectively cover composition-of-matter and methods of use of CUDC-907 as well as a broad range of proprietary chemical entities that target HDAC and PI3K enzymes, and in some instances mammalian target of rapamycin (mTOR), within a single molecule for the treatment of certain human diseases.

CUDC-427:

During the fourth quarter of 2014, the Company completed enrollment in the dose escalation cohorts of 100mg, 200mg and 300mg using a 14 days on/7 days off once daily administration schedule. During 2015, Curis plans to investigate CUDC-427 administered as monotherapy in relapsed or refractory lymphoma, including MALT lymphoma and DLBCL in an expansion cohort of up to 12 patients.

CUDC-305 (Debio 0932):

In February 2015, Curis entered into a transition agreement with Debiopharm and regained all worldwide development and commercialization rights to Debio 0932 from Debiopharm and re-designated the molecules 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 continue to further investigate CUDC-305 in non-small cell lung cancer, the Company is evaluating initiating clinical studies with CUDC-305, including in systemic mastocytosis and glioblastoma multiforme in 2015.

Upcoming Activities

Curis expects that it will make presentations at the following investor and scientific conferences through April 2015:

Cowen and Company 35th Annual Health Care Conference on March 2-4, 2015 in Boston, MA
ROTH Capital Partners 26th Annual Conference on March 8-11, 2015 in Laguna Niguel, CA
American Association for Cancer Research (AACR) Annual Meeting 2015 on April 18-22, 2015 in Philadelphia, PA

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, with IND application filings for both planned for 2015. 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 in each such program in 2015, 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' plans to present data from the dose escalation and expansion cohorts of the CUDC-907 Phase 1 trial and to initiate a CUDC-907 Phase 2 trial in combination with other agents 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; 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 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 September 30, 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 December 31,		*Year ended December 31,*	
	2014	*2013*	*2014*	*2013*
Revenues:				
Royalties	$ 1,861,569	$ 1,392,191	$ 6,757,023	$ 3,942,136
License fees	--	--	3,000,000	10,000,000
Research and development, net	131,130	131,946	86,458	1,059,896
Total revenues:	1,992,699	1,524,137	9,843,481	15,002,032
Operating expenses:				
Cost of royalty revenues	93,298	70,297	339,578	197,796
Research and development	3,479,127	2,960,987	13,659,398	12,926,834
General and administrative	3,231,362	2,976,070	11,706,754	11,293,811
Total operating expenses	6,803,787	6,007,354	25,705,730	24,418,441
Net loss from operations	(4,811,088)	(4,483,217)	(15,862,249)	(9,416,409)
Interest income	35,983	47,065	165,103	164,650
Interest expense	(913,765)	(971,559)	(3,748,374)	(3,841,646)
Change in fair value of warrant liability	--	1,209,679	716,786	771,393

Other (expense) income, net	(877,782)	285,185	(2,866,485)	(2,905,603)
Net loss	$ (5,688,870)	$ (4,198,032)	$ (18,728,734)	$ (12,322,012)
Basic and diluted net loss per common share	$ (0.07)	$ (0.05)	$ (0.22)	$ (0.15)
Basic and diluted weighted average common shares outstanding	86,010,499	85,741,278	85,974,535	82,339,493

CURIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(UNAUDITED)

	December 31, 2014	*December 31, 2013*
ASSETS		
Cash, cash equivalents and investments	$ 50,538,961	$ 68,906,307
Investments - restricted	166,487	180,364
Accounts receivable	1,960,995	1,477,188
Property and equipment, net	407,738	445,655
Goodwill	8,982,000	8,982,000
Other assets	557,388	599,294
Total assets	$ 62,613,569	$ 80,590,808
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	4,530,900	4,145,077
Debt, net	28,299,043	30,555,360
Warrant liability	--	716,786
Total liabilities	32,829,943	35,417,223
Total stockholders' equity	29,783,626	45,173,585
Total liabilities and stockholders' equity	$ 62,613,569	$ 80,590,808

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