Curis Reports Fourth Quarter and Year-End 2016 Financial Results

Company Announces $45 million Debt Transaction with HealthCare Royalty Partners Secured with Future Erivedge® Royalty

Management to host conference call today at 8:30 a.m. EST

LEXINGTON, Mass., March 09, 2017 (GLOBE NEWSWIRE) -- Curis, Inc. (NASDAQ:CRIS), a biotechnology company focused on the development and commercialization of innovative and effective drug candidates for the treatment of human cancers, today reported its financial results for the fourth quarter and year ended December 31, 2016.

"We are pleased with the progress we've made in advancing our pipeline in 2016. For CUDC-907 and CA-170, we remain focused on patient enrollment in their respective trials to assess their benefit in cancer patients. The Phase 1 trial for CA-170 continues to progress on track through the dose escalation stage, and based on the early data, we have recently received regulatory approval to begin extension of the CA-170 Phase 1 study and enroll immunotherapy-naïve patients in Korea and Spain, with additional trial centers in other European countries projected to open in the second quarter. The Phase 2 trial of CUDC-907 in patients with relapsed/refractory MYC-altered diffuse large B cell lymphoma, or DLBCL is nearing completion of patient enrollment, and our goal is to assess CUDC-907's efficacy in this patient population, as measured by the overall response rate in up to 60 patients. Depending on the Phase 2 trial results, we expect to hold discussions with the FDA regarding potential for accelerated approval of CUDC-907 as a monotherapy in this setting. In addition, we are completing IND-enabling studies of CA-327 and CA-4948," said Ali Fattaey, Ph.D., Curis's CEO."

Dr. Fattaey continued, "Our collaboration with Aurigene continues to progress well. In September 2016, we completed a $24.5M financing with Aurigene. In October 2016, we licensed a second immuno-oncology program, and designated CA-327 as an oral small molecule development candidate targeting PDL1 and TIM3. We expect to file an IND for CA-327 in 2017. Our IRAK4 kinase inhibitor development candidate, CA-4948, has progressed well in preclinical characterization and IND-enabling studies, and we expect to file an IND for CA-4948 in mid-2017."

Royalty Financing Transaction

On March 6, 2017, Curis entered into an agreement with HealthCare Royalty Partners (HCR), for a $45 million debt transaction secured with future Erivedge royalties. As part of this transaction, Curis's wholly-owned subsidiary, Curis Royalty LLC, borrowed $45 million at an annual interest rate of 9.95% interest to be repaid solely with Erivedge royalty payments received from Genentech. The transaction is expected to close later this month, at which time Curis would pay off the $18.4 million remaining balance on the existing loan from BioPharma-II.

"Erivedge represents an effective and medically important product for patients suffering from advanced forms of basal cell carcinoma, and we are pleased to partner with Curis in providing this non-dilutive financing as the company funds its oncology pipeline," said John Urquhart, Principal at HealthCare Royalty Partners.

"We continue to focus our capital and resources in developing our pipeline of innovative cancer therapies. We are especially pleased to work with HCR on this financing, which provides non-dilutive capital for our near-term development needs, while allowing us to retain the considerable upside potential in Erivedge. In its fifth year on the market, Erivedge revenue grew 21% to CHF 203 million in 2016. Genentech and Roche currently commercialize Erivedge in advanced basal cell carcinoma and are conducting clinical trials for its potential use in treating idiopathic pulmonary fibrosis and myelofibrosis," said James Dentzer, Curis's Chief Financial and Chief Administrative Officer.

Full Year and Fourth Quarter 2016 Financial Results

For the year ended December 31, 2016, Curis reported a net loss of $60.4 million, or $(0.45) per share on both a basic and diluted basis, as compared to a net loss of $59.0 million, or $(0.48) per share on both a basic and diluted basis in 2015. For the fourth quarter of 2016, Curis reported a net loss of $11.3 million or $(0.08) per share on both basic and diluted basis, as compared to a net loss of $13.5 million, or $(0.10) per share on both basic and diluted basis for the same period in 2015. The net loss for the year ended December 31, 2016 includes a non-cash in-process research and development charge of $18.0 million related to the amendment of Curis's license agreement with Aurigene. The net loss for the year ended December 31, 2015, includes a non-cash in-process research and development charge of $24.3 million related to Curis's license agreement with Aurigene.

Revenues for the year ended December 31, 2016 were $7.5 million, as compared to $7.9 million for the same period in 2015. Revenues for both periods comprise primarily royalty revenues recorded on Genentech and Roche's net sales of Erivedge®. Revenues for the fourth quarters of 2016 and 2015 were $2.4 million and $2.1 million, respectively.

Operating expenses were $65.6 million for the year ended December 31, 2016, as compared to $64.4 million for the same period in 2015. Operating expenses for the fourth quarter of 2016 were $13.1 million, as compared to $15.3 million for the same period in 2015, and comprised the following:

Costs of Royalty Revenues. Costs of royalty revenues, primarily amounts due to third-party university patent licensors in connection with Genentech and Roche's Erivedge net sales, were $0.4 million for both the years ended December 31, 2016 and 2015. Cost of royalty revenues for the fourth quarter of 2016 and 2015 were $0.1 million for both periods.

Research and Development Expenses. Research and development expenses were $31.6 million for the year ended December 31, 2016, as compared to $26.7 million for the same period in 2015. The increase was primarily due to increased direct spending related to clinical development activities of CUDC-907 and programs under the Aurigene collaboration over the prior year period. Employee-related expenses increased over the prior year period primarily due to additional headcount to support the multiple programs. Research and development expenses were $9.2 million for the fourth quarter of 2016 as compared to $12.0 million for the same period in 2015.

In-Process Research and Development Expense. In-process research and development expense was $18.0 million for the year ended December 31, 2016, as compared to $24.3 million for the same period in 2015. These charges are associated with the stock issuances of

10,208,333 and 17,120,131 shares of Curis common stock to Aurigene, in 2016 and 2015 respectively. These shares were issued as consideration for the rights granted under the terms of the September 2016 amendment to the collaboration agreement and partial consideration for the rights granted under the terms of the January 2015 collaboration agreement, respectively.

General and Administrative Expenses. General and administrative expenses were $15.6 million for the year ended December 31, 2016 as compared to $12.9 million for the same period in 2015. The increase in general and administrative expenses was driven primarily by higher personnel costs and stock-based compensation expense due to increased headcount, an increase in legal service costs and professional and consulting services. General and administrative expenses were $3.8 million for the fourth quarter of 2016, as compared to $3.2 million for the same period in prior 2015.

Other expense, net was $2.4 million for the year ended December 31, 2016, as compared to $2.5 million for the same period in 2015. Other expense, net was $0.6 million and $0.2 million for the fourth quarter of 2016 and 2015, respectively. Other expense, net primarily consisted of interest expense related to the loan made by BioPharma-II (an investment fund managed by Pharmakon Advisors) to Curis Royalty (a wholly owned subsidiary of Curis).

As of December 31, 2016, Curis's cash, cash equivalents and investments totaled $44.5 million and there were approximately 141.1 million shares of common stock outstanding.

Recent Operational Highlights

Curis - Aurigene collaboration:

In January 2017, Curis exercised its option to extend the exclusivity period with Aurigene under the collaboration, license and option agreement established in January 2015. The extension of exclusivity is associated with a payment of $7.5 million to Aurigene, payable in two equal installments. The first installment was paid in January 2017 and the second installment is estimated to be paid in the third quarter of 2017.

CA-170 (PDL1/VISTA antagonist):

In November 2016, Curis presented preliminary clinical pharmacokinetic (PK) and early biomarker data from the ongoing dose escalation stage of its Phase 1 trial of CA-170 at the Society for Immunotherapy of Cancer (SITC) Annual Meeting. Clinical data from a limited number of patients demonstrated that, similar to the preclinical findings, orally-administered CA-170 has a dose proportional and predictable PK profile in patients treated at various escalating doses. Additionally, analysis of patient blood samples showed that CA-170 is biologically active in modulating the immune system, with a several-fold increase in the percentage of circulating CD8+ T cells expressing activation markers within 24 hours of oral dosing.

CA-327 (PDL1/TIM3 antagonist):

In November 2016, Curis collaborator, Aurigene presented pre-clinical data at the SITC Annual Meeting and EORTC-NCI-AACR Molecular Targets and Cancer Therapeutics Symposium for CA-327, the development candidate targeting PDL1 and TIM3 immune checkpoints. The data from various *in vitro* and *in vivo* studies with CA-327 demonstrated potency and selectivity, oral bioavailability, desirable safety profile, and anti-tumor activity in multiple mouse syngeneic tumor models.

CUDC-907 (HDAC/PI3K inhibitor):

In December 2016, Curis presented non-clinical data from combination studies of CUDC-907 and venetoclax, a BH3 mimetic and BCL2 antagonist at the American Society of Hematology's annual meeting. In multiple DLBCL cell lines, the CUDC-907 and venetoclax combination exhibited synergistic activity resulting in reduced cell viability. The additive/ synergistic anti-tumor effects were also observed *in vivo* in mice bearing various DLBCL xenograft tumor models.

Erivedge®:

In November 2016, the European Commission granted full approval to Erivedge® (vismodegib) for the treatment of adult patients with symptomatic metastatic basal cell carcinoma (BCC) or locally advanced BCC inappropriate for surgery or radiotherapy. Erivedge was originally granted 'conditional approval' in July, 2013 in the European Union. Erivedge was approved in the U.S. in 2012 for the treatment of adults with metastatic basal cell carcinoma, or with locally advanced basal cell carcinoma that has recurred following surgery or who are not candidates for surgery or radiation. Erivedge was developed and is marketed by Roche and Genentech, a member of the Roche Group, under a collaboration agreement between Curis and Genentech.

Other:

In November 2016, Curis announced the appointment of Lori A. Kunkel, M.D. to its Board of Directors. Dr. Kunkel currently serves on the Board of Directors at Loxo Oncology, Amphivera Therapeutics Inc., Tocagen Inc., and Harpoon Therapeutics. In the past, Dr. Kunkel has served as CMO at Pharmacyclics, Inc., Proteolix Inc. (acquired by Onyx), Syndax, and ACT Biotech. She has also spent a number of years in academic/clinical medicine. She trained in internal medicine at Baylor College of Medicine, hematology at USC and oncology at UCLA, earning board certifications in these specialties.

Upcoming Activities

Curis expects that it will make presentations at the following conferences through April 2017:

Presentation of preclinical results from CA-4948 at the annual meeting of The American Association of Cancer Research in April, 2017

Conference Call Information

Curis management will host a conference call today, March 9, 2017, at 8:30 a.m. EST, 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. EST. The conference ID number is 84640331. The conference call can also be accessed on the Curis website at www.curis.com in the Investors section.

About HealthCare Royalty Partners
HCR is a private investment firm that purchases royalties and uses debt-like structures to invest in commercial or near-commercial stage life science assets. HCR has $3.4 billion in cumulative capital commitments with offices in Stamford (CT), San Francisco and Boston. Over the past decade, HCR's senior professionals have completed more than 60 healthcare investments. For more information, visit www.healthcareroyalty.com.

About Curis, Inc.
Curis is a biotechnology company seeking to develop and commercialize innovative and effective drug candidates for the treatment of human cancers, including its lead development candidate, CUDC-907 that is being investigated in 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. As part of this collaboration, Curis has exclusive licenses to oral small molecule antagonists of the PD1 and VISTA pathways, including PDL1/VISTA antagonist CA-170, and oral small molecule antagonists of the PD1 and TIM3 pathways, including PDL1/TIM3 antagonist CA-327, as well as to molecules designed to inhibit the IRAK4 kinase, including CA-4948. Curis is currently conducting a Phase 1 trial of CA-170in patients with advanced solid tumors and lymphomas. Curis is also party to a collaboration with Genentech, a member of the Roche Group, under which Genentech and Roche are commercializing Erivedge® for the treatment of advanced basal cell carcinoma, and are further developing Erivedge in other diseases including idiopathic pulmonary fibrosis and myelofibrosis. For more information, visit Curis's 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 plans, strategies and objectives of management for future operations; the Company's plans to advance its development programs, including the timing of IND filings for CA-327 and CA-4948; and the expected closing of the royalty financing transaction. 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, Curis may experience adverse results, delays and/or failures in its drug development programs and may not be able to successfully advance the development of its drug candidates in the time frames it projects, if at all. Curis's drug candidates may cause unexpected toxicities, fail to demonstrate sufficient safety and efficacy in clinical studies and/or may never achieve the requisite regulatory approvals needed for commercialization. Favorable results seen in preclinical studies and early clinical trials of Curis's drug candidates may not be replicated in later trials. There can be no guarantee that the collaboration agreement with Aurigene will continue for its full term, that Curis or Aurigene will each maintain the financial and other resources necessary to continue financing its portion of the research, development and commercialization costs, or that the parties will successfully discover, develop or commercialize drug candidates under the collaboration. Regulatory authorities may determine to delay or restrict Genentech's and/or Roche's ability to continue to develop or commercialize Erivedge in BCC. Erivedge may not demonstrate sufficient or any activity to merit its further development in disease indications other than BCC. Competing drugs may be developed that are superior to Erivedge. Curis faces risks relating to its wholly-owned subsidiary's 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 requires substantial additional capital to fund its business in the near term and such capital may not be available on reasonable terms, or at all. Curis faces substantial competition. Curis also faces risks relating to potential adverse decisions made by the FDA and other regulatory authorities, investigational review boards, and publication review bodies. 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's financial conditions. The royalty financing transaction with Healthcare Royalty may not close as anticipated. Important factors that may cause or contribute to such differences include the factors set forth under the caption "Risk Factors" in our in our most recent Form 10-K and Form 10-Q and the factors that are discussed in other filings that we periodically make with the Securities and Exchange Commission ("SEC").

In addition, any forward-looking statements represent the views of Curis only as of today and should not be relied upon as representing Curis'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, except as may be required by law.

CURIS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(UNAUDITED)
(In thousands, except share and per share data)

	Three months ended December 31,		*Year ended December 31,*	
	2016	*2015*	*2016*	*2015*
Revenues:				
Royalties	$ 2,407	$ 2,033	$ 7,810	$ 8,031
Research and development, net	(45)	59	(283)	(153)
Total revenues	2,362	2,092	7,527	7,878

Operating expenses:				
Costs of royalty revenues	121	103	399	406
Research and development	9,159	12,041	31,590	26,699
In-process research and development	-	-	17,989	24,348
General and administrative	3,845	3,194	15,588	12,906
Total operating expenses	13,125	15,338	65,566	64,359
Net loss from operations	(10,763)	(13,246)	(58,039)	(56,481)
Interest income	80	573	405	825
Interest expense	(652)	(788)	(2,777)	(3,325)
Other expense, net	(572)	(215)	(2,372)	(2,500)
Net loss	(11,335)	(13,461)	(60,411)	(58,981)
Basic and diluted net loss per common share	$ (0.08)	$ (0.10)	$ (0.45)	$ (0.48)
Basic and diluted weighted average common shares outstanding	140,715,621	128,501,098	132,785,687	123,365,195

CURIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)
(In thousands)

	December 31, 2016	*December 31, 2015*
ASSETS		
Cash, cash equivalents and investments	$ 44,485	$ 82,191
Investments — restricted	153	153
Accounts receivable	2,459	2,106
Property and equipment, net	413	278
Goodwill	8,982	8,982
Other assets	1,260	1,255
Total assets	$ 57,752	$ 94,965
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	$ 8,626	$ 6,290
Debt obligations, net	19,860	24,165
Total liabilities	28,486	30,455
Total stockholders' equity	29,266	64,510
Total liabilities and stockholders' equity	$ 57,752	$ 94,965

For More Information:
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