

CURIS INC

FORM 8-K (Current report filing)

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Address	4 MAGUIRE ROAD LEXINGTON, MA 02421
Telephone	617-503-6500
CIK	0001108205
Symbol	CRIS
SIC Code	2836 - Biological Products, Except Diagnostic Substances
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event Reported): May 2, 2017

Curis, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

000-30347
(Commission
File Number)

04-3505116
(I.R.S. Employer
Identification Number)

4 Maguire Road, Lexington, MA 02421
(Address of Principal Executive Offices) (Zip Code)

(617) 503-6500
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02. Results of Operations and Financial Condition.

On May 4, 2017, Curis, Inc. announced its financial results for the three month period ended March 31, 2017. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K and the Exhibit attached hereto shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

(b) On May 2, 2017, James R. McNab, Jr. notified the Board of Directors of Curis, Inc. (the “Company”), that, effective May 16, 2017, he will retire as the Chairman and a member of the Board of Directors. Mr. McNab’s retirement was not due to any disagreement with the Company or its management relating to the Company’s operations, policies or practices.

The Board of Directors approved a modification to Mr. McNab’s vested common stock options such that the exercise period for all such options shall be extended until May 15, 2018, unless such options expire prior to this date.

Mr. McNab was an integral part of Curis’s founding and the Company is grateful for the contributions that Mr. McNab has made during his tenure. The Board and management team join together in thanking Mr. McNab for his many years of leadership and service, and wish him well in all of his endeavors.

Item 9.01. Financial Statements and Exhibits.

(d) The Exhibit to this Current Report on Form 8-K is listed in the Exhibit Index attached hereto.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Curis, Inc.

Date: May 4, 2017

By: /s/ JAMES E. DENTZER

James E. Dentzer

Chief Financial Officer and Chief Administrative Officer

EXHIBIT INDEX

Exhibit Number

Description

99.1

Press Release dated May 4, 2017

**FOR IMMEDIATE RELEASE****For More Information:**

James E. Dentzer
Chief Financial Officer & Chief Administrative Officer
Curis, Inc.
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Curis Reports First Quarter 2017 Financial Results

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

LEXINGTON, Mass., May 4, 2017 (GLOBENEWSWIRE) — 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 first quarter ended March 31, 2017.

The Company also announced today that Chairman of the Board James R. McNab Jr. will retire from the Company's Board of Directors effective as of the date of the Company's annual shareholder meeting on May 16, 2017. Mr. McNab has been Chairman of the Board of Curis since May 2002.

Martyn D. Greenacre, a member of Curis's Board of Directors since 2000, has been nominated by the Board to be the Chairman, upon Mr. McNab's retirement. "On behalf of the Board, I would like to extend our deepest thanks to Jim McNab for his many years of leadership," said Mr. Greenacre. "We wish him well in his future endeavors."

"Jim was an integral part of Curis's founding and has continued to guide the company throughout. On behalf of management and employees of the Company, I would like to thank Jim for his many years of service" said Ali Fattaey, President and CEO.

First Quarter 2017 Financial Results

Curis reported a net loss of \$15.7 million or \$0.11 per share on both a basic and diluted basis for the first quarter of 2017 as compared to a net loss of \$9.4 million or \$0.07 per share on both a basic and diluted basis for the same period in 2016.

Revenues for the first quarter of 2017 were \$2.1 million as compared to \$1.7 million for the same period in 2016. Revenues for both periods comprise primarily royalty revenues recorded on Genentech and Roche's net sales of Erivedge[®].

Operating expenses were \$17.2 million for the first quarter of 2017 as compared to \$10.5 million for the same period in 2016 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 \$0.1 million for both the first quarter of 2017 and 2016.

Research and Development Expenses. Research and development expenses were \$13.5 million for the first quarter of 2017 as compared to \$6.8 million for the same period in 2016. The increase was primarily due to a payment to Aurigene of \$3.8 million for an exclusivity option in January 2017 and increased direct spending related to clinical activities of CUDC-907 and CA-170 over the prior year period. Employee-related expenses increased over the prior year period primarily due to additional headcount.

General and Administrative Expenses. General and administrative expenses were \$3.5 million for the first quarter of 2017 as compared to \$3.6 million for the same period in 2016. The decrease in general and administrative expenses was driven primarily by lower legal, professional and consulting services for the period.

Other expense, net was \$0.7 million for the first quarter of 2017, as compared to \$0.6 million for the same period in 2016. Other expense, net primarily consisted of interest expense related to Curis Royalty's (a wholly owned subsidiary of Curis) debt obligations.

As of March 31, 2017, Curis's cash, cash equivalents, marketable securities and investments totaled \$60.8 million and there were approximately 143.7 million shares of common stock outstanding. On a fully-diluted basis, which includes 18.7 million options, there were 162.4 million shares 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 the first quarter of 2017 and the second installment is estimated to be paid in the third quarter of 2017.

CA-4948 (IRAK4 inhibitor):

- In April 2017, Curis presented nonclinical data from the CA-4948 program. These data demonstrated that CA-4948 is a potent inhibitor of IRAK4 kinase in vitro and in vivo, and results in significant anti-tumor activity in several in vivo models of DLBCL tumors that harbor MYD88 gene mutations.

Healthcare Royalty Partners:

- In March 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 from HCR at an annual interest rate of 9.95% interest to be repaid solely with Erivedge royalty payments received from Genentech. Upon closing of the transaction on March 22, the proceeds were first used to pay off \$18.4 million in remaining loan obligations under the Company's prior loan with BioPharma-II and the residual proceeds of \$26.6 million were distributed to Curis as sole equity holder of Curis Royalty LLC.

Upcoming Activities

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

- CA-170 "Trial-in-progress" poster presentation at the 2017 American Society of Clinical Oncology (ASCO) Annual Meeting (June 2-7, 2017) in Chicago, IL
- Jefferies Healthcare Conference (June 6-9, 2017) in New York City, NY

Conference Call Information

Curis management will host a conference call today, May 4, 2017, at 8:30 a.m. EDT to discuss these financial results and 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 11306169. The conference call can also be accessed on the Curis website at www.curis.com in the Investors section.

About Curis

Curis is a biotechnology company focused on the development and commercialization of innovative and effective drug candidates for the treatment of human cancers, including its lead development candidate, CUDC-907, which 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. CA-170 is currently undergoing testing in a Phase 1 trial in 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 any expectations of revenue, expenses, earnings or losses from operations, or other financial results, statements with respect to the plans, strategies and objectives of management for future operations, the potential for the Company's proprietary drug candidates, the potential advantages and benefits of small molecule checkpoint antagonists and the Company's plans and expectations for the collaboration with Aurigene, including its plans to discover and develop multiple first-in-class oral, small molecule checkpoint antagonists for the treatment of patients with cancer. 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 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 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 and its ability to access the substantial additional capital needed to fund the growth of its business. 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)

	<i>Three months ended</i>	
	<i>2017</i>	<i>March 31,</i>
	<i>2016</i>	
Revenues:		
Royalties	\$ 2,191	\$ 1,744
Research and development, net	(60)	(18)
Total revenues:	<u>2,131</u>	<u>1,726</u>
Operating expenses:		
Costs of royalty revenues	111	89
Research and development	13,541	6,828
General and administrative	3,532	3,616
Total operating expenses	<u>17,184</u>	<u>10,533</u>
Net loss from operations	<u>(15,053)</u>	<u>(8,807)</u>
Other (expense) income	(103)	—
Interest income	70	105
Interest expense	(656)	(740)
Other expense, net	(689)	(635)
Net loss	<u>(15,742)</u>	<u>(9,442)</u>
Basic and diluted net loss per common share	<u>\$ (0.11)</u>	<u>\$ (0.07)</u>
Basic and diluted weighted average common shares	<u>142,011,776</u>	<u>129,019,984</u>

CURIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)
(In thousands)

	<i>March 31, 2017</i>	<i>December 31, 2016</i>
ASSETS		
Cash, cash equivalents and investments	\$60,802	\$ 44,485
Investments – restricted	153	153
Accounts receivable	2,195	2,459
Property and equipment, net	410	413
Goodwill	8,982	8,982
Other assets	1,221	1,260
Total assets	<u>\$73,763</u>	<u>\$ 57,752</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	\$ 7,478	\$ 8,626
Debt obligations, net	44,808	19,860
Total liabilities	52,286	28,486
Total stockholders' equity	<u>21,477</u>	<u>29,266</u>
Total liabilities and stockholders' equity	<u>\$73,763</u>	<u>\$ 57,752</u>