

CURIS INC
Form 8-K
December 14, 2016

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): December 14, 2016

CURIS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction

of incorporation)

4 Maguire Road

000-30347
(Commission

File Number)

04-3505116
(I.R.S. Employer

Identification No.)

02421

Lexington, Massachusetts
(Address of principal executive offices) **(Zip Code)**
Registrant's telephone number, including area code: (617) 503-6500

(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))

Cautionary Note Regarding Forward-Looking Statements

This Form 8-K and the exhibit attached hereto contain forward-looking statements of Curis, Inc. (Curis, we or the Company) that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Form 8-K and the attached exhibit are forward-looking statements. The words anticipate, believe, estimate, expect, intend, may, plan, predict, project, target, potential, will, would, could, s contemplate, or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among others, statements about: the initiation, timing, progress and results of our preclinical studies and clinical trials; plans to develop and commercialize our drug candidates; the timing or likelihood of regulatory filings and approvals; our commercialization, marketing and manufacturing capabilities and strategy; the rate and degree of market acceptance and clinical utility of our products; developments and projections relating to our competitors and our industry; and the potential of CUDC-907, CA-170, CA-327, CA-4948, and any additional drug candidates that we may acquire in the future. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make due to a number of important factors. For example, we may experience adverse results, delays and/or failures in our drug development programs and may not be able to successfully advance the development of our drug candidates in the time frames we project, if at all. Our 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 our 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 we or Aurigene will each maintain the financial and other resources necessary to continue financing our respective portion of the research, development and commercialization costs, or that we and Aurigene 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. We face risks relating to our 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. We will require substantial additional capital to fund our business and such capital may not be available on reasonable terms, or at all. We face substantial competition and risks relating to potential adverse decisions made by the FDA and other regulatory authorities, investigational review boards, and publication review bodies. We 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 our financial condition and our ability to access the substantial additional capital needed to fund the growth of our business.

Important factors that may cause or contribute to such differences are discussed in the Risk Factors and elsewhere in our Annual Report on Form 10-K for the year ended December 31, 2015, our Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, and other periodic filings we make with the SEC.

The forward-looking statements included in this Current Report on Form 8-K and the exhibit attached hereto represent our views as of the date of this Form 8-K. We anticipate that subsequent events and developments will cause our views to change. While we may elect to update these forward-looking statements in the future, we specifically disclaim any obligation to do so. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this Form 8-K.

Item 7.01 Regulation FD Disclosure

From time to time, we conduct meetings with third parties in which we utilize a corporate slide presentation. A copy of our current corporate slide presentation, dated December 2016, is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Form 8-K (including Exhibit 99.1) 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 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: December 14, 2016

By: /s/ James E. Dentzer
Name: James E. Dentzer
Chief Financial Officer and Chief Administrative
Title: Officer

INDEX OF EXHIBITS

Exhibit

| No. | Description |
|------------|--|
| 99.1 | Slide Presentation, dated December 2016. |