

CURIS INC
Form 8-K
November 06, 2013

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): November 6, 2013

Curis, Inc.

(Exact name of registrant as specified in charter)

Delaware
(State or other jurisdiction

of incorporation)

000-30347
(Commission

File Number)

04-3505116
(IRS Employer

Identification No.)

4 Maguire Road,

02421

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

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 (*see* General Instruction A.2. below):

- .. 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))

Item 2.02. Results of Operations and Financial Condition.

On November 6, 2013, Curis, Inc. (the Company) announced its financial results for the quarter ended September 30, 2013. 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 8.01. Other Events.

On November 6, 2013, the Company also announced, pursuant to the press release referenced in Item 2.02 to this Current Report on Form 8-K, that it had received written notification from the United States Food and Drug Administration (the FDA) that its Phase 1 study of CUDC-427 had been placed on partial clinical hold following the report of death in a patient who progressed to liver failure approximately one month following the discontinuation of CUDC-427 dosing. Under this partial clinical hold, new patients may not be enrolled in the study until the Company provides the FDA with required additional information and the FDA notifies the Company that it may re-initiate the study based on its review of the submitted information. The FDA requested the Company provide additional data and analysis on patients in the study and a proposed protocol amendment to mitigate toxicity risk. In the coming weeks, the Company expects to respond to the FDA's requests for additional information and also expects to submit an amendment to the current protocol.

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.

Date: November 6, 2013

By: /s/ Michael P. Gray
Michael P. Gray

Chief Business and Chief Financial Officer

EXHIBIT INDEX

| Exhibit No. | Description |
|--------------------|--|
| 99.1 | Press Release issued by Curis, Inc., dated November 6, 2013. |