Regulus Therapeutics Inc.
Form 8-K
February 17, 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): February 17, 2016

Regulus Therapeutics Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-35670**	**26-4738379**
(State of incorporation)	**(Commission File No.)**	**(IRS Employer Identification No.)**

3545 John Hopkins Court

Suite 210

San Diego, CA **92121**
(Address of principal executive offices) **(Zip Code)**
Registrant s telephone number, including area code: (858) 202-6300

N/A

(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 8.01 Other Events.

On February 17, 2016, we announced interim results from our ongoing Phase II clinical study evaluating RG-101, our wholly-owned GalNac-conjugated anti-miR targeting microRNA-122 for the treatment of hepatitis C virus infection, or HCV. The study was designed to evaluate a shortened, four-week treatment regimen containing a subcutaneous administration of 2 mg/kg of RG-101 at Day 1 and Day 29, in combination with four weeks of once daily approved anti-viral agents Harvoni®, Olysio®, or Daklinza®. The study enrolled 79 treatment naïve genotype 1 and 4 HCV patients (Harvoni® arm, n=27, Olysio® arm, n=27, Daklinza® arm, n=25). Thirty-eight patients have been evaluated through 8 weeks of follow up. Ninety-seven percent of those patients (37/38) had HCV RNA viral load measurements below the limit of quantification. To date, RG-101 has been generally well tolerated with the majority of adverse events considered mild or moderate, and with no study discontinuations. For those patients through 12 weeks of follow-up, 100% remained below the limit of quantification (14/14). The primary endpoint analysis (12 week follow up) for all 79 patients in the study are anticipated to be reported in late Q2 2016.

Forward-Looking Statements

Statements contained in this Current Report on Form 8-K regarding matters that are not historical facts are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including the expected timing for reporting the primary endpoint analysis for our ongoing Phase II clinical study evaluating RG-101. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Words such as believes, anticipates, plans, expects, inte will, goal, potential and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon our current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation, risks associated with the process of discovering and developing drugs and conducting clinical trials. These and other risks concerning us are described in additional detail in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2015 and in our other filings with the Securities and Exchange Commission. All forward-looking statements contained in this Current Report speak only as of the date on which they were made. We undertake no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

SIGNATURES

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: February 17, 2016

Regulus Therapeutics Inc.

By: /s/ Paul C. Grint
Paul C. Grint, M.D.
President and Chief Executive Officer