Regulus Therapeutics Inc.
Form 8-K
June 07, 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): June 7, 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.)**

10614 Science Center Drive	**92121**

San Diego, CA
(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 June 7, 2016, we issued a press release announcing top-line results from the primary endpoint analysis of one of our ongoing Phase II studies of RG-101 for the treatment of Hepatitis C Virus infection (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 4 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). The primary endpoint of the study is virologic response 12 weeks following conclusion of treatment.

Time Since Treatment Completion	RG-101 + Harvoni	RG-101 + Olysio	RG-101 + Daklinza
Week 12	27/27 (100%)	26/27 (96.3%)	22/24 (91.7%)*
Week 16	21/219 (100%)	19/20 (95.0%)	20/22 (90.9%)
Week 20	14/14 (100%)	13/15 (86.7%)	13/13 (100%)
Week 24	10/10 (100%)	8/10 (80.0%)	8/9 (88.9%)

* One patient missed the Week 12 visit. Viral load results for this patient at Week 8 and 16 were collected and indicate that the patient was a responder at both time points.

The results from this interim analysis demonstrate significant virologic response through 24 weeks of follow-up. RG-101 plus Harvoni continues to demonstrate 100% response rates. As we previously reported, the combination of RG-101 plus either Olysio or Daklinza monotherapies have seen small numbers of viral relapse. The results we report herein include four new relapses: two in the Olysio arm (weeks 20 and 32) and two in the Daklinza arm (weeks 12 and 24). RG-101 in combination with four weeks of oral DAA therapy has been generally well tolerated with the majority of adverse events considered mild or moderate, and with no study discontinuations. Commonly reported adverse events (AEs) included fatigue, headache, and injection site reactions.

Forward-Looking Statements

Statements contained in this report regarding matters that are not historical facts are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements associated with our expected ability to undertake certain activities and accomplish certain goals, including with respect to development related to RG-101, the projected timeline of clinical development activities related to RG-101, and expectations regarding future therapeutic and commercial potential of our business plans, technologies and intellectual property related to RG-101. Words such as believes, anticipates, plans, expects, intends, will, goal, potential and 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, developing and commercializing drugs that are safe and effective for use as human therapeutics, and in the endeavor of building a business around such drugs. These and other risks concerning our financial position and programs are described in additional detail in our filings with the Securities and Exchange Commission. All forward-looking statements contained in this 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.

Regulus Therapeutics Inc.

Date: June 7, 2016

By: /s/ Joseph Hagan
Joseph Hagan
Chief Operating Officer