Regulus Therapeutics Inc.
Form 8-K
February 09, 2015

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 9, 2015

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 9, 2015, we announced top-line results from the 4 mg/kg cohort and additional results from the 2 mg/kg cohort in our completed Phase 1 clinical study conducted in the Netherlands evaluating RG-101, a wholly-owned, GalNac-conjugated anti-miR targeting microRNA-122 (miR-122), for the treatment of hepatitis C virus infection (HCV). Administration of a single subcutaneous dose of 4 mg/kg of RG-101 as monotherapy resulted in significant and sustained viral load reductions in all 14 HCV patients, including difficult to treat genotypes, various liver fibrosis status and those who have experienced viral relapse after a prior interferon (IFN) containing regimen. To date, RG-101 continues to have a favorable safety profile with no serious adverse events or discontinuations reported in HCV patients.

Top-line results from the 4 mg/kg dose cohort:

In the 4 mg/kg dose cohort, 16 HCV patients were enrolled: 14 patients, 12 naïve and 2 who experienced viral relapse after a prior IFN-containing regimen, received a single subcutaneous dose of 4 mg/kg of RG-101 as monotherapy, and 2 patients received placebo.

- In the 14 HCV patients receiving RG-101, there was a mean viral load reduction of 4.8 $\log_{10}$ at day 29 (range -5.8 to -3.0); and

- 9 out of 14 patients had HCV RNA levels below the limit of quantification (<15 IU/ml) (BLOQ) at day 57 and these patients will be followed up to six months to investigate the potential for viral cures following the single administration of 4 mg/kg of RG-101.

Extended follow-up results from the 2 mg/kg dose cohort:

In October 2014, we reported interim efficacy and safety results and our first human proof of concept results from the 2 mg/kg cohort of the completed study evaluating RG-101 for the treatment of HCV.

- At day 85, 4 out of 14 treated patients with varied genotypes, liver fibrosis status and treatment history were Target Not Detected (TND); 2 of the treated patients that were BLOQ at day 57 relapsed shortly thereafter; and

- Due to the longevity of the viral responses demonstrated, the protocol is being amended to add an additional year of follow up to investigate the potential for viral cures with one single administration of RG-101.

Summary of 2 mg/kg and 4 mg/kg dose cohort results:

Treatment with a single subcutaneous dose of either 2 mg/kg or 4 mg/kg of RG-101 as monotherapy has resulted in significant and sustained viral load reductions in all 28 HCV patients in this Phase 1 trial, including difficult to treat genotypes, various liver fibrosis status and those who have experienced viral relapse after a prior IFN-containing regimen. At day 57, 15 out of 28 patients treated with one single administration of either 2 mg/kg or 4 mg/kg of RG-101 had HCV RNA levels BLOQ and 12 out of these 15 treated patients were TND.

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 our expected ability to undertake certain activities and accomplish certain goals with respect to RG-101, the projected timeline of clinical development activities related to RG-101, and expectations regarding future therapeutic and commercial potential with respect to 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, intends, 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, 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 us 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.

Date: February 9, 2015

Regulus Therapeutics Inc.

By: /s/ David L. Szekeres
David L. Szekeres
Chief Business Officer and General Counsel