Regulus Therapeutics Inc.
Form 8-K
October 22, 2014

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): October 22, 2014

Regulus Therapeutics Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-35670**	**26-4738379**
(State or other jurisdiction of incorporation)	**(Commission File No.)**	**(IRS Employer Identification No.)**
3545 John Hopkins Court		**92121**

Suite 210

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 October 22, 2014, we announced interim results from our ongoing 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, that demonstrate human proof-of-concept with a microRNA therapeutic. Our ongoing study to evaluate RG-101 is being conducted in the Netherlands and has the following four parts: (I) a single ascending-dose study in which healthy volunteer subjects receive a single subcutaneous dose of RG-101, 0.5 mg/kg, 1 mg/kg, 2 mg/kg, 4 mg/kg and 8 mg/kg or placebo; (II) a multiple-ascending dose study in which healthy volunteer subjects receive a monthly single subcutaneous dose for four months of RG-101 or placebo; (III) a single-dose drug-drug interaction study in which healthy volunteer subjects receive a single subcutaneous dose of RG-101 in combination with simeprevir, an approved direct-acting antiviral, or DAA; and (IV) a single-dose study in which HCV patients receive either a single subcutaneous dose of RG-101 or placebo at two doses, 2 mg/kg of RG-101 (the first dose cohort) or 4 mg/kg of RG-101 (the second dose cohort), to assess the safety and viral load reduction. The primary objective of the study is to evaluate safety and tolerability of RG-101 and the secondary objectives are to evaluate pharmacokinetics, viral load reduction and any impact an oral DAA, such as simeprevir, may have on the pharmacokinetics of RG-101. Up to 100 healthy volunteer subjects and HCV patients with multiple HCV genotypes and treatment history are planned to be enrolled in the study.

Interim results from the ongoing clinical study demonstrate that treatment with a single subcutaneous dose of 2 mg/kg of RG-101 as monotherapy resulted in significant and sustained reductions in HCV RNA in a varied group of patients, including difficult to treat genotypes and patients who experienced viral relapse after a prior interferon, or IFN, containing regimen. Additionally, RG-101 was safe and well tolerated and has demonstrated a very favorable pharmacokinetic profile to date, which may allow for combination with oral DAA agents to treat HCV.

In the first dose cohort of part IV of the ongoing study, 16 HCV patients were enrolled with multiple genotypes, 10 GT1s, five GT3s, and one GT4. Fourteen patients, eight naïve and six who experienced viral relapse after a prior IFN-containing regimen, received a single subcutaneous dose of 2 mg/kg of RG-101 as monotherapy, while two patients received placebo. Interim results from the ongoing clinical study are summarized below.

In the 14 HCV treated patients, there was a mean viral load reduction of 4.1 $\log_{10}$ at day 29 (range -5.8 $\log_{10}$ to -2.3 $\log_{10}$).

Six out of 14 patients had HCV RNA levels below the limit of quantification at day 29 and the three patients from this group who have reached day 57 still have HCV RNA levels below the limit of quantification.

Viral load reduction occurs within the first 96 hours and virologic response is not influenced by IL-28 genotype.

Due to the long-lasting and sustained virologic effect seen, the ongoing study protocol has been amended to follow patients for up to six months after dosing to evaluate the possibility for certain patients to achieve viral cure after a single dose of RG-101.

There were no drug-drug interactions from part III of the ongoing study in which RG-101 was combined with simeprevir (OLYSIO), an approved oral DAA (protease inhibitor), and the combination had no effect on the pharmacokinetic profile of RG-101 or simeprevir (OLYSIO).

RG-101 is safe and well tolerated with no serious adverse events reported to date.

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 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 t 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 Current Rerport 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: October 22, 2014

Regulus Therapeutics Inc.

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