Regulus Therapeutics Inc.
Form 8-K
June 01, 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 1, 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 1, 2016, we issued a press release announcing that we had expanded our clinical trial collaboration agreement with GSK for the development of RG-101, our wholly-owned, GalNAc-conjugated anti-miR that targets miR-122. In the expanded collaboration, we and GSK plan to conduct a multi-centered, randomized, dose-ranging Phase II study evaluating the combination of RG-101 and GSK s long-acting parenteral formulation of GSK2878175 as a potential single-visit cure in patients chronically infected with HCV. This study will be conducted outside the United States and is planned to begin in the fourth quarter of 2016. Based on predicted enrollment rates, interim results from this expanded collaboration should be available in the second half of 2017, enabling a potential initiation of a pivotal study in late 2017. As with the initial collaboration, both parties will share equally in the costs associated with the study. Neither we nor GSK has any further obligations or commitments to each other beyond this expanded clinical collaboration agreement.

**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 1, 2016

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