Regulus Therapeutics Inc.
Form 8-K
January 27, 2017

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): January 27, 2017

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 January 27, 2017, we announced that the U.S. Food and Drug Administration (FDA) has informed us that the full clinical hold placed on our RG-101 clinical development program in June 2016 will remain in effect pending the FDA s review of certain pre-clinical and clinical information to be submitted by us to the FDA, including a final preclinical study safety report for RG-101, final efficacy and safety data from certain clinical trials of RG-101, additional expert opinion of liver safety data in light of the proposed mechanism of hyperbilirubinemia, and an updated risk/benefit assessment of the proposed therapeutic regimens using RG-101.

We currently anticipate submitting a complete response to the FDA with the requested information in the fourth quarter of 2017. There can be no assurances as to when the clinical hold on RG-101 may be lifted, if at all.

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 the ongoing clinical hold on our RG-101 program, including our anticipated submission of a complete response to the FDA and the timing thereof. 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 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: January 27, 2017

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