Regulus Therapeutics Inc.
Form 8-K
June 27, 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 27, 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 27, 2016, we issued a press release announcing we received verbal notice from the U.S. Food and Drug Administration (FDA) that our Investigational New Drug (IND) for RG-101 for the treatment of chronic hepatitis C virus (HCV) infection has been placed on full clinical hold. We anticipate we will receive a formal clinical hold letter from the FDA within 30 days and plan to work diligently with the agency to seek the release of the clinical hold.

The FDA initiated the clinical hold after we reported a second serious adverse event (SAE) of jaundice. The SAE occurred in a HCV patient with end-stage renal disease on dialysis enrolled in its on-going Phase I US study 117 days after receiving a single dose of RG-101.

Timelines for our three on-going studies of RG-101 are not expected to be impacted as all patients have been enrolled and completed their dosing of RG-101 and will continue with protocol scheduled visits. We remain on track to deliver follow-up results from these studies at upcoming scientific meetings.

Conference Call Information

Regulus will host a conference call and webcast today at 5:00p.m. Eastern time to discuss today s announcement. A live webcast of the call will be available online at www.regulusrx.com. To access the call, please dial (877) 257-8599 (domestic) or (970) 315-0459 (international) and refer to conference ID 41706266. To access the telephone replay of the call, dial (855) 859-2056 (domestic) or (404) 537-3406 (international), passcode 41706266. The webcast and telephone replay will be archived on the company s website following the call.

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 27, 2016

By: /s/ Paul Grint, M.D.
Paul Grint, M.D.
President and CEO