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 4, 2019

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 **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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

On January 4, 2019, Regulus Therapeutics Inc. (the "Company") announced the preliminary results of a planned interim data analysis from the new mouse chronic toxicity study of RGLS4326 in development for the treatment of Autosomal Dominant Polycystic Kidney Disease ("ADPKD").

As previously reported by the Company in July 2018, and in consultation with the U.S. Food and Drug Administration ("FDA"), the Company voluntarily paused its ongoing Phase 1 Multiple Ascending Dose ("MAD") study of RGLS4326 in healthy volunteers due to unexpected observations in the 27-week mouse chronic toxicity study. The Company terminated that mouse study prematurely at week 14. The study was run in parallel to the Phase 1 program to enable initiation of the Phase 2 program in ADPKD patients upon completion of the Phase 1 MAD study. The observations from the mouse chronic toxicity study were unexpected given the favorable safety profile of RGLS4326 in previous 7-week non-GLP and GLP toxicity studies in both mice and non-human primates required for Phase 1 testing, which had no significant findings across similar dose levels and frequencies. Based upon the Company's investigation and the results announced today, the Company believes the unexpected observations from the previously terminated study were likely a result of technical issues at the contract research organization ("CRO").

In September 2018, the Company announced the initiation of a new 27-week mouse chronic toxicity study, incorporating several changes intended to address the unexpected observations in the previous mouse chronic toxicity study. Certain key changes included the use of a different CRO to conduct the study and the use of a new batch of RGLS4326.

The planned interim analysis of this study after 13-weeks of dosing has shown no adverse or other significant findings across the range of doses tested and is intended to support re-initiation of the Phase 1 MAD study after consultation with FDA. RGLS4326 has also been generally well-tolerated in the Phase 1 Single Ascending Dose ("SAD") and MAD studies in human subjects to date.

The Company plans to submit a comprehensive data package for RGLS4326 to FDA that will include the results from the planned 13-week interim analysis of the ongoing repeat mouse chronic toxicity study, as well as results from additional investigations, analytical testing, additional data from the previously terminated mouse chronic toxicity study, data from the completed Phase 1 SAD study and data from the first cohort of the Phase 1 MAD study. The Company anticipates engagement with FDA in the coming weeks to discuss the resolution of the voluntary pause in human dosing and the plan to resume the Phase 1 MAD study.

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 expected ability of the Company to undertake certain activities and accomplish certain goals (including with respect to development and other activities related to RGLS4326 and its ability to recommence human clinical trials), the projected timeline of clinical development activities, the anticipated engagement with FDA regarding the Company's RGLS4326 program and the timing thereof, and expectations regarding future therapeutic and commercial potential of the Company's business plans, technologies and intellectual property related to microRNA therapeutics and biomarkers being discovered and developed by the Company. 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 the Company’s 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 current shutdown of the U.S. Government, which may delay or otherwise inhibit the Company’s ability to engage with FDA on matters relating to RGLS4326; and 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 the Company’s financial position and programs are described in additional detail in the Company’s 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. The Company undertakes 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.

Dated: January 4, 2019

By: /s/ Joseph P. Hagan
Joseph P. Hagan
President and Chief Executive Officer