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): July 3, 2018

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 2.05 Costs Associated with Exit or Disposal Activities.

On July 5, 2018, we implemented a corporate restructuring to reduce our operating expenses, extend our cash runway and focus our resources on our most promising programs. In connection with the restructuring, we committed to a reduction in our total workforce by approximately 60% percent. The restructuring was approved by our Board of Directors on July 3, 2018, and affected employees were informed on July 5, 2018. We expect to complete the workforce reduction in the third quarter of 2018. We estimate that we will record charges of approximately $1.5 million for employee severance and other related termination benefits. Severance payments are expected to be paid in full by the end of the third quarter of 2018.

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

(b)

On July 5, 2018, we notified Mark Deeg, M.D., Ph.D., our Chief Medical Officer, that his employment will be terminated in connection with the reduction in our workforce described above under Item 2.05.

Item 8.01 Other Events.

On July 5, 2018, we announced a strategic update, corporate restructuring and pipeline update in a press release. A copy of the press release is attached as Exhibit 99.1 to this report.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release issued by Regulus Therapeutics Inc. on July 5, 2018

Forward-Looking Statements

Statements contained in this report and the attached press release 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 and other activities related to RG-012, RGLS4326, or our Hepatitis B Virus program), our estimated cash runway and anticipated cost savings associated with our planned reduction in workforce, the estimated charges to be incurred by us in connection with our planned reduction in workforce, the projected timeline of clinical development activities, and expectations regarding future therapeutic and commercial potential of our business plans, technologies and intellectual property related to microRNA therapeutics and biomarkers being discovered and developed by us. 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 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 or the attached press release 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: July 6, 2018

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

Exhibit 99.1

Regulus Announces Strategic Update and Corporate Restructuring

Efforts Aimed at Extending Cash Runway to mid-2019

LA JOLLA, Calif., July 5, 2018 – Regulus Therapeutics Inc. (Nasdaq: RGLS), a biopharmaceutical company focused on the discovery and development of innovative medicines targeting microRNAs, today announced a strategic update and corporate restructuring. With the goal of extending its cash runway, Regulus has taken the following steps: recruitment activities for the RG-012 clinical program in Alport syndrome have been paused while discussions with Sanofi to potentially restructure the partnership are ongoing; preclinical research efforts will be focused on its Hepatitis B virus (HBV) programs; and a workforce reduction of approximately 60% is being implemented. These actions are anticipated to yield over $20 million of annualized savings, which are intended to extend the Company's cash runway into mid-2019.

The Company also announced that it has voluntarily paused the Phase 1 multiple ascending dose (MAD) study for RGLS4326 due to unexpected observations in its 27-week mouse chronic toxicity study, which was designed to support the Phase 2 proof-of-concept study in Autosomal Dominant Polycystic Kidney Disease (ADPKD) previously planned to start in mid-2019. The observations in the mouse chronic toxicity study were unexpected, given the favorable safety profile of RGLS4326 in previous non-GLP and GLP toxicity studies at the same or similar doses supporting the Investigational New Drug application (IND) and Phase 1 program. In consultation with FDA, the Company has initiated investigative studies and is planning a new 27-week mouse chronic toxicity study with certain changes that are believed to address the unexpected findings. The 40-week non-human primate chronic toxicity study continues with no significant findings to date. Importantly, RGLS4326 has been generally safe and well-tolerated in the Phase 1 single ascending dose (SAD) and MAD studies to date.

"I am very disappointed that we need to take these drastic steps to preserve our capital, especially given the significant contributions by our dedicated employees to the progress made toward unlocking the potential of targeting microRNAs," said Jay Hagan, Regulus' President and Chief Executive Officer. "In the near-term, we will concentrate our efforts on investigating the unexpected mouse toxicity findings in our RGLS4326 program, advancing our HBV programs, and looking for additional ways to improve shareholder value."

Pipeline Update

RG-012 for the treatment of Alport syndrome: The Company also announced today that preliminary results from the first patients through the renal biopsy study are encouraging with kidney tissue concentrations achieved that would be predictive of therapeutic benefit based on animal disease models. In addition, modulation of the target, miR-21, was observed.

Preclinical Programs: The Company has determined that advancing its preclinical programs targeting HBV represents the most attractive opportunity in its pipeline for investment, affecting an estimated 350 million people worldwide. Regulus has identified multiple microRNA targets that serve as host factors for the virus. Targeting host factors with GalNAc-conjugated oligonucleotides directed to the liver represents a potentially attractive approach to treating the disease. Regulus and others have already demonstrated effective delivery to the liver with this technology, and Regulus has demonstrated human proof-of-concept (POC) with this approach previously with a program targeting the Hepatitis C Virus. The Company currently expects to file an IND for the HBV program in H2 2019, with the potential of achieving human POC in a Phase 1 study.

Regulus will seek to partner the balance of its preclinical programs, which include glioblastoma multiforme, NASH, and immunology.

About Regulus

Regulus Therapeutics Inc. (Nasdaq: RGLS) is a biopharmaceutical company focused on the discovery and development of innovative medicines targeting microRNAs. Regulus has leveraged its oligonucleotide drug discovery and development expertise to develop a pipeline complemented by a rich intellectual property estate in the microRNA field. Regulus maintains its corporate headquarters in La Jolla, CA. For more information, please visit http://www.regulusrx.com.

Forward-Looking Statements

Statements contained in this press release 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 Regulus to undertake certain activities and accomplish certain goals (including with respect to development and other activities related to RG-012, RGLS4326, or its Hepatitis B Virus program), Regulus' estimated cash runway and anticipated cost savings associated with its planned reduction in workforce, the projected timeline of clinical development activities, and expectations regarding future therapeutic and commercial potential of Regulus' business plans, technologies and intellectual property related to microRNA therapeutics and biomarkers being discovered and developed by Regulus. 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 Regulus' 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 Regulus' financial position and programs are described in additional detail in Regulus filings with the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. Regulus undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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