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): August 6, 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 1.01 Amendment of a Material Definitive Agreement.

On August 6, 2018, we entered into an amendment to our loan and security agreement with Oxford Finance LLC, as the collateral agent and a lender (the "Lender"), pursuant to which the Lender has lent to us $20.0 million in a term loan ("Term Loan").

Under the terms of the amendment, we are required to make payments of interest only through October 2018. Amortization payments will recommence in November 2018. We will be required to maintain cash in a collateral account controlled by the Lender of 110% of the principal balance of the Term Loan that would be outstanding on a "Cash Out Date". The Cash Out Date is calculated monthly and is the date our then held cash reserves would first be completely exhausted assuming a continuing cash burn equal to or less than 120% of our projected cash burn (at any given time on or prior to September 30, 2018) or equal to or less than 115% of our projected cash burn (at any given time on or after October 1, 2018). If our actual cash burn is greater than 120% (on or prior to September 30, 2018) or 115% (on or after October 1, 2018) of our projected cash burn through the Cash Out Date, the Cash Out Date is calculated based on our past actual three-month trailing cash burn, and in each case accounting for making all of the interest and principal payments on the Term Loan during the period, starting from the date on which the Cash Out Date is being calculated through the Cash Out Date. In the event we reduce the principal outstanding on the Term Loan to $10.0 million or less on or before November 1, 2018, the cash covenant described above would no longer apply.

Pursuant to the amendment, we granted the Lender a security interest in our intellectual property as additional collateral for the repayment of the Term Loan.

The maturity date of the Term Loan remains unchanged and the Term Loan is required to be paid in full under the current terms on June 1, 2020.

The foregoing is only a summary of the material terms of the amendment to our loan and security agreement, does not purport to be complete and is qualified in its entirety by reference to the full text of the amendment, which will be filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2018.

Item 2.02 Results of Operations and Financial Condition.

On August 9, 2018, we issued a press release announcing our financial results for the second quarter ended June 30, 2018. A copy of the press release is attached hereto as Exhibit 99.1. The information in this Item 2.02 and the attached Exhibit 99.1 are being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section. The information in this Item 2.02 and the attached exhibit shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release issued by Regulus Therapeutics Inc. on August 9, 2018 relating to financial results

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: August 9, 2018

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

Exhibit 99.1

Regulus Reports Second Quarter 2018 Financial Results and Recent Updates

Corporate Restructuring and Pipeline Focus Expected to Extend Cash Runway

Amendment to Term Loan to Provide Additional Interest-Only Period

LA JOLLA, Calif., August 9, 2018 – Regulus Therapeutics Inc. (Nasdaq: RGLS), a biopharmaceutical company focused on the discovery and development of innovative medicines targeting microRNAs, today reported financial results for the second quarter ended June 30, 2018 and provided a summary of recent events.

Second Quarter 2018 and Recent Updates

Corporate Updates

- **Corporate restructuring:** In July 2018, the Company announced a corporate restructuring and workforce reduction of approximately 60% in order to focus its pipeline and extend its cash runway, the activities of which have been substantially completed. In connection with the restructuring, the Company expects to record net charges of approximately $0.8 million for employee severance and other related termination benefits. As a result of the restructuring, the Company's annual cash burn is expected to be reduced by approximately 50% by year-end, inclusive of debt service costs.

Pipeline Updates

- **RGLS4326 for autosomal dominant polycystic kidney disease (ADPKD)**: As previously announced, due to unexpected observations in its 27-week mouse chronic toxicity study, and in consultation with FDA, the Company plans to initiate a new mouse chronic toxicity study with certain changes that are believed to address the unexpected observations. Importantly, RGLS4326 has been generally safe and well-tolerated in humans in the Phase 1 single ascending dose (SAD) and multiple ascending dose (MAD) studies to date. The Company has voluntarily paused dosing in the Phase 1 MAD study, pending results from the new chronic mouse toxicity study.
- **Advancement of Hepatitis B virus (HBV) Programs:** The Company has determined that advancing its preclinical programs targeting HBV, which affects an estimated 350 million people worldwide, represents the most attractive investment opportunity in its preclinical pipeline. 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.

- **RG-012 Program in Alport syndrome**: In July 2018, the Company announced it had paused recruitment activities for the RG-012 program in Alport syndrome while it undertook discussions with Sanofi to potentially restructure the partnership. The Company also announced that preliminary results from the first patients through the renal biopsy study were 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.

Financial Updates

- **Amendment to Term Loan:** In August 2018, the Company and Oxford entered into an amendment to the Term Loan, providing for an additional three-month interest-only period, commencing August 2018 through October 2018. Under the previous terms of the Term Loan, principal payments were due over this 3-month period totaling $2.5 million. Amortization payments will recommence in November 2018. The amendment contains a minimum cash reserve covenant, in addition to a security interest in our intellectual property as additional collateral for the repayment of the Term Loan. In the event we reduce the principal balance of the Term Loan to $10.0 million or less on or before November 1, 2018, the cash reserve covenant described above would no longer apply. There were no changes to the maturity date of the Term Loan, which is June 2020.

"The recent period has been highlighted by a challenging set of circumstances and unexpected setbacks, however we remain committed to our specific near-term objectives, namely coming to an agreement with Sanofi concerning the development of the Alport syndrome program, advancing our investigative and preclinical work on RGLS4326 to enable the Phase 1 MAD to resume, advancing our HBV programs, extending our cash runway, and looking for additional ways to improve shareholder value." said Jay Hagan, President and Chief Executive Officer of Regulus.

Financial Results

Cash Position: As of June 30, 2018, Regulus had cash, cash equivalents and short-term investments of $32.9 million.

Research and Development (R&D) Expenses: R&D expenses were $10.0 million and $21.8 million for the three and six months ended June 30, 2018, respectively, compared to $14.3 million and $30.0 million for the same periods in 2017. The decreases were primarily attributable to reductions in program-related spend for RG-101 and RGLS5040, as these programs were discontinued in 2017, in addition to reductions in personnel-related costs.

General and Administrative (G&A) Expenses: G&A expenses were $3.3 million and $7.1 million for the three and six months ended June 30, 2018, respectively, compared to $7.1 million and $11.0 million for the same periods in 2017. The decreases were primarily attributable to non-recurring severance and non-cash stock-based compensation charges in Q2 2017.

Net Loss: Net loss was $13.8 million, or $0.13 per share (basic and diluted), and $29.9 million, or $0.29 per share (basic and diluted), for the three and six months ended June 30, 2018, respectively, compared to $21.6 million, or $0.41 per share (basic and diluted), and $41.6 million, or $0.78 per share (basic and diluted), for the same periods in 2017.

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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Regulus Therapeutics Inc.

Selected Financial Information
Condensed Statement of Operations
(In thousands, except share and per share data)

	Three months ended June 30,		Six months ended June 30,	
	2018	2017	2018	2017
Revenues:				
Revenue under strategic alliances	$ 18	$ 18	$ 36	$ 36
Operating expenses:				
Research and development	10,013	14,278	21,841	30,030
General and administrative	3,349	7,057	7,122	11,016
Total operating expenses	13,362	21,335	28,963	41,046
Loss from operations	(13,344)	(21,317)	(28,927)	(41,010)
Other expense, net	(503)	(419)	(945)	(751)
Loss before income taxes	(13,847)	(21,736)	(29,872)	(41,761)
Income tax benefit (expense)	—	128	(1)	132
Net loss	$ (13,847)	$ (21,608)	$ (29,873)	$ (41,629)
Net loss per share, basic and diluted	$ (0.13)	$ (0.41)	$ (0.29)	$ (0.78)
Weighted average shares used to compute basic and diluted net loss per share:	104,319,555	53,182,330	104,169,746	53,086,887

Regulus Therapeutics Inc.
Condensed Balance Sheets
(In thousands)

	June 30, 2018 (Unaudited)	December 31, 2017
Cash, cash equivalents and short-term investments	$ 32,856	$ 60,074
Total assets	49,170	77,809
Term loan, less debt issuance costs	19,888	19,859
Stockholders' equity	10,433	35,216