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 8, 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.)**

10628 Science Center Drive, Suite 225 **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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	**RGLS**	**The Nasdaq Stock Market LLC**

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 2.02 Results of Operations and Financial Condition.

On August 8, 2019, we issued a press release announcing our financial results for the second quarter ended June 30, 2019. 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 8, 2019 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 8, 2019

By: /s/ Joseph P. Hagan
Joseph P. Hagan
President & CEO

Exhibit 99.1

Regulus Therapeutics Reports Second Quarter 2019 Financial Results and Recent Updates

Closing of First Tranche of $41.8 Million Private Placement of Equity

Term Loan Restructured Providing Up to Two Years of Interest Only and Extended Maturity Date to May 2022

Data Requirements Defined to Reinitiate Multiple Ascending Dose and Chronic Dose Studies with RGLS4326

Appointment of Cris Calsada as New Chief Financial Officer

LA JOLLA, Calif., August 8, 2019 – Regulus Therapeutics Inc. (Nasdaq: RGLS), a biopharmaceutical company focused on the discovery and development of innovative medicines targeting microRNAs (the "Company" or "Regulus"), today reported financial results for the second quarter ended June 30, 2019 and provided a summary of recent events.

"With the completed financing and restructuring of our term loan, we believe we are in a good position to work expeditiously to address the clear requirements outlined by FDA to reinitiate the MAD clinical study for RGLS4326", said Jay Hagan, CEO of Regulus. "We will also be evaluating potential options to initiate single dose studies in order to further characterize the molecule."

Second Quarter 2019 Corporate Highlights and Recent Updates

- **Private Financing:** In May 2019, the Company closed the first tranche of its $41.8 million private placement of equity (the "Private Placement"). The Company received net proceeds of approximately $15.7 million from the first tranche, after deducting placement agent fees and other offering expenses. Subject to the Company's public announcement on or before December 31, 2019 of its plan to recommence the Phase 1 multiple ascending dose ("MAD") clinical trial for RGLS4326 based upon correspondence from the United States Food and Drug Administration ("FDA"), the investors who purchased securities in the first tranche of the Private Placement have agreed to purchase shares of non-voting convertible preferred stock and accompanying warrants to purchase shares of common stock in a second closing (the "Milestone Closing"). If the Milestone Closing occurs, the gross proceeds to the Company from that closing will be approximately $25.1 million. The Company expects to use the proceeds from the Private Placement primarily to advance RGLS4326 for the treatment of autosomal dominant polycystic kidney disease ("ADPKD"), to advance select programs from its pipeline of microRNA therapies and for general corporate purposes. Excluding any potential proceeds from the Milestone Closing, the Company believes it has sufficient cash to fund operations into mid-2020.
- **Term Loan Amendments:** In May 2019, and concurrently with the Private Placement, the Company amended its Term Loan with Oxford Finance to provide a new twelve-month period of interest-only payments, commencing May 2019, and a two-year extension of its maturity date from June 2020 to May 2022. Upon the closing of the second tranche of the Company's Private Placement, the Company will receive an additional twelve-month period of interest-only payments, commencing May 2020.

- **RG-012 Transition to Sanofi:** In November 2018, the Company and Sanofi agreed to transition further development activities of the miR-21 programs, including the Company's RG-012 program, to Sanofi who will be responsible for all costs incurred in the development of these miR-21 programs (the "2018 Sanofi Amendment"). As of June 30, 2019, the transition activities, including the transfer of the investigational new drug application ("IND"), were complete. The Company received a total of $6.8 million in upfront and material transfer-related payments, which were recognized as revenue in the three months ended March 31, 2019. Regulus is also eligible to receive up to $40 million in clinical milestone payments.

- **Lease Agreement:** In June 2019, the Company entered into an amendment of its lease (the "Lease Amendment") of 24,562 square feet located at 10628 Science Center Drive Suite 100, San Diego, California 92121. Under the terms of the Lease Amendment, the expiration of the lease was accelerated from June 30, 2023 to June 30, 2019, and the lease terminated on July 1, 2019. Concurrently with the Lease Amendment, the Company entered into a new lease agreement (the "New Lease") for 8,727 square feet located at 10628 Science Center Drive, Suite 225, San Diego, California, 92121, which it uses as its new principal offices and laboratory for research and development. This relocation reduced the Company's facility size by approximately 65% and reduced its future contractual lease obligations by approximately 78%.

- **Management Transition:** In July 2019, the Company appointed Cris Calsada as its new Chief Financial Officer, effective August 30, 2019. Ms. Calsada joins Regulus from Sanifit where she has served as Chief Financial Officer since December 2017. Ms. Calsada brings to Regulus' senior management team a unique combination of financial, operational and managerial experience. She has over 20 years of leadership experience in the life sciences and technology industries. Prior to her employment with Sanifit, Ms. Calsada was self-employed as a finance consultant to various life sciences companies. From 2004 until its acquisition in 2015, she served in positions of increasing responsibility with Ambrx, most recently serving as its Chief Operating Officer and Vice President of Finance. Prior to Ambrx, she worked for Sony Online Entertainment as its Executive Director of Finance and Controller. Earlier in her career, she practiced as a certified public accountant. Ms. Calsada received a B.S. in Business Administration with emphasis in Accounting from San Diego State University and an M.B.A. from the University of Southern California Marshall School of Business. Ms. Calsada's appointment follows the resignation of the Company's previous Chief Financial Officer, Dan Chevallard, in July 2019.

Program Updates

- **RGLS4326 for ADPKD:** In January 2019, the Company announced data from a planned interim analysis of a new mouse chronic toxicity study after 13 weeks of dosing in which no adverse or other significant findings across the range of doses tested were shown. In January 2019, the Company submitted a comprehensive data package for RGLS4326 to FDA that included the results from the planned 13-week interim analysis of the 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 I single ascending dose ("SAD") study and data from the first cohort of the Phase I MAD study, to support its plan to resume the Phase I MAD study. After review of the requested submission, FDA notified the Company of additional nonclinical data requirements and placed the IND on a partial clinical hold, formalizing the specific requirements to initiate the MAD study and further proceed into chronic dosing in ADPKD patients. The additional data requirements have been outlined in two parts. In order to resume the MAD study, FDA has requested the final reports from the chronic toxicity studies in both mice and non-human primates and satisfactory related analyses to ensure subjects can be safely dosed. Additional data and analyses from new nonclinical studies, planned to be generated over the next several quarters, will be required for chronic dosing, and may also be used to support the resumption of the MAD study. Regulus is allowed to proceed with additional SAD clinical studies as part of the process to gather additional supporting information to guide the future development of the program.

- **Anti-miR-132 for Nonalcoholic Steatohepatitis (NASH):** In April 2019, Regulus presented a late breaker poster at the EASL International Liver Congress™ describing the development of its lead anti-miR-132 for the treatment of NASH. Across multiple animal models of NASH, the lead candidate demonstrated improvement in key endpoints, including NAFLD Activity Score (NAS), liver transaminases, hyperglycemia, and disease-related gene expression. In the diet-induced NASH mouse model (Amylin model) after two to four weekly doses, early onset of improvement across multiple disease parameters including liver triglycerides and blood levels of transaminases was observed. After nine weeks of treatment, there was evidence of sustained benefit with significant improvement of liver fibrosis and hyperglycemia compared to control-treated animals. The Company believes that targeting dysregulated microRNA in a complex disease like NASH may offer a unique mechanism of action from other programs in development. The Company plans to seek a partner to further advance the development of this program.

Second Quarter 2019 Financial Results

Cash Position: As of June 30, 2019, Regulus had $19.6 million in cash and cash equivalents.

Revenue: Revenue was less than $0.1 million and $6.8 million for the three and six months ended June 30, 2019, respectively, compared to less than $0.1 million for each the three and six months ended June 30, 2018. The increase for the six months ended June 30, 2019 was attributable to revenue recognition of the upfront payments received under the 2018 Sanofi Amendment related to the transfer of RG-012.

Research and Development (R&D) Expenses: R&D expenses were $1.8 million and $7.8 million for the three and six months ended June 30, 2019, compared to $10.0 million and $21.8 million for the same periods in 2018. The decreases were driven by decreases in external development expenses, primarily attributable to the voluntary pause of the RGLS4326 Phase 1 MAD clinical study in the third quarter of 2018 and commencement of the transfer of the RG-012 program to Sanofi in the fourth quarter of 2018. Additionally, the decreases were driven by reductions in personnel and internal expenses, primarily attributable to a reduction in costs subsequent to our corporate restructuring in the third quarter of 2018.

General and Administrative (G&A) Expenses: G&A expenses were $2.9 million and $6.4 million for the three and six months ended June 30, 2019, compared to $3.3 million and $7.1 million for the same periods in 2018. These amounts reflect personnel-related and ongoing general business operating costs.

Net Loss: Net loss was $5.0 million, or $0.30 per share (basic and diluted), and $8.3 million, or $0.61 per share (basic and diluted), for the three and six months ended June 30, 2019, respectively, compared to $13.8 million, or $1.59 per share (basic and diluted), and $29.9 million, or $3.44 per share (basic and diluted), for the same periods in 2018. Historical and current period net loss per share values have been retroactively adjusted to reflect our October 2018 reverse stock split.

About Autosomal Dominant Polycystic Kidney Disease (ADPKD)

ADPKD, caused by the mutations in the PKD1 or PKD2 genes, is among the most common human monogenic disorders and a leading cause of end-stage renal disease. The disease is characterized by the development of multiple fluid filled cysts primarily in the kidneys, and to a lesser extent in the liver and other organs. Excessive kidney cyst cell proliferation, a central pathological feature, ultimately leads to end-stage renal disease in approximately 50% of ADPKD patients by age 60.

About RGLS4326

RGLS4326 is a novel oligonucleotide designed to inhibit miR-17 and designed to preferentially target the kidney. Preclinical studies with RGLS4326 have demonstrated direct regulation of PKD1 and PKD2 in human ADPKD cyst cells, a reduction in kidney cyst formation, improved kidney weight/body weight ratio, decreased cyst cell proliferation, and preserved kidney function in mouse models of ADPKD.

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, California. 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, RGLS5579 or its other preclinical programs), Regulus' sales of securities, including timing, size and completion of the Milestone Closing, its estimated cash runway, 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,	
	2019	2018	2019	2018
Revenues:				
Revenue under strategic alliances	$ 18	$ 18	$ 6,796	$ 36
Operating expenses:				
Research and development	1,836	10,013	7,819	21,841
General and administrative	2,850	3,349	6,383	7,122
Total operating expenses	4,686	13,362	14,202	28,963
Loss from operations	(4,668)	(13,344)	(7,406)	(28,927)
Other expense, net	(347)	(503)	(869)	(945)
Loss before income taxes	(5,015)	(13,847)	(8,275)	(29,872)
Income tax expense	(1)	—	(1)	(1)
Net loss	$ (5,016)	$ (13,847)	$ (8,276)	$ (29,873)
Net loss per share, basic and diluted	$ (0.30)	$ (1.59)	$ (0.61)	$ (3.44)
Weighted average shares used to compute basic and diluted net loss per share:	16,705,587	8,693,788	13,560,183	8,681,311

	June 30, 2019	December 31, 2018
	(Unaudited)	
Cash and cash equivalents	$19,571	$ 13,935
Total assets	25,691	27,927
Term loan, less debt issuance costs	14,621	16,575
Stockholders' equity (deficit)	4,743	(5,854)