REGULUS THERAPEUTICS INC.

FORM 8-K
(Current report filing)

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Address	10614 SCIENCE CENTER DRIVE SAN DIEGO, CA 92121
Telephone	858-202-6300
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Sector	Healthcare
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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): May 2, 2017

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 2.02 Results of Operations and Financial Condition.

On May 4, 2017, we issued a press release announcing our financial results for the first quarter ended March 31, 2017. 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 2.05 Costs Associated with Exit or Disposal Activities.

On May 2, 2017, we implemented a corporate restructuring to streamline our operations, 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 30% percent to 65 employees. The restructuring was approved by our Board of Directors on May 2, 2017, and affected employees were informed on May 4, 2017. We expect to complete the workforce reduction in May 2017. We estimate that we will record charges of approximately $2.0 million for employee severance and other related termination benefits. Severance payments are expected to be paid in full by the end of the second quarter of 2017.

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

On May 4, 2017, Paul C. Grint, M.D. resigned as our President and Chief Executive Officer and as a director, effective immediately. Dr. Grint has also withdrawn himself as a nominee for director at our 2017 annual meeting of stockholders. In connection with his resignation, and subject to our receiving an effective release and waiver of claims from Dr. Grint, Dr. Grint will receive (1) a lump sum severance payment equal to 12 months of his base salary in effect at the time of his resignation, (2) a lump sum cash amount equal to 229.56% multiplied by the total cost of the projected premiums for group medical, dental and vision insurance for a period of 12 months and (3) vesting acceleration of all outstanding options or other equity incentive awards held by Dr. Grint that are subject to time-based vesting as of the time of his resignation. In addition, subject to Dr. Grint's consent and our receipt of an effective release and waiver of claims from Dr. Grint, the post-termination exercise period of all outstanding options held by Dr. Grint will be extended to one year following the date of his resignation.

On May 4, 2017, Joseph P. Hagan, our Chief Operating Officer, was appointed to the position of President and Chief Executive Officer, principal executive officer and as a director, effective immediately. Any shares voted by proxy for the election of Dr. Grint as a director at our 2017 annual meeting of stockholders, scheduled to be held on June 1, 2017 at 9:00 a.m. local time at our principal executive offices, will instead be voted for the election or Mr. Hagan, as substitute nominee.

As part of his appointment to President and Chief Executive Officer, on May 4, 2017, the Board of Directors increased Mr. Hagan's base annual compensation to $500,000 and his target bonus to 50% of his base salary. In addition, Mr. Hagan was granted an option to purchase 750,000 shares of our common stock, at a grant price equal to our stock's closing price on the date of grant. Twenty-five percent of the shares underlying the stock options will vest on the first anniversary of the date of grant with the remainder to vest in equal monthly installments over the following three years, such that the option is fully vested four years after the date of grant, subject to Mr. Hagan's continued service to us through each vesting date.

Mr. Hagan, age 48, served as our Chief Operating Officer, principal financial officer and principal accounting officer from January 2016 until his appointment as our President and Chief Executive Officer on May 4, 2017. From June 2011 through December 2015, Mr. Hagan served as the Executive Vice President, Chief Financial Officer and Chief Business Officer of Orexigen Therapeutics, Inc. From May 2009 to June 2011, Mr. Hagan served as Orexigen's Senior Vice President, Corporate Development, Strategy and Communications. From September 2004 to April 2008, Mr. Hagan served as Managing Director of Amgen Ventures. Prior to starting the Amgen Ventures Fund, Mr. Hagan served as Head of Corporate Development for Amgen Inc. Before joining Amgen, Mr. Hagan spent five years in the bioengineering labs at Genzyme and Advanced Tissue Sciences. Mr. Hagan has served on the board of directors of Zosano Pharma, a publicly traded biotechnology company, since May 2015. He received an M.B.A. from Northeastern University and a B.S. in Physiology and Neuroscience from the University of California, San Diego. Our Board of Directors believes that Mr. Hagan's experience in the biotechnology industry, as well as his service as an executive officer of our company, qualify him to serve on our Board of Directors.

On May 4, 2017, our Board of Directors appointed Daniel Chevallard as our Chief Financial Officer and our principal financial and accounting officer. Prior to his appointment, Mr. Chevallard had served as our Vice President, Finance and Accounting since May 2013 and as Vice President, Accounting and Financial Reporting commencing in December 2012. Prior to joining Regulus, Mr. Chevallard held various senior roles in corporate finance, accounting and financial reporting including Controller and Senior Director, Finance with Prometheus Laboratories Inc. (acquired by Nestle´ Health Science in July 2011) from April 2006 to December 2012. From September 2001 to April 2006, Mr. Chevallard was employed by public accounting firm Ernst & Young, LLP in their assurance services practice. Mr. Chevallard received his Bachelor of Accountancy from the University of San Diego and is a Certified Public Accountant in the state of California.

In addition, on May 4, 2017, Timothy Wright, M.D., our Chief Research & Development Officer, was granted an option to purchase 350,000 shares of our common stock, at a grant price equal to our stock's closing price on the date of grant. Twenty-five percent of the shares underlying the stock option will vest on the first anniversary of the date of grant with the remainder to vest in equal monthly installments over the following three years, such that the option is fully vested four years after the date of grant, subject to Dr. Wright's continued service to us through each vesting date.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release issued by Regulus Therapeutics Inc. on May 4, 2017 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: May 4, 2017

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

EXHIBIT INDEX

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99.1	Press release issued by Regulus Therapeutics Inc. on May 4, 2017 relating to financial results

Exhibit 99.1

Regulus Reports First Quarter 2017 Financial Results and Corporate Restructuring

Company to Restructure Operations Accompanied by a Workforce Reduction

Dr. Paul Grint, President and CEO to Resign; Jay Hagan to Succeed Him

Conference Call Today at 5:00 p.m. ET

LA JOLLA, Calif., May 4, 2017 – Regulus Therapeutics Inc . (Nasdaq: RGLS), a biopharmaceutical company leading the discovery and development of innovative medicines targeting microRNAs, today reported financial results for the three months ended March 31, 2017. The Company also announced a corporate restructuring plan to streamline its operations as it focuses on its most promising discovery and development programs.

The restructuring includes an immediate workforce reduction of approximately 30%, which is expected to result in approximately $6.0 million in annual savings after one-time restructuring costs. Also in line with the restructuring, the Board of Directors has accepted the resignation of Dr. Paul C. Grint, President and Chief Executive Officer and director, effective immediately, and appointed Joseph P. "Jay" Hagan, the Company's Chief Operating Officer, to the position of President and Chief Executive Officer and director, also effective immediately. The Company also promoted Daniel R. Chevallard, its Vice President, Finance and Accounting, to the position of Chief Financial Officer, effective immediately.

"We are very grateful for the leadership of Dr. Grint and the many contributions of our other impacted employees who have dedicated themselves to Regulus' efforts in advancing the science of microRNAs," said Stelios Papadopoulos, Chairman of the Board of Directors. "We are confident that Regulus is well positioned for success under Jay's guidance."

"Our priorities remain on our most promising programs allowing us to achieve anticipated milestones," said Jay Hagan, President and Chief Executive Officer of Regulus. "We continue to advance our clinical and pre-clinical pipeline, and importantly, are on track to commence the Phase II HERA and renal biopsy studies for RG-012 as planned."

Pipeline Update

RG-012 for the treatment of Alport Syndrome: The Company has completed dosing of RG-012 in its Phase I multiple ascending dose (MAD) study and has selected the dose for the upcoming Phase II HERA and renal biopsy studies, which is expected to commence mid-2017. Preliminary data from the MAD study indicated that RG-012 was well tolerated with no serious adverse events (SAEs) reported in any subjects. The plasma PK profile of RG-012 was in-line with expectations, with a dose dependent increase in plasma exposure seen across the three dose groups. Data from the renal biopsy study is anticipated by year-end 2017, and interim data from the Phase II HERA study is anticipated in mid-2018.

Q1 Financial Results

Cash Position: Cash, cash equivalents and short-term investments were $57.5 million at March 31, 2017, compared with $76.1 million at December 31, 2016.

Research and Development (R&D) Expenses: R&D expenses were $15.8 million for the quarter ended March 31, 2017, compared to $16.8 million for the quarter ended March 31, 2016. The decrease in R&D expenses was primarily driven by a decrease in spend on the RG-101 program due to the FDA clinical hold, partially offset by an increase in internal costs attributable to our preclinical pipeline.

General and Administrative (G&A) Expenses: G&A expenses were $4.0 million for the quarter ended March 31, 2017, compared to $5.1 million for the quarter ended March 31, 2016.

Revenue: Revenue was less than $0.1 million for the quarter ended March 31, 2017, compared to $0.5 million for the quarter ended March 31, 2016.

Net Loss: Net loss was $20.0 million, or $0.38 per share (basic and diluted), for the quarter ended March 31, 2017, compared to a net loss of $21.2 million, or $0.40 per share (basic and diluted), for the quarter ended March 31, 2016.

Conference Call Details

Regulus will host a conference call and webcast at 5:00 p.m. Eastern Time today to discuss first quarter financial results and provide a general business update. 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 ID12962939. To access the replay of the call, dial (855) 859-2056 (domestic) or (404) 537-3406 (international), passcode 12962939. The webcast and telephone replay will be archived on the company's website following the call.

About Regulus

Regulus Therapeutics Inc. (Nasdaq: RGLS) is a biopharmaceutical company leading the discovery and development of innovative medicines targeting microRNAs. Regulus has leveraged its oligonucleotide drug discovery and development expertise to develop a well-balanced microRNA therapeutics pipeline complemented by a rich intellectual property estate to retain its leadership in the microRNA field. Regulus is advancing several programs in renal, hepatic and central nervous systems diseases, both independently and with our strategic alliance partners, Sanofi and AstraZeneca. 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-101 or RG-012), 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.

Investor Relations Contact:

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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 March 31,	
	2017	2016
Revenues:		
Revenue under strategic alliances	$ 18	$ 489
Operating expenses:		
Research and development	15,752	16,764
General and administrative	3,959	5,103
Total operating expenses	19,711	21,867
Loss from operations	(19,693)	(21,378)
Other (expense) income, net	(332)	166
Loss before income taxes	(20,025)	(21,212)
Income tax benefit	4	5
Net loss	$ (20,021)	$ (21,207)
Net loss per share, basic and diluted	$ (0.38)	$ (0.40)
Weighted average shares used to compute basic and diluted net loss per share:	52,990,383	52,710,672

Regulus Therapeutics Inc.
Condensed Balance Sheets
(In thousands)

	March 31, 2017	December 31, 2016
Cash, cash equivalents and short-term investments	$ 57,464	$ 76,111
Total assets	80,174	100,661
Term loan, less debt issuance costs	19,816	19,802
Stockholders' equity	$ 38,728	$ 56,075