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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

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**FORM 8-K**

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**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 10, 2018**

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**Regulus Therapeutics Inc.**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State  
of incorporation)

**001-35670**  
(Commission  
File No.)

**26-4738379**  
(IRS Employer  
Identification No.)

**10614 Science Center Drive**  
**San Diego, CA**  
(Address of principal executive offices)

**92121**  
(Zip Code)

**Registrant's telephone number, including area code: (858) 202-6300**

**N/A**  
(Former name or former address, if changed since last report.)

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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.

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**Item 2.02 Results of Operations and Financial Condition.**

On May 10, 2018, we issued a press release announcing our financial results for the first quarter ended March 31, 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.

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**Item 9.01 Financial Statements and Exhibits.**

**(d) Exhibits.**

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Press release issued by Regulus Therapeutics Inc. on May 10, 2018 relating to financial results</a>

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**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 10, 2018

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



## Regulus Reports First Quarter 2018 Financial Results and Pipeline Progress

*Two pre-clinical programs advance towards clinical candidates*

*Conference call today at 5:00 p.m. ET*

**LA JOLLA, Calif., May 10, 2018** – Regulus Therapeutics Inc. (Nasdaq: RGLS), a biopharmaceutical company leading the discovery and development of innovative medicines targeting microRNAs, today reported financial results for the first quarter ended March 31, 2018 and provided a pipeline update.

“We are very pleased with the progress being made on advancing our pipeline, including the recent initiation of the multiple ascending dose (MAD) study for RGLS4326; the advancement of two new pre-clinical programs in important areas of unmet need; and the continued advancement of the RG-012 program,” said Jay Hagan, President and Chief Executive Officer of Regulus. “These two new pre-clinical programs represent attractive areas of development for Regulus beyond our two chronic kidney disease programs.”

### Pipeline Update

- **RGLS4326 for autosomal dominant polycystic kidney disease (ADPKD):** As previously announced, a Phase 1 MAD study was recently initiated in healthy volunteers. This trial was initiated based on data from the ongoing Phase 1 single ascending dose (SAD) trial, in which RGLS4326 has been determined to be well tolerated to date. The Phase 1 SAD study has completed dose escalation and continues in the planned follow-up phase, which is on-track for completion in the second half of 2018. Data from both studies will provide pharmacokinetics and safety data in advance of the Phase 2 proof-of-concept (POC) study estimated for initiation in the second half of 2019.
- **Pre-clinical programs:** Based on robust human in vitro data and murine in vivo data, the Company announced today it is advancing programs in Hepatitis B virus and immunology (targets undisclosed).
- **RG-012 for Alport syndrome:** The Phase 2 HERA study is ongoing and data from the Phase 1 renal biopsy study is anticipated by year-end 2018.

### Financial Results

**Cash Position:** As of March 31, 2018, Regulus had cash, cash equivalents and short-term investments of \$45.1 million.

**Research and Development (R&D) Expenses:** R&D expenses were \$11.8 million for the quarter ended March 31, 2018, compared to \$15.8 million for the quarter ended March 31, 2017. The decrease was primarily the result of a reduction in personnel-related costs subsequent to our May 2017 corporate restructuring and the wind-down of clinical activities related to the RG-101 program.

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**General and Administrative (G&A) Expenses:** G&A expenses were \$3.8 million for the quarter ended March 31, 2018, compared to \$4.0 million for the quarter ended March 31, 2017.

**Revenue:** Revenue was less than \$0.1 million for the quarters ended March 31, 2018 and 2017.

**Net Loss:** Net loss was \$16.0 million, or \$0.15 per share (basic and diluted), for the quarter ended March 31, 2018, compared to a net loss of \$20.0 million, or \$0.38 per share (basic and diluted), for the quarter ended March 31, 2017.

#### **Conference Call Details**

Regulus will host a conference call and webcast today at 5:00 p.m. Eastern Time 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](http://www.regulusrx.com). To access the call, please dial (877) 257-8599 (domestic) or (970) 315-0459 (international) and refer to conference ID 8993969. To access the replay of the call, dial (855) 859-2056 (domestic) or (404) 537-3406 (international), conference ID 8993969. 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 clinical stage 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. 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 or RGLS4326), 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:**

Allison Wey  
858-202-6321  
[awey@regulusrx.com](mailto:awey@regulusrx.com)

**Regulus Therapeutics Inc.**  
**Selected Financial Information**  
**Condensed Statement of Operations**  
(In thousands, except share and per share data)

	Three months ended March 31,	
	2018	2017
<b>Revenues:</b>		
Revenue under strategic alliances	\$ 18	\$ 18
<b>Operating expenses:</b>		
Research and development	11,828	15,752
General and administrative	3,773	3,959
Total operating expenses	15,601	19,711
Loss from operations	(15,583)	(19,693)
Other expense, net	(441)	(332)
Loss before income taxes	(16,024)	(20,025)
Income tax (expense) benefit	(1)	4
Net loss	\$ (16,025)	\$ (20,021)
Net loss per share, basic and diluted	\$ (0.15)	\$ (0.38)
Weighted average shares used to compute basic and diluted net loss per share:	104,018,273	52,990,383

	March 31, 2018	December 31, 2017
Cash, cash equivalents and short-term investments	\$ 45,134	\$ 60,074
Total assets	62,079	77,809
Term loan, less debt issuance costs	19,874	19,859
Stockholders' equity	22,876	35,216