

REGULUS THERAPEUTICS INC.

FORM 8-K (Current report filing)

Filed 11/07/17 for the Period Ending 11/07/17

Address	10614 SCIENCE CENTER DRIVE SAN DIEGO, CA, 92121
Telephone	858-202-6300
CIK	0001505512
Symbol	RGLS
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

**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): November 7, 2017

Regulus Therapeutics Inc.

(Exact name of registrant as specified in its charter)

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.)

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 November 7, 2017, we issued a press release announcing our financial results for the third quarter ended September 30, 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 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by Regulus Therapeutics Inc. on November 7, 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: November 7, 2017

By: /s/ Joseph P. Hagan

Joseph P. Hagan
President and Chief Executive Officer



Regulus Reports Third Quarter 2017 Financial Results and Recent Events

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

LA JOLLA, Calif., November 7, 2017 – Regulus Therapeutics Inc. (Nasdaq: RGLS), a biopharmaceutical company leading the discovery and development of innovative medicines targeting microRNAs, today summarized recent events and reported financial results for the three and nine months ended September 30, 2017.

“The third quarter was marked by the successful completion of our financing, as well as significant operational progress on our two clinical programs,” said Jay Hagan, President and Chief Executive Officer of Regulus. “We are very pleased that both of our Alport studies are now active, the investigational new drug (IND) for the treatment of autosomal dominant polycystic kidney disease (ADPKD) has been filed, and a Phase I study remains on track to initiate by year-end.”

Third Quarter Corporate Highlights and Recent Events

- In July 2017, Regulus completed a public offering of its common stock, and received net proceeds of approximately \$43.0 million after deducting underwriting discounts, commissions and other offering expenses.
- In September, Regulus initiated HERA, the Phase II randomized, double-blinded, placebo-controlled study evaluating the safety and efficacy of RG-012 in Alport syndrome patients. In parallel, the Phase I renal biopsy study was also initiated.
- Recently, Regulus filed an IND application with the FDA for RGLS4326, targeting microRNA-17 for the treatment of ADPKD.

Third Quarter Financial Results

Cash Position: As of September 30, 2017, Regulus had cash, cash equivalents and short-term investments of \$71.4 million.

Research and Development (R&D) Expenses: R&D expenses were \$12.7 million and \$42.7 million for the three and nine months ended September 30, 2017, respectively, compared to \$14.6 million and \$49.3 million for the same periods in 2016. The decrease in R&D expenses for the three months ended September 30, 2017 compared to 2016 was driven by the planned reduction in personnel-related costs as a result of our May 2017 corporate restructuring. The decrease in R&D expenses for the nine months ended September 30, 2017 compared to 2016 was primarily driven by the wind-down of clinical activities related to the RG-101 program.

Revenue: Revenue was less than \$0.1 million for each of the three and nine months ended September 30, 2017, compared to \$0.2 million and \$1.2 million for the same periods in 2016.

Net Loss: Net loss was \$15.8 million and \$57.5 million for the three and nine months ended September 30, 2017, respectively, compared to a net loss of \$19.5 million and \$61.8 million for the same periods in 2016. Basic and diluted net loss per share was \$0.18 and \$0.88 for the three and nine months ended September 30, 2017, respectively, compared to \$0.37 and \$1.17 for the same periods in 2016.

Conference Call Details

Regulus will host a conference call and webcast today at 5:00 p.m. Eastern Time to discuss third quarter 2017 financial results and corporate highlights. 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 ID 9297128. To access the telephone replay of the call, dial (855) 859-2056 (domestic) or (404) 537-3406 (international), conference ID 9297128. 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

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

	Three months ended September 30,		Nine months ended September 30,	
	2017	2016	2017	2016
	(Unaudited)			
Revenues:				
Revenue under strategic alliances	\$ 18	\$ 204	\$ 54	\$ 1,176
Operating expenses:				
Research and development	12,697	14,554	42,727	49,326
General and administrative	2,736	4,842	13,752	13,609
Total operating expenses	15,433	19,396	56,479	62,935
Loss from operations	(15,415)	(19,192)	(56,425)	(61,759)
Other expense, net	(420)	(323)	(1,171)	(66)
Loss before income taxes	(15,835)	(19,515)	(57,596)	(61,825)
Income tax benefit (expense)	7	(4)	139	9
Net loss	<u>\$ (15,828)</u>	<u>\$ (19,519)</u>	<u>\$ (57,457)</u>	<u>\$ (61,816)</u>
Net loss per share, basic and diluted	<u>\$ (0.18)</u>	<u>\$ (0.37)</u>	<u>\$ (0.88)</u>	<u>\$ (1.17)</u>
Weighted average shares used to compute basic and diluted net loss per share:	<u>90,072,045</u>	<u>52,835,414</u>	<u>65,550,749</u>	<u>52,776,459</u>

	September 30, 2017	December 31, 2016
	(Unaudited)	
Cash, cash equivalents and short-term investments	\$ 71,370	\$ 76,111
Total assets	90,847	100,661
Term loan, less debt issuance costs	19,845	19,802
Stockholders' equity	48,582	56,075