# 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 8, 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 2.02 Results of Operations and Financial Condition.**

On November 8, 2018, we issued a press release announcing our financial results for the third quarter ended September 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 November 8, 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: November 8, 2018

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

**Exhibit 99.1**

**Regulus Reports Third Quarter 2018 Financial Results and Recent Updates**

*$47 Million Restructured Sanofi Collaboration Executed*

*Initiated New Chronic Mouse Toxicity Study for RGLS4326; Data Anticipated in Q1 2019*

**LA JOLLA, Calif., November 8, 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 third quarter ended September 30, 2018 and provided a summary of recent events.

**Third Quarter 2018 Corporate Highlights and Recent Updates**

- **Amended and restructured its Collaboration and License Agreement with Sanofi:** In November, Regulus and Sanofi agreed to restructure their Collaboration and License Agreement and immediately transfer development responsibilities of RG-012 for the treatment of Alport syndrome to Sanofi. Sanofi will assume all future costs and development activities associated with the advancement of RG-012, currently in Phase 2 for the treatment of Alport syndrome. Under the terms of the Amendment, Regulus is eligible to receive approximately $7 million in upfront and material transfer payments. Regulus is also eligible to receive up to $40 million in development milestone payments, including a $10 million payment for an interim enrollment milestone. In addition, Sanofi will reimburse Regulus for certain out-of-pocket expenses associated with transition activities and assume Regulus' upstream license royalty obligations.
- **Initiated new chronic mouse toxicity study for RGLS4326; data anticipated in Q1 2019:** In September 2018, and in consultation with the FDA, the Company initiated a new 27-week chronic mouse toxicity study for RGLS4326 for the treatment of autosomal dominant polycystic kidney disease (ADPKD), incorporating several changes believed to address the unexpected findings in the earlier terminated chronic mouse toxicity study. This study is ongoing, and data are anticipated in Q1 2019. The Company anticipates the advancement of the RGLS4326 clinical program upon successful resolution of the unexpected findings.
- **Completed reverse stock split and regained compliance with NASDAQ listing requirements:** In a special meeting of stockholders, held September 28, 2018, stockholders voted to approve a proposal authorizing the Board of Directors of the Company to amend the Company's certificate of incorporation to affect a reverse stock split of Regulus' outstanding common shares. Following the special meeting of stockholders, the Board of Directors approved a 1-for-12 reverse stock split. The Company's shares began trading on a split-adjusted basis on October 4, 2018. On October 18, 2018, The Nasdaq Stock Market notified Regulus that it had regained compliance with the minimum bid price requirement for continued listing on The Nasdaq Global Market.

"The recently announced Sanofi restructuring represents a significant achievement for Regulus, bringing non-dilutive capital and eliminating future spend for this partnered program. Importantly, we are eligible to receive approximately $17 million in upfront and milestone payments anticipated over the next twelve months," said Jay Hagan, President and Chief Executive Officer of Regulus. "In July, we established several near-term key objectives, including reducing our cash burn, restructuring the Sanofi collaboration, advancing our prioritized pipeline, including ADPKD, and positioning other programs for business development opportunities. Regulus has made significant progress towards completing all of these objectives, and we look forward to the continued advancement of our ADPKD and HBV programs."

**Program Updates**

- **Presented preclinical data supporting RGLS4326 as a novel therapeutic for the treatment of ADPKD at the American Society of Nephrology's Kidney Week 2018:** In October 2018, Regulus presented three posters during the American Society of Nephrology's Kidney Week describing the discovery and preclinical evaluation of RGLS4326, a novel single-stranded, chemically-modified oligonucleotide designed to preferentially target the kidney and inhibit miR-17 functions to treat ADPKD. In preclinical studies, RGLS4326 inhibited miR-17 activity and reduced cyst formation and proliferation of primary cyst cultures derived from human donors with ADPKD. The data presented also demonstrated that RGLS4326 has favorable pharmacokinetic and pharmacodynamic profiles in normal and polycystic kidney disease (PKD) mouse models, where preferential distribution to kidney and localization to collecting duct cysts were evident. Furthermore, data demonstrated that RGLS4326 directly modulates expression of genes implicated in ADPKD pathogenesis including Pkd1 and Pkd2, and conferred efficacy in multiple PKD mouse models following subcutaneous administration.
- **Advancement of Hepatitis B virus (HBV) Programs:** The Company has identified multiple human microRNA targets that serve as host factors for the virus. Compounds directed at modulating these targets are under active *in vitro* and *in vivo* preclinical investigation. The Company believes that targeting a host factor in the liver represents a unique mechanism of action for treatment of the virus compared to other programs in development and holds the potential for achieving a functional cure. The Company currently expects to file an IND for the HBV program in the second half of 2019, with the potential of achieving human proof-of-concept in a Phase 1 study.
- **Additional Program Updates:** In September 2018, the Company announced progress of its glioblastoma multiforme (GBM) and non-alcoholic steatohepatitis (NASH) preclinical programs. The Company's GBM program, targeting *micro*RNA-10b, demonstrated statistically significant improvements in survival as both a monotherapy as well as in combination with temozolomide (TMZ) in an orthotopic GBM animal model. The Company's lead NASH 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 2-4 weekly doses, early onset of improvement across multiple disease parameters including liver triglycerides and blood levels of transaminases was observed. The Company plans to seek partners to further advance these programs' development.

**Third Quarter 2018 Financial Results**

**Cash Position:** As of September 30, 2018, Regulus had $20.5 million in cash, cash equivalents and short-term investments. Under the terms of the Sanofi Amendment, Regulus is eligible to receive approximately $7 million in upfront and material transfer payments. Including these additional proceeds, the Company expects its cash runway to extend through Q2 2019.

**Research and Development (R&D) Expenses:** R&D expenses were $6.9 million and $28.7 million for the three and nine months ended September 30, 2018, respectively, compared to $12.7 million and $42.7 million for the same periods in 2017. The decreases were primarily attributable to the pausing of the RG-012 and RGLS4326 programs early in the third quarter of 2018, the discontinuation of the RG-101 and RGLS5040 programs in 2017 and reductions in personnel-related expenses primarily attributable to our corporate restructurings.

**General and Administrative (G&A) Expenses:** G&A expenses were $3.0 million and $10.1 million for the three and nine months ended September 30, 2018, respectively, compared to $2.7 million and $13.8 million for the same periods in 2017. The increase for the three months ended September 30, 2018 as compared to the three months ended September 30, 2017 was driven by non-recurring severance charges recorded in the third quarter of 2018 in connection with our July 2018 corporate restructuring. The decrease for the nine months ended September 30, 2018 as compared to the nine months ended September 30, 2017 was driven by non-recurring severance charges and non-recurring, non-cash stock-based compensation charges recorded in connection with our May 2017 corporate restructuring.

**Revenue:** Revenue was less than $0.1 million for each of the three and nine months ended September 30, 2018 and 2017.

**Net Loss:** Net loss was $10.3 million, or $1.18 per share (basic and diluted), and $40.1 million, or $4.62 per share (basic and diluted), for the three and nine months ended September 30, 2018, respectively, compared to $15.8 million, or $2.11 per share (basic and diluted), and $57.5 million, or $10.52 per share (basic and diluted), for the same periods in 2017. Historical and current period net loss per share values have been retroactively adjusted to reflect our October 2018 reverse stock split.

**Upcoming Events**

- On November 14, 2018, Regulus will present survival data on its lead anti-miR candidate targeting microRNA-10b for glioblastoma multiforme at the Society for Neuro-Oncology Meeting in New Orleans, Louisiana.
- On November 14, 2018, Regulus will present a corporate overview at the Stifel 2018 Healthcare Conference in New York.

**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.

**Investor Relations Contact:**

Dan Chevallard
Chief Financial Officer
858-202-6376
**dchevallard@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, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| Revenues: | | | | |
| Revenue under strategic alliances | $ 18 | $ 18 | $ 54 | $ 54 |
| Operating expenses: | | | | |
| Research and development | 6,879 | 12,697 | 28,720 | 42,727 |
| General and administrative | 2,993 | 2,736 | 10,115 | 13,752 |
| Total operating expenses | 9,872 | 15,433 | 38,835 | 56,479 |
| Loss from operations | (9,854) | (15,415) | (38,781) | (56,425) |
| Other expense, net | (419) | (420) | (1,365) | (1,171) |
| Loss before income taxes | (10,273) | (15,835) | (40,146) | (57,596) |
| Income tax benefit | — | 7 | — | 139 |
| Net loss | $ (10,273) | $ (15,828) | $ (40,146) | $ (57,457) |
| Net loss per share, basic and diluted | $ (1.18) | $ (2.11) | $ (4.62) | $ (10.52) |
| Weighted average shares used to compute basic and diluted net loss per share: | 8,703,626 | 7,506,529 | 8,688,831 | 5,463,096 |

| | September 30, 2018 | December 31, 2017 |
|---|---|---|
| | (Unaudited) | |
| Cash, cash equivalents and short-term investments | $ 20,517 | $ 60,074 |
| Total assets | 34,768 | 77,809 |
| Term loan, less debt issuance costs | 19,069 | 19,859 |
| Stockholders' equity | 1,578 | 35,216 |