Regulus Therapeutics Inc.
Form 8-K
February 05, 2014

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): January 30, 2014

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.)**
3545 John Hopkins Court		**92121**
Suite 210		

San Diego, CA
(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))

Item 1.01 Entry into a Material Definitive Agreement.

Option Letter Amendment

On January 30, 2014, Regulus Therapeutics Inc. (the Company) and Sanofi entered into an amendment (the Option Letter Amendment) to that certain Option Letter Agreement dated June 21, 2013 (the Option Letter Agreement), pursuant to which the Company and Sanofi agreed to extend the exclusivity period for the Sanofi Option (as defined in the Company s Current Report on Form 8-K filed with the Securities and Exchange Commission (SEC) on June 26, 2013) and the exclusivity period for the Company Option (as defined in the Company s Current Report on Form 8-K filed with the SEC on June 26, 2013) from January 30, 2014 to February 14, 2014. A copy of the Option Letter Amendment is attached as Exhibit 99.1 hereto and is incorporated herein by reference.

Second Amended and Restated Collaboration and License Agreement

On February 4, 2014, the Company entered into a Second Amended and Restated Collaboration and License Agreement with Sanofi (the Second Restatement), which amends, restates and supersedes the Amended and Restated Collaboration and License Agreement entered into by the Company and Sanofi in July 2012 (which in turn amended, restated and superseded the Collaboration and License Agreement entered into by the Company and Sanofi in June 2010). The Second Restatement also supersedes the Option Letter Agreement, as amended by the Option Letter Amendment.

Under the terms of the Second Restatement, the Company and Sanofi have extended their strategic alliance to discover, develop, and commercialize microRNA therapeutics to focus on specific orphan disease and oncology targets. The Second Restatement provides that the Company will lead development of three of the Company s therapeutic programs (each, a Program):

- The preclinical fibrosis program targeting microRNA-21 (miR-21), for the treatment of Alport Syndrome, an orphan, life-threatening genetic kidney disease with no approved therapy (the miR-21 Fibrosis Program);
- the preclinical program targeting miR-21 for oncology indications (the miR-21 Oncology Program); and
- the preclinical program targeting microRNA-221/microRNA-222 (miR-221/222) for oncology indications (the miR-221/222 Oncology Program).

The Company has agreed to use its commercially reasonable efforts to advance a clinical candidate in each of the Programs to proof of concept in a human clinical trial (POC) and is responsible for conducting the development and compound manufacturing activities necessary for achievement of POC, at the Company s cost. Sanofi has the right but not the obligation to perform mutually-agreed development activities complementary to the Company s efforts in each Program, at Sanofi s cost. If a clinical candidate in any of the Programs achieves POC, Sanofi has the option (an Option), exercisable within 90 days after POC achievement in such Program (the Option Period), to assume all costs, responsibilities and obligations for further development and commercialization of such Program, and upon such exercise Sanofi will have an exclusive, worldwide license to develop and commercialize microRNA therapeutic products containing microRNA compounds that were the subject of such Program (Program Products), provided that if Sanofi exercises its Option with respect to any Program, the Company will have the option to co-promote any Program Product from such Program with Sanofi in the United States.

If Sanofi chooses to exercise its Option for any Program, Sanofi will reimburse the Company for a significant portion of the preclinical and clinical development costs incurred by the Company in performing such Program and will also pay the Company an Option exercise fee for such Program. Sanofi will be entitled to credit $1.25 million of the $2.5 million upfront option fee paid by Sanofi to the Company pursuant to the Option Letter Agreement against the Option exercise fee for the first Program with respect to which Sanofi exercises its Option. In addition, if Sanofi exercises its Option with respect to any Program, Sanofi will be entitled to credit the costs incurred by it in performing mutually-agreed activities related to such Program against the Option exercise fee for such Program, up to a maximum of $10.0 million in the aggregate for any and all Programs with respect to which Sanofi exercises its Option.

Under the Second Restatement, Sanofi retains its existing exclusive, worldwide license (the miR-21 License) to develop and commercialize microRNA therapeutic products targeting miR-21 (miR-21 Products). However, if Sanofi does not exercise its Option for an miR-21 Program within 90 days after achievement of POC in such miR-21 Program, or if an miR-21 Program is terminated before achievement of POC in such miR-21 Program, Program Products containing any of the miR-21 compounds that were the subject of such miR-21 Program (miR-21 Program Products) will be excluded from the miR-21 License, and the Company will have the exclusive right to develop and commercialize such miR-21 Program Products, without further obligation to Sanofi.

If Sanofi exercises its Option with respect to the miR-221/222 Program, Sanofi will receive an exclusive, worldwide license to develop and commercialize microRNA therapeutic products containing miR-221/222 compounds (miR-221/222 Products), subject to the Company s option to co-promote MiR-221/222 Products from the MiR-221/222 Program with Sanofi in the United States.

If Sanofi exercises its Option with respect to at least one of the miR-21 Programs, the Company is eligible to receive clinical and regulatory milestone payments of up to $125.0 million, in the aggregate, for the first and second miR-21 Program Products to achieve the applicable clinical and regulatory milestones, as well as additional regulatory milestone payments on the subsequent achievement of regulatory milestones by any other miR-21 Program Product for a different indication. If Sanofi exercises its Option with respect to the miR-221/222 Program, the Company is eligible to receive regulatory milestone payments of up to $70.0 million for the first miR-221/222 Product to achieve such regulatory milestones.

The Company is also eligible to receive commercial milestone payments of up to an aggregate of $120.0 million if Sanofi exercises both its Option for at least one miR-21 Program and its Option for the miR-221/222 Program. In addition, the Company is entitled to receive royalties based on a percentage of net sales of miR-21 Program Products and miR-221/222 Products which, in the case of sales in the United States, will be in the middle of the 10 to 20% range, and, in the case of sales outside of the United States, will range from the low end to the middle of the 10 to 20% range, depending upon the volume of sales.

If the Company exercises its option to co-promote a Program Product, the Company will continue to be eligible to receive royalties on net sales of such Program Product in the United States at the same rate, unless the Company elects to share a portion of Sanofi s profits from sales of such Program Product in the United States in lieu of royalties.

In the case of miR-21 Products other than miR-21 Program Products, the Company is entitled to receive preclinical, clinical and regulatory milestone payments of up to $118.0 million for the first such miR-21 Product to achieve such milestones, and additional regulatory milestone payments on subsequent achievement of regulatory milestones by any other miR-21 Product (excluding an MiR-21 Program Product) for a different indication. In addition, the Company is entitled to receive royalties on miR-21 Products other than miR-21 Program Products based on a percentage of net sales which will range from the mid-single digits to the low end of the 10 to 20% range, depending upon the volume of sales.

Sanofi may terminate the Second Restatement in full or on a product-by-product basis by giving 30 days prior written notice to the Company. Either party may also terminate the Second Restatement for a material breach by the other party which remains uncured after 120 days notice of such breach, except that (a) the Company may not exercise this termination right for an miR-21 Product until after the earlier of (i) the exercise of the Option for at least one of the mir-21 Programs and (ii) the expiration of the Option Periods with respect to both of the miR-21 Programs without Sanofi s exercise of either of such Options, and (b) the Company may not exercise this termination right for an miR-221/222 Product until after the exercise of the Option for the miR-221/222 Program. In the event a Program or the Second Restatement is terminated by Sanofi, the rights to develop and commercialize Program Products from the terminated Program(s) (including the right to sublicense these rights to a third party) returns to the Company.

In addition, if rights to any Program Product from a Program with respect to which Sanofi exercised its Option revert to the Company after Sanofi has completed at least one Phase 2 clinical trial of such Program Product following such exercise, then, if the Company sublicenses such Program Product to a third party, the Company will be required to pay a percentage of sublicense revenues to Sanofi in the low end of the 10 to 20% range, and if the Company commercializes such Program Product on its own, the Company will be required to pay royalties to Sanofi as a percentage of net sales in the low single digits.

The foregoing description of the Second Restatement is qualified in its entirety by reference to the Second Restatement, a copy of which will be filed as an exhibit to the Company s Annual Report on Form 10-K for the year ended December 31, 2013.

Common Stock Purchase Agreement

On February 4, 2014, in connection with the entry into the Second Restatement, the Company entered into a Common Stock Purchase Agreement (the Purchase Agreement) with Aventis Holdings Inc. (Aventis), an entity affiliated with Sanofi, pursuant to which the Company issued and sold 1,303,780 shares of the Company s common stock (the Shares) to Aventis at a purchase price of $7.67 per share (representing the average of the daily volume weighted average prices per share of the Company s common stock as reported on The Nasdaq Global Market during the 30 trading days ending on the date immediately preceding the date of the Purchase Agreement) and an aggregate purchase price of $10.0 million. A copy of the Purchase Agreement is attached as Exhibit 99.2 hereto and is incorporated herein by reference.

Registration Rights Agreement

On February 4, 2014, the Company also entered into an Registration Rights Agreement with Aventis (the Registration Rights Agreement), pursuant to which Aventis will have the right to require the Company to register the Shares on a Form S-3 registration statement with the SEC or to include the Shares in a registration statement filed by the Company. Aventis right to request a registration of the Shares will terminate on February 4, 2016. A copy of the Registration Rights Agreement is attached as Exhibit 99.3 hereto and is incorporated herein by reference.

Item 3.02 Unregistered Sales of Equity Securities.

The information relating to the issuance and sale of the Shares to Aventis in Item 1.01 of this Current Report is incorporated herein by reference. The aggregate purchase price of the Shares was $10.0 million, representing a per Share price of $7.67. The purchase price of the Shares was paid for by Aventis in immediately available funds.

The sales and issuance of the Shares were not registered under the Securities Act of the 1933, as amended (the Securities Act), or any state securities laws. We have relied on the exemption from the registration requirements of the Securities Act by virtue of Section 4(a)(2) thereof and Rule 506, Regulation D thereunder. In connection with Aventis execution of the Purchase Agreement, Aventis represented to the Company that it is an accredited investor as defined in Regulation D of the Securities Act and that the securities purchased by Aventis were acquired solely for its own account and for investment purposes and not with a view to the future sale or distribution by Aventis.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Option Letter Amendment by and between Regulus Therapeutics Inc. and Sanofi dated January 30, 2014
99.2	Common Stock Purchase Agreement by and between Regulus Therapeutics Inc. and Aventis Holdings Inc., dated February 4, 2014

99.3	Registration Rights Agreement by and between Regulus Therapeutics Inc. and Aventis Holdings Inc., dated February 4, 2014

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: February 5, 2014

By: /s/ Kleanthis G. Xanthopoulos
Kleanthis G. Xanthopoulos, Ph.D.
President and Chief Executive Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Option Letter Amendment by and between Regulus Therapeutics Inc. and Sanofi dated January 30, 2014
99.2	Common Stock Purchase Agreement by and between Regulus Therapeutics Inc. and Aventis Holdings Inc., dated February 4, 2014
99.3	Registration Rights Agreement by and between Regulus Therapeutics Inc. and Aventis Holdings Inc., dated February 4, 2014