

Regulus Therapeutics Inc.
Form 8-K
June 26, 2013

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): February 21, 2013

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.)

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3545 John Hopkins Court

92121

Suite 210

(Zip Code)

San Diego, CA

(Address of principal executive offices)

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 with Sanofi

On June 21, 2013, Regulus Therapeutics Inc. (the Company) entered into an option letter agreement (the Option Letter) with Sanofi. Under the terms of the Option Letter, Sanofi will have the exclusive right (the Sanofi Option) to negotiate with the Company to enter into a development and license agreement for the co-development and commercialization of, among other things, certain unencumbered microRNA targets and microRNA biomarkers (the microRNA Collaboration Agreement). The Sanofi Option will expire on December 31, 2013 or upon execution of the microRNA Collaboration Agreement, whichever occurs first, subject to a 30-day extension in the event the parties are in active negotiations or drafting of the microRNA Collaboration Agreement as of December 31, 2013.

In addition, pursuant to the Option Letter the Company will have the exclusive right (the Company Option) to negotiate with Sanofi to enter into a co-development and commercialization agreement (the miR-21 Co-Development Agreement) pursuant to which the Company would obtain the right to co-develop and commercialize with Sanofi certain miR-21 antagomirs in oncology and in Alport's disease, a genetic disorder characterized by endstage kidney disease and hearing loss. The Company Option will expire on December 31, 2013 or upon execution of the miR-21 Co-Development Agreement, whichever occurs first, subject to a 30-day extension in the event the parties are in active negotiations or drafting of the miR-21 Co-Development Agreement as of December 31, 2013. During the period of the Company Option, the Company will continue to perform specified research activities under the miR-21 program pursuant to the Amended and Restated Collaboration and License Agreement dated July 16, 2012 between the Company and Sanofi and Sanofi will have no obligation to provide research funding or payment with respect to such work.

Pursuant to the Option Letter, Sanofi will pay \$2.5 million to the Company, \$1.25 million of which will be creditable by Sanofi against any future payments payable to the Company under either the miR-21 Co-Development Agreement or the microRNA Collaboration Agreement.

The foregoing description of the Option Letter is qualified in its entirety by reference to the Option Letter, a copy of which will be filed by the Company with the Securities and Exchange Commission (SEC) following the date hereof.

Amendment to Collaboration and Licence Agreement with Biogen Idec MA Inc.

On June 24, 2013, the Company and Biogen Idec MA Inc. (Biogen) entered into an amendment (the Biogen Amendment) to the Collaboration and License Agreement dated August 15, 2012 between the Company and Biogen (the Biogen Agreement). The Biogen Amendment provides for, among other things, revised terms with respect to phase 1 of the research plan under the Biogen Agreement and revised payment provisions relating to the phase 1 milestones. The Biogen Amendment does not modify the maximum dollar amount the Company was originally eligible to receive in connection with phase 1 milestones under the Biogen Agreement.

The foregoing description of the Biogen Amendment is qualified in its entirety by reference to the Biogen Amendment, a copy of which will be filed by the Company with the SEC following the date hereof.

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

(b)

On June 21, 2013, Garry E. Menzel, Ph.D., resigned as the Company's Chief Operating Officer and Executive Vice President, Finance. Dr. Menzel resigned in connection with his acceptance of a position at a large publicly-held healthcare services company.

(c)

On June 24, 2013, Kleantlis G. Xanthopoulos, Ph.D., the Company's President and Chief Executive Officer, was appointed as the principal financial and accounting officer of the Company. Dr. Xanthopoulos will retain his current title as President and Chief Executive Officer. The information required by Items 401(b), (d) and (e) and Item 404(a) of Regulation S-K promulgated by the SEC with respect to Dr. Xanthopoulos is disclosed in the Company's Proxy Statement on Schedule 14A filed by the Company with the SEC on April 30, 2013 in connection with the Company's 2013 Annual Meeting of Stockholders, and is incorporated herein by reference.

Item 8.01 Other Events.

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On February 21, 2013, the Company and BMR-3545-3575 John Hopkins LP (BMR) entered into an amendment (the Lease Amendment) to the Lease dated March 19, 2010, as amended, between the Company and BMR. Under the terms of the Lease Amendment, BMR granted the Company, in exchange for a corresponding increase in the Company s monthly base rent, a non-exclusive license to use an additional 64 square feet of space in the common area of the building in which the Company leases its principal offices solely for the purpose of installing, operating, maintaining, replacing, altering and removing information technology equipment.

The foregoing description of the Lease Amendment is qualified in its entirety by reference to the Lease Amendment, a copy of which is attached to this report as Exhibit 99.1 and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

| Exhibit No. | Description |
|-------------|---|
| 99.1 | Fifth Amendment to Lease, dated February 21, 2013, by and between BMR-3545-3575 JOHN HOPKINS LP and Regulus Therapeutics Inc. |

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: June 26, 2013

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

EXHIBIT INDEX

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