

Edgar Filing: Spark Therapeutics, Inc. - Form 8-K

Spark Therapeutics, Inc.
Form 8-K
January 24, 2018

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 24, 2018

Spark Therapeutics, Inc.
(Exact Name of Registrant as Specified in its Charter)

Delaware 001-36819 46-2654405
(State or Other Jurisdiction (Commission (IRS Employer
of Incorporation) File Number) Identification No.)

3737 Market Street
Suite 1300 19104
Philadelphia, PA
(Address of Principal Executive Offices) (Zip Code)

Registrant's telephone number, including area code: (888) 772-7560
(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))

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Indicate by check mark whether the registrant is an emerging growth company as defined in 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 1.01 Entry into a Material Definitive Agreement.

On January 24, 2018 (the “Effective Date”), Spark Therapeutics, Inc. (the “Company”) entered into a Licensing and Commercialization Agreement (the “License Agreement”) with Novartis Pharma AG (“Novartis”) to develop and commercialize voretigene neparvovec outside the U.S. The Company also entered into a Supply Agreement with Novartis, dated as of the Effective Date (the “Supply Agreement”) to manufacture and supply all of the requirements of Novartis for voretigene neparvovec.

Under the terms of the License Agreement, the Company has granted Novartis an exclusive right and license, with the right to grant certain sublicenses, under the Company’s intellectual property reasonably necessary or useful for the development or commercialization of LUXTURNA™ for the treatment, prevention, cure or control of RPE65-mediated inherited retinal disease (IRD) in humans outside the U.S.

Novartis will pay the Company a non-refundable, non-creditable, one-time payment of \$105 million within five business days following the Effective Date. The Company is eligible to receive an additional \$25 million in cash if investigational voretigene neparvovec is approved by the European Medicines Agency, as well as up to in aggregate \$40 million in cash based on receipt of initial sales outside the U.S. in certain markets. The Company is also entitled to receive royalty payments at a flat mid-twenties percentage of net sales on a royalty-region by royalty-region basis, subject to reduction and extension in certain circumstances.

Under the License Agreement, the Company will retain regulatory responsibility for obtaining approval for LUXTURNA by the European Medicines Agency; however, Novartis will have regulatory responsibility for obtaining approval for LUXTURNA for countries outside of the U.S. and the E.U.

The License Agreement continues until the last to complete royalty term, which is on a royalty-region by royalty-region basis for 12 years from the first commercial sale in such region of LUXTURNA, but may be extended in a country until regulatory exclusivity expires in that country or on a region-by-region basis until aggregate net sales fall below a certain threshold. Either party may terminate the License Agreement upon the other party’s uncured material breach of the License Agreement, insolvency, or bankruptcy. Novartis may terminate the License Agreement at any time upon one year’s prior written notice to the Company. Novartis may also terminate the License Agreement in the event there is an uncured material breach of the Supply Agreement by Spark resulting in Novartis taking over manufacturing of LUXTURNA or in the event Spark undergoes a change of control.

Under the Supply Agreement, the Company has agreed to supply all of the commercial supply of LUXTURNA required by Novartis, subject to certain conditions. The Supply Agreement continues until the expiration or early termination of the License Agreement. Either party may also terminate the Supply Agreement upon the other party’s uncured material breach of the Supply Agreement, insolvency or bankruptcy.

The foregoing descriptions of the License Agreement and the Supply Agreement do not purport to be complete and are subject to, and qualified in their entirety by reference to, the full text of the License Agreement and the Supply Agreement. The Company intends to file a copy of the License Agreement and the Supply Agreement with the Company’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2018.

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.

SPARK THERAPEUTICS,
INC.

Date: January 24, 2018 By: /s/ Joseph W. La Barge
Joseph W. La Barge
Chief Legal Officer