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 3, 2018

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

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

3737 Market Street **Suite 1300** **Philadelphia, PA**	**19104**
(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))

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 8.01 Other Events.

On January 3, 2018, Spark Therapeutics, Inc., announced that the wholesale acquisition cost for LUXTURNA™ (voretigene neparvovec-rzyl) is $425,000 per dose or per eye. Spark Therapeutics also announced three new payer programs: an outcomes-based rebate arrangement with a long-term durability measure, an innovative contracting model and a proposal to CMS under which payments for LUXTURNA would be made over time. Together, these initiatives aim to help ensure eligible U.S. patients have access to LUXTURNA, a one-time gene therapy indicated for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy. Spark Therapeutics has reached agreement in principle with Harvard Pilgrim to make LUXTURNA available under the outcomes-based rebate arrangement and the innovative contracting model that aims to reduce risk and financial burden for payers and treatment centers. Spark Therapeutics also has reached an agreement in principle with affiliates of Express Scripts to enable the innovative contracting model.

Indication and Important Safety Information for LUXTURNA

LUXTURNA (voretigene neparvovec-rzyl) is an adeno-associated virus vector-based gene therapy indicated for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy.

Patients must have viable retinal cells as determined by the treating physicians.

Warnings and Precautions

- Endophthalmitis may occur following any intraocular surgical procedure or injection. Use proper aseptic injection technique when administering LUXTURNA, and monitor for and advise patients to report any signs or symptoms of infection or inflammation to permit early treatment of any infection.
- Permanent decline in visual acuity may occur following subretinal injection of LUXTURNA. Monitor patients for visual disturbances.
- Retinal abnormalities may occur during or following the subretinal injection of LUXTURNA, including macular holes, foveal thinning, loss of foveal function, foveal dehiscence, and retinal hemorrhage. Monitor and manage these retinal abnormalities appropriately. Do not administer LUXTURNA in the immediate vicinity of the fovea. Retinal abnormalities may occur during or following vitrectomy, including retinal tears, epiretinal membrane, or retinal detachment. Monitor patients during and following the injection to permit early treatment of these retinal abnormalities. Advise patients to report any signs or symptoms of retinal tears and/or detachment without delay.
- Increased intraocular pressure may occur after subretinal injection of LUXTURNA. Monitor and manage intraocular pressure appropriately.
- Expansion of intraocular air bubbles Instruct patients to avoid air travel, travel to high elevations or scuba diving until the air bubble formed following administration of LUXTURNA has completely dissipated from the eye. It may take one week or more following injection for the air bubble to dissipate. A change in altitude while the air bubble is still present can result in irreversible vision loss. Verify the dissipation of the air bubble through ophthalmic examination.
- Cataract Subretinal injection of LUXTURNA, especially vitrectomy surgery, is associated with an increased incidence of cataract development and/or progression.

Adverse Reactions

- In clinical studies, ocular adverse reactions occurred in 66% of study participants (57% of injected eyes), and may have been related to LUXTURNA, the subretinal injection procedure, the concomitant use of corticosteroids, or a combination of these procedures and products.
- The most common adverse reactions (incidence 5% of study participants) were conjunctival hyperemia (22%), cataract (20%), increased intraocular pressure (15%), retinal tear (10%), dellen (thinning of the corneal stroma) (7%), macular hole

(7%), subretinal deposits (7%), eye inflammation (5%), eye irritation (5%), eye pain (5%), and maculopathy (wrinkling on the surface of the macula) (5%).

Immunogenicity

Immune reactions and extra-ocular exposure to LUXTURNA in clinical studies were mild. No clinically significant cytotoxic T-cell response to either AAV2 or RPE65 has been observed. Study participants received systemic corticosteroids before and after subretinal injection of LUXTURNA to each eye, which may have decreased the potential immune reaction to either AAV2 or RPE65.

Pediatric Use

Treatment with LUXTURNA is not recommended for patients younger than 12 months of age, because the retinal cells are still undergoing cell proliferation, and LUXTURNA would potentially be diluted or lost during the cell proliferation. The safety and efficacy of LUXTURNA have been established in pediatric patients. There were no significant differences in safety between the different age subgroups.

Clinical Trial Overview of LUXTURNA™ (voretigene neparvovec-rzyl)

The safety and efficacy of LUXTURNA were assessed in one open-label, dose-exploration Phase 1 safety study (n=12) and one open-label, randomized, controlled Phase 3 efficacy and safety study (n=31) in pediatric and adult participants (range 4 to 44 years) with biallelic RPE65 mutation-associated retinal dystrophy and sufficient viable retinal cells.

Of the 31 participants enrolled in the Phase 3 study, 21 were randomized to receive subretinal injection of LUXTURNA and 10 were randomized to the control (non-intervention) group. One participant in the intervention group discontinued from the study prior to treatment and one participant in the control group withdrew consent and was discontinued from the study. All nine participants randomized to the control group elected to crossover and receive LUXTURNA after one year of observation. All participants in these studies continue to be followed for long-term safety and efficacy. LUXTURNA Phase 3 clinical trial data, including data from the intervention group of all randomized participants through the one-year time point has been previously reported in (The Lancet).

The efficacy of LUXTURNA in the Phase 3 study was established based on the multi-luminance mobility test (MLMT) score change from baseline to one year. MLMT was designed to measure changes in functional vision as assessed by the ability of a participant to navigate a course accurately and at a reasonable pace at seven different levels of illumination, ranging from 400 lux (corresponding to a brightly lit office) to one lux (corresponding to a moonless summer night). Each light level was assigned a score ranging from zero to six, with a higher score indicating that a participant could pass MLMT at a lower light level. A score of negative one was assigned to participants who could not pass MLMT at a light level of 400 lux. MLMT score change was defined as the difference between the score at baseline and the score at one year with a positive score change indicating that a participant was able to complete MLMT at a lower light level. Additional clinical outcomes included white light full-field light sensitivity threshold (FST) testing and visual acuity.

LUXTURNA Phase 3 clinical study results showed a statistically significant difference between the intervention group (n=21) and control participants (n=10) at one year in median bilateral MLMT score change (intervention minus control group difference of 2; p=0.001) and median first-treated eye MLMT score change (intervention minus control group difference of 2; p=0.003). After crossing over to receive LUXTURNA, participants in the control group showed a similar response to those in the intervention group. The median bilateral MLMT score change of two was observed for the intervention group at the 30-day timepoint. This change score has been sustained for at least three years for the original intervention group and at least two years in the crossover group in the Phase 3 clinical study. In addition, participants who received LUXTURNA showed a statistically significant improvement from baseline to one year in white light FST in the intervention group compared to the control group. The change in visual acuity from baseline to one year was not significantly different between the intervention and control participants.

The U.S. Prescribing Information for LUXTURNA includes the following Warnings and Precautions: endophthalmitis; permanent decline in visual acuity; retinal abnormalities; increased intraocular pressure; expansion of intraocular air bubbles; and cataract. The most common adverse reactions (incidence □ 5%) were conjunctival hyperemia, cataract, increased

intraocular pressure, retinal tear, dellen (thinning of the corneal stroma), macular hole, subretinal deposits, eye inflammation, eye irritation, eye pain and maculopathy (wrinkling on the surface of the macula).

Cautionary note on forward-looking statements

This report contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding the company's product LUXTURNA™ (voretigene neparvovec-rzyl). The words ''anticipate,'' ''believe,'' ''expect,'' ''intend,'' ''may,'' ''plan,'' ''predict,'' ''will,'' ''would,'' ''could,'' ''should,'' ''continue'' and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Any forward-looking statements are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in, or implied by, such forward-looking statements. These risks and uncertainties include, but are not limited to, the risk that: (i) we do not enter into agreements with Harvard Pilgrim, affiliates of Express Scripts or other commercial insurers to make LUXTURNA available for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy; (ii) payers, health benefit providers, physicians and hospitals do not believe access to therapy is a shared responsibility; (iii) our payer and patient offerings will not ensure eligible patients have the coverage and financial support they need to gain access to LUXTURNA and the required specialized medical care; (iv) payers terminate any agreements they enter into with us; (v) our proposal to the Centers for Medicare & Medicaid Services (CMS) is not accepted; (vi) in the event our proposal to CMS does result in our ability to offer an installment option, payers do not accept alternative payment options from our distributor; (vii) the improvements in functional vision demonstrated by LUXTURNA in our clinical trials may not be sustained over extended periods of time; and (vii) any one or more of our product candidates in preclinical or clinical development will not successfully be developed and commercialized. For a discussion of other risks and uncertainties, and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements, see the "Risk Factors" section, as well as discussions of potential risks, uncertainties and other important factors, in our Annual Report on Form 10-K, our Quarterly Reports on Form 10-Q and other filings we make with the Securities and Exchange Commission. All information in this report is as of the date of the release, and Spark undertakes no duty to update this information unless required by law.

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 3, 2018

By: /s/ Joseph W. La Barge
Joseph W. La Barge
Chief Legal Officer