

**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): July 20, 2017**

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

**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**001-36819**  
(Commission  
File Number)

**46-2654405**  
(IRS Employer  
Identification No.)

**3737 Market Street  
Suite 1300  
Philadelphia, PA**  
(Address of Principal Executive Offices)

**19104**  
(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.

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**Item 8.01**            **Other Events.**

On July 20, 2017, Spark Therapeutics, Inc., issued a press release announcing that the Offices of Orphan Products Development and Pediatric Therapeutics of the U.S. Food and Drug Administration have designated investigational LUXTURNA™ (voretigene neparvovec) as a drug for a rare pediatric disease.

A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

**Item 9.01.**            **Financial Statements and Exhibits.**

(d) Exhibits

Exhibit 99.1                      Press release issued by Spark Therapeutics, Inc., dated July 20, 2017.

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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: July 21, 2017

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

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**Exhibit Index**

Exhibit 99.1

Press release issued by Spark Therapeutics, Inc., dated July 20, 2017.

## Spark Therapeutics Receives Rare Pediatric Disease Designation for Investigational LUXTURNA™ (voretigene neparvovec) from FDA

PHILADELPHIA, July 20, 2017--[Spark Therapeutics](#) (NASDAQ:ONCE), a fully integrated gene therapy company dedicated to challenging the inevitability of genetic disease, announced today that the Offices of Orphan Products Development and Pediatric Therapeutics of the U.S. Food and Drug Administration (FDA) have designated investigational LUXTURNA™ (voretigene neparvovec) as a drug for a rare pediatric disease. Under FDA's Rare Pediatric Disease Priority Review Voucher program, companies who receive approval for a new drug application or Biologics License Application (BLA) for a rare pediatric disease may be eligible to receive a voucher for a Priority Review of a subsequent marketing application for a different product. The Priority Review Voucher may be used by the company or sold to a third party.

FDA's Office of Tissues and Advanced Therapies currently is reviewing the BLA for LUXTURNA for the treatment of patients with vision loss due to confirmed biallelic *RPE65* mutation-associated retinal dystrophy under a Priority Review designation with a Prescription Drug User Fee Act (PDUFA) action date of Jan. 12, 2018.

LUXTURNA has the potential to be both the first pharmacologic treatment for an inherited retinal disease (IRD) and the first gene therapy for a genetic disease approved in the United States. A natural history study has shown that people with this IRD eventually progress to complete blindness.

### About Spark Therapeutics

Spark Therapeutics, a fully integrated company, strives to challenge the inevitability of genetic disease by discovering, developing, and delivering gene therapies that address inherited retinal diseases (IRDs), neurodegenerative diseases, as well as diseases that can be addressed by targeting the liver. Our validated platform successfully has delivered proof-of-concept data with investigational gene therapies in the retina and liver. Our most advanced investigational candidate, with proposed trade name LUXTURNA™ (voretigene neparvovec), is currently under Priority Review with FDA for the treatment of biallelic *RPE65*-mediated IRD and has been designated for a rare pediatric disease. It previously received breakthrough therapy and orphan product designations from FDA and orphan product designations from the European Medicines Agency (EMA). The pipeline also includes *SPK-7001* in a Phase 1/2 trial for choroideremia, and two hemophilia development programs: *SPK-9001* (which also has received both breakthrough therapy and orphan product designations by FDA, and access to the Priority Medicines (PRIME) Program by the EMA) in a Phase 1/2 trial for hemophilia B being developed in collaboration with Pfizer, and *SPK-8011*, in a Phase 1/2 trial for hemophilia A to which Spark Therapeutics retains global commercialization rights. For more information, visit [www.sparktx.com](http://www.sparktx.com).

### Cautionary note on forward-looking statements

This release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding the company's product candidate LUXTURNA™ (voretigene neparvovec). 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) our BLA submitted for LUXTURNA to the FDA may not be approved;

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(ii) the data from our Phase 3 clinical trial of LUXTURNA may not support labeling for all biallelic *RPE65* mutations other than Leber congenital amaurosis (LCA); (iii) the improvements in functional vision demonstrated by LUXTURNA in our clinical trials may not be sustained over extended periods of time; and (iv) FDA may ultimately determine not to award the Company a priority review voucher. 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 press release is as of the date of the release, and Spark undertakes no duty to update this information unless required by law.

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