

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

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 July 17, 2017, Spark Therapeutics, Inc., issued a press release announcing that the U.S. Food and Drug Administration (FDA) has accepted for filing the Biologics License Application and granted Priority Review for voretigene neparvovec, an investigational, potential one-time gene therapy candidate for the treatment of patients with vision loss due to confirmed biallelic RPE65-mediated inherited retinal disease, which has the proposed trade name LUXTURNA™ (voretigene neparvovec). FDA has assigned a Prescription Drug User Fee Act date of January 12, 2018 for its review of LUXTURNA.

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 17, 2017.

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 17, 2017 By: /s/ Joseph W. La Barge
Joseph W. La Barge
Chief Legal Officer

Exhibit Index

Exhibit 99.1 Press release issued by Spark Therapeutics, Inc., dated July 17, 2017.