Spark Therapeutics, Inc.
Form 8-K
May 19, 2016

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): May 19, 2016

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))

Item 8.01. Other Information

On May 19, 2016, Spark Therapeutics, Inc. (the "Company") issued a joint press release with Pfizer Inc. announcing that new data will be presented on June 11 at the European Hematology Association's (EHA) 21st Congress. These data will show encouraging initial observations for the first subjects dosed in the Phase 1/2 clinical trial of SPK-9001, the lead investigational compound in the SPK-FIX program, which is being studied for the treatment of Hemophilia B.

Data available today demonstrate that the first three subjects enrolled in the study experienced AAV-mediated Factor IX activity levels following one administration of SPK-9001 at the initial dose level (5×10^{11} vg/kg) studied in the trial. Factor IX activity levels in the first two subjects without prior history of liver disease, rose consistently through the first four weeks post-administration.

At the time of abstract submission, the first subject stabilized at 28% of normal at eighteen weeks, and the second subject at 30% of normal at seven weeks post-administration. Factor IX activity level in the third subject, with a history of liver disease, also rose consistently and was at 16% of normal at three weeks post-administration. Data from a natural history of patients with hemophilia suggest that circulating factor activity levels sustained at a threshold of greater than or equal to 12% of normal generally are considered to be sufficient to reduce the risk of joint bleeds and the need for prophylactic clotting factor infusions.

Over the combined 28 weeks of observation reported in the abstract, none of the three subjects received regular infusions of Factor IX concentrates to prevent bleeding events. Only one precautionary infusion has taken place due to a suspected ankle bleed in one subject two days after administration of vector. SPK-9001 has been well-tolerated and no subjects have needed, or received, immunosuppression.

Spark and Pfizer entered into a collaboration in 2014, under which Spark will be responsible for conducting all Phase 1/2 studies for any product candidates that may be developed under the SPK-FIX program, while Pfizer will assume responsibility for pivotal studies, any regulatory activities and potential global commercialization of any products that may result from the collaboration.

Up-to-date results from the trial will be presented at the EHA Congress on June 11 by Dr. Spencer Sullivan, an Assistant Professor of Pediatrics and Medicine at the University of Mississippi Medical Center, one of the trial investigators.

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: May 19, 2016	By:	/s/ Joseph W. La Barge Joseph W. La Barge General Counsel