

**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): February 22, 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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Item 2.02. Results of Operations and Financial Condition

On February 22, 2017, Spark Therapeutics, Inc. (the “Company”) issued a press release announcing unaudited consolidated financial results for the year ended December 31, 2016. A copy of the press release is being filed as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Form 8-K (including Exhibit 99.1) shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by preference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

The following exhibit relating to Item 2.02 shall be deemed to be furnished, and not filed:

Exhibit 99.1	Press release issued by Spark Therapeutics, Inc., dated February 22, 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: February 22, 2017

By: /s/ Joseph W. La Barge
Joseph W. La Barge
General Counsel

Exhibit Index

Exhibit 99.1	Press release issued by Spark Therapeutics, Inc., dated February 22, 2017.
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Spark Therapeutics Reports 2016 Financial Results and Business Highlights

Investigational voretigene neparvovec Biologics License Application (BLA) on track for completion in early 2017

Three additional clinical-stage programs continue to advance, including initiation of hemophilia A Phase 1/2 trial

PHILADELPHIA, Feb. 22, 2017 (Globe Newswire)- Spark Therapeutics (NASDAQ: ONCE), a fully integrated gene therapy company dedicated to challenging the inevitability of genetic disease, today announced financial results for the year 2016 and updated investors on business highlights.

“In 2016, we strengthened our gene therapy platform with proof-of-concept data validating two distinct target tissues - the retina and the liver - while continuing to expand our fully integrated capabilities,” said Jeffrey D. Marrazzo, chief executive officer. “We are in the final stages of completing our rolling BLA submission for investigational voretigene neparvovec for biallelic *RPE65*-mediated inherited retinal disease (IRD). Another highlight of the year was the release of encouraging investigational *SPK-9001* Phase 1/2 trial data that give us hope that we may be able to eliminate the need for regular infusions to control and prevent bleeding episodes for people living with hemophilia B. We look forward to continued innovation, execution and growth in 2017, which may be a historic year for Spark Therapeutics and for patients as we potentially deliver what has been unimaginable before - the first gene therapy in the U.S. for a genetic disease.”

Twelve-month highlights:

Advanced investigational voretigene neparvovec for the treatment of biallelic RPE65-mediated IRD:

- Significant progress on regulatory submissions
 - Clinical modules of the BLA have been submitted to the U.S. Food and Drug Administration (FDA)
 - Finished required work for all 24 assays and necessary manufacturing runs, with submission of the CMC module pending the finalization of remaining release and stability testing
 - MAA submission expected to shortly follow BLA completion
- FDA granted request to amend the orphan drug designation to “the treatment of inherited retinal dystrophy due to biallelic *RPE65* mutations,” which aligns with the proposed scientifically appropriate labeling
- Disclosed significant new clinical data that further enhance the compelling package of clinical data supporting our BLA submission for investigational voretigene neparvovec
 - Sustained four-year average improvement in functional vision and visual function across a Phase 1 cohort
 - Showed one-year efficacy data from the Phase 3 crossover group
 - Sustained two-year average improvement in functional vision and visual function across the original intervention group from the Phase 3 clinical trial
 - Showed a mean increase in visual field (VF) of 302.1 sum total degrees from baseline at year one, while the control group saw a mean decrease of 76.7 sum total degrees (nominal $p = 0.006$)
 - Safety results in the clinical program have been consistent to date
- Presented natural history data confirming early, profound vision loss with continuous decline to complete blindness and loss of functional vision
 - Confirmed degenerative course of biallelic *RPE65*-mutation-associated IRD and enhanced the understanding of the clinical significance of voretigene neparvovec clinical trial results
 - Showed statistically significant effect of age on both visual acuity (VA) ($p < 0.001$) and on VF - both Goldmann III4e and V4e ($p = 0.0001$)

Progressed two hemophilia programs, including encouraging preliminary proof-of-concept in hemophilia B:

- Completed enrollment of 10 participants in *SPK-9001* Phase 1/2 trial, in collaboration with Pfizer

- Released data on the first nine participants in the trial, all of whom to date have experienced beneficial effect from the investigational therapy. Eight of the nine participants saw a 100 percent reduction in the use of factor concentrates and in the number of confirmed bleeds. One participant has taken precautionary factor concentrate infusions for suspected bleeds.
- Only two of the first nine participants have experienced asymptomatic, transient elevation in liver enzymes associated with a T-cell response; both were put on a course of tapering corticosteroids and neither has experienced a bleed or needed factor concentrates
- Received breakthrough therapy designation from the FDA
- Initiated Phase 1/2 clinical trial for *SPK-8011* in hemophilia A

Advancing investigational SPK-7001 for choroideremia:

- Enriching dataset in current Phase 1/2 trial by expanding the current dose cohort with an additional five participants

Bolstered organizational capabilities, human capital, technology platform and financial position as we expand our fully integrated organization

- Continued preparations for potential market introduction of investigational voretigene neparvovec in U.S. and E.U.
- Continued to grow our team across all disciplines, with the number of employees now at more than 200
- Further strengthened our technology platform with collaborations, including licensing Selecta Biosciences' proprietary synthetic vaccine particles to potentially enable re-dosing patients receiving gene therapies in up to five targets including factor VIII for hemophilia A
- Balance sheet remains strong, with \$318.1 million in cash and cash equivalents and marketable securities at Dec. 31, 2016, which excludes the \$15.0 million milestone payment we earned from Pfizer in December 2016.

Financial results

Year Ended December 31, 2016 and 2015

In the year ended Dec. 31, 2016, we recognized \$20.2 million in revenue, which was all associated with our Pfizer agreement, and included a \$15.0 million milestone payment that was earned in December 2016. In the year ended Dec. 31, 2015, we recognized \$22.1 million in revenue, of which \$20.2 million was associated with our Pfizer agreement, and included a \$15.0 million milestone payment that was achieved in December 2015.

Our research and development expenses for the year ended Dec. 31, 2016 were \$86.4 million versus \$46.0 million for the year ended Dec. 31, 2015. The \$40.4 million increase was due to a \$30.1 million increase in internal research and development expenses, due to increased effort and headcount in research, technical operations and manufacturing, medical affairs, diagnostics, quality assurance and quality control and an increase of \$10.3 million in external research and development.

Our acquired in-process research and development expense for the year ended Dec. 31, 2016 was \$11.1 million. This amount represents the upfront payment related to a license agreement entered into with Selecta Biosciences, Inc. We had no acquired in-process research and development expense for the year ended Dec. 31, 2015.

General and administrative expenses for the year ended Dec. 31, 2016 were \$48.1 million versus \$23.4 million for the year ended Dec. 31, 2015. General and administrative expenses consist primarily of salaries and related costs, including stock-based compensation, legal and patent costs and other professional fees. The \$24.7 million increase primarily was due to an increase of \$15.2 million in salaries and related costs, including stock-based compensation, linked to increased headcount, and an increase of \$9.5 million in launch preparation activities for voretigene neparvovec, legal and patent expenses, professional fees and other operating costs.

Our net loss applicable to common stockholders for the year ended Dec. 31, 2016 was \$123.7 million, or (\$4.29)

basic and diluted net loss per common share, as compared with a net loss applicable to common stockholders of \$47.8 million, or (\$2.10) basic and diluted net loss per common share for the year ended Dec. 31, 2015.

As of Dec. 31, 2016, Spark had cash and cash equivalents and marketable securities of \$318.1 million, which does not include the \$15.0 million milestone payment we received in January from Pfizer.

Conference call details

Spark Therapeutics will host a conference call and audio webcast to discuss corporate and financial results for full year 2016 and recent events today, Feb. 22, at 8:30 a.m. ET. The call can be accessed by dialing the numbers below or by visiting the "Investors" section at www.sparktx.com.

U.S. Dial-in Number: (855) 851-4526

International Dial-in Number: (720) 634-2901

Passcode: 69899623

A replay of the call will be available for one week following the call by dialing the numbers below or also available on our website.

Replay Dial-in Number: (855) 859-2056

Replay International Dial-in Number: (404) 537-3406

Passcode: 69899623

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, voretigene neparvovec, in development for the treatment of biallelic *RPE65*-mediated IRD, has received orphan designations in the U.S. and European Union, and breakthrough therapy designation in the U.S. 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) 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. To learn more about us and our growing pipeline, visit 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 candidates, including voretigene neparvovec, *SPK-9001* and *SPK-8011*. 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) the data from our Phase 3 clinical trial of voretigene neparvovec may not support labeling for all biallelic *RPE65* mutations other than Leber congenital amaurosis (LCA); (ii) the improvements in functional vision demonstrated by voretigene neparvovec in our clinical trials may not be sustained over extended periods of time; and (iii) we could experience delays in submitting our regulatory filings, including our Biologics Licensing Application with FDA and, once submitted, such regulatory filings may not be approved; (iv) preclinical results for our product candidate, *SPK-8011*, for hemophilia A may not translate to humans in clinical trials; (v) our lead *SPK-FIX* product candidate, *SPK-9001*, may not produce sufficient data in our Phase 1/2 clinical trial to warrant further development; (vi) our overall collaboration with Pfizer may not be successful; 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 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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Spark Therapeutics, Inc.
Consolidated balance sheets
(unaudited)

	December 31, 2015	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	\$ 293,530,590	\$ 58,923,097
Marketable securities	—	237,242,655
Other receivables	16,944,568	16,780,917
Prepaid expenses	1,132,626	1,647,008
Total current assets	311,607,784	314,593,677
Marketable securities	—	21,900,129
Property and equipment, net	16,999,445	19,794,306
Acquired in-process research and development	—	15,490,000
Goodwill	—	2,096,119
Other assets	1,165,285	924,579
Total assets	<u>\$ 329,772,514</u>	<u>\$ 374,798,810</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 9,687,594	\$ 9,928,737
Accrued expenses	6,529,263	13,826,920
Current portion of long-term debt	—	302,013
Current portion of deferred rent	715,959	771,196
Current portion of deferred revenue	5,182,835	5,168,674
Total current liabilities	22,115,651	29,997,540
Long-term debt	—	1,224,003
Long-term deferred rent	8,084,509	7,498,419
Long-term deferred revenue	9,034,559	3,865,885
Deferred tax liability	—	1,936,250
Total liabilities	39,234,719	44,522,097
Stockholders' equity:		
Preferred stock, \$0.001 par value. Authorized, 5,000,000 shares; no shares issued or outstanding	—	—
Common stock, \$0.001 par value. Authorized, 150,000,000 shares; 27,082,493 shares issued and 27,073,287 outstanding at December 31, 2015; 30,873,430 shares issued and 30,864,224 outstanding at December 31, 2016	27,083	30,874
Additional paid-in capital	419,791,732	583,973,682
Accumulated other comprehensive loss	—	(794,296)
Treasury stock, at cost 9,206 shares at December 31, 2015 and 2016	(552,636)	(552,636)
Accumulated deficit	(128,728,384)	(252,380,911)
Total stockholders' equity	290,537,795	330,276,713
Total liabilities and stockholders' equity	<u>\$ 329,772,514</u>	<u>\$ 374,798,810</u>

Spark Therapeutics, Inc.
Consolidated statements of operations
(unaudited)

	For the Year Ended December 31,		
	2014	2015	2016
Revenues	\$ 633,932	\$ 22,063,674	\$ 20,182,835
Operating expenses:			
Research and development	16,351,005	46,029,314	86,379,405
Acquired in-process research and development	750,000	—	11,132,146
General and administrative	7,863,256	23,352,171	48,070,317
Total operating expenses	24,964,261	69,381,485	145,581,868
Loss from operations	(24,330,329)	(47,317,811)	(125,399,033)
Interest income, net	5,520	192,033	1,746,506
Net loss	(24,324,809)	(47,125,778)	(123,652,527)
Preferred stock dividends	(707,342)	(634,794)	—
Net loss applicable to common stockholders	\$ (25,032,151)	\$ (47,760,572)	\$ (123,652,527)
Basic and diluted net loss per common share	\$ (4.64)	\$ (2.10)	\$ (4.29)
Weighted average basic and diluted common shares outstanding	5,397,599	22,710,105	28,804,133

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