

**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): November 7, 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.

Item 2.02. Results of Operations and Financial Condition

On November 7, 2017, Spark Therapeutics, Inc. issued a press release announcing unaudited consolidated financial results for the quarter ended September 30, 2017. 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 Current Report on 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 reference 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 November 7, 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: November 7, 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 November 7, 2017.

Spark Therapeutics Reports Third Quarter 2017 Financial Results and Recent Business Progress

PHILADELPHIA, Nov. 7, 2017 (GLOBE NEWSWIRE)- Spark Therapeutics (NASDAQ: ONCE), a fully integrated gene therapy company dedicated to challenging the inevitability of genetic disease, announced today financial results for the third quarter of 2017 and recent business progress.

“We have made important progress over the last several months with investigational LUXTURNA™ (voretigene neparvovec) for patients with biallelic *RPE65*-mediated inherited retinal disease (IRD),” said Jeffrey D. Marrazzo, chief executive officer of Spark Therapeutics. “We are very pleased with the outcome of the Advisory Committee meeting, including the unanimous vote to recommend approval of LUXTURNA, with the completion of FDA pre-approval inspections of our manufacturing facility and clinical trial sites, as well as with our progress preparing for the potential launch of this first pharmacologic treatment for an IRD.”

Additional highlights

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

- U.S. Food and Drug Administration’s (FDA) Cellular, Tissue and Gene Therapies Advisory Committee unanimously recommended (16-0) approval of LUXTURNA
- Completed FDA pre-approval inspections with no major observations cited
- Marketing Authorization Application (MAA) has been validated by European Medicines Agency (EMA)

Progressed hemophilia programs:

- Dosed two additional participants in *SPK-8011* Phase 1/2 clinical trial - a second participant at 1e12 vg/kg and a first participant at a third dose of 2e12 vg/kg, bringing the number of participants enrolled to five
- *SPK-8011* data and *SPK-9001* interim data accepted for oral presentations at American Society of Hematology (ASH) annual meeting on Dec. 11, 2017
- Entered into an amendment to the license agreement for *SPK-9001* with Pfizer; will receive from Pfizer initial \$10 million cash payment and up to an additional \$15 million in potential milestone payments upon completion of certain transition activities

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

- Entered into a licensing agreement with Genethon for the development and commercialization of an adeno-associated viral (AAV) gene therapy targeting the liver to address a rare genetic disease
 - Appointed Federico Mingozzi, Ph.D., as chief scientific officer
 - Strong balance sheet with \$574.9 million in cash, cash equivalents and marketable securities as of Sept. 30, 2017
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Financial results for the quarter ended September 30, 2017

Three Months Ended September 30, 2017 and 2016

In the three months ended September 30, 2017 and 2016, we recognized \$1.9 million and \$1.3 million, respectively, of revenue associated with our Pfizer collaboration.

Our research and development expenses for the three months ended September 30, 2017 were \$39.3 million versus \$22.4 million for the three months ended September 30, 2016. The \$17.0 million increase was due to a \$14.6 million increase in internal research and development expenses, primarily due to increased headcount, and an increase of \$2.4 million in external research and development costs. The increase in external research and development was primarily from an increase of \$2.3 million in our SPK-FVIII program and \$0.1 million in our other clinical programs.

General and administrative expenses for the three months ended September 30, 2017 were \$26.6 million versus \$12.0 million for the three months ended September 30, 2016. The \$14.6 million increase was primarily due to an increase of \$7.2 million in salaries and related costs, including stock-based compensation, as a result of increased headcount, an increase of \$2.6 million in launch preparation activities for LUXTURNA and \$4.8 million in legal and patent expenses, professional fees and other operating costs.

Our net loss for the three months ended September 30, 2017 was \$65.0 million, or (\$1.90) basic and diluted net loss per common share, as compared with a net loss of \$32.6 million, or (\$1.07) basic and diluted net loss per common share for the three months ended September 30, 2016.

Nine Months Ended September 30, 2017 and 2016

In the nine months ended September 30, 2017 and 2016, we recognized \$4.7 million and \$3.9 million, respectively, of revenue associated with our Pfizer collaboration.

Our research and development expenses for the nine months ended September 30, 2017 were \$104.7 million versus \$60.3 million for the nine months ended September 30, 2016. The \$44.4 million increase was due to a \$35.4 million increase in internal research and development expenses, primarily due to increased headcount, and an increase of \$9.0 million in external research and development. The increase in external research and development was primarily from an increase of \$2.9 million in expenses related to LUXTURNA, \$2.3 million in our SPK-FVIII program, \$2.0 million in our other clinical programs, and \$1.8 million in our programs in preclinical development.

During the nine months ended September 30, 2017, we recorded a non-cash impairment charge of \$15.7 million related to acquired in-process research and development from a March 2016 acquisition. Additionally, we recognized an income tax benefit of \$1.0 million related to the reversal of the deferred tax liability associated with the IPR&D during the nine months ended September 30, 2017.

General and administrative expenses for the nine months ended September 30, 2017 were \$74.8 million versus \$31.6 million for the nine months ended September 30, 2016. The \$43.2 million increase was primarily due to an increase of \$20.7 million in salaries and related costs, including stock-based compensation, as a result of increased headcount, an increase of \$7.4 million in launch preparation activities for LUXTURNA and \$15.1 million in legal and patent expenses, professional fees and other operating costs.

Our net loss for the nine months ended September 30, 2017 was \$191.7 million, or (\$5.89) basic and diluted net loss per common share, as compared with a net loss of \$86.8 million, or (\$3.08) basic and diluted net loss per common share for the nine months ended September 30, 2016.

As of September 30, 2017, we had cash and cash equivalents and marketable securities of \$574.9 million, with 36.9 million shares outstanding.

Conference call details

Spark Therapeutics will host a conference call and audio webcast, today, Tuesday, Nov. 7, at 8:30 a.m. ET, to discuss financial results for the third quarter of 2017 and recent business progress. 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: 5468349

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: 5468349

About Spark Therapeutics

At Spark Therapeutics, a fully integrated company committed to discovering, developing and delivering gene therapies, we challenge the inevitability of genetic diseases, including blindness, hemophilia and neurodegenerative diseases. We have successfully applied our technology directed to the retina and liver, and currently have four programs in clinical trials or under regulatory review, including the first potential gene therapy for a genetic disease in the United States and product candidates that have shown promising early results in patients with hemophilia. At Spark, we see the path to a world where no life is limited by genetic disease. For more information, visit www.sparktx.com, and follow us on [Twitter](#) and [LinkedIn](#).

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 LUXTURNA (voretigene neparvovec), *SPK-7001*, *SPK-9001* and *SPK-8011*. 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) our BLA or MAA for LUXTURNA may not be approved by the FDA or EMA, respectively; (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; (iv) interim data from our *SPK-7001* Phase 1/2 clinical trial, including data to be generated from our recently expanded cohort, may not support further development of this product candidate; (v) our early preliminary clinical results for our product candidate, *SPK-8011*, for hemophilia A may not be sustained or sufficient to support further development; (vi) we may be unsuccessful in achieving higher factor VIII activity levels through dose escalation in our phase 1/2 clinical trial of *SPK-8011*; (vii) our lead *SPK-FIX* product candidate, *SPK-9001*, may not produce sufficient data in our Phase 1/2 clinical trial to warrant further development; (viii) our early preliminary data in our phase 1/2 clinical trial of *SPK-8011* have yet to be audited and therefore are subject to confirmation in connection with a clinical trial audit; and (ix) 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 Therapeutics undertakes no duty to update this information unless required by law.

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Spark Therapeutics, Inc.
Consolidated Balance Sheets
(Unaudited)

	December 31, 2016	September 30, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 58,923,097	\$ 146,434,119
Marketable securities	237,242,655	332,265,302
Other receivables	16,780,917	6,000,121
Prepaid expenses and other current assets	1,647,008	4,443,407
Total current assets	314,593,677	489,142,949
Marketable securities	21,900,129	96,199,671
Property and equipment, net	19,794,306	25,364,940
Acquired-in-process research and development	15,490,000	—
Goodwill	1,160,104	1,236,817
Other assets	924,579	723,806
Total assets	\$ 373,862,795	\$ 612,668,183
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 9,928,737	\$ 9,561,865
Accrued expenses	13,826,920	15,677,442
Current portion of long-term debt	302,013	309,455
Current portion of deferred rent	771,196	1,043,375
Current portion of deferred revenue	5,168,674	4,377,284
Total current liabilities	29,997,540	30,969,421
Long-term debt	1,224,003	990,973
Long-term deferred rent	7,498,419	10,302,813
Long-term deferred revenue	3,865,885	—
Deferred tax liability	1,000,235	—
Total liabilities	43,586,082	42,263,207
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; 30,873,430 shares issued and 30,864,224 shares outstanding as of December 31, 2016; 36,946,198 shares issued and 36,926,603 shares outstanding as of September 30, 2017	30,874	36,947
Additional paid-in capital	583,973,682	1,015,363,029
Accumulated other comprehensive (loss) income	(794,296)	232,444
Treasury stock, at cost, 9,206 shares as of December 31, 2016 and 19,595 shares as of September 30, 2017	(552,636)	(1,185,509)
Accumulated deficit	(252,380,911)	(444,041,935)
Total stockholders' equity	330,276,713	570,404,976
Total liabilities and stockholders' equity	\$ 373,862,795	\$ 612,668,183

Spark Therapeutics, Inc.
Consolidated Statements of Operations
(Unaudited)

	<u>Three months ended September 30,</u>		<u>Nine months ended September 30,</u>	
	<u>2016</u>	<u>2017</u>	<u>2016</u>	<u>2017</u>
Revenues	\$ 1,302,789	\$ 1,899,575	\$ 3,880,046	\$ 4,657,275
Operating expenses:				
Research and development	22,384,109	39,341,386	60,257,545	104,678,902
Acquired in-process research and development	—	1,750,000	—	5,207,142
Impairment of acquired in-process research and development	—	—	—	15,696,017
General and administrative	12,049,954	26,640,443	31,600,567	74,782,867
Total operating expenses	<u>34,434,063</u>	<u>67,731,829</u>	<u>91,858,112</u>	<u>200,364,928</u>
Loss from operations	(33,131,274)	(65,832,254)	(87,978,066)	(195,707,653)
Interest income, net	568,867	1,112,745	1,162,833	2,230,306
Loss before income taxes	(32,562,407)	(64,719,509)	(86,815,233)	(193,477,347)
Income tax (expense) benefit	—	(292,402)	—	1,816,323
Net loss	<u>\$ (32,562,407)</u>	<u>\$ (65,011,911)</u>	<u>\$ (86,815,233)</u>	<u>\$ (191,661,024)</u>
Basic and diluted net loss per common share	<u>\$ (1.07)</u>	<u>\$ (1.90)</u>	<u>\$ (3.08)</u>	<u>\$ (5.89)</u>
Weighted average basic and diluted common shares outstanding	<u>30,368,354</u>	<u>34,258,328</u>	<u>28,218,850</u>	<u>32,516,829</u>

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