

**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 8, 2018

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 May 8, 2018, Spark Therapeutics, Inc. issued a press release announcing unaudited consolidated financial results for the quarter ended March 31, 2018. 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 May 8, 2018.](#)

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 8, 2018

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 May 8, 2018.](#)

Spark Therapeutics Reports First Quarter 2018 Financial Results and Recent Business Progress

Achieved historic milestone with first patients treated with LUXTURNA™ (voretigene neparvovec-rzyl)

PHILADELPHIA, May 8, 2018 (GLOBE NEWSWIRE)- Spark Therapeutics (NASDAQ: ONCE), a fully integrated gene therapy company dedicated to challenging the inevitability of genetic disease, announced today corporate and financial results for the first quarter of 2018 and recent business progress.

“We are encouraged by the initial launch of LUXTURNA™ (voretigene neparvovec-rzyl). We are pleased that three patients were treated with LUXTURNA in the first quarter as we remain focused on working closely with treatment centers and payers to support timely access to the product,” said Jeffrey D. Marrazzo, chief executive officer of Spark Therapeutics. “Additionally, we progressed our pipeline of investigational gene therapies, including continuing to enroll our Phase 1/2 clinical trial of *SPK-8011* in hemophilia A and advancing our preparations for a Phase 3 clinical trial of *SPK-8011*.”

Recent highlights

Launched LUXTURNA in U.S., with three patients treated at different treatment centers - Massachusetts Eye and Ear in Boston, Bascom Palmer Eye Institute in Miami and The Vision Center at Children’s Hospital of Los Angeles

- Utilized direct-to-payer contracting
- Strong progress on commercial coverage, with more than 60 percent of commercial lives covered by acceptable medical policy
- Continued encouraging discussions with Centers for Medicare & Medicaid Services (CMS) on proposal for an installment payment option and flexibility to offer greater outcomes-based rebates

Progressed Marketing Authorization Application with European Medicines Agency (EMA) for investigational voretigene neparvovec; on track for regulatory action in Q3 2018

- Successfully completed EMA inspection of manufacturing facility in Philadelphia

Advanced two investigational hemophilia programs with no reported serious adverse events, thrombotic events or inhibitors to date

- Completed expanded enrollment in the Phase 1/2 clinical trial for *SPK-9001* in hemophilia B using vector generated from an enhanced manufacturing process designed to support commercial requirements
- Continued to enroll participants in the Phase 1/2 clinical trial for *SPK-8011* in hemophilia A

Bolstered financial position:

- Strong balance sheet with \$587.5 million in cash, cash equivalents and marketable securities as of March 31, 2018
- Entered into agreement to sell rare pediatric disease priority review voucher for \$110.0 million

Financial results for the quarter ended March 31, 2018

In the three months ended March 31, 2018, we recognized \$15.7 million in total revenue, of which \$2.4 million was net sales of LUXTURNA and \$13.3 million was associated with collaboration and supply agreements with Pfizer. In the three months ended March 31, 2017, we recognized \$1.3 million in revenue associated with our Pfizer agreement.

Cost of goods sold in the three months ended March 31, 2018 was \$0.1 million and consists of manufacturing, shipping and other costs, as well as royalties. A substantial portion of the production of our current inventory was completed prior to the U.S. Food and Drug Administration (FDA) approval and, therefore, was expensed as research and development expense last year.

Cost of contract revenue in the three months ended March 31, 2018 was \$0.9 million, and consists of manufacturing and other costs associated with our contract agreements.

Research and development expenses for the three months ended March 31, 2018, were \$30.1 million versus \$32.7 million for the three months ended March 31, 2017. The \$2.6 million decrease was due to a \$0.7 million decrease in internal research and development expenses and a \$1.9 million decrease in external research and development expenses. The \$0.7 million decrease in internal research and development was primarily due to a decrease in salaries and other related costs associated with LUXTURNA, which were allocated to inventory upon FDA approval. The \$1.9 million decrease in external research and development expenses was primarily due to a \$3.3 million decrease in expenses related to LUXTURNA and other clinical programs and a \$0.3 million decrease in other pipeline products, offset by an increase of \$1.7 million in expenses related to our hemophilia A program.

Selling, general and administrative expenses for the three months ended March 31, 2018, were \$33.5 million versus \$21.4 million for the three months ended March 31, 2017. The \$12.1 million increase primarily was due to an increase of \$7.0 million in salaries and related costs, including stock-based compensation, due to increased headcount to support the LUXTURNA launch, an increase of \$1.0 million in launch activities for LUXTURNA and \$4.1 million in legal and patent expenses, professional fees and other operating costs.

Our net loss applicable to common stockholders for the three months ended March 31, 2018 was \$46.4 million, or (\$1.25) basic and diluted net loss per common share, as compared to a net loss applicable to common stockholders of \$52.3 million, or (\$1.70) basic and diluted net loss per common share, for the three months ended March 31, 2017.

Conference call details

Spark Therapeutics will host a conference call and audio webcast, today, Tuesday, May 8, at 8:30 a.m. ET, to discuss corporate and financial results for the quarter that ended March 31, 2018. 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: 1483429

A replay of the call will be available for one week following the call and can be accessed by dialing (855) 859-2056 (domestic) or (404) 537-3406 (international), and entering passcode 1483429, or by visiting the "Investors" section at www.sparktx.com.

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 in the first FDA-approved gene therapy in the U.S. for a genetic disease, and currently have three programs in clinical trials, including 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 press 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, *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 MAA for LUXTURNA may not be approved by EMA; (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) in ex-US geographies; (iii) the improvements in functional vision demonstrated by LUXTURNA in our clinical trials may not be sustained over extended periods of time; (iv) voretigene neparvovec may not be approved in any markets outside of the U.S.; (v) if voretigene neparvovec is approved, Novartis may not be successful in commercializing or selling it in one or more markets; (vi) we may not receive any additional milestone or royalty payments from Novartis, Pfizer or our other collaborators; (vii) we may not close the transaction for the sale of our PRV voucher; (viii) our early preliminary clinical results for our product candidate, *SPK-8011*, for hemophilia A, may not be sustained or sufficient to support further development; (ix) we may be unsuccessful in achieving higher factor VIII activity levels through dose escalation in our Phase 1/2 clinical trial of *SPK-8011*; (x) we are unable to enter into agreements with payers for the provision of LUXTURNA; (xi) we will not be able to reach agreement with the Centers for Medicare & Medicaid Services (CMS) regarding LUXTURNA; (xii) our lead *SPK-FIX* product candidate, *SPK-9001*, may not produce sufficient data in our Phase 1/2 clinical trial to warrant further development; (xiii) 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; and (xiv) 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 press 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)
(in thousands, except share and per share data)

	December 31, 2017	March 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 96,748	\$ 127,687
Marketable securities	423,419	459,863
Trade and other receivables	7,906	21,180
Inventory	—	5,560
Prepaid expenses	5,093	6,684
Total current assets	533,166	620,974
Marketable securities	20,035	—
Property and equipment, net	61,713	62,874
Goodwill	1,254	1,290
Other assets	628	2,566
Total assets	\$ 616,796	\$ 687,704
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 14,183	\$ 15,156
Accrued expenses	24,697	13,868
Current portion of long-term debt	312	315
Current portion of deferred rent	969	979
Current portion of deferred revenue	11,969	22,712
Current other liabilities	1,557	1,609
Total current liabilities	53,687	54,639
Long-term debt	912	832
Long-term deferred rent	8,318	8,093
Long-term deferred revenue	—	105,000
Other liabilities	40,255	39,470
Total liabilities	103,172	208,034
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; 37,131,626 shares issued and 37,111,404 shares outstanding as of December 31, 2017; 37,275,791 shares issued and 37,222,651 shares outstanding as of March 31, 2018	37	37
Additional paid-in capital	1,026,590	1,040,906
Accumulated other comprehensive loss	(5,914)	(1,055)
Treasury stock, at cost, 20,222 shares as of December 31, 2017 and 53,140 shares as of March 31, 2018	(1,226)	(2,982)
Accumulated deficit	(505,863)	(557,236)
Total stockholders' equity	513,624	479,670
Total liabilities and stockholders' equity	\$ 616,796	\$ 687,704

Spark Therapeutics, Inc.
Consolidated Statements of Operations
(Unaudited)
(in thousands, except share and per share data)

	Three months ended March 31,	
	2017	2018
Revenues:		
Product sales, net	\$ —	\$ 2,419
Contract revenue	1,274	13,257
Total revenues	1,274	15,676
Operating expenses:		
Cost of product sales	—	121
Cost of contract revenue	—	869
Research and development	32,735	30,109
Selling, general and administrative	21,413	33,489
Total operating expenses	54,148	64,588
Loss from operations	(52,874)	(48,912)
Unrealized gain on equity investments	—	364
Interest income, net	585	2,185
Loss before income taxes	(52,289)	(46,363)
Income tax expense	—	(10)
Net loss	\$ (52,289)	\$ (46,373)
Basic and diluted net loss per common share	\$ (1.70)	\$ (1.25)
Weighted average basic and diluted common shares outstanding	30,771,867	37,046,235

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