

**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 9, 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 May 9, 2017, Spark Therapeutics, Inc. (the “Company”) issued a press release announcing unaudited consolidated financial results for the quarter ended March 31, 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 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 9, 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: May 9, 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 May 9, 2017.

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

Work on U.S. Biologics License Application (BLA) for investigational voretigene neparvovec is complete

Interim results from SPK-7001 Phase 1/2 clinical trial in choroideremia reported; continuing enrollment targeting participants at earlier stage of disease

PHILADELPHIA, May 9, 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 first quarter of 2017 and recent business progress.

“I’m pleased to announce that our work on the rolling BLA for voretigene neparvovec for biallelic *RPE65*-mediated inherited retinal disease is now complete. The application formally will be submitted to the FDA next week,” said Jeffrey D. Marrazzo, chief executive officer. “We are excited to reach this major milestone, and will now shift our immediate regulatory focus to completing the Marketing Authorization Application submission for Europe by the end of July. Today, we report interim results of our second investigational gene therapy for a retinal disease, *SPK-7001* in choroideremia, and that we plan to provide an initial update on the Phase 1/2 trial for *SPK-8011* in hemophilia A in July or August 2017.”

Recent highlights

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

- Progressed regulatory submissions in U.S. and EU
 - U.S. BLA is complete and ready for submission next week

Announced interim results of investigational SPK-7001 for choroideremia Phase 1/2 clinical trial:

- Reported interim safety results for the first 10 participants with later-stage disease
 - No reported product-related serious adverse events (SAEs) and one procedure-related SAE
 - As of the March 29, 2017 data cutoff, interim efficacy analysis of the first 10 participants in the Phase 1/2 clinical trial did not show consistent and conclusive evidence of effect at the duration of follow-up in later-stage participants
 - However, non-significant differences between the injected and control eye were observed on one or more endpoints in four of the 10 participants in favor of the injected eye
 - Expanded enrollment of the second dose cohort with focus on participants with earlier-stage disease
 - Three of the five participants already have been enrolled
-

Reported updated data from investigational SPK-9001 for hemophilia B Phase 1/2 clinical trial at Hemostasis and Thrombosis Research Society 2017 Scientific Symposium:

- No SAEs have been reported to date, including no factor IX inhibitors and no thrombotic events
- Since vector administration, as of data cutoff of March 24, 2017, among the 10 participants, the annualized infusion rate had been reduced by 99 percent, and the annualized bleeding rate had been reduced by 96 percent
 - Nine of the 10 infused participants had not taken any factor IX concentrates to prevent or control bleeding events
 - Mean steady-state factor IX activity level post-12 weeks treatment for the 10 participants was a sustained 33 percent
- Two participants who experienced an asymptomatic, transient elevation in liver enzymes or a decline in FIX activity and received a tapering dose of oral corticosteroids, have completed their steroid taper. Importantly, both participants, now at 14 weeks and eight weeks post-cessation of steroids, have shown stable factor IX activity levels
 - Neither participant has experienced a bleed nor taken factor IX concentrates

Bolstered organizational capabilities and human capital:

- Continued preparations for potential introduction of investigational voretigene neparvovec in U.S. and EU
- Continued to grow our team across all disciplines, with the number of employees now at more than 240
- Balance sheet remains strong, with \$285.4 million in cash and cash equivalents and marketable securities at March 31, 2017

Financial results for the quarter ended March 31, 2017

In each of the three months ended March 31, 2017 and 2016, we recognized \$1.3 million of revenue associated with our Pfizer collaboration.

Spark Therapeutics' research and development expenses for the three months ended March 31, 2017 were \$32.7 million, compared with \$18.2 million for the three months ended March 31, 2016. The \$14.5 million increase was due to an \$11.4 million increase in internal research and development expenses, primarily due to significantly increased headcount, and an increase of \$3.1 million in external research and development, primarily from an increase of \$1.3 million in expenses related to studies to support and certain launch preparation activities for voretigene neparvovec, and an increase in our other clinical programs of \$1.2 million and \$0.6 million related to our other product candidates.

General and administrative expenses for the three months ended March 31, 2017 were \$21.4 million, compared with \$8.9 million for the three months ended March 31, 2016. The \$12.5 million increase was primarily due to an

increase of \$6.3 million in salaries and related costs, including stock-based compensation, due to increased headcount, and an increase of \$6.2 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 three months ended March 31, 2017 was \$52.3 million, or \$1.70 basic and diluted net loss per common share, as compared with a net loss applicable to common stockholders of \$25.6 million, or \$0.95 basic and diluted net loss per common share for the three months ended March 31, 2016.

As of March 31, 2017, we had cash and cash equivalents and marketable securities of \$285.4 million, with 31.1 million shares outstanding.

Conference call details

Spark Therapeutics will host a conference call and audio webcast, today, Tuesday, May 9, at 8:30 a.m. ET, to discuss corporate and financial results for the quarter that ended March 31, 2017. 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: 13840065

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: 13840065

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 by the FDA, and access to the PRiority MEdicines (PRIME) Program by the EMA) 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-7001*, *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) our BLA being submitted to the FDA may not be accepted, or, if accepted, may not be approved; (ii) 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); (iii) the improvements in functional vision demonstrated by voretigene neparvovec 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) preclinical results for our product candidate, *SPK-8011*, for hemophilia A may not translate to humans in clinical trials; (vi) our lead *SPK-FIX* product candidate, *SPK-9001*, may not produce sufficient data in our Phase 1/2 clinical trial to warrant further development; 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, 2016	March 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 58,923,097	\$ 27,495,174
Marketable securities	237,242,655	226,199,646
Other receivables	16,780,917	5,946,802
Prepaid expenses and other current assets	1,647,008	3,713,708
Total current assets	314,593,677	263,355,330
Marketable securities	21,900,129	31,700,984
Property and equipment, net	19,794,306	23,097,630
Acquired in-process research and development	15,490,000	14,950,531
Goodwill	1,160,104	1,119,564
Other assets	924,579	853,510
Total assets	\$ 373,862,795	\$ 335,077,549
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 9,928,737	\$ 14,021,116
Accrued expenses and other	13,826,920	9,097,776
Current portion of long-term debt	302,013	304,473
Current portion of deferred rent	771,196	1,140,735
Current portion of deferred revenue	5,168,674	5,168,674
Total current liabilities	29,997,540	29,732,774
Long-term debt	1,224,003	1,146,956
Long-term deferred rent	7,498,419	11,086,281
Long-term deferred revenue	3,865,885	2,591,418
Deferred tax liability	1,000,235	965,401
Total liabilities	43,586,082	45,522,830
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 at December 31, 2016; 31,086,809 shares issued and 31,077,603 shares outstanding at March 31, 2017	30,874	31,087
Additional paid-in capital	583,973,682	596,436,232
Accumulated other comprehensive loss	(794,296)	(1,689,721)
Treasury stock, at cost, 9,206 shares at December 31, 2016 and March 31, 2017	(552,636)	(552,636)
Accumulated deficit	(252,380,911)	(304,670,243)
Total stockholders' equity	330,276,713	289,554,719
Total liabilities and stockholders' equity	\$ 373,862,795	\$ 335,077,549

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

	Three months ended March 31,	
	2016	2017
Revenues	\$ 1,288,628	\$ 1,274,467
Operating expenses:		
Research and development	18,251,900	32,735,033
General and administrative	8,873,861	21,413,818
Total operating expenses	27,125,761	54,148,851
Loss from operations	(25,837,133)	(52,874,384)
Interest income	260,422	585,052
Net loss	\$ (25,576,711)	\$ (52,289,332)
Basic and diluted net loss per common share	\$ (0.95)	\$ (1.70)
Weighted average basic and diluted common shares outstanding	26,807,380	30,771,867

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