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 6, 2018

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))

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 6, 2018, Spark Therapeutics, Inc. issued a press release announcing unaudited consolidated financial results for the quarter ended September 30, 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 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 6, 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: November 6, 2018

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 6, 2018.

Exhibit 99.1

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

PHILADELPHIA, Nov. 6, 2018 (GLOBE NEWSWIRE)- Spark Therapeutics (NASDAQ: ONCE), a fully integrated, commercial gene therapy company dedicated to challenging the inevitability of genetic disease, announced today corporate and financial results for the third quarter of 2018 and recent business progress.

"In the third quarter, we made significant progress with LUXTURNA (voretigene neparvovec-rzyl) both in terms of sales growth and medical policy coverage expansion. We have also made important advancements in preparing for the Phase 3 run-in study of investigational *SPK-8011* for hemophilia A before year end," said Jeffrey D. Marrazzo, chief executive officer of Spark Therapeutics. "Additionally, we continue to capitalize on our proven and proprietary adeno-associated viral (AAV) gene therapy platform to develop liver-directed therapeutics. During the quarter we updated preclinical data on our investigative gene therapy for Pompe disease, which we expect to advance into the clinic in 2019."

Recent business highlights

Continued strong execution of LUXTURNA® (voretigene neparvovec)

- Shipped 24 vials of LUXTURNA in the U.S. in the third quarter of 2018
- Treated first two patients under the Spark PATH (Pioneering Access To Healthcare) outcomes-based contracting model
- Approximately 85 percent of commercial lives are covered by a satisfactory medical policy and all major, national payers now provide coverage for LUXTURNA
- Approximately 50 percent of government-covered lives are covered by satisfactory medical policy, with first government beneficiary treated
- Received positive opinion recommending LUXTURNA approval from the Committee for Medicinal Products for Human Use of the European Medicines Agency (EMA)

Progressed clinical programs for hemophilia A

- Expanding Phase 1/2 study for *SPK-8011* to include additional participants and preparing to initiate an observational Phase 3 run-in study by the end of year
- Preliminary Phase 1/2 data for *SPK-8011* accepted for oral presentation at American Society of Hematology (ASH) annual meeting
- Received orphan drug designation for *SPK-8011* from European Commission

- Received FDA clearance of Investigational New Drug (IND) application for *SPK-8016*, a novel, internally developed AAV gene therapy candidate aimed at addressing the hemophilia A inhibitor market

Completed all obligations in the transition of SPK-9001 *for hemophilia B to Pfizer*

- Pfizer announced in July the initiation of observational Phase 3 run-in study
- Delivered a batch of *SPK-9001* drug substance to Pfizer for use in initial dosing of the Phase 3 clinical trial

Presented IND-enabling study results for SPK-3006*, a liver-directed AAV gene therapy for Pompe disease*

- Announced new preclinical data at World Muscle Society International Congress showing decreased glycogen accumulation, increased survival and improved cardiac, respiratory and muscle function after administration of secretable, modified acid alpha-glucosidase (GAA) enzyme produced by *SPK-3006* in acid alpha-glucosidase knockout (Gaa-/-) mice
- Administration of a single infusion at three ascending doses in non-human primates demonstrated dose-dependent expression of GAA in plasma, reaching plasma levels that were equivalent to those found to be therapeutically effective in Pompe mice
- Plan to submit IND application and Clinical Trial Application to regulatory agencies and initiate a global Phase 1/2 clinical trial in adult participants in 2019

Bolstered human capital and Philadelphia facilities to support our fully integrated organization

- Appointed Kathleen Reape, M.D., head of Clinical R&D, as chief medical officer and Ron Philip, head of Global Commercial, as chief commercial officer
- Expanded our research & development facilities in West Philadelphia

Financial results for the three and nine months ended Sept. 30, 2018

Three Months Ended Sept. 30, 2018 and 2017

In the three months ended Sept. 30, 2018, we recognized $10.7 million in total revenue, of which $8.9 million was net sales of LUXTURNA and $1.8 million was associated with our agreements with Pfizer. In the three months ended Sept. 30, 2017, we recognized $1.9 million in total revenue associated with our Pfizer agreement.

Cost of goods sold in the three months ended Sept. 30, 2018, was $0.3 million, which consists of manufacturing, shipping and other costs, as well as royalties. A substantial portion of the inventory sold during the period was produced prior to FDA approval and, therefore, was expensed as research and development in 2017.

Our research and development expenses for the three months ended Sept. 30, 2018, were $32.8 million versus $39.3 million for the three months ended Sept. 30, 2017. The $6.5 million decrease was due to a decrease of $9.9 million in internal research and development expenses partially offset by a $3.4 million increase in external research and development expenses. The $9.9 million reduction in internal research and development expenses

primarily was the result of $5.9 million less in stock-based compensation and a decrease of $5.0 million in salaries and other related costs associated with LUXTURNA, which are allocated to inventory post-FDA approval. These costs were offset by a $1.0 million increase in rent and depreciation allocations. The $3.4 million growth in external research and development expenses primarily resulted from a $5.9 million increase in expenses related to our hemophilia A program, offset by $2.5 million less in expenses related to LUXTURNA.

We did not incur any acquired in-process research and development (IPR&D) expense during the three months ended Sept. 30, 2018. Our acquired IPR&D expense for the three months ended Sept. 30, 2017, was $1.8 million, related to a licensing agreement in 2017.

Selling, general and administrative expenses for the three months ended Sept. 30, 2018, were $29.3 million versus $26.6 million for the three months ended Sept. 30, 2017. The $2.7 million increase primarily was due to growth of $2.2 million in salaries and related costs, including stock-based compensation as a result of additional headcount and an increase of $1.3 million in legal and patent expenses, professional fees and other operating costs, offset by a reduction of $0.8 million in launch activities for LUXTURNA.

Our net loss for the three months ended Sept. 30, 2018, was $47.4 million, or ($1.26) basic and diluted net loss per common share, as compared to a net loss of $65.0 million, or ($1.90) basic and diluted net loss per common share, for the three months ended Sept. 30, 2017.

Nine Months Ended Sept. 30, 2018 and 2017

In the nine months ended Sept. 30, 2018, we recognized $51.6 million in total revenue, of which $15.6 million was net sales of LUXTURNA and $36.0 million was associated with our agreements with Pfizer. In the nine months ended Sept. 30, 2017, we recognized $4.7 million in total revenue associated with our Pfizer agreement.

Cost of goods sold in the nine months ended Sept. 30, 2018, was $0.7 million, which consists of manufacturing, shipping and other costs, as well as royalties. A substantial portion of the inventory sold during the period was produced prior to FDA approval and, therefore, was expensed as research and development expense last year.

Cost of contract revenue in the nine months ended Sept. 30, 2018, was $5.1 million, which consists of manufacturing and other costs associated with our agreements.

Our research and development expenses for the nine months ended Sept. 30, 2018, were $88.5 million compared with $104.7 million for the nine months ended Sept. 30, 2017. The $16.2 million decrease was due to a $16.4 million reduction in internal research and development expenses offset by growth of $0.2 million in external research and development expenses. The $16.4 million reduction in internal research and development expense primarily was the result of salaries and other LUXTURNA costs being reallocated to inventory following FDA

approval, as well as costs associated with contract revenue. The increase in external research and development expenses resulted from $10.1 million in expenses related to our hemophilia A program and $0.5 million in programs in preclinical development, offset by a $7.4 million decrease in expenses related to LUXTURNA and $3.0 million in other clinical programs.

We did not incur any acquired IPR&D expense during the nine months ended Sept. 30, 2018. Our acquired IPR&D expense for the nine months ended Sept. 30, 2017, was $5.2 million, primarily related to a licensing agreement in 2017.

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

Selling, general and administrative expenses for the nine months ended Sept. 30, 2018, were $92.5 million compared with $74.8 million for the nine months ended Sept. 30, 2017. The $17.7 million growth primarily was due to an increase of $12.6 million in salaries and related costs, including stock-based compensation, as a result of continued growth in our headcount and a $6.5 million increase in legal and patent expenses, professional fees and other operating costs. These costs were offset by a reduction of $0.9 million related to facilities and $0.5 million in launch activities for LUXTURNA.

We recognized $110.0 million of other income during the nine months ended Sept. 30, 2018, from the sale of our rare pediatric disease priority review voucher (PRV).

Our net loss for the nine months ended Sept. 30, 2018, was $13.6 million, or ($0.36) basic and diluted net loss per common share, as compared to a net loss of $191.7 million, or ($5.89) basic and diluted net loss per common share, for the nine months ended Sept. 30, 2017. Our loss for the nine months ended Sept. 30, 2018, was favorably impacted by the sale of our PRV in the second quarter.

As of Sept. 30, 2018, we had cash and cash equivalents, restricted cash and marketable securities of $671.4 million, with 37.6 million shares outstanding.

Conference call details
Spark Therapeutics will host a conference call and audio webcast, today, Tuesday, Nov. 6, at 8:30 a.m. ET, to discuss corporate and financial results for the quarter ended Sept. 30, 2018. The call can be accessed by dialing the numbers below or by visiting the “Investors” section of the Spark Therapeutics website at www.sparktx.com.

U.S. Dial-in Number: (855) 851-4526
International Dial-in Number: (720) 634-2901
Passcode: 2370749

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 2370749, or by visiting the “Investors” section at www.sparktx.com.

About Spark Therapeutics

At Spark Therapeutics, a fully integrated, commercial company committed to discovering, developing and delivering gene therapies, we challenge the inevitability of genetic diseases, including blindness, hemophilia, lysosomal storage disorders 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-3006,* 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) we may not continue to grow our sales and expand our medical policy coverage for LUXTURNA; (ii) our Marketing Authorization Application for LUXTURNA may not be approved by EMA; (iii) the improvements in functional vision demonstrated by LUXTURNA in our clinical trials may not be sustained over extended periods of time; (iv) we are unable to maintain or continue to enter into agreements with payers for the provision of LUXTURNA; (v) we will not be able to reach agreement with the Centers for Medicare & Medicaid Services (CMS) regarding LUXTURNA; (vi) our early preliminary clinical results for our product candidate, *SPK-8011*, for hemophilia A, may not be sustained; (vii) we may not be successful in initiating a Phase 3 clinical trial for *SPK-8011* and the timing and design of such trial may vary from our expectations; (viii) we may not advance our *SPK-3006* program into the clinic when anticipated, or at all; (ix) the data for *SPK-3006* IND-enabling studies may not be sustained; (x) our preliminary results of scale-up to non-human primates supporting the initiation of clinical studies of *SPK-3006* in humans may not be sustained; and (xi) 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.

Investor Contact:
Ryan Asay
Ryan.asay@sparktx.com
(215) 239-6424

Media Contact:
Monique da Silva
Monique.dasilva@sparktx.com
(215) 282-7470

Spark Therapeutics, Inc.
Consolidated Balance Sheets
(Unaudited)
(in thousands, except share and per share data)

	December 31, 2017	September 30, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 96,748	$ 161,557
Marketable securities	423,419	428,919
Trade and other receivables	7,906	13,506
Inventory	—	20,738
Prepaid expenses and other current assets	5,093	10,492
Total current assets	533,166	635,212
Restricted cash	—	53,000
Marketable securities	20,035	27,964
Property and equipment, net	61,713	87,280
Goodwill	1,254	1,214
Other assets	628	2,732
Total assets	$ 616,796	$ 807,402
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 14,183	$ 18,048
Accrued expenses	24,697	35,092
Current portion of long-term debt	312	3,320
Current portion of deferred rent	969	1,051
Current portion of deferred revenue	11,969	—
Current other liabilities	1,557	1,808
Total current liabilities	53,687	59,319
Long-term debt	912	47,671
Long-term deferred rent	8,318	7,658
Long-term deferred revenue	—	105,000
Other liabilities	40,255	37,879
Total liabilities	103,172	257,527
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; 37,684,255 shares issued and 37,610,295 shares outstanding as of September 30, 2018	37	38
Additional paid-in capital	1,026,590	1,078,989
Accumulated other comprehensive (loss) income	(5,914)	(225)
Treasury stock, at cost, 20,222 shares as of December 31, 2017 and 73,960 shares as of September 30, 2018	(1,226)	(4,498)
Accumulated deficit	(505,863)	(524,429)
Total stockholders' equity	513,624	549,875
Total liabilities and stockholders' equity	$ 616,796	$ 807,402

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

	Three months ended September 30,		Nine months ended September 30,	
	2017	2018	2017	2018
Revenues:				
Product sales, net	$ —	$ 8,866	$ —	$ 15,599
Contract revenue	1,900	1,841	4,657	35,969
Total revenues	1,900	10,707	4,657	51,568
Operating expenses:				
Cost of product sales	—	318	—	708
Cost of contract revenue	—	—	—	5,111
Research and development	39,341	32,829	104,679	88,462
Acquired in-process research and development	1,750	—	5,207	—
Impairment of acquired in-process research and development	—	—	15,696	—
Selling, general and administrative	26,641	29,305	74,783	92,543
Total operating expenses	67,732	62,452	200,365	186,824
Loss from operations	(65,832)	(51,745)	(195,708)	(135,256)
Unrealized gain on equity investments	—	1,672	—	4,291
Interest income, net	1,112	2,714	2,231	7,420
Other income	—	—	—	110,000
Loss before income taxes	(64,720)	(47,359)	(193,477)	(13,545)
Income tax benefit (expense)	(292)	2	1,816	(20)
Net loss	$ (65,012)	$ (47,357)	$ (191,661)	$ (13,565)
Basic and diluted net loss per common share	$ (1.90)	$ (1.26)	$ (5.89)	$ (0.36)
Weighted average basic and diluted common shares outstanding	34,258,328	37,498,616	32,516,829	37,267,942

# # #