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): August 7, 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 August 7, 2018, Spark Therapeutics, Inc. issued a press release announcing unaudited consolidated financial results for the quarter ended June 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 August 7, 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: August 7, 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 August 7, 2018.

Exhibit 99.1

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

As of July 13, 2018, preliminary Phase 1/2 data for investigational SPK-8011 *for hemophilia A show:*

- *A 97-percent reduction in annualized bleeding rate (ABR) and 97-percent reduction in annualized infusion rate (AIR) across all 12 participants in the study*
- *Evidence of stable, durable expression, with no decline in plateau FVIII levels, in both participants in the $5x10^{11}$ vg/kg cohort who have been followed for greater than one year*
- *A dose response as demonstrated by FVIII expression ranging from 16 to 49 percent, with a mean of 30 percent post 12 weeks in five of the participants in the $2x10^{12}$ vg/kg cohort*

Company plans to take SPK-8011 *at a dose of $2x10^{12}$ vg/kg into Phase 3 clinical trials, beginning with a run-in study in fourth quarter of 2018*

PHILADELPHIA, Aug. 7, 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 second quarter of 2018 and recent business progress.

"We had a strong second quarter, starting with the shipment of 12 vials of LUXTURNA (voretigene neparvovec-rzyl) as well as the work that went into the completion in early July of the transition to Pfizer and Phase 3 initiation of *SPK-9001* for hemophilia B, now known as fidanacogene elaparvovec. In addition, based on the totality of the data in our Phase 1/2 clinical trial of investigational *SPK-8011* for hemophilia A, we are pleased to announce our plans to initiate a Phase 3 run-in study in the fourth quarter of 2018," said Jeffrey D. Marrazzo, chief executive officer of Spark Therapeutics. "As a result of our progress year to date, our product portfolio continues to mature with a commercially approved gene therapy in the U.S., an investigational gene therapy in fidanacogene elaparvovec having entered Phase 3 development in partnership with Pfizer and investigational gene therapies approaching Phase 3 with *SPK-8011* for hemophilia A, in Phase 1/2 with *SPK-7001* for choroideremia and in IND-enabling studies with *SPK-GAA* for Pompe disease."

Investigational *SPK-8011* moving to Phase 3

As of the July 13, 2018, data cutoff, 12 participants in the Phase 1/2 trial have received a single administration of investigational *SPK-8011*, including two at a dose of $5x10^{11}$ vector genomes (vg)/kg body weight, three at a dose of $1x10^{12}$ vg/kg and seven at a dose of $2x10^{12}$ vg/kg. Across all participants, at all three doses, beginning four weeks after vector infusion, there has been a 97-percent reduction in annualized bleeding rate (ABR) and a 97-percent reduction in annualized infusion rate (AIR). The first two trial participants, who have been followed for greater than one year, have shown stable FVIII activity levels since reaching plateau for up to 66 weeks, with follow up ongoing. Additionally, there is evidence of a dose-dependent increase in mean FVIII activity levels across the three dose cohorts.

Five of the participants in the $2x10^{12}$ vg/kg cohort have FVIII activity levels between 16 and 49 percent, with follow-up ranging from 12 to 30 weeks. The mean FVIII activity for these five participants is 30 percent, based on average FVIII levels post-12 weeks after vector infusion. These five participants have reduced their overall ABR by 100 percent and reduced their overall AIR by 100 percent (calculated based on data after week four). The other two participants in the $2x10^{12}$ vg/kg cohort had an immune response that caused their FVIII levels to decline to less than 5 percent. Clinically, both participants have moved from prophylactic to on-demand treatment and have seen meaningful reductions in their bleeding and infusion rates. One of these participants did not rapidly respond to oral steroids and he elected to be admitted to the hospital to receive two intravenous (IV) methylprednisolone infusions rather than have the infusions on an outpatient basis. The event was subsequently resolved. The admission to hospital for these infusions met the criteria for a serious adverse event (SAE).

Of note, across the study, seven of the 12 participants received a tapering course of oral steroids in response to an alanine aminotransferase (ALT) elevation above patient baseline, declining FVIII levels and/or positive IFN-g enzyme-linked immunospots (ELISPOTs). For these seven participants, steroids led to normalization of ALT and ELISPOTs. For all but the two above mentioned $2x10^{12}$ vg/kg cohort participants, oral steroids led to stabilization of target FVIII levels.

"The clinical and safety profile of *SPK-8011* has been highly encouraging, with no FVIII inhibitors observed. Transaminase elevations above the upper limit of normal has been seen in only three of 12 participants, with no evidence of persistent transaminase elevations. We believe, based on the tempo and magnitude of the immune responses observed, that a prophylactic course of steroids will suppress these responses and should lead to long-term expression of FVIII above 12 percent in all participants at a dose of $2x10^{12}$ vg/kg of *SPK-8011*. We plan to implement this prophylactic approach to steroid administration moving forward," said Katherine A. High, M.D., president and head of research and development at Spark Therapeutics. "These early data further support the dramatic impact on patient outcomes that can result from factor activity levels above 12 percent and bring us closer to our goal of one day eliminating spontaneous bleeding altogether, while potentially freeing patients with hemophilia A from the need for regular infusions."

Based on the totality of the results to date, Spark Therapeutics intends to initiate a Phase 3 run-in study in the fourth quarter of 2018. Following completion of the run-in study, Phase 3 participants are expected to receive $2x10^{12}$ vg/kg of *SPK-8011*. Additional details on the Phase 3 trial design will be determined following continued discussions with FDA and EMA, which are expected in the fourth quarter.

Finally, the company has successfully scaled-up its mammalian-based manufacturing process in suspension to a capacity level of 200 liters and amended its agreement with Brammer Bio to secure a dedicated manufacturing suite, both of which will enable Spark Therapeutics to meet supply needs for Phase 3 clinical development as well as expected commercial requirements.

Additional recent highlights

Continued strong execution of LUXTURNA launch in U.S., with 12 vials shipped in the second quarter of 2018 and patients now treated in six treatment centers

- Continued traction with Spark Therapeutics' innovative payer and distribution models with commercial payers, with numerous administrations to date having been covered using Spark PATH (Pioneering Access To Healthcare)
- Strong progress gaining commercial coverage, with approximately 80 percent of commercial lives covered by acceptable medical policy; signed insurance coverage contracts with two of the largest national health plans and three Blues plans
- Advancing ongoing discussions with the Centers for Medicare & Medicaid Services (CMS), U.S. Department of Health and Human Services (HHS) and others to align on proposal for an installment payment option and flexibility to offer greater outcomes-based rebates

Completed transition of SPK-9001, *or fidanacogene elaparvovec, to Pfizer that has initiated a Phase 3 lead-in study*

- Provided a Phase 1/2 data update at the World Federation of Hemophilia 2018 World Congress, showing factor activity levels in 13 participants ranging from 14 to 77 percent (beginning at 12 weeks through 52 weeks of follow-up) with an average factor activity level of approximately 36 percent
- Reported a 98-percent reduction in ABR and a 99-percent reduction in AIR for all 15 Phase 1/2 participants, with both data points beginning four weeks after vector infusion
- Evidence of long-term durability with more than two years of follow-up in some participants, with infrequent and transient transaminase elevations

Bolstered financial position:

- Strong balance sheet with $656.8 million in cash, cash equivalents and marketable securities as of June 30, 2018

Financial results for the three and six months ended June 30, 2018

Three Months Ended June 30, 2018 and 2017

In the three months ended June 30, 2018, we recognized $25.2 million in total revenue, of which $4.3 million was net sales of LUXTURNA and $20.9 million was associated with our agreements with Pfizer. In the three months ended June 30, 2017, we recognized $1.5 million in total revenue associated with our Pfizer agreement.

Cost of goods sold in the three months ended June 30, 2018 was $0.3 million, which 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 FDA approval and, therefore, was expensed as research and development expense last year.

Cost of contract revenue in the three months ended June 30, 2018 was $4.2 million, which consists of manufacturing and other costs, associated with our agreements.

Our research and development expenses for the three months ended June 30, 2018 were $25.5 million versus $33.0 million for the three months ended June 30, 2017. The $7.5 million decrease was due to a decrease of $6.2 million in internal research and development expenses and $1.3 million in external research and development expenses. The $6.2 million decrease in internal research and development expenses primarily was due to a decrease in salaries and other related costs associated with LUXTURNA, which were allocated to inventory upon FDA approval. The $1.3 million decrease in external research and development expenses primarily was due to a $3.9 million decrease in expenses related to LUXTURNA and other clinical programs, offset by an increase of $2.6 million in expenses related to our hemophilia A program.

We did not incur any acquired in-process research and development expense during the three months ended June 30, 2018. Our acquired in-process research and development expense for the three months ended June 30, 2017 was $3.1 million, related to a licensing agreement in 2017.

During the three months ended June 30, 2017, we recorded a non-cash impairment charge of $15.7 million related to acquired in-process research and development, or IPR&D, attained 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 IPR&D during the three months ended June 30, 2017.

Selling, general and administrative expenses for the three months ended June 30, 2018, were $29.7 million versus $26.7 million for the three months ended June 30, 2017. The $3.0 million increase primarily was due to an increase of $3.4 million in salaries and related costs, including stock-based compensation, due to increased headcount primarily to support the LUXTURNA launch and $0.3 million in legal and patent expenses, professional fees and other operating costs, offset by a decrease of $0.7 million in launch activities for LUXTURNA.

We recognized $110.0 million during the three months ended June 30, 2018, in other income for the sale of our rare pediatric disease priority review voucher, or PRV.

Our net income for the three months ended June 30, 2018, was $80.2 million, or $2.15 basic and $2.07 diluted net income per common share, respectively, as compared to a net loss of $74.4 million, or ($2.40) basic and diluted net loss per common share, for the three months ended June 30, 2017. Second quarter results were favorably impacted by the sale of our PRV to Jazz Pharmaceuticals for $110 million.

Six Months Ended June 30, 2018 and 2017

In the six months ended June 30, 2018, we recognized $40.8 million in total revenue, of which $6.7 million was net sales of LUXTURNA and $34.1 million was associated with our agreements with Pfizer. In the six months ended June 30, 2017, we recognized $2.8 million in total revenue associated with our Pfizer agreement.

Cost of goods sold in the six months ended June 30, 2018 was $0.4 million, which 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 FDA approval and, therefore, was expensed as research and development expense last year.

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

Our research and development expenses for the six months ended June 30, 2018 were $55.6 million compared with $65.3 million for the six months ended June 30, 2017. The $9.7 million decrease was due to a $6.5 million decrease in internal research and development expenses, primarily due to salaries and other costs associated with LUXTURNA, which were allocated to inventory upon FDA approval, and a decrease of $3.2 million in external research and development. The decrease in external research and development primarily was due to a $5.0 million decrease in expenses related to LUXTURNA, a $2.3 million decrease in other clinical programs and a $0.2 million decrease in programs in preclinical development. These decreases were offset by an increase of $4.2 million in expenses related to our hemophilia A program.

We did not incur any acquired in-process research and development expense during the six months ended June 30, 2018. Our acquired in-process research and development expense for the six months ended June 30, 2017 was $3.5 million, related to a licensing agreement in 2017.

During the six months ended June 30, 2017, we recorded a non-cash impairment charge of $15.7 million related to acquired IPR&D attained 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 IPR&D during the six months ended June 30, 2017.

Selling, general and administrative expenses for the six months ended June 30, 2018 were $63.2 million compared with $48.1 million for the six months ended June 30, 2017. Selling, general and administrative expenses consist primarily of salaries and related costs, including stock-based compensation, legal and patent costs, facility costs and other professional fees. The $15.1 million increase primarily was due to an increase of $10.4 million in salaries and related costs, including stock-based compensation, due to increased headcount primarily to support the LUXTURNA launch, an increase of $0.4 million in launch activities for LUXTURNA and $4.4 million in legal and patent expenses, professional fees and other operating costs.

We recognized $110.0 million during the six months ended June 30, 2018, in other income for the sale of our rare pediatric disease PRV.

Our net income for the six months ended June 30, 2018, was $33.8 million, or $0.91 basic and $0.88 diluted net income per common share, respectively, as compared to a net loss of $126.6 million, or ($4.10) basic and diluted net loss per common share, for the six months ended June 30, 2017. Our profit for the six months ended June 30, 2018 were favorably impacted by the sale of our PRV to Jazz Pharmaceuticals for $110 million.

As of June 30, 2018, we had cash and cash equivalents and marketable securities of $656.8 million, with 37.5 million shares outstanding.

Conference call details
Spark Therapeutics will host a conference call and audio webcast, today, Tuesday, Aug. 7, at 8:30 a.m. ET, to discuss corporate and financial results for the quarter that ended June 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: 5389949

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 5389949, 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,* 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 early preliminary clinical results for our product candidate, *SPK-8011*, for hemophilia A, may not be sustained; (ii) our implementation of a prophylactic approach to steroid administration for subjects participating in our *SPK-8011* clinical trials may not prevent an immune response; (iii) 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; (iv) our MAA for LUXTURNA may not be approved by EMA; (v) 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; (vi) the improvements in functional vision demonstrated by LUXTURNA in our clinical trials may not be sustained over extended periods of time; (vii) voretigene neparvovec may not be approved in any markets outside of the U.S.; (viii) if voretigene neparvovec is approved, Novartis may not be successful in commercializing or selling it in one or more markets; (ix) we may not receive any additional milestone or royalty payments from Novartis, Pfizer or our other collaborators; (x) we are unable to maintain or continue 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) 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 (xiii) 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	June 30, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 96,748	$ 201,086
Marketable securities	423,419	446,141
Trade and other receivables	7,906	25,239
Inventory	—	12,674
Prepaid expenses and other current assets	5,093	6,414
Total current assets	533,166	691,554
Marketable securities	20,035	9,552
Property and equipment, net	61,713	68,698
Goodwill	1,254	1,223
Other assets	628	2,492
Total assets	$ 616,796	$ 773,519
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 14,183	$ 8,785
Accrued expenses	24,697	23,849
Current portion of long-term debt	312	317
Current portion of deferred rent	969	989
Current portion of deferred revenue	11,969	1,841
Current other liabilities	1,557	1,656
Total current liabilities	53,687	37,437
Long-term debt	912	752
Long-term deferred rent	8,318	7,914
Long-term deferred revenue	—	105,000
Other liabilities	40,255	38,676
Total liabilities	103,172	189,779
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; 37,543,411 shares issued and 37,476,978 shares outstanding as of June 30, 2018	37	38
Additional paid-in capital	1,026,590	1,065,438
Accumulated other comprehensive (loss) income	(5,914)	(643)
Treasury stock, at cost, 20,222 shares as of December 31, 2017 and 66,433 shares as of June 30, 2018	(1,226)	(4,020)
Accumulated deficit	(505,863)	(477,073)
Total stockholders' equity	513,624	583,740
Total liabilities and stockholders' equity	$ 616,796	$ 773,519

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

	Three months ended June 30,		Six months ended June 30,	
	2017	2018	2017	2018
Revenues:				
Product sales, net	$ —	$ 4,314	$ —	$ 6,733
Contract revenue	1,483	20,871	2,758	34,128
Total revenues	1,483	25,185	2,758	40,861
Operating expenses:				
Cost of product sales	—	269	—	390
Cost of contract revenue	—	4,242	—	5,111
Research and development	32,989	25,524	65,338	55,633
Acquired in-process research and development	3,070	—	3,457	—
Impairment of acquired in-process research and development	15,696	—	15,696	—
Selling, general and administrative	26,729	29,749	48,142	63,238
Total operating expenses	78,484	59,784	132,633	124,372
Loss from operations	(77,001)	(34,599)	(129,875)	(83,511)
Unrealized gain on equity investments	—	2,255	—	2,619
Interest income, net	532	2,521	1,117	4,706
Other income	—	110,000	—	110,000
Income (loss) before income taxes	(76,469)	80,177	(128,758)	33,814
Income tax benefit (expense)	2,109	(12)	2,109	(22)
Net income (loss)	$ (74,360)	$ 80,165	$ (126,649)	$ 33,792
Basic net income (loss) per common share	$ (2.40)	$ 2.15	$ (4.10)	$ 0.91
Diluted net income (loss) per common share	$ (2.40)	$ 2.07	$ (4.10)	$ 0.88
Weighted average basic common shares outstanding	30,968,450	37,254,003	30,870,740	37,150,693
Weighted average diluted common shares outstanding	30,968,450	38,702,598	30,870,740	38,385,097

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