

**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**

May 3, 2017
Date of Report (Date of earliest event reported)

Flex Pharma, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36812
(Commission File Number)

46-5087339
(IRS Employer Identification No.)

800 Boylston Street, 24th Floor
Boston, MA
(Address of principal executive offices)

02199
(Zip Code)

Registrant's telephone number, including area code: **(617) 874-1821**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations of the registrant under any of the following provisions:

- 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 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 3, 2017, Flex Pharma, Inc. issued a press release announcing its financial results for the quarter ended March 31, 2017. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

The information in this Item 2.02 and Exhibit 99.1 hereto is being furnished and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference into any filing under the Exchange Act or the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Flex Pharma, Inc. dated May 3, 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.

Flex Pharma, Inc.

Dated: May 3, 2017

By: /s/ Robert Hadfield
Robert Hadfield
General Counsel and Secretary

INDEX TO EXHIBITS

Exhibit No.	Description
99.1	Press Release of Flex Pharma, Inc. dated May 3, 2017.

Flex Pharma Reports First Quarter 2017 Financial Results

-- FDA Clears IND for FLX-787 to Commence US Phase 2 Trial in ALS --

-- US Phase 2 Trials in ALS and CMT Expected to Commence Summer 2017 --

Conference Call Scheduled Today at 8:45 a.m. ET

[Click to Tweet this News \(UPDATE\)](#)

May 3, 2017

Boston, MA - [Flex Pharma, Inc.](#) (NASDAQ: FLKS), a biotechnology company that is developing innovative and proprietary treatments for cramps and spasms associated with severe neurological diseases such as amyotrophic lateral sclerosis (ALS) and multiple sclerosis (MS) and peripheral neuropathies such as Charcot-Marie-Tooth (CMT), today reported financial results for the quarter ended March 31, 2017 and provided an update on its clinical development and corporate activities.

"Now that our IND is active for our ALS study, we are poised to expand our clinical program and will submit a protocol to the FDA to start a clinical trial of FLX-787 to treat patients with CMT neuropathy. With two Phase 2 clinical trials in ALS and CMT expected to initiate this summer in the US, together with our exploratory Phase 2 studies already underway in Australia, FLX-787 will be amongst the most advanced, novel compounds in the clinic for ALS and CMT," stated Christoph Westphal, M.D., Ph.D., Chair and CEO of Flex Pharma. "Our efforts are focused on creating value by accelerating the development of FLX-787 to address the significant unmet medical need of patients suffering from debilitating cramps and spasms as a consequence of severe neurological diseases."

During the quarter, the Company also continued to build the market for its new consumer product, HOTSHOT®, which was launched in June of 2016. "HOTSHOT has built a base of loyal, repeat customers in the first 9 months on the market, and usage has been growing amongst endurance athletes and hundreds of professional and collegiate teams who rely on HOTSHOT to treat and prevent exercise-associated muscle cramps in addition to other Neuro Muscular Performance benefits related to recovery and muscle soreness," said Kathie Lindemann, Chief Operating Officer. "As we move into the warmer months and the busy racing season, we are seeing an expected increase in HOTSHOT usage."

Recent Business Highlights

- Clinical Efforts
 - In April, the Company's investigational new drug (IND) application for FLX-787 for patients with ALS became effective, allowing the Company to commence its U.S. Phase 2 clinical trial of FLX-787 in ALS patients who suffer from cramps as a consequence of the disease.
 - In its abstract titled, "Chemical Neuro Stimulation by FLX-787, a co-activator of TRPA1/TRPV1, for the Potential Treatment of Cramps, Spasms and Spasticity," the Company presented human efficacy data from its study in nocturnal leg cramps (NLC) at the American Academy of Neurology (AAN) 69th Annual Meeting in Boston, MA. When a neurologist evaluated, in a blinded manner, subjects likely to have NLC based upon a questionnaire administered after the study was completed, the data from first treatment exposure of these 26 subjects showed a statistically significant effect in the reduction in cramp frequency when compared to placebo ($p=0.03$).
 - New data presented at AAN from a separate study conducted by independent researchers provides genetic validation that the transient receptor potential (TRP) A1 ion channel, the pharmacological target of FLX-787, is linked to human muscle cramp fasciculation syndrome. In the Biller et al. abstract titled "Identification of a novel TRPA1 mutation associated with carbamazepine-responsive cramp-fasciculation syndrome" the authors at NYU and Mount Sinai conclude that their findings "further clarify the functional role of human TRPA1, and underscores the importance of this ion channel as a potential therapeutic target."
 - Consumer Launch
 - For the quarter ended March 31, 2017, the Company recorded approximately \$243,000 in total revenue for its consumer product, HOTSHOT, reflecting the expected impact of seasonality. Launched in June 2016, HOTSHOT is a new 1.7 fluid ounce sports shot that is scientifically proven to prevent and treat muscle cramps by stopping them where they start: at the nerve.
 - In March, the journal of *Muscle & Nerve* published the randomized, placebo-controlled, double-blind study of athletes, conducted by researchers at the esteemed Noll Laboratory at Penn State University. The study shows that targeting TRP channels through activators contained in HOTSHOT was significantly effective at mitigating muscle cramps in a novel volitional cramp model. The published findings from Penn State indicate
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that taking HOTSHOT decreased the duration and intensity of cramps in this carefully controlled experiment. In addition, when cramps did occur, study participants reported decreased muscle soreness immediately after the cramp ended.

- In February, Tim Reed, the reigning IRONMAN 70.3® champion, became an official brand ambassador for HOTSHOT. Reed started racing with HOTSHOT a year ago and, in 2016, had the most successful year of his career with wins at the IRONMAN 70.3 Asia Pacific Championship, IRONMAN® Australia and the IRONMAN 70.3 World Championship.
- Strengthened Leadership Team
 - In April, William K. McVicar, Ph.D. joined Flex Pharma as President of Research and Development, bringing approximately 30 years of clinical development experience to the Company. Prior to joining Flex Pharma, Dr. McVicar served as Executive Vice President of Pharmaceutical Development, Chief Scientific Officer, and President during his tenure at Inotek. As Vice President of Development Operations at Sepracor, he oversaw the development, FDA review, and approval of multiple NDAs and SNDAs, including BROVANA®, XOPENEX MDI®, and XOPENEX's pediatric approval, which were each approved in a single 10-month review cycle. Prior to Sepracor, Dr. McVicar held various positions of increasing responsibility at Sandoz, Novartis and Rhone Poulenc Rorer.

First Quarter 2017 Financial Results

- **Cash Position:** As of March 31, 2017, Flex Pharma had cash, cash equivalents and marketable securities of \$52.8 million. During the three months ended March 31, 2017, cash, cash equivalents and marketable securities decreased by \$8.3 million.
 - **Total Revenue:** Total revenue for the three months ended March 31, 2017, was approximately \$243,000, including approximately \$2,000 of other revenue.
 - **Cost of Product Revenue:** Cost of product revenue for the three months ended March 31, 2017 was approximately \$79,000.
 - **R&D Expense:** Research and development expense for the three months ended March 31, 2017 was \$3.9 million. Research and development expense for this quarter primarily included costs associated with the Company's clinical studies of FLX-787, IND-supporting activities,
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personnel costs (including salaries and stock-based compensation costs), FLX-787 production costs and external consultant costs.

- **SG&A Expense:** Selling, general and administrative expense for the three months ended March 31, 2017 was \$4.6 million. Selling, general and administrative expense for this quarter primarily included personnel costs (including salaries and stock-based compensation costs), sales, marketing and fulfillment costs related to HOTSHOT, legal costs and external consultant costs.
- **Net Loss and Cash Flow:** Net loss for the three months ended March 31, 2017 was (\$8.3) million, or (\$0.49) per share and included \$1.2 million of stock compensation expense. As of March 31, 2017, Flex Pharma had 17,029,249 shares of common stock outstanding, which excludes approximately 0.9 million shares of stock that remain subject to vesting. The net loss for the first quarter of 2017 was primarily driven by the Company's operating expenses related to its research and development efforts, costs associated with HOTSHOT, and general and administrative costs.

Financial Guidance

Based on its current operating plans and cash, cash equivalents and marketable securities position, Flex Pharma expects to have sufficient capital to fund its operations into early 2019.

Upcoming Events and Presentations

- Jefferies Healthcare Conference, June 6-9, 2017 in New York, NY
- JMP Securities Life Sciences Conference, June 20-21, 2017 in New York, NY

Conference Call and Webcast

The company will host a conference call and webcast today at 8:45 a.m. ET to provide an update on the company and discuss financial results for the first quarter of 2017. To access the conference call, please dial (855) 780-7202 (U.S. and Canada) or (631) 485-4874 (International) five minutes prior to the start time. A live webcast may be accessed in the Investors section of the company's website at www.flex-pharma.com. Please log on to the Flex Pharma website approximately 15 minutes prior to the scheduled webcast to ensure adequate time for any software downloads that

may be required. A replay of the webcast will be available on Flex Pharma's website for three months.

About Flex Pharma

Flex Pharma, Inc. is a biotechnology company that is developing innovative and proprietary treatments for cramps and spasms associated with the severe neurological diseases of ALS, MS and peripheral neuropathies such as Charcot-Marie-Tooth (CMT). Flex Pharma was founded by National Academy of Science members Rod MacKinnon, M.D. (2003 Nobel Laureate), and Bruce Bean, Ph.D., recognized leaders in the fields of ion channels and neurobiology, along with Chair and CEO Christoph Westphal, M.D., Ph.D.

Forward-Looking Statements

This press release contains forward-looking statements for purposes of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things: the design and timing of ongoing and anticipated clinical studies, our expectations regarding the availability of our capital resources, and our commercialization plans for our consumer product. These forward-looking statements are based on management's expectations and assumptions as of the date of this press release and are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those expressed or implied by such statements. These risks and uncertainties include, without limitation: the status, timing, costs, results and interpretation of our clinical studies; the uncertainties inherent in conducting clinical studies; results from our ongoing and planned preclinical development; expectations of our ability to make regulatory filings and obtain and maintain regulatory approvals; our ability to successfully commercialize our consumer product; results of early clinical studies as indicative of the results of future trials; availability of funding sufficient for our foreseeable and unforeseeable operating expenses and capital expenditure requirements; other matters that could affect the availability or commercial potential of our consumer or drug product candidates; the inherent uncertainties associated with intellectual property; and other factors discussed in greater detail under the heading "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2016 and subsequent filings with the Securities and Exchange Commission (SEC). You are encouraged to read our filings with the SEC, available at www.sec.gov, for a discussion of these and other risks and uncertainties. Any

forward-looking statements that we make in this press release speak only as of the date of this press release. We assume no obligation to update our forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

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Contact:

Elizabeth Woo

SVP, Investor Relations & Corporate Communications

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617-874-1829

- Financial Tables to Follow -

Flex Pharma, Inc.
Unaudited Selected Consolidated Balance Sheet Information
(in thousands)

	March 31, 2017	December 31, 2016
Assets:		
Cash and cash equivalents	\$ 21,072	\$ 22,416
Marketable securities	31,743	38,659
Accounts receivable	19	12
Inventory	414	454
Prepaid expenses and other current assets	1,586	926
Property and equipment, net	479	556
Other assets	192	192
Total assets	\$ <u>55,505</u>	\$ <u>63,215</u>
Liabilities and stockholders' equity:		
Accounts payable and accrued expenses	\$ 3,130	\$ 3,780
Deferred revenue	81	88
Other liabilities	67	30
Stockholders' equity	52,227	59,317
Total liabilities and stockholders' equity	\$ <u>55,505</u>	\$ <u>63,215</u>

Unaudited Condensed Consolidated Statements of Operations
(in thousands, except loss per share amounts)

	Three Months Ended March 31, 2017	Three Months Ended March 31, 2016
Net product revenue	\$ 241	\$ —
Other revenue	2	—
Total revenue	<u>243</u>	<u>—</u>
Costs and expenses:		
Cost of product revenue	79	197
Research and development	3,915	4,387
Selling, general and administrative	4,595	5,111
Total costs and expenses	<u>8,589</u>	<u>9,695</u>
Loss from operations	(8,346)	(9,695)
Interest income, net	78	103
Net loss	<u>\$ (8,268)</u>	<u>\$ (9,592)</u>
Net loss per share-basic and diluted	<u>\$ (0.49)</u>	<u>\$ (0.61)</u>
Weighted-average number of common shares outstanding (1)	<u>16,874</u>	<u>15,844</u>

- (1) As of March 31, 2017, the Company had issued approximately 5.4 million shares of restricted stock that are subject to vesting. Of these shares, approximately 4.5 million shares had vested at March 31, 2017 and are outstanding for purposes of computing weighted average shares outstanding. The remaining shares will be included in the weighted average share calculation as such shares vest over approximately the next 0.9 years.