

**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 2, 2018

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 2, 2018, Flex Pharma, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2018. 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 2, 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.

Flex Pharma, Inc.

Dated: May 2, 2018

By: /s/ John McCabe
John McCabe
Chief Financial Officer

Flex Pharma Reports First Quarter 2018 Financial Results

-- Positive Anti-Cramping Effect of FLX-787 Reported in Recent MS study --

-- FLX-787 Phase 2 ALS & CMT Clinical Studies Ongoing --

Conference Call Scheduled Today at 9:00 a.m. ET

May 2, 2018

Boston, MA - [Flex Pharma, Inc.](#) (NASDAQ: FLKS), a clinical-stage biotechnology company that is developing innovative and proprietary treatments in Phase 2 randomized, controlled trials for muscle cramps, spasms and spasticity associated with severe neurological diseases such as multiple sclerosis (MS), amyotrophic lateral sclerosis (ALS) under FDA Fast Track designation, and Charcot-Marie-Tooth (CMT) neuropathy, today reported financial results for the quarter ended March 31, 2018 and provided an update on its clinical development and corporate activities.

"The past few months have been particularly rewarding on the clinical front, as we achieved significant milestones with positive data in two serious and distinctly different neurological diseases: MS and ALS. We believe these data demonstrate the clear potential of FLX-787 to reduce painful cramps and spasms in these patient populations," stated Bill McVicar, Ph.D., President and CEO of Flex Pharma. "Fueled by the consistent efficacy demonstrated by FLX-787 against cramps and spasms, and the potential to impact spasticity, I am excited to be driving towards important readouts for our clinical programs over the next year."

Business Highlights

- Clinical Efforts
 - In March, the Company announced positive topline data for FLX-787 from its exploratory Phase 2 trial in MS patients with frequent muscle cramps/spasms and spasticity. FLX-787 at a dose of 19 mg, taken orally twice daily, in a liquid formulation was evaluated in an exploratory Phase 2 randomized, double-blinded, placebo-controlled, cross-over trial in 57 MS patients. In the evaluation of FLX-787 for its impact on MS patients' cramps/spasms and spasticity, pre-specified analyses of the parallel portion of the study showed the following:
 - A statistically significant 27.3% reduction in the frequency of cramps/spasms compared with control (p=0.001)
 - A 1.4 day increase in cramp/spasm-free days per 14 day period compared with control (p=0.046)
 - Clinician-rated improvement in spasticity with FLX-787 treatment was significantly better than control (p=0.010)
 - Treating physicians reported that 7 of 28 (25%) patients on FLX-787 had "Much Improved" or "Very Much Improved" spasticity versus 0 of 26 (0%) on control based upon the Clinical Global Impression of Change in Spasticity

- FLX-787 was generally well tolerated and resulted in no drug-related serious adverse events. GI-related adverse events (diarrhea and nausea) were infrequently reported with FLX-787.
 - In April, the Company initiated an open-label, single dose study in ALS patients to assess the impact of FLX-787 on bulbar functions, including swallowing.
- Consumer
 - For the quarter ended March 31, 2018, the Company recorded approximately \$179,000 in total revenue for its consumer product, HOTSHOT®.
 - In January 2018, the Company announced that it engaged an investment banking firm to assist with the consideration of strategic alternatives for the HOTSHOT consumer business. That review is in progress and the Company expects to report the results of the review in the near future.

First Quarter 2018 Financial Results

- **Cash Position:** As of March 31, 2018, Flex Pharma had cash, cash equivalents and marketable securities of \$23.9 million, estimated to fund operations to mid-2019. During the three months ended March 31, 2018, cash, cash equivalents and marketable securities decreased by \$9.4 million, which is higher than the estimated spend for future quarters. The timing of clinical trial billings and annual bonus payments related to 2017 impacted the cash used in operations during the first quarter, and spend on the consumer business is expected to be lower.
- **Total Revenue:** Total revenue for the three months ended March 31, 2018 was approximately \$179,000.
- **Cost of Product Revenue:** Cost of product revenue for the three months ended March 31, 2018 was approximately \$84,000. There were no inventory write-offs during the three months ended March 31, 2018.
- **R&D Expense:** Research and development expense for the three months ended March 31, 2018 was \$4.7 million. Research and development expense for this period primarily included costs associated with the Company's clinical studies of FLX-787, 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, 2018 was \$3.7 million. Selling, general and administrative expense for this period primarily included personnel costs (including salaries and stock-based compensation costs), sales, marketing and fulfillment costs related to HOTSHOT, legal and professional costs, and external consultant costs.
- **Net Loss and Cash Flow:** Net loss for the three months ended March 31, 2018 was (\$8.2) million, or (\$0.46) per share and included \$0.9 million of stock-based compensation expense. As of March 31, 2018, Flex Pharma had 17,980,852 shares of common stock outstanding. The net loss for the first quarter of 2018 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 to mid-2019.

Upcoming Events and Presentations

- Jefferies 2018 Global Healthcare Conference, June 5-8, 2018 in New York, NY.

Conference Call and Webcast

The company will host a conference call and webcast today at 9:00 a.m. ET to provide an update on the company and discuss first quarter 2018 financial results. 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. Conference ID number 3478819. 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 clinical-stage biotechnology company that is developing innovative and proprietary treatments in Phase 2 randomized, controlled trials for cramps, spasms and spasticity associated with the severe neurological diseases of ALS, MS and peripheral neuropathies such as Charcot-Marie-Tooth (CMT). The Company's lead candidate, FLX-787, is being developed under Fast Track designation for the treatment of severe muscle cramps associated with ALS. 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 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. These 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; and our expectations regarding the availability of our capital resources. 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; and the inherent uncertainties associated with intellectual property. Other factors that may cause actual results to differ from those expressed or implied in the forward-looking statements in this press release are discussed in our filings with the U.S. Securities and Exchange Commission (SEC), including the "Risk Factors" contained therein. 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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- Financial Tables to Follow -

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

	March 31, 2018	December 31, 2017
Assets:		
Cash and cash equivalents	\$ 21,948	\$ 19,186
Marketable securities	1,999	14,130
Accounts receivable	13	10
Inventory	418	432
Prepaid expenses and other current assets	1,261	777
Property and equipment, net	267	331
Other assets	127	127
Total assets	\$ 26,033	\$ 34,993
Liabilities and stockholders' equity:		
Accounts payable and accrued expenses	\$ 4,062	\$ 5,717
Deferred revenue	—	72
Other liabilities	83	98
Stockholders' equity	21,888	29,106
Total liabilities and stockholders' equity	\$ 26,033	\$ 34,993

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

	Three Months Ended March 31, 2018	Three Months Ended March 31, 2017
Net product revenue	\$ 177	\$ 241
Other revenue	2	2
Total revenue	<u>179</u>	<u>243</u>
Costs and expenses:		
Cost of product revenue	84	79
Research and development	4,680	3,915
Selling, general and administrative	3,697	4,595
Total costs and expenses	<u>8,461</u>	<u>8,589</u>
Loss from operations	(8,282)	(8,346)
Interest income, net	59	78
Net loss	<u>\$ (8,223)</u>	<u>\$ (8,268)</u>
Net loss per share-basic and diluted	<u>\$ (0.46)</u>	<u>\$ (0.49)</u>
Weighted-average number of common shares outstanding (1)	<u>17,894</u>	<u>16,874</u>

(1) In 2014, the Company issued approximately 5.4 million shares of restricted stock that vested over four years, through February 2018. These shares were considered outstanding for purposes of computing weighted average shares as they vested. All of these shares have vested and are considered outstanding as of March 31, 2018.