

**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**

**August 1, 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, 24<sup>th</sup> 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 August 2, 2017, Flex Pharma, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 30, 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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.**

On August 1, 2017, the Company entered into an Amended and Restated Executive Employment Agreement with William McVicar, President and Chief Executive Officer (the "Agreement"). Pursuant to the Agreement, Dr. McVicar will receive an annual base salary of \$475,000 and is eligible for an annual bonus that targets fifty percent (50%) of his annualized base salary based upon an assessment of Dr. McVicar's performance and the attainment of targeted goals established for the Company by the Board of Directors of the Company. In the event that he is terminated without Cause (as defined in the Agreement) or resigns for Good Reason (as defined in the Agreement) prior to a Change in Control (as defined in the Agreement), Dr. McVicar will be entitled to severance in the form of salary continuation for 12 months at his then-current base salary and the Company will pay, for up to 12 months, that portion of the COBRA premiums that the Company paid prior to such termination. In the event that he is terminated without Cause or resigns for Good Reason during the period beginning 30 days prior to and ending 12 months following a Change in Control, Dr. McVicar will be entitled to severance in the form of salary continuation for twelve months at his then-current base salary and the target bonus payment for the year in which the termination occurs. Dr. McVicar will also be eligible for all other compensation and benefit plans available to the Company's employees.

The foregoing description of the terms of the Agreement does not purport to be a complete description and is qualified in its entirety by reference to the Amendment that will be filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the three months ending September 30, 2017.

**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 August 2, 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: August 2, 2017

By: /s/ Robert Hadfield

Robert Hadfield

General Counsel and Secretary

## INDEX TO EXHIBITS

<b>Exhibit No.</b>	<b>Description</b>
99.1	Press Release of Flex Pharma, Inc. dated August 2, 2017.

## Flex Pharma Reports Second Quarter 2017 Financial Results

-- FLX-787 Granted Fast Track Designation for ALS --

-- US Phase 2 ALS Trial Initiated under IND --

-- US Phase 2 CMT Trial Commencing Third Quarter --

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

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August 2, 2017

Boston, MA - [Flex Pharma, Inc.](#) (NASDAQ: FLKS), a clinical-stage biotechnology company that is developing innovative and proprietary treatments for cramps and spasticity associated with severe neurological diseases such as multiple sclerosis (MS), Charcot-Marie-Tooth (CMT) and amyotrophic lateral sclerosis (ALS) under FDA Fast Track designation, today reported financial results for the quarter ended June 30, 2017 and provided an update on its clinical development and corporate activities.

“We have accomplished a number of important development objectives over these past few months. First and foremost, the recent Fast Track designation represents a validation by FDA that cramps are a severe, unmet medical need in ALS. We see greater collaboration with FDA under Fast Track as an important catalyst in our efforts to accelerate the development of FLX-787 to address the suffering of patients with painful, debilitating cramps as a consequence of their severe neurological disease,” stated Dr. William McVicar, President and CEO of Flex Pharma. “In addition, our IND became effective, allowing us to expand our clinical program to the US, and we have now initiated our Phase 2 ALS trial, with our Phase 2 CMT trial soon to follow. The team is focused on the execution of these new Phase 2 IND studies, as well as completion of the ongoing exploratory Phase 2 spasticity study in MS in Australia. These studies are expected to yield several important data readouts in 2018.”

### Recent Business Highlights

- Clinical Efforts
  - In early August, the Company initiated its Phase 2 randomized, controlled, double-blinded, parallel design trial in the US, referred to as the COMMEND trial, to evaluate

FLX-787, the Company's co-activator of TRPA1 and TRPV1, in patients with motor neuron disease (MND), focused on ALS, who suffer from cramps. The Company expects to report topline results from this study in the middle of 2018.

- In July, the Company announced that the Food and Drug Administration (FDA) granted Fast Track Designation for the development of FLX-787 to treat severe muscle cramps in patients with ALS. There are currently no drugs approved in the US for this condition. Fast Track Designation is intended to accelerate the clinical development and review of drugs to treat serious conditions that address an unmet medical need. In addition, the Company announced that it has prioritized the larger US Phase 2 ALS trial over the small, exploratory Australian ALS study due to several advantages of the US Phase 2 ALS trial. As a result, the exploratory Australian ALS study will end early, with roughly a dozen patients.
- In June, the Inherited Neuropathies Consortium (INC) voted to endorse the Company's US Phase 2 Trial of FLX-787 in CMT patients who suffer from cramps. The INC is an integrated group of academic medical centers, patient support organizations, and clinical research resources dedicated to conducting clinical research in CMT and to improving the care of patients ([www.rarediseasesnetwork.org/cms/inc](http://www.rarediseasesnetwork.org/cms/inc)). There are currently no drug products approved in the US for this condition. The Company expects to begin enrolling US patients during the third quarter in this randomized, controlled, double-blinded, parallel design study, referred to as the COMMIT trial.
- 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 US 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) 69<sup>th</sup> Annual Meeting in Boston, MA in April. 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 ( $p=0.03$ ).

- Consumer Business

- For the quarter ended June 30, 2017, the Company recorded approximately \$336,000 in total revenue for its consumer product, HOTSHOT<sup>®</sup>, launched in June 2016. The Company expects full year revenues for 2017 to exceed 2016.
- IRONMAN<sup>®</sup> and HOTSHOT, the only scientifically proven solution for preventing and treating muscle cramps, have partnered to designate HOTSHOT as the Official Muscle Cramp Product of the IRONMAN US Series. To aid athletes, HOTSHOT will be on-course at all the remaining 2017 IRONMAN events in the US, as well as at the 2017 IRONMAN and IRONMAN 70.3 World Championship events.
- Strengthened Leadership Team
  - In July, Flex Pharma's Board of Directors appointed William McVicar, Ph.D., as President and CEO. Dr. McVicar brings approximately 30 years of clinical development experience to the Company, formerly serving as the Company's President of Research and Development. In June, Christoph Westphal, M.D., Ph.D., transitioned from his role as CEO and continues to serve as Flex Pharma's Chairman of the Board. 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<sup>®</sup>, XOPENEX MDI<sup>®</sup>, 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.

## Second Quarter 2017 Financial Results

- **Cash Position:** As of June 30, 2017, Flex Pharma had cash, cash equivalents and marketable securities of \$47.1 million. During the three months ended June 30, 2017, cash, cash equivalents and marketable securities decreased by \$5.7 million.
- **Total Revenue:** Total revenue for the three months ended June 30, 2017 was approximately \$336,000, including approximately \$5,000 of other revenue.
- **Cost of Product Revenue:** Cost of product revenue for the three months ended June 30, 2017 was approximately \$145,000.

- **R&D Expense:** Research and development expense for the three months ended June 30, 2017 was \$4.1 million. Research and development expense for this quarter 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 June 30, 2017 was \$5.0 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 June 30, 2017 was (\$8.8) million, or (\$0.51) per share and included \$1.1 million of stock-based compensation expense. As of June 30, 2017, Flex Pharma had 17,285,926 shares of common stock outstanding, which excludes approximately 0.7 million shares of stock that remain subject to vesting. The net loss for the second 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.

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## Upcoming Events and Presentations

- H.C. Wainwright Rodman & Renshaw Annual Healthcare Conference, September 11-12, 2017 in New York, NY
- Cantor Fitzgerald Global Healthcare Conference, September 25-26, 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 second quarter of 2017. To access the



conference call, please dial (855) 780-7202 (US 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](http://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.

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### **About Flex Pharma**

Flex Pharma, Inc. is a clinical-stage biotechnology company that is developing innovative and proprietary treatments for cramps 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 Chair 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 trials, including the timing for results of our clinical trials, the level of future interaction we may have with FDA, our expectations relating to HOTSHOT revenue 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 and drive customers to purchase HOTSHOT; 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](http://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:

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Flex Pharma, Inc.

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617-874-1829

- Financial Tables to Follow -

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

	June 30, 2017	December 31, 2016
<b>Assets:</b>		
Cash and cash equivalents	\$ 39,127	\$ 22,416
Marketable securities	7,996	38,659
Accounts receivable	35	12
Inventory	688	454
Prepaid expenses and other current assets	1,209	926
Property and equipment, net	448	556
Other assets	127	192
<b>Total assets</b>	<b>\$ 49,630</b>	<b>\$ 63,215</b>
<b>Liabilities and stockholders' equity:</b>		
Accounts payable and accrued expenses	\$ 4,936	\$ 3,780
Deferred revenue	97	88
Other liabilities	92	30
Stockholders' equity	44,505	59,317
<b>Total liabilities and stockholders' equity</b>	<b>\$ 49,630</b>	<b>\$ 63,215</b>

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

	Three Months Ended June 30, 2017	Three Months Ended June 30, 2016	Six Months Ended June 30, 2017	Six Months Ended June 30, 2016
Net product revenue	\$ 331	\$ 113	\$ 571	\$ 113
Other revenue	5	—	7	—
Total revenue	<u>336</u>	<u>113</u>	<u>578</u>	<u>113</u>
Costs and expenses:				
Cost of product revenue	145	111	224	308
Research and development	4,076	6,095	7,991	10,482
Selling, general and administrative	4,991	5,378	9,586	10,490
Total costs and expenses	<u>9,212</u>	<u>11,584</u>	<u>17,801</u>	<u>21,280</u>
Loss from operations	(8,877)	(11,471)	(17,223)	(21,167)
Interest income, net	72	108	150	211
Net loss	<u>\$ (8,805)</u>	<u>\$ (11,363)</u>	<u>\$ (17,073)</u>	<u>\$ (20,956)</u>
Net loss per share-basic and diluted	<u>\$ (0.51)</u>	<u>\$ (0.71)</u>	<u>\$ (1.00)</u>	<u>\$ (1.31)</u>
Weighted-average number of common shares outstanding (1)	<u>17,130</u>	<u>16,106</u>	<u>17,003</u>	<u>15,975</u>

(1) As of June 30, 2017, the Company had issued approximately 5.4 million shares of restricted stock that are subject to vesting. Of these shares, approximately 4.8 million shares had vested at June 30, 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 0.7 years.