

**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**

November 2, 2016
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))
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Item 2.02 Results of Operations and Financial Condition.

On November 2, 2016, Flex Pharma, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2016. 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 November 2, 2016.

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: November 2, 2016

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

INDEX TO EXHIBITS

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99.1	Press Release of Flex Pharma, Inc. dated November 2, 2016.

Flex Pharma Reports Third Quarter 2016 Financial Results

-- Exploratory Phase 2 MS & ALS Studies with FLX-787 Underway --

-- HOTSHOTTM Net Product Revenue of \$586,000 --

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

November 2, 2016

Boston, MA - Flex Pharma, Inc. (NASDAQ: FLKS), a biotechnology company developing innovative and proprietary treatments for nocturnal leg cramps (NLC), spasms associated with severe neuromuscular conditions such as multiple sclerosis (MS) and amyotrophic lateral sclerosis (ALS), and exercise-associated muscle cramps (EAMC), today reported financial results for the quarter ended September 30, 2016 and provided an update on its clinical development, consumer product launch and corporate activities.

"Over the past year we have gained important insights from our exploratory studies that will inform our human efficacy studies moving forward," said Flex Pharma Chief Medical Officer Thomas Wessel, M.D., Ph.D. "Our single agent candidate, chemically synthesized, TRP ion channel activator, FLX-787, has been studied in over 100 human subjects treated for several weeks at therapeutic doses, which provides an unusually extensive human safety and efficacy experience for an agent at this stage of development and bodes well for our Phase 2 studies."

"Our drug development efforts with FLX-787 in NLC, MS and ALS continue to advance," stated Christoph Westphal, M.D., Ph.D., Chair and CEO of Flex Pharma. "Flex is well funded through late 2018, and we remain committed to executing upon our mission of helping patients and consumers who suffer from debilitating cramps."

"On the consumer side, in just a few short months, we have over 15,000 unique customers and well over 50 professional and collegiate teams that have ordered HOTSHOT, representing a wonderful early platform for the brand," noted Kathie Lindemann, Chief Operating Officer of Flex Pharma. "The performance of HOTSHOT in its first full quarter post-launch demonstrates a healthy start to the consumer business, following our cult brand strategy targeted at endurance athletes."

Recent Business Highlights

- Clinical Efforts
 - The Company initiated an exploratory Phase 2 study in ALS patients in Australia in September. The randomized, controlled, blinded, cross-over study is designed to evaluate the safety and efficacy of FLX-787 in up to 50 patients who suffer from cramps, spasms and/or spasticity as a consequence of ALS. In June, the Company initiated a similar exploratory Phase 2 study in MS patients with FLX-787.
 - In October, the Company provided a NLC regulatory and clinical update for FLX-787, a topically-acting, selective transient receptor potential (TRP) ion channel agonist: (1) In written responses to the Company's pre-IND meeting request, FDA indicated that cramp frequency "could be an acceptable primary efficacy endpoint." FDA also recommended that the Company utilize a parallel design in a planned IND-opening study. (2) While statistically significant results were seen in some, but not all, of the crossover endpoints, FLX-787 has shown positive signals on muscle cramping in the parallel design portion of two exploratory human proof-of-concept NLC studies. Data from these exploratory studies, and a statistically significant sigmoidal dose-response curve in a human electrically-induced cramp study, supports further evaluation and development of FLX-787 in subjects with NLC and other indications. (3) The Company is planning a parallel design Phase 2 study in NLC to be initiated in the first half of 2017, after its IND application has been accepted.
 - Consumer Product (HOTSHOT)
 - In its first full quarter post-launch, HOTSHOT recorded approximately \$586,000 of net product revenue.
 - As an official sponsor of the 2016 IRONMAN® World Championship in October, HOTSHOT was sampled at the IRONMAN Village throughout the week and available on the race course. More than 25 athletes represented TeamHOTSHOT on race day. HOTSHOT will be sampled at the upcoming New York City Marathon.
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- In July, *The Wall Street Journal* published the article, "[A New Way to Prevent Muscle Cramps](#)", discussing the breakthrough science behind HOTSHOT. The article was a top ranked story on wsj.com for a week. HOTSHOT has also been featured in several subsequent publications: [Wired.com](#), [Men's Fitness online](#), [LAVA Magazine](#) (official magazine of IRONMAN), [Esquire online](#), and [The Daily Burn](#).
- Corporate Highlights
 - In August, W. Larry Kenney, Ph.D., Professor of Physiology and Kinesiology at Penn State University, joined the Company's Scientific Advisory Board. As the Marie Underhill Noll Chair in Human Performance and Professor of Physiology and Kinesiology at Penn State University, Dr. Kenney's research is focused on human physiological responses and adaptations to exercise and extreme environments. Dr. Kenney served as President of the American College of Sports Medicine from 2003-2004. He serves on the American Council of Exercise Scientific Advisory Panel, Nike's Science Advisory Board, and chaired the Gatorade® Sports Science Institute for several years. Dr. Kenney received his Ph.D. in Physiology from Penn State.

Third Quarter 2016 Financial Results

- **Cash Position:** As of September 30, 2016, Flex Pharma had cash, cash equivalents and marketable securities of \$67.3 million. During the quarter ended September 30, 2016, cash, cash equivalents and marketable securities decreased by \$7.5 million.
 - **Net Product Revenue:** Net product revenue for the three months ended September 30, 2016 was approximately \$586,000.
 - **Cost of Product Revenue:** Cost of product revenue for the three months ended September 30, 2016 was approximately \$221,000 and included an inventory reserve of approximately \$33,000.
 - **R&D Expense:** Research and development expense for the three months ended September 30, 2016 was \$5.7 million. Research and development expense for the third quarter primarily included costs associated with the Company's clinical studies of FLX-787, IND-supporting
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activities, personnel costs (including salaries and stock-based compensation costs), and external consultant costs.

- **SG&A Expense:** Selling, general and administrative expense for the three months ended September 30, 2016 was \$5.4 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 launching the Company's consumer brand and product, legal costs, and external consultant costs.
- **Net Loss:** Net loss for the three months ended September 30, 2016 was (\$10.6) million, or (\$0.65) per share. Net loss for the three months ended September 30, 2016 included \$1.9 million of stock-based compensation expense. As of September 30, 2016, Flex Pharma had 16,518,347 shares of common stock outstanding, which excludes approximately 1.4 million shares of stock that remain subject to vesting. The net loss for the third quarter of 2016 was primarily driven by the Company's operating expenses related to its research and development efforts, costs associated with the development and launch of the Company's consumer brand and product, and general and administrative costs.

Financial Guidance

On the basis of Flex Pharma's current operating plans, the Company expects that its current cash, cash equivalents and marketable securities position will be sufficient to fund its operations through late 2018, assuming no receipt of proceeds from potential business development partnerships, equity financings or debt drawdowns.

Upcoming Events and Presentations

- Jefferies London Healthcare Conference, November 16-17, 2016 in London, UK
- Piper Jaffray Healthcare Conference, November 29-30, 2016 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 third quarter 2016 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.

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 nocturnal leg cramps, cramps and spasms associated with severe neuromuscular conditions such as MS and ALS, and exercise-associated muscle cramps. 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.

Visit www.TeamHOTSHOT.com for updates and to learn more about HOTSHOT™, the Company's consumer product which is scientifically proven to prevent and treat muscle cramps.

HOTSHOT is a consumer product that is marketed to endurance athletes for exercise-associated muscle cramps. HOTSHOT complements the Company's drug development business and is not intended to diagnose, treat, cure or prevent any disease.

Follow Flex Pharma (@flexpharma) and HOTSHOT (@Team_HOTSHOT) on Twitter

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 plans regarding the commercialization of 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, the commercialization of our consumer product; anticipated positioning and product attributes of 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 product 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, 2015 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

Flex Pharma, Inc.

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- Financial Tables to Follow -

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

	September 30, 2016	December 31, 2015
Assets		
Cash and cash equivalents	\$ 27,830	\$ 66,687
Marketable securities	39,504	26,965
Accounts receivable	22	—
Inventory	231	—
Prepaid expenses and other current assets	1,554	909
Property and equipment, net	619	382
Other assets	191	127
Total assets	<u>\$ 69,951</u>	<u>\$ 95,070</u>
Liabilities and stockholders' equity		
Accounts payable and accrued expenses	\$ 3,806	\$ 2,823
Deferred revenue	81	—
Other liabilities	36	55
Stockholders' equity	<u>66,028</u>	<u>92,192</u>
Total liabilities and stockholders' equity	<u>\$ 69,951</u>	<u>\$ 95,070</u>

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

	Three Months Ended September 30, 2016	Three Months Ended September 30, 2015	Nine Months Ended September 30, 2016	Nine Months Ended September 30, 2015
Net product revenue	\$ 586	\$ —	\$ 699	\$ —
Other revenue	13	—	13	—
Total revenue	<u>599</u>	<u>—</u>	<u>712</u>	<u>—</u>
Costs and expenses:				
Cost of product revenue	221	—	529	—
Research and development	5,665	3,445	16,148	9,440
Selling, general and administrative	5,448	4,722	15,937	11,843
Total costs and expenses	<u>11,334</u>	<u>8,167</u>	<u>32,614</u>	<u>21,283</u>
Loss from operations	(10,735)	(8,167)	(31,902)	(21,283)
Interest income, net	98	14	309	34
Net loss	<u>\$ (10,637)</u>	<u>\$ (8,153)</u>	<u>\$ (31,593)</u>	<u>\$ (21,249)</u>
Net loss per share-basic and diluted	<u>\$ (0.65)</u>	<u>\$ (0.53)</u>	<u>\$ (1.96)</u>	<u>\$ (1.57)</u>
Weighted-average number of common shares outstanding (1)	<u>16,362</u>	<u>15,290</u>	<u>16,105</u>	<u>13,520</u>

(1) As of September 30, 2016, the Company had issued approximately 5.4 million shares of restricted stock that are subject to vesting. Of these shares, approximately 4.0 million shares had vested at September 30, 2016 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 1.4 years.