# 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 3, 2016**
Date of Report (Date of earliest event reported)

# Flex Pharma, Inc.

(Exact name of registrant as specified in its charter)

| **Delaware** | **001-36812** | **46-5087339** |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (IRS Employer Identification No.) |

| **800 Boylston Street, 24th Floor Boston, MA** | **02199** |
|---|---|
| (Address of principal executive offices) | (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))

**Item 2.02 Results of Operations and Financial Condition.**

On August 3, 2016, Flex Pharma, Inc. issued a press release announcing its financial results for the quarter ended June 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

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release of Flex Pharma, Inc. dated August 3, 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: August 3, 2016

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

**INDEX TO EXHIBITS**

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|---|---|
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## Flex Pharma Reports Second Quarter 2016 Financial Results

*-- Single Agent Human Efficacy Study in NLC Fully Enrolled Ahead of Plan with Topline Results Expected by Year End --*

*-- Phase 2 MS Study of FLX-787 Initiated in June; Phase 2 ALS Study to Start in the Coming Months --*

*-- First Consumer Product Scientifically Proven to Treat and Prevent Muscle Cramps Launched in June --*

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

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August 3, 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 June 30, 2016 and provided an update on its clinical development, consumer product launch and corporate activities.

"The clinical and consumer arms of the business continue to advance. With our single agent molecule TRP ion channel activator, we initiated and completed enrollment, well ahead of plan, in our human efficacy NLC study. Additionally with FLX-787, we initiated our Phase 2 MS study, and expect to start our Phase 2 ALS study in the coming months. We are also pleased with the solid launch of HOTSHOT™, the first scientifically proven consumer product to prevent and treat exercise-associated muscle cramps, which is exceeding our initial expectations," stated Christoph Westphal, M.D., Ph.D., Chair and CEO of Flex Pharma. "Flex is well funded through the middle of 2018, with approximately $75 million in cash and investments at quarter end, and well-positioned to execute upon our mission of helping patients and consumers."

"Flex Pharma is developing the leading pharmaceutical agent for nocturnal leg cramps. The rapid enrollment in our NLC study underscores the substantial unmet need for the millions of people who suffer from this painful condition and currently have no safe and effective therapeutic options," said Flex Pharma Chief Medical Officer Thomas Wessel, M.D., Ph.D., who served as the medical lead for three products approved in the United States: Razadyne®, Lunesta® and Ampyra®. "We are supplementing our NLC development program by running an additional, small, dose-ranging, randomized, controlled, cross-over study of the single molecule TRP activator. Preliminary interim results are promising. We anticipate providing more details from this added human efficacy study in the fall."

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"Chemical Neuro Stimulation is the process whereby small molecules activate TRP ion channels topically, which we hypothesize leads to sensory stimulation that in turn reduces hyperexcitability in motor neurons at multiple levels in the spinal cord," said Dr. Rod MacKinnon, Nobel Laureate and Flex Pharma Scientific Co-Founder, Board Member, and Scientific Advisory Board Co-Chair. "Because we believe there are common underlying mechanisms at play, the data generated over the past year support our belief that our treatments have the potential to benefit a large number of people afflicted by cramps and spasms."

**Recent Business Highlights**

- Clinical Efforts
  - On July 26, 2016, the Company announced the completion of enrollment, well ahead of plan, in a human proof-of-concept efficacy study in NLC which was initiated in May. The randomized, blinded, controlled, cross-over study is designed to evaluate the safety and efficacy of its single agent - a chemically synthesized, single molecule, transient receptor potential (TRP) ion channel activator, formulated as an orally disintegrating tablet - in over 50 subjects who suffer from nocturnal leg cramps on a frequent basis.

  - In June 2016, the Company initiated a Phase 2 efficacy study in MS patients in Australia. The randomized, controlled, blinded, cross-over study is designed to evaluate the safety and efficacy of FLX-787, the Company's single molecule, chemically synthesized, TRP ion channel activator, in up to 50 patients who suffer from cramps, spasms and/or spasticity as a consequence of MS.

  - The Company expects to initiate a Phase 2 efficacy study in ALS patients in Australia in the coming months. The randomized, controlled, blinded, cross-over study is designed to evaluate the safety and efficacy of FLX-787, the Company's single molecule, chemically synthesized, TRP ion channel activator, in up to 50 patients who suffer from cramps, spasms and/or spasticity as a consequence of ALS.

  - In April 2016, the Company presented results from its positive human NLC study, which was selected as one of only 14 abstracts for late-breaking presentations at the American Academy of Neurology (AAN) Annual Meeting. In this randomized, controlled, blinded study of subjects with frequent nocturnal leg cramps, the Company's extract formulation demonstrated statistically significant positive human efficacy on multiple key endpoints: muscle cramp frequency ($p<0.05$); cramp-free days ($p<0.01$); the physician-rated Clinical Global Impression of Change (CGI-C) ($p<0.01$); specific sleep disturbance measures ($p<0.05$); and specific pain measures ($p<0.01$). The positive effects were seen across a broad range of enrolled subjects; in addition, a subset of patients showed pronounced benefit. Additionally, the product appeared to be safe and well-tolerated and there were no serious adverse events reported. The topline results from this study were first reported in February 2016.

- Consumer Product Launch

- In April 2016, leading academics at The Pennsylvania State University (PSU) presented a positive effect of the Company's proprietary formulation on athletic human muscle cramps at the Experimental Biology conference. The Company's proprietary consumer product formulation showed a statistically significant benefit in reducing muscle cramps in athletes as compared to vehicle control (as measured by the intensity-duration profile of voluntarily induced muscle cramps).

- On June 2, 2016, the Company announced the launch of its cornerstone consumer product, HOTSHOT™, the first scientifically proven formula to prevent and treat muscle cramps, on its branded website www.TeamHOTSHOT.com. The product also became available at select specialty retailers in Boston, Boulder and Los Angeles. For more information, please refer to the press release: SCIENTIFIC BREAKTHROUGH IN SPORTS NUTRITION TO CHANGE THE GAME FOR MILLIONS OF ENDURANCE ATHLETES

- At the American College of Sports Medicine (ACSM) Annual Meeting in Boston on June 2, 2016, Bruce Bean, Ph.D., Harvard Medical School Professor of Neurophysiology, Flex Pharma Co-Founder and Scientific Advisory Board Co-Chair, and Tom Wessel, M.D., Neurologist and Flex Pharma Chief Medical Officer, discussed this breakthrough in sports science during the symposium, "Etiology and Treatment of Exercise Associated Muscle Cramps."

- During the week of July 11th, *The Wall Street Journal* published the article, "*A New Way to Prevent Muscle Cramps*", discussing our breakthrough science behind HOTSHOT™. The article was a top ranked story on wsj.com for a week. HOTSHOT™ has also been featured in several recent publications: *Wired.com, Men's Fitness online*, *LAVA Magazine* (official magazine of IRONMAN®), *Esquire online,* and *The Daily Burn.*

**Second Quarter 2016 Financial Results**

- **Cash Position:** As of June 30, 2016, Flex Pharma had cash, cash equivalents and marketable securities of $74.9 million. During the quarter ended June 30, 2016, cash, cash equivalents and marketable securities decreased by $9.5 million.

- **Net Revenue:** Net revenue for the three months ended June 30, 2016 was $112,685, comprised primarily of sales from pre-launch orders and online purchases from June 2-9, 2016.

- **Cost of Revenue:** Cost of revenue for the three months ended June 30, 2016 was $110,931. Cost of revenue for the quarter included product costs of $35,313, manufacturing overhead costs of $34,918 and an inventory write-off of $40,700.

- **R&D Expense:** Research and development expense for the three months ended June 30, 2016 was $6.1 million. Research and development expense for the second quarter primarily included costs associated with the Company's clinical studies of its single molecule, chemically synthesized, TRP ion channel activator, clinical studies of FLX-787, IND-supporting

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 June 30, 2016 was $5.4 million. Selling, general and administrative expense for this period primarily included personnel costs (including salaries and stock-based compensation costs), costs related to developing and launching the Company's consumer brand and product, legal costs, and external consultant costs.

- **Net Loss:** Net loss for the three months ended June 30, 2016 was ($11.4) million, or ($0.71) per share. Net loss for the three months ended June 30, 2016 included $2.0 million of stock-based compensation expense. As of June 30, 2016, Flex Pharma had 16,260,781 shares of common stock outstanding, which excludes approximately 1.7 million shares of stock that remain subject to vesting. The net loss for the second 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**

Based on its current cash, cash equivalents and marketable securities position, Flex Pharma expects to have sufficient capital to fund its operations through the middle of 2018.

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**Upcoming Events and Presentations**

- BioCentury NewsMakers conference, September 9, 2016 in New York, NY
- Rodman & Renshaw conference, September 12-13, 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 second 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.

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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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- Financial Tables to Follow -

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

| | June 30, 2016 | December 31, 2015 |
|---|---|---|
| **Assets** | | |
| Cash and cash equivalents | $ 38,941 | $ 66,687 |
| Marketable securities | 35,913 | 26,965 |
| Accounts receivable | 12 | - |
| Inventory | 274 | - |
| Prepaid expenses and other current assets | 2,259 | 909 |
| Property and equipment, net | 637 | 382 |
| Other assets | 192 | 127 |
| Total assets | $ 78,228 | $ 95,070 |
| | | |
| **Liabilities and stockholders' equity** | | |
| Accounts payable and accrued expenses | $ 3,307 | $ 2,823 |
| Deferred revenue | 65 | - |
| Other liabilities | 41 | 55 |
| Stockholders' equity | 74,815 | 92,192 |
| Total liabilities and stockholders' equity | $ 78,228 | $ 95,070 |

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

| | Three Months Ended June 30, 2016 | Three Months Ended June 30, 2015 | Six Months Ended June 30, 2016 | Six Months Ended June 30, 2015 |
|---|---|---|---|---|
| Net revenue | $ 113 | $ - | $ 113 | $ - |
| Costs and expenses: | | | | |
| Cost of revenue | 111 | - | 308 | - |
| Research and development | 6,095 | 3,190 | 10,482 | 5,995 |
| Selling, general and administrative | 5,378 | 3,904 | 10,490 | 7,121 |
| Total costs and expenses | 11,584 | 7,094 | 21,280 | 13,116 |
| | | | | |
| Loss from operations | (11,471) | (7,094) | (21,167) | (13,116) |
| Interest income, net | 108 | 16 | 211 | 20 |
| Net loss | $ (11,363) | $ (7,078) | $ (20,956) | $ (13,096) |
| | | | | |
| Net loss per share–basic and diluted | $ (0.71) | $ (0.47) | $ (1.31) | $ (1.04) |
| | | | | |
| Weighted-average number of common shares outstanding (1) | 16,106 | 15,035 | 15,975 | 12,621 |

(1) As of June 30, 2016, the Company had issued approximately 5.4 million shares of restricted stock that are subject to vesting. Of these shares, approximately 3.7 million shares had vested at June 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 1.67 years.