# **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

February 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)

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)) 

02199

(Zip Code)

#### Item 8.01 Other Events.

On February 2, 2016, Flex Pharma, Inc. issued a press release announcing results of its nocturnal leg cramp study. The full text of this press release is included as Exhibit 99.1 to this Current Report on Form 8-K.

#### Item 9.01 Financial Statements and Exhibits.

#### (d) Exhibits

| Exhibit No. | Description   |
|-------------|---|
| 99.1        | Press Release issued by Flex Pharma, Inc. on February 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: February 2, 2016

By: /s/ Robert Hadfield

Robert Hadfield General Counsel

## INDEX TO EXHIBITS

Description

99.1 Press Release issued by Flex Pharma, Inc. on February 2, 2016



## Flex Pharma Announces Positive Human Efficacy in Nocturnal Leg Cramp Study

-- Statistically Significant Efficacy Demonstrated on Key Endpoints in Randomized, Controlled, Blinded Study --

-- Company to Host Conference Call and Webcast Tuesday Feb 2nd at 9am --

February 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, and exercise-associated muscle cramps, announced today that its extract formulation demonstrated efficacy in treating NLC in a randomized, controlled, blinded study. Statistically significant effects (p<0.05) were demonstrated on key endpoints: muscle cramp frequency; the physician-rated Clinical Global Impression of Change (CGI-C); specific sleep disturbance measures; and specific pain measures. Additionally, the product appeared to be safe and well-tolerated and there were no serious adverse events reported. The magnitude of efficacy in this study on reduction in muscle cramps appears similar to published quinine efficacy studies. Quinine, the only therapeutic intervention for leg cramps with randomized, controlled, blinded study support for efficacy, is associated with serious adverse events and was banned for the treatment of leg cramps by the FDA. Flex Pharma expects to present detailed results of this study at a future medical meeting.

The Company estimates that NLC affects four million Americans nightly; there is no approved therapeutic in the United States to treat this condition. The randomized, blinded, controlled, crossover study evaluated 50 healthy subjects (50-77 years of age) who experienced nocturnal leg cramps at least four nights per week. After an initial placebo run-in period, the subjects were randomized to either control or study product for two weeks. Subjects were then crossed over to the other treatment for another two-week period so that each subject acted as his or her own control.

"Based upon these results, we plan to initiate our next study in nocturnal leg cramps later this year with a single molecule, selective and specific transient receptor potential (TRP) ion channel agonist," 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®. "Additionally, our studies in MS and ALS with our drug candidate, FLX-787, are expected to initiate outside the U.S. this year."

"Flex Pharma is at the forefront of clinical development in nocturnal leg cramps, and the statistically significant human efficacy data generated in this study may provide a promising new treatment in the future for the millions of patients who currently have no safe and effective therapeutic options," noted John Winkelman, M.D., Ph.D., Chief of the Sleep Disorders Clinical Research Program at Massachusetts General Hospital and Flex Pharma Scientific Advisory Board member.

"As a medical scientist, it is fulfilling to confirm the potential positive impact of Chemical Neuro Stimulation -- the process by which a small molecule chemical signal, acting topically, is translated into an electrical signal for the benefit of patients," said Dr. Rod MacKinnon, Nobel Laureate and Flex Pharma Scientific Co-Founder, Board Member, and Scientific Advisory Board Co-Chair. "Based upon the results from this nocturnal leg cramp study, it appears that Chemical Neuro Stimulation may prove to be helpful to the millions afflicted with nocturnal leg cramps, to those suffering from exercise-associated muscle cramps, and hopefully also to those with severe neuromuscular disorders such as MS and amyotrophic lateral sclerosis."

## **Conference Call Information**

Flex Pharma will host a conference call and webcast February 2, 2016 beginning at 9:00 a.m. ET. To participate in the conference call, please dial (855) 780-7202 (domestic) or (631) 485-4874 (international) and refer to conference ID 44087940. The webcast will be accessible live in the Investors and Media section of the company's website at www.flex-pharma.com.

## **About Flex Pharma**

Flex Pharma, Inc. is a biotechnology company that is developing innovative and proprietary treatments for nocturnal leg cramps, spasms associated with severe neuromuscular conditions such as ALS and MS, 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.

## **Cautionary Note on 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. We may, in some cases, use terms such as "predicts," "believes," "potential," "proposed," "continue," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Forward-looking statements

include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things: our expectations regarding future studies of our current product candidates, including the success and timing of these studies; our beliefs regarding the potential benefits of our current product candidates; and expectations regarding the number of individuals that may suffer from nocturnal leg cramps. 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 interpretations of our clinical studies; the uncertainties inherent in conducting clinical studies, including receiving regulatory approval to conduct these studies; the fact that we rely on third parties to manufacture and conduct the clinical studies of our product candidates, which could delay or limit future development or regulatory approval; results from ongoing and planned preclinical development; expectations of our ability to make regulatory filings and obtain and maintain regulatory approvals; our ability to develop and commercialize our consumer product; anticipated positioning and product attributes of our consumer product; results of early clinical studies as indicative of results of future trials; 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, 2014 and subsequent filings with the Securities and Exchange Commission (SEC). You are encouraged to read Flex Pharma's 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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