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

October 13, 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 8.01 Other Events.

On October 13, 2016, Flex Pharma, Inc. issued a press release providing a nocturnal leg cramp regulatory and clinical update. A copy of this press release is filed herewith as Exhibit 99.1 and the information contained therein is incorporated by reference into this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated October 13, 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: October 13, 2016

By: /s/ Robert Hadfield
Robert Hadfield
General Counsel

INDEX TO EXHIBITS

Exhibit No.	Description
99.1	Press Release dated October 13, 2016

FLEXPharma

Flex Pharma Provides FLX-787 Nocturnal Leg Cramp Regulatory and Clinical Update

-- Efficacy Signals Seen in Subanalyses of Exploratory Human Studies of FLX-787 --

-- Parallel Design Phase 2 Trial Planned for First Half 2017 Based upon FDA Pre-IND Responses --

-- Conference Call and Webcast today at 8:45 a.m. ET --

October 13, 2016

Boston, MA - Flex Pharma, Inc. (NASDAQ: FLKS) today provided a nocturnal leg cramp (NLC) regulatory and clinical update for FLX-787, a topically-acting, selective transient receptor potential (TRP) ion channel agonist, which the Company is evaluating for the treatment of nocturnal leg cramps (NLC), multiple sclerosis (MS), amyotrophic lateral sclerosis (ALS), and other disorders.

- In written responses to the Company's pre-IND meeting request received in September 2016, 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 due to the potential for confounding clinical results caused by carry-over effects, unblinding and other concerns with crossover studies.
- 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 sigmoidal dose-response curve in a human electrically-induced cramp study warrant further evaluation and development of FLX-787 in subjects with NLC.
- The Company is planning a parallel design Phase 2 study in NLC to be initiated in the first half of 2017, after the IND application has been submitted and accepted.

Update on Exploratory, Proof-of-Concept Human studies:

1. Exploratory NLC Study of FLX-787 oral disintegrating tablet (ODT)

In this randomized, blinded, controlled, crossover study, 72 subjects (40-79 years of age) who reported to suffer from nocturnal leg cramps at least four nights per week were enrolled at three clinical sites. After an initial two-week placebo run-in

period, subjects were randomized to either 17mg ODT FLX-787 or ODT placebo for three weeks. Subjects were then crossed over to the other treatment for an additional three weeks.

Although preliminary analysis of the entire crossover data set did not demonstrate a statistically significant difference versus placebo on the pre-specified endpoints of muscle cramp frequency or cramp-free nights, a number of concerns have been identified that potentially impact data interpretation at one of the sites. When data from this site are excluded and analysis is restricted to patients from the two other sites (n=37), FLX-787 shows a strong trend on muscle cramp frequency ($p=0.06$) during the initial two-week parallel design of the study versus placebo as compared to baseline run-in period, despite the limited data set not being adequately powered to show statistical significance. We continue to analyze the data between the sites to determine which of the issues, if any, may be meaningful. We believe that FLX-787 was well-tolerated, with no serious adverse events reported.

2. Exploratory, sequential, multiple crossover NLC Study of FLX-787 formulations

In order to help inform the optimal dose and design of the Phase 2 clinical trial expected to begin next year, the Company also conducted a sequential, multiple crossover study to generate safety and efficacy data in subjects exposed to different formulations and dosages of FLX-787. The 29 subjects in this study had participated in the prior NLC crossover study with the Company's extract formulation. In this study of FLX-787, the subjects received liquid or ODT formulations of FLX-787 and matched placebos, in four rapidly successive crossover periods.

Muscle cramp frequency was reduced ($p<0.05$) at two weeks in the parallel portion of the first phase which tested 19 mg of FLX-787 in liquid formulation versus placebo. We believe this human efficacy data further supports the use of a parallel design in future studies, consistent with FDA recommendations. In the crossover data sets, efficacy ($p<0.05$) was generally seen for the pre-specified endpoints of muscle cramp frequency and cramp free nights in the early study arms. In the latter arms, FLX-787 did not show statistical significance versus placebo, which we believe resulted from a potential carryover effect.

3. Human Dose-Ranging Efficacy Study in Electrically-Induced Cramps

In recent months, the Company has continued to evaluate FLX-787 using its electrically-induced cramp model. In a study of five subjects, an ODT formulation of FLX-787 reduced the intensity and duration of electrically-induced muscle cramps in a dose-dependent manner ($p<0.05$). Seven doses (0.5 , 2.5, 6, 10, 18, 32, and 60 mg) of FLX-787, representing more than a 100-fold range, showed an effect consistent with a classic sigmoidal dose response curve, with virtually no effect at the lowest doses and a maximal effect at the highest doses.

"We believe that the data sets reported here, which include efficacy signals from two exploratory NLC human efficacy studies and a clear dose-response curve in our electrically-induced human cramp model, establish the positive effects of FLX-787 on human muscle cramping," 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®." Over the past year we have gained important insights from these exploratory studies regarding subject characteristics, clinical endpoints, dosing and formulation that will inform our human efficacy studies moving forward. We believe the magnitude of beneficial effect found in these studies, as well as in our previously reported efficacy study, bode well for our planned Phase 2 study."

"Having studied repeated dosing of FLX-787 in over 100 human subjects, we have an unusually extensive human safety and efficacy experience for an agent at this stage of development. We look forward to advancing our drug development efforts," said Dr. Christoph Westphal, Flex Pharma CEO.

Data from the human studies outlined above will be presented at future medical meetings.

Conference Call Information

Flex Pharma will host a conference call and webcast Thursday, October 13, 2016 beginning at 8:45 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 99423526. 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 design, 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; 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, 2015 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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