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

April 19, 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 7.01 Regulation FD Disclosure.

On April 19, 2016, Flex Pharma, Inc. (the "Company") will present a poster and provide a presentation, each of which is entitled "*Orally-administered TRPV1 and TRPA1 Activators Reduce Night Leg Cramps in a Randomized, Blinded, Placebo-Controlled, Crossover Human Trial,*" at the Annual Meeting of the American Academy of Neurology. The poster and presentation are furnished herewith as Exhibits 99.1 and 99.2, respectively.

Forward-Looking Statements.

Statements contained in, or incorporated by reference into, this Current Report on Form 8-K regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Risks are described more fully in the Company's filings with the Securities and Exchange Commission, including without limitation the Company's most recent Annual Report on Form 10-K and other documents subsequently filed with or furnished to the Securities and Exchange Commission. All forward-looking statements contained in this Current Report on Form 8-K speak only as of the date on which they were made. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

The information contained in this Item 7.01 and Exhibits 99.1 and 99.2 attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under 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	Flex Pharma, Inc. poster.
99.2	Flex Pharma, Inc. presentation.

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: April 19, 2016

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

INDEX TO EXHIBITS

Exhibit No.	Description
99.1	Flex Pharma, Inc. poster.
99.2	Flex Pharma, Inc. presentation.

Orally-administered TRPV1 and TRPA1 Activators Reduce Night Leg Cramps in a Randomized, Blinded, Placebo-Controlled, Crossover Human Trial

Poster No. 013

Cermak, J.M., Rosen, L.B., Hegarty, B.W., Bean, B.P., MacKinnon, R., Westphal, C.H., and Wessel, T.

Flex Pharma, Inc. Boston, MA 02199

FLEXPharma

Novel Treatments for Neuromuscular Conditions

Summary

Nocturnal leg cramps (NLC) affect millions of Americans, and there are no FDA-approved drug therapies. Recent experimental evidence argues that hyperexcitability of alpha-motor neurons is central to generating muscle cramps. Initial observations in athletes led to the hypothesis that activation of TRPV1/TRPA1 ion channels in mucous membranes of the oropharynx/upper GI tract increases inhibitory tone in the spinal cord, dampening motor neuron hyperexcitability. Recent evidence in electrically- and volitionally-induced cramps in athletes supports this hypothesis.

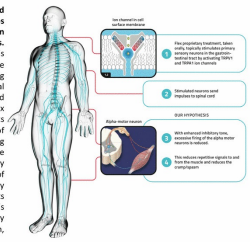
We investigated the safety and efficacy of a proprietary formulation of TRP activators (TRP-Stim) in NLC in a randomized, blinded, placebo-controlled, crossover trial in subjects with cramps at least 4 nights/week. After an initial placebo run-in period, 51 evaluable subjects (50-77 years) were randomized to either placebo or TRP-Stim for two weeks, then crossed over for two weeks.

Statistically significant effects were demonstrated on key endpoints: cramp frequency (p<0.05); cramp-free days (p<0.01), the physician-rated Clinical Global Impression of Change (p<0.01); and specific sleep disturbance (p<0.05) and pain measures (p<0.01). The product appeared to be safe and well-tolerated, with no serious adverse events. The magnitude of cramp reduction appears to be similar to published "Class 1 level" quinine efficacy studies (quinine was banned by the FDA for leg cramps due to safety issues) (1). Finally, a subset of subjects had a pronounced clinical benefit.

These results demonstrate that TRP activation can reduce NLC. This supports the novel concept of Chemical Neuro Stimulation, a process whereby small molecules activate TRP ion channels topically, leading to sensory stimulation that in turn reduces hyperexcitability in motor neurons at multiple levels in the spinal cord. The human efficacy signals generated in this study hold promise as a new approach in treating NLC and cramps in neurological disorders. Based upon these results, we plan to initiate studies with a chemically-synthesized single molecule TRP activator in potential indications such as NLC, MS and ALS.

Background

Figure 1. Overview of suspected mechanism of muscle cramps and methods of cramp inhibition by activation of TRP ion channels. Muscle cramping and spasticity is thought to be caused by the uncontrolled and repetitive firing of α-motor neurons in the spinal cord (2, 3), resulting in maintained contraction of the muscle. Flex Pharma's proprietary products exploit a general principle of neural circuits whereby strong excitatory sensory input from one source enhances overall inhibitory tone by increased recruitment of inhibitory neurons, thereby reducing excitability in other parts of the circuit (4). Flex Pharma's products stimulate primary sensory neurons in the mouth, esophagus and stomach by activating TRPV1 and TRPA1 ion channels (5,6). When activated, these sensory neurons, which project both directly and indirectly to the spinal cord, enhance the inhibitory tone in spinal cord circuits to reduce repetitive firing of α-motor neurons which prevents or reduces the frequency and intensity of muscle cramps and spasms.

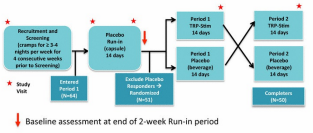


Methods

Nocturnal leg cramps (NLC)

- 50% of those over the age of 50 suffer from NLC with increasing prevalence and frequency with age; Over 4 million in the US over age 65 suffer daily.
- Quinine, prescribed in the United Kingdom for NLC, is associated with thrombocytopenia, hypersensitivity reactions and QT prolongation and is no longer approved in the US for NLC, and no approved drug alternative exists in the US to treat NLC.

Figure 2. Multi-Center Trial in NLC: A randomized, double-blind, placebo-controlled, double cross-over study to evaluate the effects of a Flex product on the frequency of nocturnal foot and/or leg cramps when self-administered approximately 45 minutes before going to bed.



Baseline assessment at end of 2-week Run-in period

Objectives & Endpoints

Objective: To assess the safety, tolerability, and exploratory efficacy of TRP-stimulator extracts vs. control beverage over a 2-weeks period on Nocturnal Legs Cramps (NLC) as assessed by the following endpoints:

Efficacy – Change from baseline in:

1) Total number of cramps per period; (Reported daily by subjects through an Interactive Voice Response System (IVRS))
2) Number of cramp-free days per period; (Reported daily by subjects through an Interactive Voice Response System (IVRS))
3) Cramp pain/intensity assessments; (Reported daily by subjects through an Interactive Voice Response System (IVRS))
4) Clinical Global Impression of Change; (Assessed by sites at the end-of-period study visits)
5) Quality of Life SF-36; and (Assessed by sites at the end-of-period study visits)
6) Insomnia Severity Index (Assessed by sites at the end-of-period study visits)

Safety:

Safety endpoints will be the reported SAEs and unexpected AEs to the study treatment, vital signs, and laboratory assessments.

Disposition and Demographics

Disposition

- Overall, 64 subjects enrolled in Placebo Run-in
- 13 subjects discontinued after Placebo Run-in:
  - 9 for placebo response (CGI > 3 after placebo)
  - ~ 15% placebo run-in exclusion rate
  - 1 for IVRS noncompliance, 1 for HbA1c out-of-range, 1 for no-show
  - 1 for con med carisoprodol (centrally acting muscle relaxant)
- 51 subjects were randomized to Periods 1 & 2
  - 50 subjects complete
  - 1 subject discontinued due to Adverse Event (AE) of UTI

Demographics

- Of the N=51 randomized subjects:
  - 65 % were female; 35 % were male
  - 92% were White, 8 % were Black or African-American
  - 8% were Hispanic or Latino; 92% were non-Hispanic or Latino
  - Mean age was 60.5 years (range 50-77)
  - Mean BMI was 29 (range 21 – 46)

Results

Figure 3. TRP-Stim treatment results in significant differences relative to placebo across multiple clinically meaningful endpoints.

	Mean			Median		
Change from Baseline in:	TRP-Stim	Placebo	p-value	TRP-Stim	Placebo	p-value*
Total Cramps/ Period	-7.0	-5.0	<0.05	-6	-4	<0.05
Total Cramp-Free Days/ Period	2.3	1.3	<0.01	2	1	<0.01
CGI	3.1	3.6	<0.01	3	4	<0.01
VAS Pain Intensity						
• Mean / Period	-6.7	-3.6	0.051			
• Mean / Last 3 Days of Period	-7.5	-4.3	<0.01			

Insomnia Severity Index (5 items):	TRP-Stim	Placebo	p-value
Sub-question Q1b:			
• Difficulty staying asleep**	39%	33%	<0.05

- p-values from Wilcoxon Signed Rank Test
- ** Responder analysis (answer of 'none' or 'mild')

Green = statistically significant; amber = trend toward significance

Figure 4. Graphical representation of the mean daily cramp frequency for each cross-over period (Periods 1 and 2). The TRP-Stim treatment arms display nominal increasing efficacy over the course of each crossover period, whereas the placebo arms show no improvement over the 14-day periods.

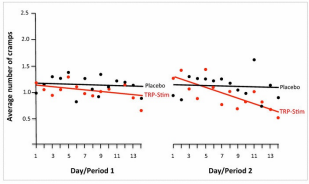
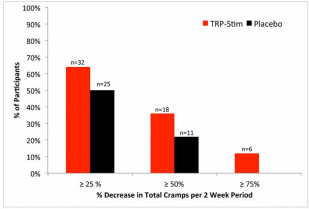


Figure 5. Percentage of participants who experienced at least a 25%, 50%, or 75% decrease in the total number of cramps over the two week study period. Those individuals receiving TRP-Stim demonstrated a more pronounced cramp reduction than Placebo in all groups, with only TRP-Stim showing a ≥75% reduction.



Results, cont.

Figure 6. Clinical Global Impression of Change (CGI-C) by Treatment. Responders were defined as those who scored 1 or 2 on the CGI-C, as assessed by the site principal investigators. TRP-Stim beverage treatment led to 40% of subjects being considered Responders vs. only 24% with Placebo beverage.

Scale (Score)	Run-in N=62	TRP-Stim N=50	Placebo N=49
Very Much Improved (1)	1 (2%)	7 (14%)	3 (6%)
Much Improved (2)	6 (10%)	13 (26%)	9 (18%)
Minimally Improved (3)	7 (11%)	16 (32%)	11 (22%)
No Change (4)	34 (55%)	8 (16%)	18 (37%)
Minimally Worse (5)	8 (13%)	1 (2%)	3 (6%)
Much Worse (6)	1 (2%)	2 (4%)	0 (0%)
Very Much Worse (7)	5 (8%)	3 (6%)	5 (10%)

Red font = excluded after Placebo Run-in due to placebo response

Responders = Much or Very Much Improved compared to Baseline

- 40 % Responders on TRP-Stim Beverage
- 24 % Responders on Placebo Beverage

Summary & Conclusions

- Nocturnal leg cramps affect millions of Americans, but no approved drug therapy for NLC currently exists (quinine was banned by the FDA for leg cramps due to safety issues).
- Flex-100 investigated the safety and efficacy of TRP activators in a randomized, blinded, placebo-controlled, cross-over study in healthy subjects (50-77 years) suffering ≥ 4 night leg cramps/week.
- Treatment with TRP activators resulted in statistically significant effects on clinically meaningful endpoints: cramp frequency (p<0.05); cramp-free days (p<0.01), physician-rated Clinical Global Impression of Change (p<0.01); "difficulty staying asleep" (p<0.05) and VAS pain intensity over the last 3 days of each treatment period (p<0.01).
- 12% of subjects when treated with TRP activators experienced a ≥ 75% decrease in total cramps experienced over the two week treatment period.
- There were no serious adverse events; all adverse events reported were mild or moderate, transient and primarily gastrointestinal: "tingling lips" and "dyspepsia" were the most frequent.
- The magnitude of cramp reduction appears to be similar to published "Class 1 level" quinine efficacy studies.
- Chemical Neuro Stimulation of TRPV1 and TRPA1 channels in the oral mucosa may be a generally applicable method to treat disorders stemming from α-motor neuron hyperexcitability.
- Clinical studies will be initiated using the chemically-synthesized single molecule TRP activator in potential indications such as NLC, MS and ALS.

References

1. Katzberg HD, Khan AH and So YT. *Neurology.* **74**(8):691-6, 2010.
2. Minetto MA, Holobar A, Botter A, and Farina D. *Exerc. Sport Sci. Rev.* **41**(1): 3-10, 2013.
3. Milanov, I. *Electromyogr Clin Neurophysiol.* **32** (2): 73-9, 1994.
4. Okun, M. & Lampl, I. *Nature Neurosci.* **11**: 535–537, 2008.
5. Beilefeldt et al., *Am J Physiol Gastrointest Liver Physiol* 294: G130–G138, 2008.
6. Yu et al., *Am J Physiol Gastrointest Liver Physiol* 297: G34–G42, 2009.

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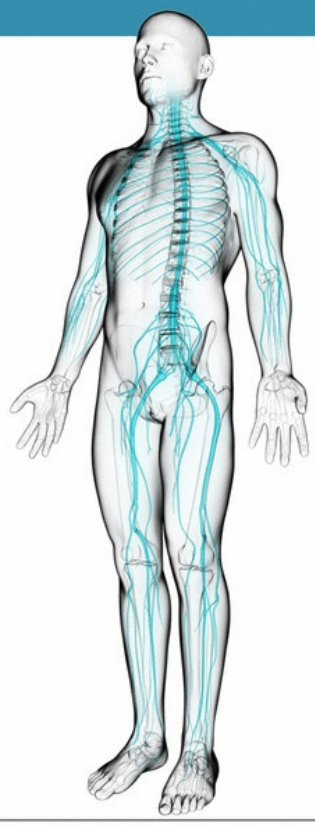
Orally-administered TRPV1 and TRPA1 Activators Reduce Night Leg Cramps in a Randomized, Blinded, Placebo-Controlled, Crossover Human trial

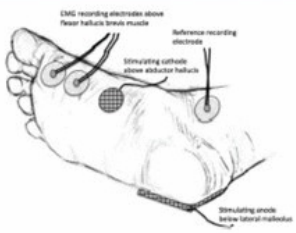


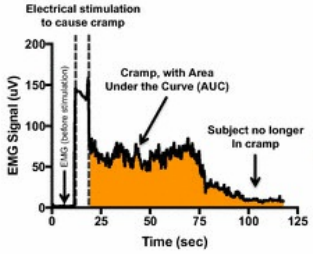
Jennifer Cermak, Laura B. Rosen, Brooke Hegarty, Bruce Bean, Rod MacKinnon, Christoph Westphal, and Thomas Wessel

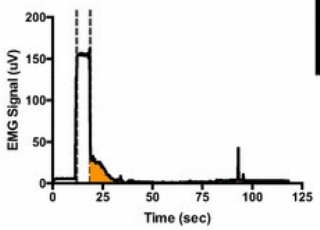
AAN Meeting, Vancouver, BC
April 19, 2016

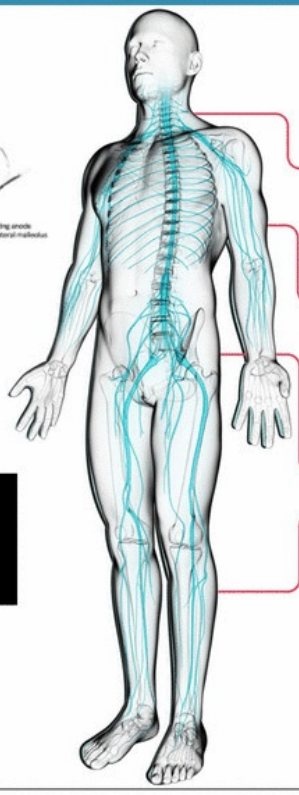
Therapeutic Mechanism: Chemical Neuro Stimulation

Electrically Induced Cramp (EIC) Model

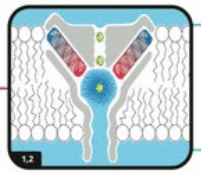








Ion channel in cell surface membrane

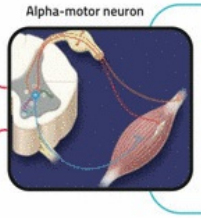


1 Flex proprietary treatment, taken orally, topically stimulates primary sensory neurons in the gastrointestinal tract by activating TRPV1 and TRPA1 ion channels

2 Stimulated neurons send impulses to spinal cord

OUR HYPOTHESIS

Alpha-motor neuron



3 With enhanced inhibitory tone, excessive firing of the alpha motor neurons is reduced.

4 This reduces repetitive signals to and from the muscle and reduces the cramp/spasm

1 Doyle, et al., MacKinnon, The Structure of the Potassium Channel: Molecular Basis of K+ Conduction and Selectivity, April 1998, Science

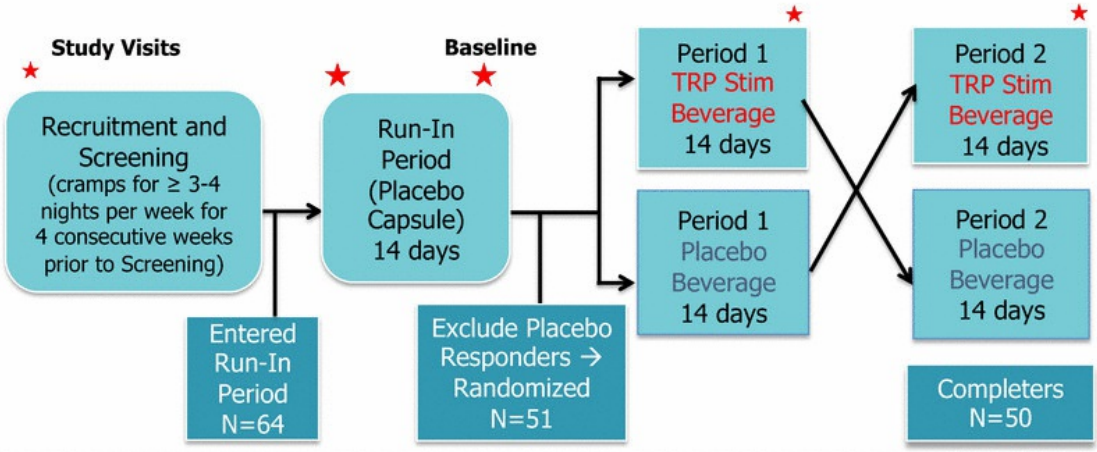
2 Caterina, et al., Julius, The capsaicin receptor: a heat-activated ion channel in the pain pathway, October 1997, Nature

Flex-100 Nocturnal Leg Cramps Study

Nocturnal leg cramps (NLC)

- 50% >age 50 have NLC and >4 million in the US >65 years suffer daily
- Quinine (Rx for NLC in UK) is associated with thrombocytopenia, hypersensitivity reactions and QT prolongation and was banned by FDA for NLC in 1994

Flex multicenter US Trial in NLC: Randomized, double-blind, placebo-controlled, 2-period cross-over study to evaluate the effects of TRP stim on the frequency of NLC when taken ~ 45 minutes before going to bed



Flex-100 Results

- Treatment with TRP activators resulted in concordant clinically meaningful effects:
  - Cramp frequency ($p<0.05$)
  - Cramp-free days ($p<0.01$)
  - Physician-rated Clinical Global Impression of Change ($p<0.01$)
  - "Difficulty staying asleep" question on ISI ($p<0.05$)
  - VAS pain intensity over the last 3 days of each treatment period ($p<0.05$)
- Large proportion of patients had a positive and consistent beneficial response
- 40% vs 24% "Very much improved" and "Much improved" on CGI-C
- No serious adverse events; generally well tolerated
- Magnitude of cramp reduction appears to be similar to published "Class 1 level" quinine efficacy studies (AAN evidence-based review, Katzberg et al, 2010)
- Chemical Neuro Stimulation of TRPV1 and TRPA1 channels in the oral mucosa may be a general method to treat disorders stemming from α-motor neuron hyperexcitability
- Clinical studies are being initiated using a potent single-molecule TRP activator for NLC and neurological indications ALS and MS