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

December 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 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On December 13, 2016, the Compensation Committee of the Board of Directors of Flex Pharma, Inc. (the "Company") approved the promotion of John McCabe from Vice President, Finance to Chief Financial Officer. In connection with such promotion, Mr. McCabe and the Company entered into an amendment to Mr. McCabe's executive employment agreement providing for, among other things, an increase of Mr. McCabe's base salary to $300,000 and his target bonus to forty percent (40%) of his base salary.

The foregoing summary of the amendment to Mr. McCabe's executive employment agreement is qualified in its entirety by the full text of the amendment, which is filed herewith as Exhibit 10.1 and incorporated herein by reference.

Item 7.01. Regulation FD Disclosure.

A copy of the slide presentation that will be used by representatives of the Company in connection with investor meetings or presentations from time to time (the "Corporate Presentation") is attached to this Current Report on Form 8-K as Exhibit 99.1. The Corporate Presentation is current as of December 15, 2016, and the Company disclaims any obligation to correct or update this material in the future.

The information in Item 7.01 of this Form 8-K (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), 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, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit 99.1, which relates to Item 7.01 above, shall be deemed to be furnished and not filed.

Exhibit No.	Description
10.1	Amendment to Executive Employment Agreement dated December 14, 2016 between John McCabe and the Company
99.1	Corporate Presentation current as of December 15, 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: December 15, 2016

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

INDEX TO EXHIBITS

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AMENDMENT TO EXECUTIVE EMPLOYMENT AGREEMENT

This AMENDMENT TO EXECUTIVE EMPLOYMENT AGREEMENT (the "***Amendment***") between Flex Pharma, Inc., a Delaware corporation (the "***Company***"), and John McCabe (the "***Executive***") is effective as of December 14, 2016 (the "***Effective Date***"). Capitalized terms not otherwise defined herein shall have the meanings ascribed to them in the Employment Agreement (as defined below).

W I T N E S S E T H:

WHEREAS the Company and Executive entered into that certain Executive Employment Agreement dated May 27, 2015 (the "***Employment Agreement***") and the parties now wish to amend certain terms of the Employment Agreement as set forth herein.

NOW THEREFORE, in consideration of the foregoing, of the mutual promises contained herein and of other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereby agree as follows:

1. **AMENDMENT TO POSITION & DUTIES**. Section 2 of the Employment Agreement is hereby deleted in its entirety and replaced with the following:

> "**2. POSITION & DUTIES**. During the Employment Term, the Executive shall serve as the Company's Chief Financial Officer. As Chief Financial Officer, the Executive shall have such duties, authorities and responsibilities commensurate with the duties, authorities and responsibilities of persons in similar capacities in similarly sized companies and such other duties and responsibilities as the Company's Chief Executive Officer shall designate that are consistent with the Executive's position as Chief Financial Officer. During the Employment Term, the Executive shall use his best efforts to perform faithfully and efficiently the duties and responsibilities assigned to the Executive hereunder and devote all of the Executive's business time (excluding periods of PTO and other approved leaves of absence) to the performance of the Executive's duties with the Company."

2. **AMENDMENT TO BASE SALARY**. Effective January 1, 2017, the Base Salary for the Executive set forth in Section 4 of the Employment Agreement is hereby increased to $300,000.

3. **AMENDMENT TO TARGET BONUS**. For the 2017 calendar year and each full calendar year during the Employment Term thereafter, the Target Bonus set forth in Section 5 of the Employment Agreement is hereby increased to forty percent (40%) of the Base Salary.

4. **MISCELLANEOUS.** Executive acknowledges that his employment with the Company will continue to remain "at-will." All other terms and provisions of the Employment Agreement not expressly modified hereby shall remain in full force and effect. This Amendment shall take effect as of the date hereof. This Amendment shall be binding upon and inure to the benefit of all of the parties to the Employment Agreement, their successors and assigns, heirs, devisees, legates and personal representatives. All other terms and provisions of the Employment Agreement not expressly modified by this Amendment shall remain in full force and effect. This Amendment may be executed in multiple counterparts, each of which shall be deemed an original for all purposes and all of which shall be deemed collectively to be one agreement. This Amendment shall be governed by and construed in accordance with the Commonwealth of Massachusetts applicable to contracts made and to be performed therein, without giving effect to the principles thereof relating to the conflict of laws.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement, effective as of the date first written above.

FLEX PHARMA, INC.

By: /s/ Christoph Westphal
Name: Christoph Westphal
Title: CEO

EXECUTIVE

/s/ John McCabe

Novel Treatments for Neuromuscular Conditions

Forward-Looking Statements

Any statements in this presentation and the oral commentary about future expectations, plans and prospects for the company, including statements about the company's strategy, future operations, development of its consumer and drug product candidates, plans for potential future product candidates and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "suggest," "target," "potential," "will," "approximately," "development plans," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the status, timing, design, costs, results and interpretation of the company's 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, our ability to commercialize our consumer products; positioning and product attributes of our consumer products; results of early clinical studies as indicative of the results of future trials; availability of funding sufficient for the company's foreseeable and unforeseeable operating expenses and capital expenditure requirements; other matters that could affect the availability or commercial potential of the company's consumer or drug product candidates; the inherent uncertainties associated with intellectual property; and other factors discussed in the Risk Factors set forth in the company's Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) and in other filings the company makes with the SEC from time to time. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. The forward-looking statements in this presentation represent our views as of the date of this presentation. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this presentation.

This presentation also contains estimates and other statistical data made by independent parties and by the company relating to market size and growth and other data about the company's industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions and estimates of the company's future performance and the future performance of the markets in which the company operates are necessarily subject to a high degree of uncertainty and risk.

This presentation contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this presentation, including logos, artwork and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

ORIGIN STORY

Flex Pharma Overview

- Innovative treatments for a broad range of painful and debilitating muscle cramps, spasms and spasticity based upon novel insights regarding neuromuscular physiology from our co-founders (ion channels and TRP biology, MacKinnon Nobel Prize 2003)

- FLX-787: MS & ALS exploratory human POC studies initiated in 2016; results in H2 2017. Phase 2 NLC study to initiate H1 2017.

- Data in human settings involving muscle cramps:
    1. NLC: efficacy signals in 2 exploratory randomized, blinded, controlled, cross-over POC studies with FLX-787 (n=37 subanalysis, n=29)
    2. NLC: statistically significant positive effect in a randomized, blinded, controlled, cross-over study with extract formulation (n=50)
    3. Electrically-induced cramp (EIC) model: sigmoidal dose response curve (n=5), $p<0.05$. Randomized, blinded, controlled efficacy with 100+ subjects & over 200 safety/efficacy data points

Management Team and Board of Directors

Management Team

- **Christoph Westphal**, MD PhD, CEO; Cofounder/Lead investor ALNY MNTA XLRN SIRT Alnara CNCE VSTM OVAS
- **Rob Hadfield**, General Counsel; Cooley LLP, Kiva Systems, SG Cowen
- **Kathie Lindemann**, COO; DAVIDs TEA, Starbucks
- **John McCabe**, CFO; Ariad, Charles River Associates, Biogen, Arthur Andersen
- **Angelene Simonello,** VP Corporate and Program Development; Viacell, Biogen
- **Thomas Wessel**, MD PhD, CMO; JNJ (Razadyne®), SEPR (Lunesta®), ACOR (Ampyra®)
- **Elizabeth Woo**, SVP, Investor Relations; Biogen, Ironwood, Cubist

Board of Directors

- **Jeff Capello**, former CFO Ortho-Clinical Diagnostics; BOD OVAS, former Boston Scientific CFO, PKI, PWC
- **Peter Barton Hutt**, former Chief Counsel FDA; Sirtris, Momenta, Concert, Covington and Burling
- **Marc Kozin**, LEK Consulting, former President of North American practice; BOD OVAS, ECYT, DYAX, UFPT
- **Rod MacKinnon**, MD, Co-founder, Chair, SAB; Nobel Prize 2003, ion channels; Professor, Rockefeller; NAS
- **Rob Perez**, former CEO Cubist; former Biogen, BOD AMAG, CDTX
- **Stuart Randle**, Ivenix CEO, former CEO GI Dynamics, former CEO ACT Medical, Baxter
- **John Sculley**, former CEO Pepsi (current owner of Gatorade), former CEO Apple
- **Michelle Stacy**, former Keurig President, Gillette/P&G, BOD iRobot

Scientific Advisory Board & Select Investors

Scientific Advisory Board

Rod MacKinnon, MD, Cofounder, Chair, SAB; Nobel Prize 2003, ion channels; Professor, Rockefeller; National Academy of Science (NAS)

Bruce Bean, PhD, Cofounder, Chair, SAB; Winthrop Professor, Harvard Med; Neurophysiology; NAS

W. Larry Kenney, PhD; Penn State Univ Professor Physiology

Alfred Sandrock, MD, PhD; Neurologist, Chief Medical Officer of Biogen

Roger Tung, PhD; Medicinal chemist, Vertex, Merck (inventor multiple drugs); CEO, Concert

Chris Walsh, PhD; Professor Emeritus, Harvard Med; Genzyme, Verastem, Sirtris; NAS

John Winkelman, MD, PhD; Chief Sleep Disorders, MGH; BWH, RLS clinical development

Sports Team investors

Wyc Grousbeck, Managing Partner, Governor, CEO Boston Celtics

KPC Venture Capital (Kraft family), Owner New England Patriots, New England Revolution

PagsGroup (Steve Pagliuca), Managing Partner, Bain Capital; Managing Partner, Boston Celtics

Mark Wan, Causeway Partners; Minority Owner: Boston Celtics, SF 49ers

Christoph Westphal, Minority Owner Boston Celtics

Large and Diverse Market Opportunities

Muscle Cramps & Spasticity in Neuromuscular Conditions

Multiple Sclerosis, ALS/Motor Neuron Disease

U.S. Patient Population

- MS: 250K – 350K patients[3]
- ALS: 12K patients[4]

Nocturnal Leg Cramps

Sudden painful contraction reducing sleep quality

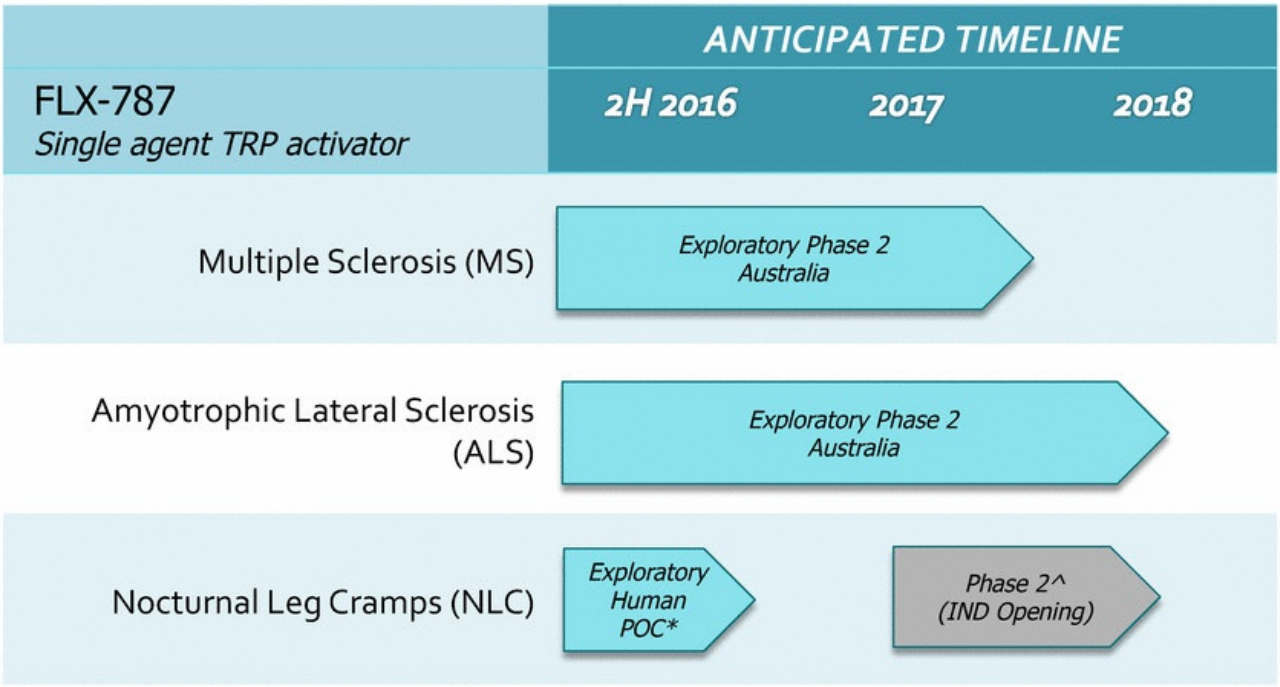
No drug approved in the U.S.

U.S. Patient Population

- 37% prevalence for 50+ yo[1]
- ~4M over 65 yo suffer daily[2]

1 Naylor & Young, A General Population Survey of Rest Cramps, *Age and Ageing* 1994.23 418-420
2 Management estimates based on third party survey results
3 National Institute of Neurological Disorders and Stroke
4 Morbidity and Mortality Weekly Report July 2014

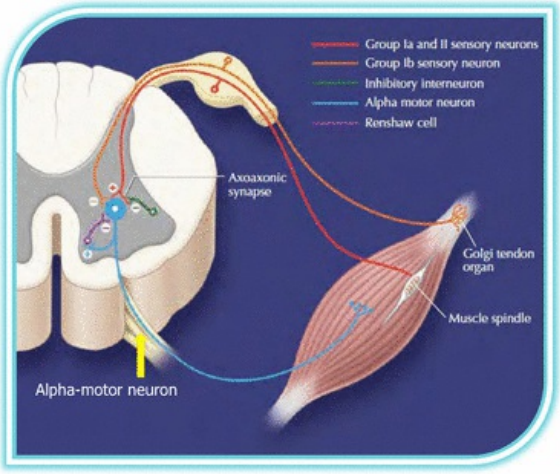
Flex Pharma Development Path



All Studies are randomized, controlled, blinded
*Study conducted under dietary supplement guidelines
^ Subject to FDA review of IND application

Neurogenic Origin of Muscle Cramping/Spasms

Cramps and spasms are generally NOT caused by dehydration, lactic acid build-up or electrolyte imbalances affecting the muscle

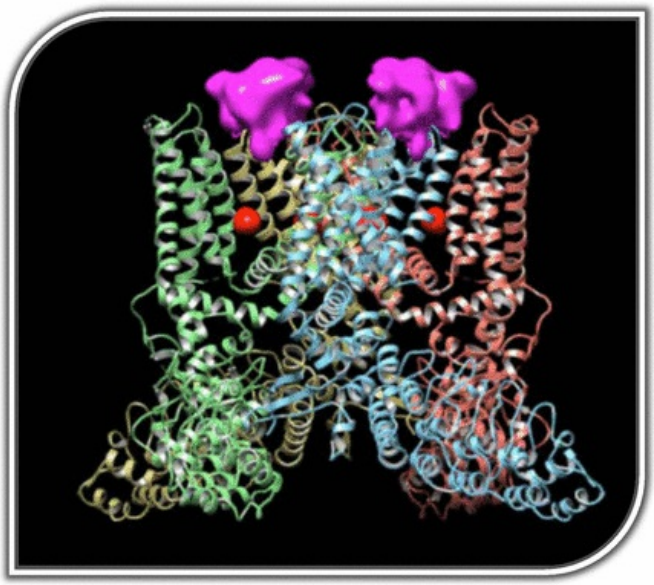


- Muscle cramping is caused by excessive firing of alpha-motor neurons in the spinal cord, which trigger a painful contraction of the muscle
- Repetitive muscle use induces hyperexcitability of alpha-motor neurons, causing them to fire excessively and trigger cramping

Hyperexcitability of alpha-motor neurons is also a likely basis for spasticity and spasms

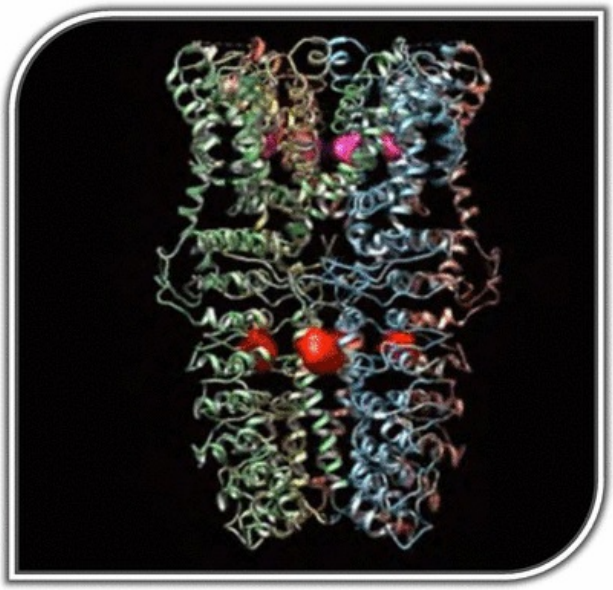
TRP Ion Channel Co-crystal Structures – Flex Drug Targets in Two Recent Nature Papers

TRPV1



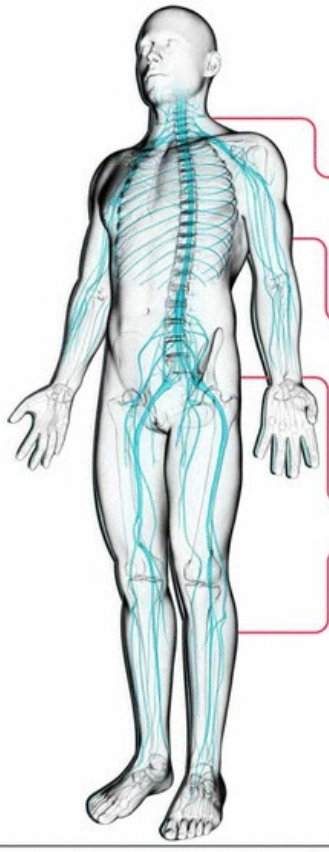
E. Cao, M. Liao, Y. Cheng and D. Julius, *Nature*, 5 Dec 2013

TRPA1



C.E. Paulsen, J. Armache, Y. Gao, Y. Cheng and D. Julius, *Nature*, 8 April 2015

Chemical Neuro Stimulation of Vagus Nerve



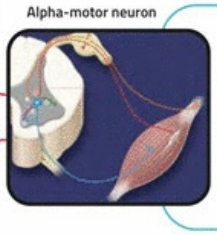
Ion channel in cell surface membrane

1 Flex proprietary treatment, taken orally, topically stimulates primary sensory neurons in the gastroin-testinal 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.

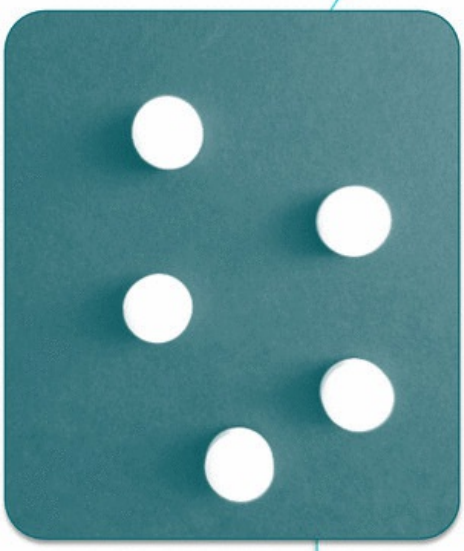
4 This reduces repetitive signals to and from the muscle and reduces the cramp/spasm

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

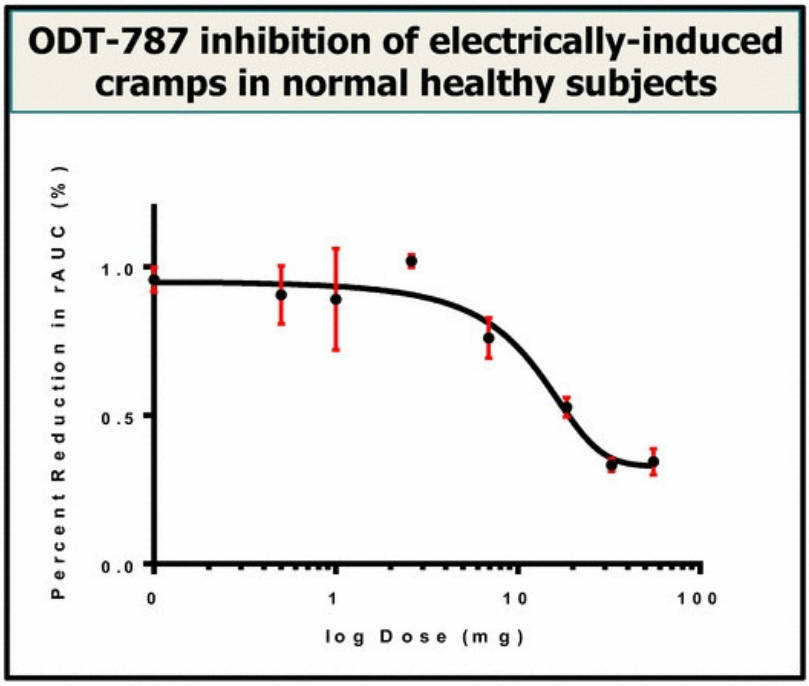
FLX-787 Orally Disintegrating Tablet (ODT)

FLX-787 Tablets



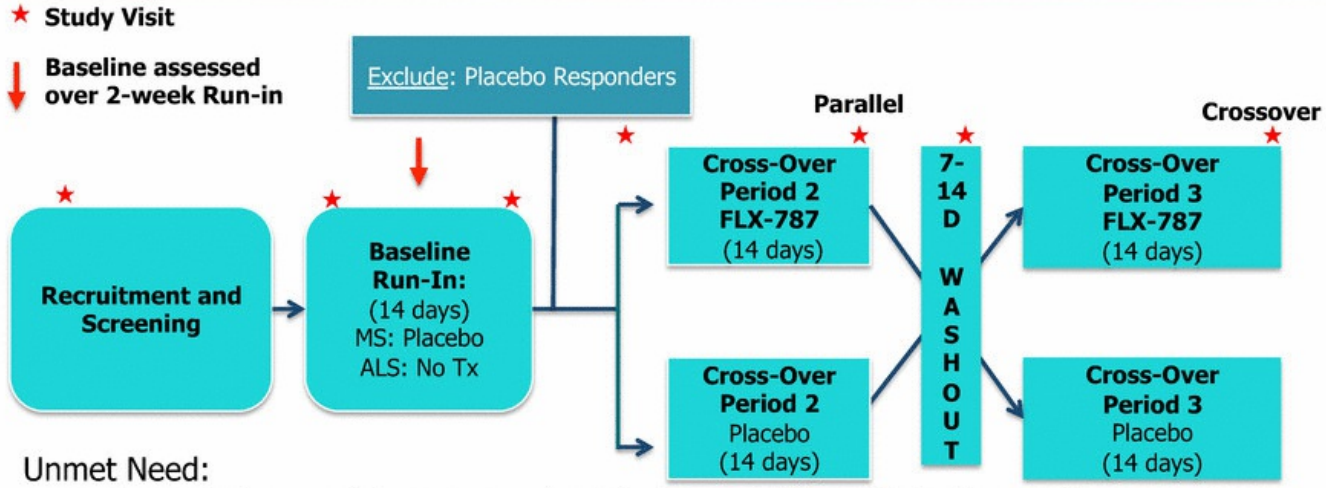
- **Single agent molecule** selected on the basis of potency and efficacy in human electrically-induced cramp model
- **Optimized ODT formulation** to cover TRPV1 and TRPA1 receptors in mucous membranes
- **Reduced risk of aspiration** for patients across all potential indications

Dose Response Demonstrated in Human EIC model



- 7 doses of FLX-787 yield classic sigmoidal dose curve (n=5, $p<0.05$)
- Initial human PK (n=4) indicates no measurable systemic exposure of parent drug in plasma at potential therapeutic dose

MS & ALS Exploratory Studies



Unmet Need:
current agents have safety concerns (quinine) or sedating effects (benzodiazepenes)

MS
- n~50; 19mg liquid, 2x/day
- Initiated June 2016; Results H2 2017
- Spasticity (Tardieu, Ashworth), Cramping in patients who cramp, sleep, safety

ALS
- n<50; 30mg ODT, 3x/day
- Initiated Sept 2016; Results 2017/2018
- Cramping, spasticity, sleep

Effect Size Comparison

Effect sizes calculated for the parallel portion of the cross-over studies are on-average larger than those reported in the quinine clinical literature^

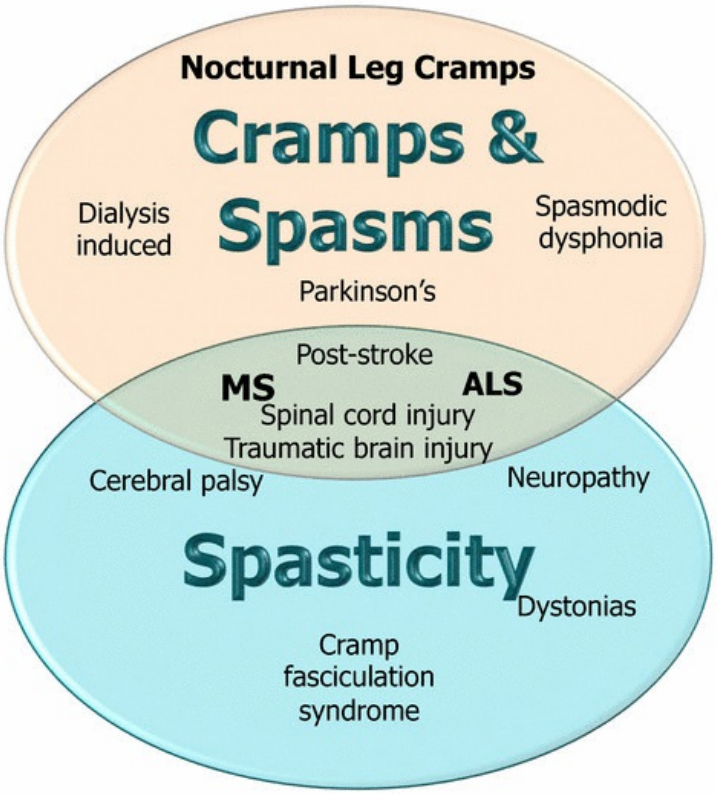
Endpoint	Treatment/Study	N_{Total}	$N_{Eff\ size}$	p-value	Effect Size
Cramp Frequency	TRP-Stim	50	50	0.08	0.46
	FLX-787 (ODT)/Study 1*	72	37	0.06	0.77
	FLX-787 (liq)/Study 2	29	29	0.02	0.94

* The effect size of Study 1 is a sub-analysis (n=37) excluding data from 1 site (n=35).

- Exploratory ANOVA analyses across studies showed a period effect within each cross-over
- To avoid the potential influence of carry-over on effect size estimates were calculated from the first exposure in each study
- Average effect size of cramp frequency derived from quinine literature is **0.12** (95%CI[-3.5,-1.36]).[1]

^ Presented at 2016 Society for Neuroscience, Nov 15, 2016.
1 El-Tawil S. et al.. *Cochrane Database of Systematic Reviews* Issue 12, Art. No.: CD005044, 2010.

Potential across Many Indications

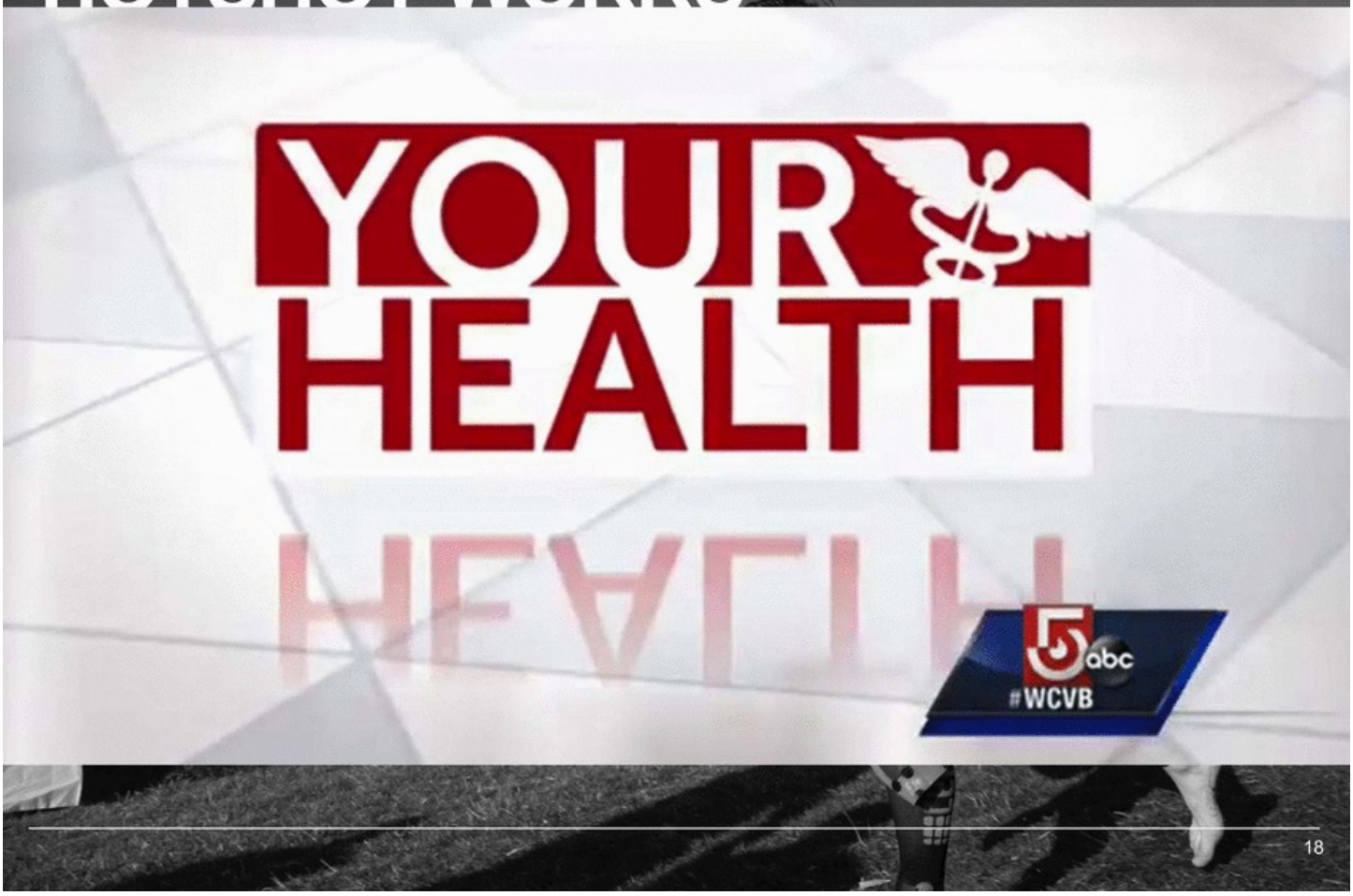


- Muscle cramps is a common occurrence in healthy and neurological populations
- Large unmet medical need, not covered by quinine or other drugs like benzodiazepines
- Chemical Neuro Stimulation implies topical application and rapid reflex-like response
- Expect minimal to no systemic exposure, no anticipated drug-drug interactions, good option for polypharmacy patients

Anticipated Upcoming Milestones

- H1 2017: IND filing
- H1 2017: Initiate Phase 2 NLC study
- H2 2017: Exploratory Phase 2 MS study readout
- 2017/2018: Exploratory Phase 2 ALS study readout

HOTSHOT WORKS



FIRST & ONLY PRODUCT SCIENTIFICALLY PROVEN TO PREVENT & TREAT MUSCLE CRAMPS

A proprietary formulation of organic ingredients that stop muscle cramps where they start. At the nerve.

PREVENT

Drink a 1.7 oz. HOTSHOT 15-30 minutes before exercise to boost your Neuromuscular Performance and prevent muscle cramps. Feel it work from the first kick to the warm afterglow.

TREAT

Drink a 1.7 oz. HOTSHOT at the first sign of cramping. It starts working in minutes.

RECOVER

Drink a 1.7 oz. HOTSHOT after activity to prevent post-exercise cramping.

A New Way to Prevent Muscle Cramps

EATING & DRINKING

Freestyle Fried Rice

Doctors Treat First Patient With Newly Approved Heart Stent

Radiologists Take On Bigger Role in Diagnosing

ACHES A Can Ne Match Stop Cl

LIFE

A New Way to Prevent Muscle Cramps

Nobel Prize winner Rod MacKinnon found that pungent and spicy tastes can hinder neurological misfires that cause cramps

Unexpected muscle cramps are the bane of existence for the best athletes in the world and weekend warriors and are unpredictable pains that seem to arise at the worst possible time. WSJ's Matthew Futterman discusses the new thinking on cramps with Lee Hawkins. Photo: Getty

By MATTHEW FUTTERMAN

July 11, 2016 1:03 p.m. ET

69 COMMENTS

Could there finally be a way to prevent muscle cramps?

As long as people have played sports, unexpected muscle cramps have been an Achilles' heel for everyone from aspiring Olympians to weekend warriors.

For decades physicians and other experts in sports medicine have theorized that a cramp

HOTSHOT

HOW HOTSHOT WORKS: TRP ACTIVATION

THE OPPORTUNITY

Cramp Incidence

- 68% of triathletes (lifetime) [1]
- 60% of cyclists (lifetime) [1]
- 30-50% of marathon runners (lifetime) [1, 2]

1 – Schwellnus MP et al. Muscle cramping in athletes – risk factors, clinical assessment, and management. *Clin Sports Med* 27(1):183-194, 2008
2 – Minetto MA et al. Origin and development of muscle cramps. *Exerc Sports Sci Rev* 41(1):3-10, 2013

ENDORSEMENTS

SHALANE FLANAGAN
USA Marathon Runner

"Thank you #ITSTHENERVE for a great workout today."

AMY CRAGG
USA Marathon Runner

"Happy to have Shalane Flanagan and #ITSTHENERVE by my side for the long run!"

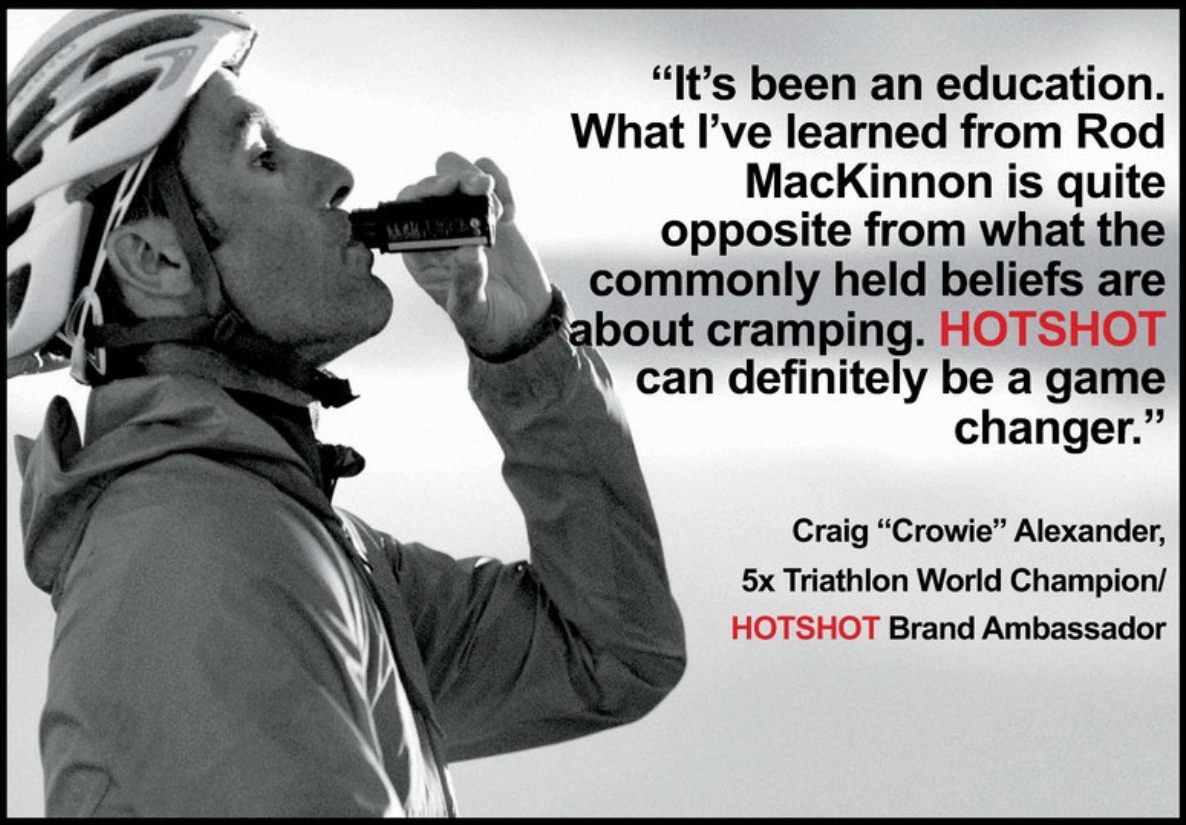
EVAN JAGER
USA Steeplechase

"Thanks to #ITSTHENERVE for cramp-free steeplechase training and races!"

COLLEEN QUIGLEY
USA Steeplechase

"Thanks to #ITSTHENERVE for keeping me cramp-free during this very important time in my training!"

BRAND AMBASSADOR

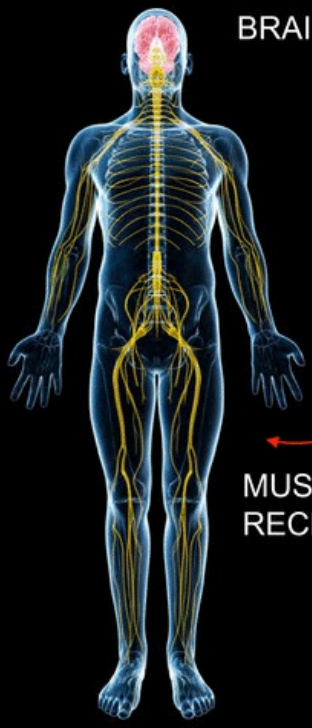


"It's been an education. What I've learned from Rod MacKinnon is quite opposite from what the commonly held beliefs are about cramping. HOTSHOT can definitely be a game changer."

Craig "Crowie" Alexander,
5x Triathlon World Champion/
HOTSHOT Brand Ambassador

BRAND AMBASSADOR

A MUSCLE CRAMP IS A FAILURE IN NEURO MUSCULAR PERFORMANCE



Signals from the brain to the spinal cord balance the activity of motor neurons

Alpha motor neurons, residing in the spinal cord, are what control the contraction of muscles

If alpha motor neurons become hyper-excitable and start to fire repetitively, a muscle cramp can occur

NMP

Neuro Muscular Performance refers to consistent, and closely integrated function of nerves and muscles. It's how an athlete's nerves and muscles work together in an optimal way.

HOTSHOT boosts your NMP to stop muscle cramps by treating the nerve. When you're cramp free you can push harder, train longer, finish stronger.

We continue to study the potential benefits of improved Neuro Muscular Performance.

PREMIUM PACKAGING

LOHSHOT

SINGLE BOTTLE

1.7 OZ.

$7

12-PACK

12-PACK

$65

6-PACK

6-PACK

$35

LAUNCHED!

1.7 OZ. of Neuro Muscular Performance

PRODUCT
- Natural, Organic, NSF Certified for Sport®

PLACEMENT:
- TeamHOTSHOT.com
- Specialty retailers in Boston, Boulder & LA

PROMOTION
- Face-to-face events to cultivate influencers
- Authentic brand ambassadors (Crowie, Flanagan)
- Word of mouth amplified through social media
- Targeted media (LAVA, Competitor, VELO, etc)

2016 Net Revenues
- Q2: $113K
- Q3: $586K
- ~20K customers

Financial Profile

- NASDAQ: FLKS
- $67.3 M Cash balance as of 9/30/16
- Cash into Q1 2019 based on current operating plan
- ~17.9 million shares outstanding
- No debt

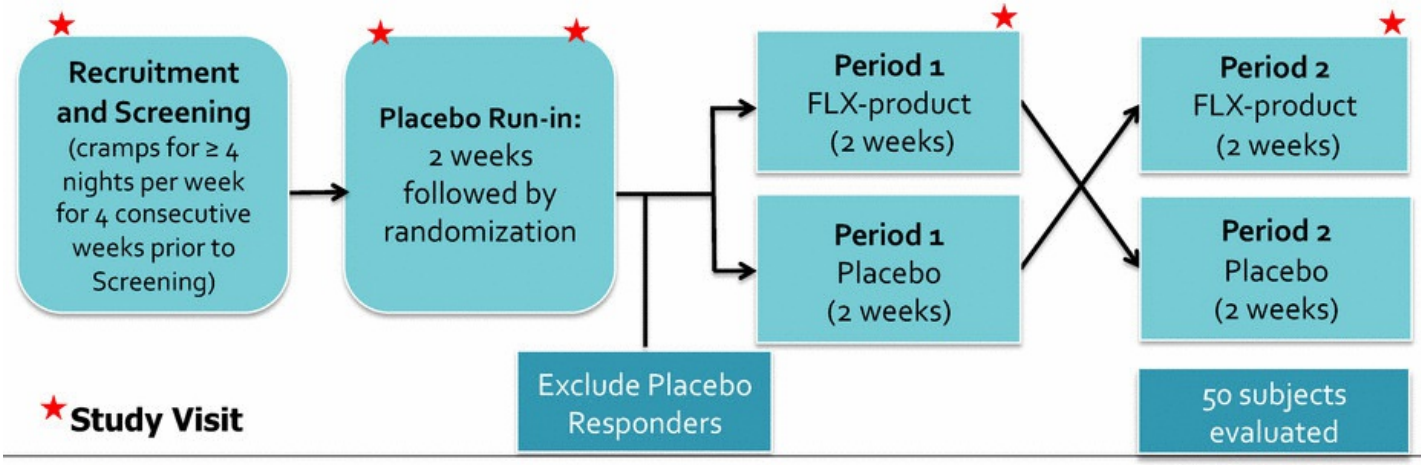
FLEXPharma

Novel Treatments for Neuromuscular Conditions

NASDAQ: FLKS

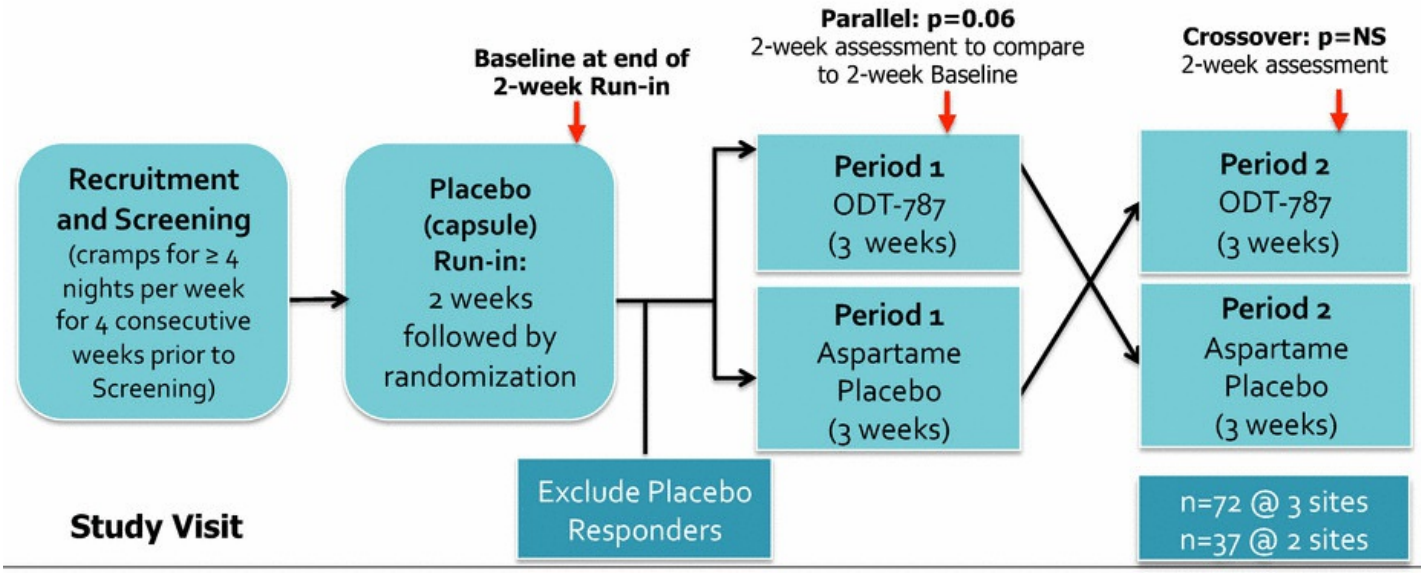
NLC POC Study of Extract Formulation: Positive (p<0.05) Human Efficacy (N=50)

- Selected for AAN April 2016 Late-Breaker poster & presentation
- TRP activators resulted in statistically significant effects on multiple efficacy 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), VAS pain intensity over the last 3 days of each treatment period (p<0.01)
- Magnitude of efficacy in this study on reduction in muscle cramps appears similar to published "Class 1 level" quinine efficacy studies
- Extract formulation was safe and well-tolerated; no SAEs reported



NLC Exploratory POC Studies of FLX-787

- Study 1: Efficacy Signals (cramp frequency, p=0.06) with ODT in subanalysis (n=37) of parallel portion
  - Data from 1 site (n=35) excluded
- Study 2 (dosing/formulation): Significant effect (cramp frequency, p<0.05) in first exposure parallel analysis (repeated, sequential, multiple crossovers, n=29 from prior NLC study)
  - Statistically significant on some, but not all crossover endpoints



NLC Key Learnings: Topical Neurostimulation of TRPA1 & TRPV1 Channels Reduces Muscle Cramping in Humans

Efficacy Signals Warrant Further NLC Development

- FLX-787 has shown positive signals on muscle cramping in the parallel design portion of two exploratory human proof-of-concept NLC studies.
- FLX-787 has shown a sigmoidal dose-response curve in a human electrically-induced cramp model.
- FLX-787 thus far is well tolerated and safe, and no SAEs have been reported.

Key Learnings

- Patient selection and data capture & monitoring are critical issues of focus in the upcoming clinical studies.
- Given potential carry-over effects in cross-over studies, and consistent with FDA guidance, future FLX-787 studies in NLC will be parallel design.

Next Steps

- Initiate IND-opening Phase 2 parallel design study in H1 2017, after the IND has been accepted.

NLC Market Opportunity

Unmet Need

- Sudden painful contractions negatively impacting sleep and quality of life
- No drug approved in the U.S. In 1994, FDA banned use of quinine for treatment of leg cramps due to association with serious and life-threatening adverse events (primarily thrombocytopenia)

Affected U.S. Population

- 37% prevalence for 50+ yo[1]
- Approximately 4M people over 65 yo suffer daily[2]
- NLC population increasing dramatically given aging US demographics

Significant Demand

- 4.5 Million Quinine sulfate prescriptions in 2013 in UK (1/5 of the US population)

1 Naylor & Young, A General Population Survey of Rest Cramps, *Age and Ageing* 1994.23 418-420
2 Management estimates based on third party survey results
*Two published studies of quinine treatment in muscle cramps that were categorized as Class I level of evidence by Katzberg et al for the American Academy of Neurology in 2010:

- *Randomised controlled trial of hydroquinine in muscle cramps.* Jansen et al, Lancet 1997; 349: 528-32.
- *Effectiveness of quinine in treating muscle cramps: a double-blind, placebo-controlled, parallel-group, multicentre trial.* Diener et al. Int J Clin Pract. 2002 May;56(4):243-6.

Comprehensive meta-analysis of quinine studies by the Cochrane Collaboration in 2010.

Broad Intellectual Property

Broad initial applications covering HOTSHOT and FLX-787 that should provide the basis for an expanded patent portfolio

- Applications Covering FLX-787
  - Composition and method of use application covering one or more TRP activators for the treatment of muscle cramps and spasms associated with disease
  - Composition and method of use application covering FLX-787 and other single molecules for the treatment of muscle cramps and spasms associated with disease
- Applications Covering HOTSHOT
  - Methods of use application covering two or more TRP activators for treating EAMC and NLC
  - Compositions of TRP activators based on HOTSHOT formulation