

**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**

November 6, 2017

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)

02199

(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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company x

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. x

Item 2.02 Results of Operations and Financial Condition.

On November 6, 2017, Flex Pharma, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2017. 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 8.01 Other Events.

On November 6, 2017, the Company issued a press release relating to the results from its clinical trial of amyotrophic lateral sclerosis (ALS) patients with frequent muscle cramps. The Company will host a conference call and live webcast with a slide presentation on Monday, November 6, at 8:45 a.m. EDT. A copy of this press release and slide presentation are filed herewith as Exhibits 99.2 and 99.3, respectively, 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Flex Pharma, Inc. announcing financial results, dated November 6, 2017.
99.2	Press Release of Flex Pharma, Inc. announcing clinical trial results, dated November 6, 2017.
99.3	Flex Pharma, Inc. Slide 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: November 6, 2017

By: /s/ Robert Hadfield

Robert Hadfield

General Counsel and Secretary

INDEX TO EXHIBITS

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Flex Pharma Reports Third Quarter 2017 Financial Results

-- Recent Positive Topline Data Reported from Exploratory Phase 2 Trial of FLX-787 in ALS --

-- Two US Phase 2b Trials in ALS and CMT Initiated under IND; Data Readouts in 2018 --

-- Development Efforts Expanding into Dysphasia --

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

November 6, 2017

Boston, MA - [Flex Pharma, Inc.](#) (NASDAQ: FLKS), a clinical-stage biotechnology company that is developing innovative and proprietary treatments in Phase 2 randomized, controlled trials for cramps and spasticity associated with severe neurological diseases such as multiple sclerosis (MS), Charcot-Marie-Tooth (CMT) and amyotrophic lateral sclerosis (ALS) under FDA Fast Track designation, today reported financial results for the quarter ended September 30, 2017 and provided an update on its clinical development and corporate activities.

"We are encouraged by the consistently positive impact of FLX-787 across multiple efficacy endpoints related to cramping and the associated pain from our small, exploratory Phase 2 trial in Australian ALS patients that provides the first clinical evidence of effect for our lead candidate in patients with underlying neurological disease. Our development programs are steadily advancing. We have initiated our Phase 2b ALS trial under Fast Track designation, and, more recently, our Phase 2b CMT trial. These two studies, as well as the ongoing exploratory spasticity study in MS in Australia, are expected to yield several important data readouts in 2018," stated Dr. William McVicar, President and CEO of Flex Pharma. "I am also excited to begin testing potential new applications of our chemical neurostimulation technology to address dysphagia, or difficulty swallowing, in ALS, in addition to cramping in renal failure patients during or between dialysis sessions. We expect to begin studying these indications in the next six months."

Recent Business Highlights

- Clinical Efforts
 - In November, the Company announced positive topline data for FLX-787 from its Australian ALS trial of patients who cramp frequently. In the 8 patients who completed the trial per protocol, FLX-787 demonstrated a statistically significant percentage reduction from baseline in both cramp-associated pain intensity ($p < 0.05$) and stiffness ($p < 0.05$), relative to placebo control, based on Numerical Rating Scales (NRS). Strong and consistent trends were demonstrated on multiple endpoints, including: percentage reduction in the number of cramps from baseline ($p = 0.08$), increase in cramp free days from baseline ($p = 0.09$), and improvements on both Patient (PGIC; $p = 0.06$) and Clinician (CGIC; $p = 0.06$) Global Impression of Change. FLX-787 was generally well tolerated in

all patients. In July 2017, the Company announced that it had stopped this study after 12 patients were randomized.

- In October, the Company initiated a Phase 2b randomized, controlled, double-blinded, parallel design trial in the US, referred to as the COMMIT trial. The COMMIT trial will evaluate FLX-787, the Company's co-activator of TRPA1 and TRPV1, in patients with Charcot-Marie-Tooth, who suffer from painful, debilitating cramps. The Company expects to report topline results from this study in the third quarter of 2018.
- In August, the Company initiated its Phase 2b randomized, controlled, double-blinded, parallel design trial in the US, referred to as the COMMEND trial, to evaluate FLX-787, the Company's co-activator of TRPA1 and TRPV1, in patients with motor neuron disease (MND), focused on ALS, who suffer from cramps. The Company expects to report topline results from this study in the third quarter of 2018.
- In July, the Company announced that the Food and Drug Administration (FDA) granted Fast Track Designation for the development of FLX-787 to treat severe muscle cramps in patients with ALS. There are currently no drugs approved in the US for this condition. Fast Track Designation is intended to accelerate the clinical development and review of drugs to treat serious conditions that address an unmet medical need.

- **Consumer Business**

- For the quarter ended September 30, 2017, the Company recorded approximately \$414,000 in total revenue for its consumer product, HOTSHOT®, launched in June 2016. The Company expects full year revenues for 2017 to exceed 2016.

- **Strengthened Leadership Team**

- In October, Flex Pharma announced that Roger Tung, Ph.D. was appointed to its Board of Directors. Dr. Tung is the scientific co-founder of Concert Pharmaceuticals, where he serves as President and CEO. Prior to Concert, Dr. Tung was a founding scientist at Vertex. Dr. Tung has more than 30 years of experience in the global biopharmaceutical industry.
- In July, Flex Pharma's Board of Directors appointed William McVicar, Ph.D., as President and CEO. Dr. McVicar brings approximately 30 years of clinical development experience to the Company, formerly serving as the Company's President of Research and Development. In June, Christoph Westphal, M.D., Ph.D., transitioned from his role as CEO and continues to serve on Flex Pharma's Board. Prior to joining Flex Pharma, Dr. McVicar served as Executive Vice President of Pharmaceutical Development, Chief Scientific Officer, and President during his tenure at Inotek. As Vice President of Development Operations at Sepracor, he oversaw the development, FDA review, and approval of multiple NDAs and SNDAs, including BROVANA®, XOPENEX MDI®, and XOPENEX's pediatric approval, which were each approved in a single 10-month review cycle. Prior to Sepracor, Dr. McVicar held various positions of increasing responsibility at Sandoz, Novartis and Rhone Poulenc Rorer.

Third Quarter 2017 Financial Results

- **Cash Position:** As of September 30, 2017, Flex Pharma had cash, cash equivalents and marketable securities of \$38.9 million. During the three months ended September 30, 2017, cash, cash equivalents and marketable securities decreased by \$8.2 million.
- **Total Revenue:** Total revenue for the three months ended September 30, 2017 was approximately \$414,000, including approximately \$7,000 of other revenue.
- **Cost of Product Revenue:** Cost of product revenue for the three months ended September 30, 2017 was approximately \$149,000.
- **R&D Expense:** Research and development expense for the three months ended September 30, 2017 was \$4.7 million. Research and development expense for this quarter primarily included costs associated with the Company's clinical studies of FLX-787, personnel costs (including salaries and stock-based compensation costs), FLX-787 production costs and external consultant costs.
- **SG&A Expense:** Selling, general and administrative expense for the three months ended September 30, 2017 was \$4.9 million. Selling, general and administrative expense for this quarter primarily included personnel costs (including salaries and stock-based compensation costs), sales, marketing and fulfillment costs related to HOTSHOT, legal and professional costs and external consultant costs.
- **Net Loss and Cash Flow:** Net loss for the three months ended September 30, 2017 was (\$9.3) million, or (\$0.54) per share and included \$1.0 million of stock-based compensation expense. As of September 30, 2017, Flex Pharma had 17,541,377 shares of common stock outstanding, which excludes approximately 0.4 million shares of stock that remain subject to vesting. The net loss for the third quarter of 2017 was primarily driven by the Company's operating expenses related to its research and development efforts, costs associated with HOTSHOT, and general and administrative costs.

Financial Guidance

Based on its current operating plans and cash, cash equivalents and marketable securities position, Flex Pharma expects to have sufficient capital to fund its operations into early 2019.

Conference Call and Webcast

The Flex Pharma management team will host a conference call and live webcast with slides today, Monday, November 6, at 8:45 a.m. ET to provide an update on the company and discuss the information in this press release.

Date: Monday, November 6, 2017

Time: 8:45 a.m. ET

Dial-in: (855) 780-7202 (US or Canada) or (631) 485-4874 (International)

Replay: (855) 859-2056 (US or Canada) or (404) 537-3406 (International)

Conference ID: 3497649

The live webcast and accompanying slides can be under the Investors section of the company's website at www.flex-pharma.com. A replay of the webcast will be available on Flex Pharma's website for three months after the call.

About Flex Pharma

Flex Pharma, Inc. is a clinical-stage biotechnology company that is developing innovative and proprietary treatments in Phase 2 randomized, controlled trials for cramps and spasticity associated with the severe neurological diseases of ALS, MS and peripheral neuropathies such as Charcot-Marie-Tooth (CMT). The Company's lead candidate, FLX-787, is being developed under Fast Track designation for the treatment of severe muscle cramps associated with ALS. 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 Christoph Westphal, M.D., Ph.D.

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 trials, including the timing for results of our clinical trials, the level of future interaction we may have with FDA, our expectations relating to HOTSHOT revenue and our expectations regarding the availability of our capital resources. 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; our ability to successfully commercialize our consumer product and drive customers to purchase HOTSHOT; 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 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, 2016 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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Contact:
Elizabeth Woo
SVP, Investor Relations & Corporate Communications
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- Financial Tables to Follow -

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

	September 30, 2017	December 31, 2016
Assets:		
Cash and cash equivalents	\$ 20,152	\$ 22,416
Marketable securities	18,776	38,659
Accounts receivable	35	12
Inventory	534	454
Prepaid expenses and other current assets	1,057	926
Property and equipment, net	401	556
Other assets	253	192
Total assets	\$ 41,208	\$ 63,215
Liabilities and stockholders' equity:		
Accounts payable and accrued expenses	\$ 4,816	\$ 3,780
Deferred revenue	98	88
Other liabilities	113	30
Stockholders' equity	36,181	59,317
Total liabilities and stockholders' equity	\$ 41,208	\$ 63,215

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

	Three Months Ended September 30, 2017	Three Months Ended September 30, 2016	Nine Months Ended September 30, 2017	Nine Months Ended September 30, 2016
Net product revenue	\$ 407	\$ 586	\$ 978	\$ 699
Other revenue	7	13	14	13
Total revenue	<u>414</u>	<u>599</u>	<u>992</u>	<u>712</u>
Costs and expenses:				
Cost of product revenue	149	221	373	529
Research and development	4,739	5,665	12,731	16,148
Selling, general and administrative	4,935	5,448	14,521	15,937
Total costs and expenses	<u>9,823</u>	<u>11,334</u>	<u>27,625</u>	<u>32,614</u>
Loss from operations	(9,409)	(10,735)	(26,633)	(31,902)
Interest income, net	77	98	228	309
Net loss	<u>\$ (9,332)</u>	<u>\$ (10,637)</u>	<u>\$ (26,405)</u>	<u>\$ (31,593)</u>
Net loss per share-basic and diluted	<u>\$ (0.54)</u>	<u>\$ (0.65)</u>	<u>\$ (1.54)</u>	<u>\$ (1.96)</u>
Weighted-average number of common shares outstanding (1)	<u>17,386</u>	<u>16,362</u>	<u>17,132</u>	<u>16,105</u>

(1) As of September 30, 2017, the Company had issued approximately 5.4 million shares of restricted stock that are subject to vesting. Of these shares, approximately 5.0 million shares had vested at September 30, 2017 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 0.4 years.

**Flex Pharma Reports Positive Topline Data
from Exploratory Phase 2 Trial of FLX-787 in ALS**

-- Statistically Significant Reduction in Cramp-Associated Pain Intensity and Stiffness; Strong and Consistent Trends on Multiple Endpoints Including Anti-Cramp Activity --

-- First Clinical Evidence of Effect for FLX-787 in Neurological Disease --

-- US Phase 2b Trial of FLX-787 for ALS Cramping Ongoing under Fast Track Designation --

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

[Click to Tweet this News](#)

November 6, 2017

Boston, MA - [Flex Pharma, Inc.](#) (NASDAQ: FLKS), a clinical-stage biotechnology company that is developing innovative and proprietary treatments in Phase 2 randomized, controlled trials for cramps and spasticity associated with severe neurological diseases such as multiple sclerosis (MS), Charcot-Marie-Tooth (CMT) and amyotrophic lateral sclerosis (ALS) under FDA Fast Track designation, today announced positive topline data for FLX-787 from its randomized, double-blinded, placebo-controlled, cross-over Australian trial in ALS patients with frequent muscle cramps. The study was terminated early to focus the Company's resources on the ongoing US Phase 2b ALS study (COMMEND).

"We are encouraged by the consistently positive impact of FLX-787 across multiple efficacy endpoints related to cramping and the associated pain, despite the small number of patients completing the study," said Dr. William McVicar, Flex Pharma President and CEO. "These data demonstrate the potential for FLX-787 to benefit ALS patients who suffer from frequent cramping in our ongoing Phase 2b trial, the COMMEND study. With data readouts in MS, ALS, and CMT expected over the next year, we are excited to advance the development of FLX-787, under Fast Track designation for ALS-associated cramping."

In eight patients who completed the trial per protocol, FLX-787 demonstrated a statistically significant ($p < 0.05$) percentage reduction from baseline in both cramp-associated pain intensity and stiffness, relative to placebo control, based on daily patient assessments by Numerical Rating Scale (NRS). Strong and consistent trends were demonstrated on multiple endpoints, including: percentage reduction in the number of cramps from baseline ($p = 0.08$), increase in cramp free days from baseline ($p = 0.09$), and improvements on both the Patient (PGIC; $p = 0.06$) and Clinician (CGIC; $p = 0.06$) Global Impression of Change. FLX-787 was generally well tolerated.

In the patients completing both cross-over periods per protocol:

- FLX-787 showed a median 31% reduction in cramps from baseline versus 0.1% reduction for patients while on placebo control;
- Patients had a median of 4.4 cramp free days versus 0 for placebo control;
- Patients evaluated themselves as improved with FLX-787 treatment 50% of the time versus 12.5% with placebo control (PGIC); and
- Clinicians blinded to treatments evaluated 50% of patients as improved with FLX-787 versus 0% for placebo control (CGIC).

The Company also analyzed the Period 1 and Period 2 results of all patients randomized in the

trial and believes the cross-over results are not driven by a cross-over bias or unblinding effect.

“Nearly all ALS patients report cramps and the majority seek treatment to relieve their suffering from painful cramping and yet there are no approved therapies in the US. This data set provides the first clinical evidence that FLX-787 has an effect in patients with underlying neurological disease and demonstrates the utility of chemical neurostimulation in treating symptoms arising from motor neuron hyperexcitability,” said Flex Pharma Chief Medical Officer Thomas Wessel, M.D., Ph.D. “In prior studies, FLX-787 has demonstrated similar efficacy profiles in individuals with normally functioning nervous systems such as those suffering from nocturnal leg cramps and healthy normal volunteers studied in our electrically-induced cramp model.”

Data from this study outlined above will be presented at future medical meetings.

Phase 2 Trial Design

This randomized, blinded, placebo-controlled Phase 2 clinical trial, had originally planned to enroll up to 60 subjects with ALS or primary lateral sclerosis (PLS) patients with frequent muscle cramps in Australia. Due to the challenge of enrolling ALS patients from a limited population in Australia, and a greater priority placed on the completion of the larger US Phase 2b trial, the Company announced in July 2017 that we stopped the trial after 12 patients were randomized. Of these, 8 patients completed both cross-over periods and received both FLX-787 and the placebo control. Patients were given 19 mg of FLX-787, formulated as an orally disintegrating tablet (ODT) or placebo control, two or three times daily. The trial included a 14-day run-in period with no treatment to establish baseline characteristics, followed by treatment periods during which patients received FLX-787 or placebo in the first 14-day treatment period before “crossing-over” to the other treatment for an additional 14-day treatment period. The exploratory study was designed to evaluate a number of endpoints relating to cramping frequency, cramp-associated pain, spasticity, stiffness, global impression of change by the patient and the clinician, quality of life, sleep and safety. Eight patients completed both crossover conditions and were included in the primary per protocol analysis.

About the COMMEND Clinical Trial

The COMMEND trial is an ongoing Phase 2b clinical trial designed to evaluate FLX-787 in patients with motor neuron disease (MND), focused on ALS, who suffer from cramps. This randomized, controlled, double-blinded, parallel design trial in the US includes a 28-day run-in period to establish a baseline in cramp frequency. Patients are then randomized to 30 mg of FLX-787 administered three times a day, or control, for 28 days. Patients will be evaluated for changes in cramp frequency as the primary endpoint, with a number of secondary endpoints, including the PGIC, CGIC, cramp-related pain and spasticity.

Details of this trial can be found at clinicaltrials.gov.

Conference Call & Webcast Information

The Flex Pharma management team will host a conference call and live webcast with slides with the investment community today, Monday, November 6, at 8:45 a.m. ET to discuss the information in this press release.

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FLEXPharma

Novel Treatments for Severe Neurological Diseases

NASDAQ: FLKS
6 November 2017



Forward-Looking Statements

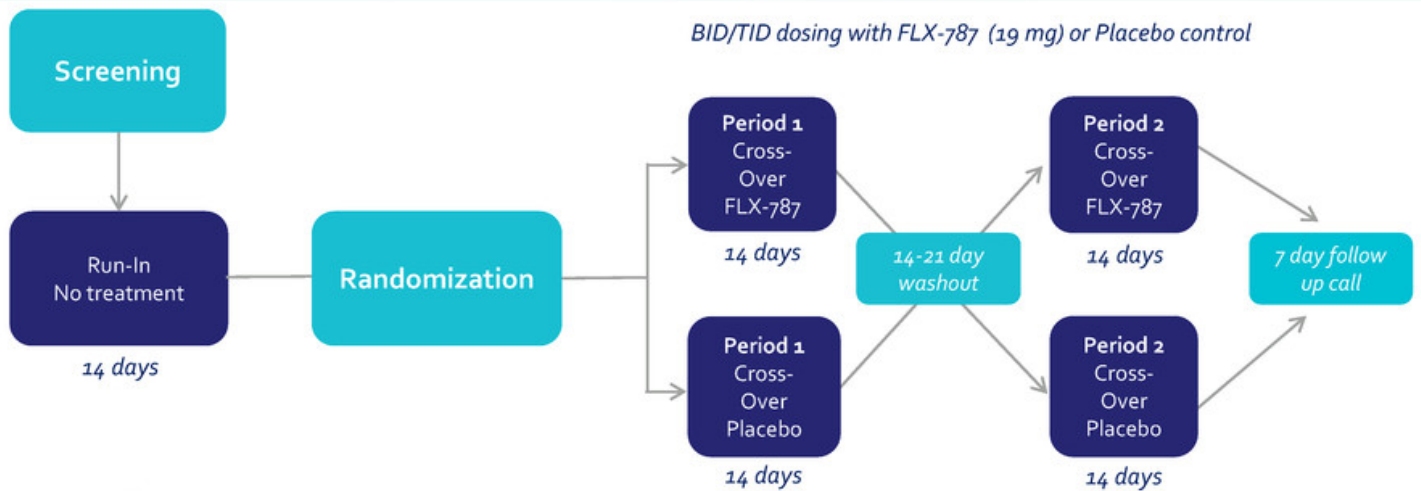
Any statements in this presentation and the oral commentary about future expectations, plans and prospects for the company, including statements about the company's strategy, future operations, ongoing clinical trials, development of its consumer and drug product candidates, plans for potential future 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.

Exploratory Cramping/Spasticity Study in MND

Under Australian Clinical Trial Notification (CTN)



Inclusion Criteria:

1. Diagnosed with Amyotrophic Lateral Sclerosis (ALS) or Progressive Lateral Sclerosis (PLS) for at least 1 month
2. > 12 cramps per month (approximately 3 per week)
3. Spasticity of at least 3 months duration that is not completely relieved by current therapy

- **Randomized, Double-blind, Placebo-controlled, Cross-over Study to Evaluate Efficacy and Tolerability of FLX-787 in Patients with Motor Neuron Disease**
- N=8 per protocol subjects. Terminated early to focus resources on larger Phase 2b US trial
- Orally Disintegrating Tablet (ODT) of 19 mg FLX-787 (spicy) or Placebo (sweet)

FLX-787 Reduces Pain from Cramping ($p < 0.05$) and Associated Stiffness ($p < 0.05$) in ALS Patients

- **FLX-787 treatment was associated with improvements in cramping and related symptoms, from pre-treatment baselines, including:**
 - Decreased Pain Intensity (NRS) associated with most painful cramp ($p < 0.05$)
 - Decreased Stiffness (NRS) ($p < 0.05$)
 - Greater Percentage Reduction of Cramps from baseline (~30% decrease) ($p = 0.08$)
 - Increased Number of Cramp Free Days ($p = 0.09$)
 - Improved Patient ($p = 0.06$) and Clinician ($p = 0.06$) Global Impression of Change
- Statistically significant improvements*
- Improvements approaching statistical significance*
- **These data, the first in patients with serious neurological disease, indicate the potential of FLX-787 to alleviate cramps and cramp-related symptoms.**
 - 19 mg FLX-787 (BID or TID) were generally well tolerated in subjects with MND. No drug-related SAEs or discontinuations were reported. A few GI-related AEs (abdominal pain, diarrhea) were reported with FLX-787.
 - The comparison of Period 1 and Period 2 results suggest the cross-over results are not driven by a cross-over bias or unblinding effect. (see appendix)
 - **Results confirm the potential of the ongoing 100 subject, parallel design, ALS trial with 4 weeks of run-in and treatment, utilizing a more robust 30 mg TID dose.**

Summary Efficacy Results

(Per Protocol Population; N=8)

Efficacy Endpoint	Run-In		Flex-787		Control		P
	Mean	Median	Mean	Median	Mean	Median	
Total Number of Cramps % change from Baseline	68.72	37.33	46.04	21.27	71.31	39.42	0.08
			-27.60	-31.09	5.92	-0.11	
Number of Cramp Free Days # of days change from Baseline	1.60	1.17	4.65	4.35	1.66	0.00	0.09
			3.05	2.29	0.06	0.00	

Statistical Treatment Comparisons (Medians)

	Run-In	Flex-787	Control	P
Total NRS Pain Intensity Score of Most Painful Cramp % Change from Baseline	50.75	-13.65	19.00	<0.05
Total NRS Spasticity Score* % Change from Baseline	62.46	-14.53	0.00	0.16
Total NRS Stiffness Score % Change from Baseline	61.38	-9.84	12.07	<0.05

Notes: Baseline is the corresponding value from Run-in period. P-values are from Wilcoxon signed rank test of the paired treatment differences, data are reported as medians.

*Of note, baseline spasticity levels in the patient population were modest, and spasticity assessed by Modified Ashworth and Tardieu scales were not consistent with a treatment difference.

Clinical & Patient Global Impression of Change

(Per Protocol Population, N=8)

Clinical Global Impression Assessment of Change (CGI - C)*

P= 0.06

Scale (Score)	FLX-787 N=8	Control N=8
Very Much Improved (1)	1 (12.5%)	0 (0.0%)
Much Improved (2)	1 (12.5%)	0 (0.0%)
Minimally Improved (3)	2 (25.0%)	0 (0.0%)
No Change (4)	4 (50.0%)	6 (75.0%)
Minimally Worse (5)	0 (0.0%)	2 (25.0%)
Much Worse (6)	0 (0.0%)	0 (0.0%)
Very Much Worse (7)	0 (0.0%)	0 (0.0%)

- Clinicians blinded to treatments evaluated 50% of patients as improved with FLX-787, compared to 0% with Control treatment

Patient Global Impression Assessment of Change (PGI - C)*

P= 0.06

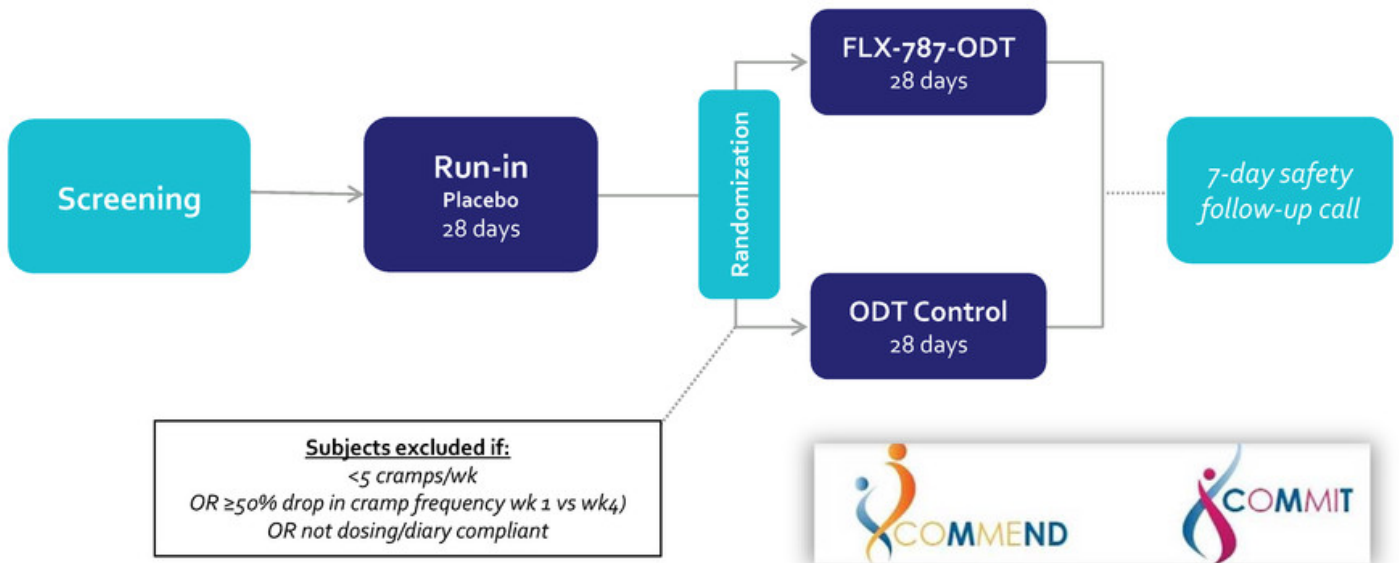
Scale (Score)	FLX-787 N=8	Control N=8
Very Much Improved (1)	0 (0.0%)	0 (0.0%)
Much Improved (2)	1 (12.5%)	0 (0.0%)
Minimally Improved (3)	3 (37.5%)	1 (12.5%)
No Change (4)	4 (50.0%)	5 (62.5%)
Minimally Worse (5)	0 (0.0%)	2 (25.0%)
Much Worse (6)	0 (0.0%)	0 (0.0%)
Very Much Worse (7)	0 (0.0%)	0 (0.0%)

- Patients evaluated themselves as improved with FLX-787 treatment 50% of the time, compared to 12.5% with Control treatment

* For PGI-C "Compared to your condition at baseline (the beginning of this study period), how much has your condition changed?" and for CGI-C "Rate total change in the subject's symptoms whether or not, in your clinical judgment, it is due entirely to drug treatment. Compared to his/her condition since last visit, how much has he/she changed".

Ongoing Phase 2 Studies in ALS & CMT

Randomized, Blinded Phase 2 Trials under US IND



- ALS: Cramps, spasticity, ALS-FRS, pain (PGIC), sleep, QoL, safety
- CMT: Cramps, pain (PGIC), sleep, QoL, safety
- 30mg FLX-787 ODT three times daily vs. Control
- Parallel design, N~100
- Data 3Q 2018

Severe and Debilitating Muscle Cramps: Significant Morbidity and Medical Need in Neurological Diseases

- No FDA approved treatment
- 95% of ALS patients report cramps¹
- Cramps can be frequent: median of 4 cramps/day²
- 55% of ALS patients with pain attributed that pain to muscle cramps³
- 57% of ALS patients to seek treatments directed at limiting cramps⁴
- Cramping interferes with sleep and reduces QoL for patients suffering from degenerative neurological diseases⁵

FLX-787 granted Fast Track designation for the treatment of severe muscle cramps associated with ALS (July 2017)

1. Caress, JB, et al, Muscle Nerve. 2016 April;53(4): 513-517/ 2 Stephens HE 2016, Caress JB 2016, Weiss MD 2016, Weber M 2010/ 3 Bedlack RS, 2009 Stephens, Joyce, Oskarsson. National Study of Muscle Cramps in ALS in the USA, 2016a / 4 Ganzini et al, Correlates of suffering in amyotrophic lateral sclerosis. Neurology 1999 Apr 22;52(7):1434-40 / 5 Hanisch F, Skudlarek A, Berndt J, Kornhuber ME, Brain Behav. 2015 Mar;5(3)

Limitations of Current Cramp Treatments

Many patients seek and receive treatments that are ineffective or un-safe¹

Frequency of Use ↑	Baclofen	<ul style="list-style-type: none"> • Spasticity Tx, Limited cramp efficacy • Sedating, ataxia (incoordination), memory problems
	Quinine	<ul style="list-style-type: none"> • Malaria Tx, Not approved for NLC • Black Box warning
	Mexiletine	<ul style="list-style-type: none"> • Anti-arrhythmia • Black Box warning
	Benzodiazepines	<ul style="list-style-type: none"> • Sedating, ataxia • Addictive

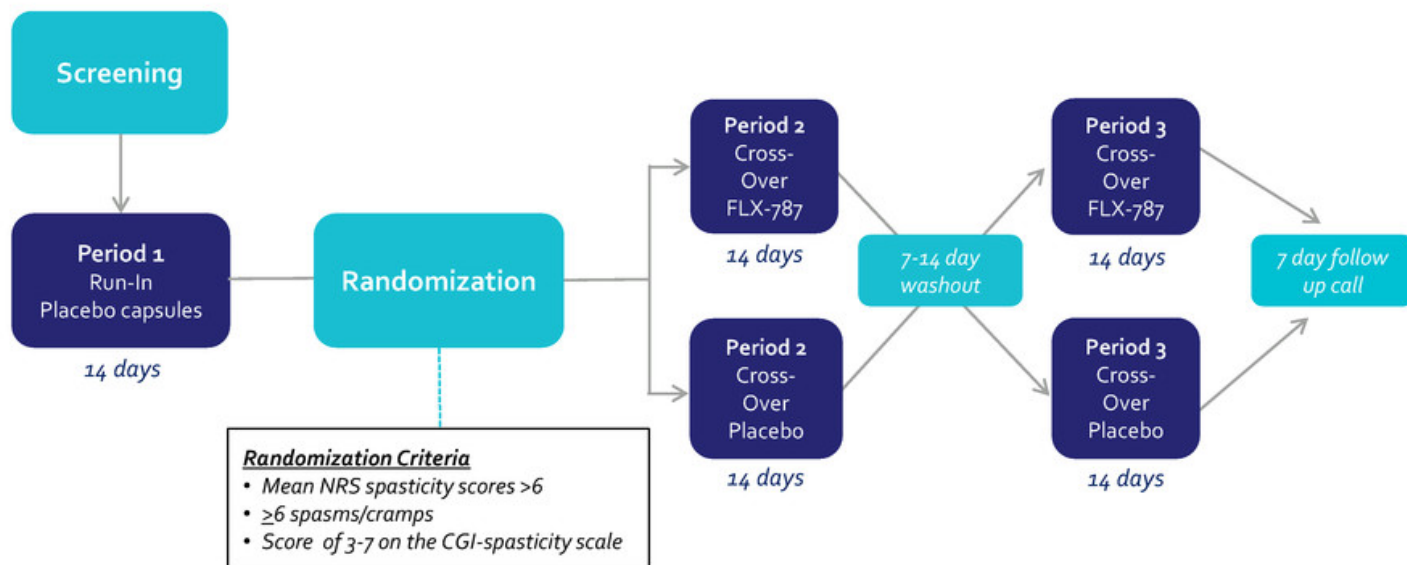
Quinine BLACK BOX Hematologic Toxicity
 serious and life-threatening toxicity incl. thrombocytopenia and HUS/TTP may occur w/ use for nocturnal leg cramp tx or prevention; TTP-assoc. chronic renal impairment reported; risk assoc. w/ nocturnal leg cramp use in absence of evidence of efficacy does not outweigh any potential benefit

Mexiletine BLACK BOX Increased Mortality
 excessive mortality or nonfatal cardiac arrest rate (7.7% encainide/flecainide vs. 3% placebo) in asymptomatic non-life-threatening ventricular arrhythmias w/ MI 6 days - 2 years prior; restrict use to life-threatening ventricular arrhythmias, no survival benefit in pts w/o life-threatening arrhythmias

¹ Stephens, Joyce, Oskarsson. National Study of Muscle Cramps in ALS in the USA, 2016a

Ongoing Exploratory Spasticity Study in MS

Under Australian Clinical Trial Notification (CTN)



MS – Spasticity - Randomized, Double-blind, Placebo-controlled, Cross-over Study

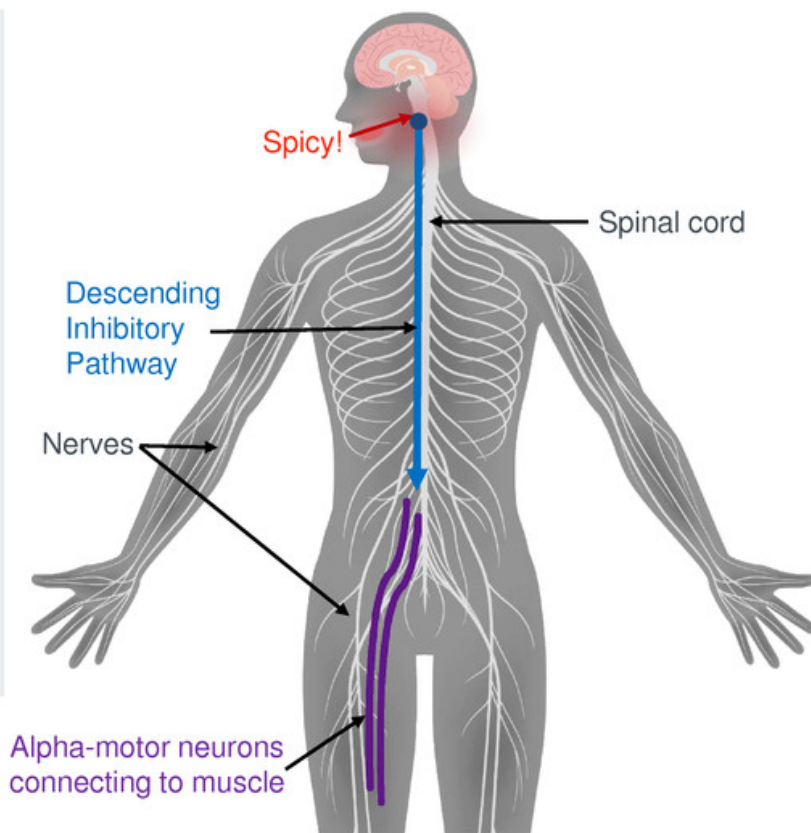
- N=45-50
- 19 mg BID FLX-787 liquid vs. placebo
- Spasticity, cramps/spasms, pain, sleep, QoL, safety
- Trends/Signals in Q1 2018

MOA for Topical Modulation of CNS by FLX-787: Stimulation-Processing-Motor Output

1 Sensory neurons with TRPA1/V1 channels stimulated by FLX-787

2 Central processing in brainstem leads to inhibition through descending fibers in spinal cord

3 Firing of alpha-motor neurons slows down halting muscle cramp



Potential Applications of Chemical Neurostimulation

Muscle Cramping:

ALS, CMT, MS, **Renal Dialysis**,
Chemotherapy Induced Nausea,
Hereditary Spastic Paraplegia

Autonomic Control:

Migraine/Cluster Headache, Overactive
Bladder, Obstructive Sleep Apnea,
Raynaud's, Gastroparesis, Emesis,
Menstrual Cramping

Non-autonomic Control (complex motor):

Cervical Dystonia, Bruxism, **Dysphagia**

Neuro-Psychiatric:

Epilepsy, Depression, PTSD, Tinnitus,
Panic Attack

Renal Dialysis:

- In the US, ~468,000 individuals are on hemodialysis¹.
- **Cramping was the most common reason (17.9%) for early terminations** from hemodialysis sessions.²
 - 850,000 sessions terminated early (of 70MM sessions)
- FLX-787 has demonstrated anti-cramping activity in an EIC model and in NLC subjects with intact nervous systems.

Dysphagia (Difficult/Unsafe Swallowing):

- Dysphagia emerges in more than **80% of ALS patients** during the advanced phases of the disease³
 - Aspiration pneumonia is a common cause of death in ALS⁴
- **40% to 95% of persons with Parkinson Disease** have dysphagia⁵
- TRP channel activators such as piperine⁶ and ginger extract⁷ have been shown to improve swallowing in the elderly

1. United States Renal Data Service 2015 Annual Data Report/ 2. Rocco MV and Burkart JM, J Am Soc Nephrol. 1993; 4:1178-1183/ 3. Muscaritoli M, et al, Nutrition(2012) 28(10):959-66/ 4. Cook LJ, Kahrillas PJ. Gastroenterology 1999; 116: 455-78/ 5. K Tjaden, Top Geriatr Rehabil. 2008 ; 24(2): 115-126/ 6. Rofes L, et al, J. Gastroenterol(2014) 49: 1517-1523/ 7. Hirata A, et al, Biol. Pharm. Bull(2016) 39, 1107-1111

Anticipated Upcoming Milestones



H1 2017: File IND (Effective April)



July 2017: Fast Track Designation for ALS



Q3 2017: Initiate ALS/MND Phase 2 parallel-design study (US)



Oct. 2017: Initiate CMT Phase 2 parallel-design study (US)



2018: Clinical Readouts

- Exploratory MS Spasticity Phase 2 study (Australia)
- Phase 2 ALS trial (US)
- Phase 2 CMT trial (US)
- Phase 2a Renal Dialysis Cramping (Observational)
- Phase 2a Dysphagia (swallowing difficulty)/tongue fasciculations in ALS

Financial Profile

NASDAQ: FLKS

~\$39 M Cash balance as of 9/30/17

**Cash into early 2019 based on
current operating plan**

~17.9 million shares outstanding

No debt

FLEXPharma

Novel Treatments for Neuromuscular Conditions

APPENDICES

Study Objectives and Endpoints

The objectives are:

To assess the effects of FLX-787 on muscle cramps, spasticity and sleep as measured by:

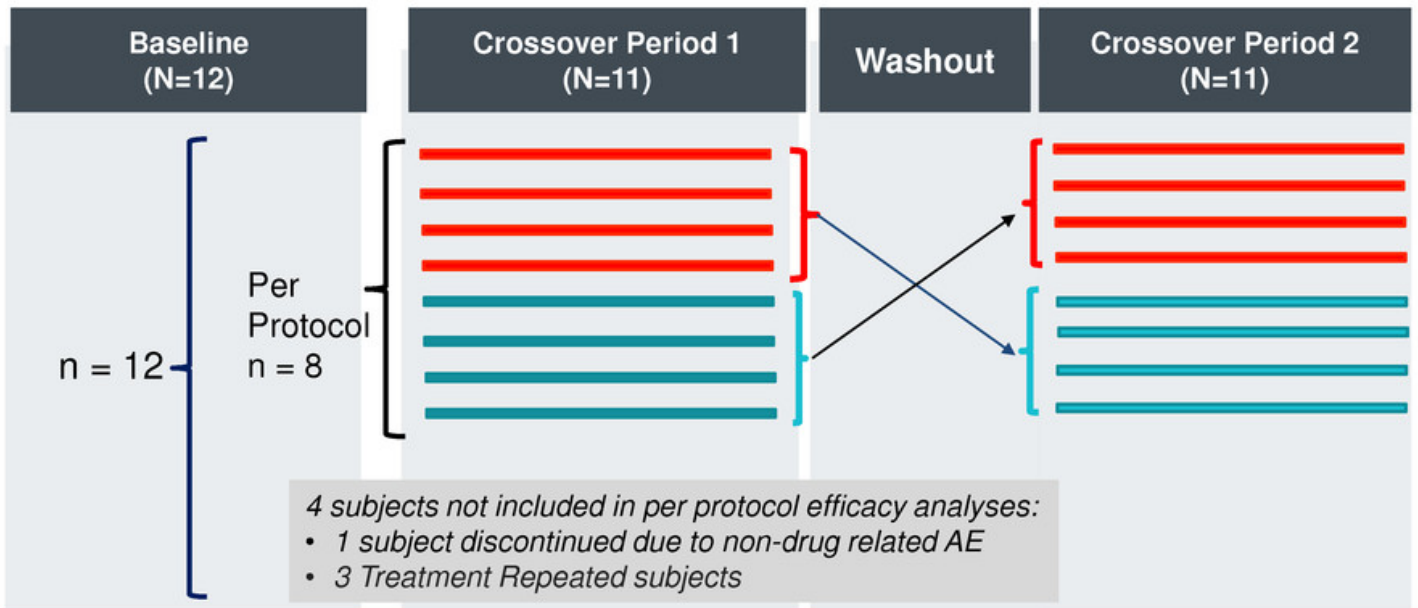
- Number of Cramps, and the Number of Cramp Free Days
- Pain and Intensity of Cramps
- Numerical Rating Scale (NRS) for Spasticity
- Modified Ashworth Scale (MAS)
- Tardieu Scale
- Patient Global Impression of Change (PGI-C) scale
- Clinical Global Impression of Change (CGI-C) scale
- Insomnia Severity Index (ISI) Survey*
- ALS Assessment Questionnaire (ALSAQ)*
- Penn Spasm Frequency Scale (PSFS)*

And, to assess the safety and tolerability of FLX-787 treatment in subjects with ALS, as determined by:

- Adverse Events (AEs)
- Laboratory Evaluations, Vital Signs, and ECGs

* Analysis pending

Patient Disposition and Analysis Populations



Per Protocol Population:

- N=8 received and completed both treatments
- All efficacy analyses based upon this population

Control 
FLX-787 

Data Consistency in Cross-over Periods 1 and 2*

	Period 1 Analysis 1 (n=11)		Period 2 Analysis 2 (n=11)	
	Median Control	Median FLX-787	Median Control	Median FLX-787
Cramp-free days				
Change	0.0	3.5	0.0	6.4
Number of cramps				
% change	-8.2	-21.7	-6.5	-76.9
Pain				
% change	-7.7	4.4	9.6	-67.9
Spasticity				
% change	-1.5	-55.1	-2.8	-3.5
Stiffness				
% change	10.6	0.0	-3.0	0.0

Conclusion: The comparison of Period 1 and Period 2 results suggest the cross-over results are not driven by a cross-over bias or unblinding effect.

* Ad hoc analysis

