

**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**

March 8, 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))
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Item 2.02 Results of Operations and Financial Condition.

On March 8, 2017, Flex Pharma, Inc. issued a press release announcing its financial results for the year ended December 31, 2016. 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 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Flex Pharma, Inc. dated March 8, 2017.

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: March 8, 2017

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

INDEX TO EXHIBITS

Exhibit No.	Description
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Flex Pharma Reports Year End 2016 Financial Results

-- IND Submission for FLX-787 On Track for H1 2017 --

-- Phase 2 ALS & CMT Studies with FLX-787 Planned to Initiate This Year --

-- Successful Launch Year for HOTSHOT® Consumer Brand; Revenue Exceeds Expectations --

Conference Call Scheduled Today at 8:30 a.m. ET

March 8, 2017

Boston, MA - [Flex Pharma, Inc.](#) (NASDAQ: FLKS), a biotechnology company that is developing innovative and proprietary treatments for cramps and spasms associated with severe neurological diseases such as amyotrophic lateral sclerosis (ALS) and multiple sclerosis (MS) and peripheral neuropathies such as Charcot-Marie-Tooth (CMT), today reported financial results for the year ended December 31, 2016 and provided an update on its clinical development and corporate activities.

"When we initiate our Phase 2 clinical studies in ALS and CMT later this year, FLX-787 will be amongst the most advanced, novel clinical compounds in development for these conditions," stated Christoph Westphal, M.D., Ph.D., Chair and CEO of Flex Pharma. "With over \$61 million in cash and investments at year end, Flex is well funded through early 2019 to execute upon our value-creating objectives."

"Our IND application for FLX-787 will be submitted in the next few weeks, and we have attracted several ALS and CMT investigators who are enthusiastic about enrolling in our parallel-design phase 2 studies here in the United States. We are focused on accelerating development of FLX-787 in the severe neurological diseases of ALS, MS and CMT, all areas of high unmet medical need," said Flex Pharma Chief Medical Officer Thomas Wessel, M.D., Ph.D. "Since the hyperactive alpha-motor neuron is the final common pathway involved in fasciculations, cramps, spasms and spasticity, we believe our approach with FLX-787, a dual TRPA1 and TRPV1 activator, may benefit patients afflicted with numerous neurological diseases."

"In our clinical studies, we continue to explore the impact of Chemical Neuro Stimulation -- the process by which a chemical signal, acting topically, is translated into an electrical signal for the benefit of patients -- which we hope will prove to be helpful to those with severe neurological disorders. We are encouraged by the initial response HOTSHOT has received from more than 20,000 endurance and professional athlete customers, and over 200 professional, collegiate and high

school sports teams, indicating that Chemical Neuro Stimulation is helping many who suffer from debilitating cramps,” said Dr. Rod MacKinnon, Nobel Laureate and Flex Pharma Scientific Co-Founder, Board Member, and Scientific Advisory Board Co-Chair.

Business Highlights

- Clinical Efforts
 - In January 2017, the Company announced that it is prioritizing its clinical programs in the severe neurological diseases of ALS, MS and peripheral neuropathies such as Charcot-Marie Tooth. The Company intends to initiate additional Phase 2 studies in ALS and CMT in the US this year with FLX-787, its transient receptor potential (TRP) ion channel activator, formulated as an oral disintegrating tablet.
 - In 2016, exploratory Phase 2 efficacy studies were initiated in MS and ALS patients in Australia with FLX-787, the Company’s TRP ion channel activator. The randomized, controlled, blinded, cross-over studies are designed to evaluate the safety and efficacy of FLX-787 in patients who suffer from cramps, spasms and/or spasticity as a consequence of ALS and MS.
 - The Company’s results in its initial study of NLC was selected for late-breaking oral and poster presentations at the American Academy of Neurology (AAN) 68th Annual Meeting held in Vancouver, B.C., Canada in April 2016. Only 14 abstracts were selected as late-breaking presentations at the AAN annual meeting. Details from the study, titled “Orally-administered TRPV1 and TRPA1 activators reduce Night Leg Cramps in a randomized, blinded, placebo-controlled, crossover human trial,” were presented during the Emerging Science Session.
 - Over the past year, Flex Pharma presented positive human efficacy data from randomized, controlled studies at several scientific and medical meetings, including the AAN, Experimental Biology, the American College of Sports Medicine (ACSM), the Society for Neuroscience, and the Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS).
 - In October 2016, the Company announced a strong statistical trend of FLX-787 in an exploratory human nocturnal leg cramps (NLC) study in reducing muscle cramp frequency ($p=0.06$) during the initial two-week parallel design of the study versus placebo as compared to the baseline run-in period. This analysis was based upon data from patients
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restricted to two sites (n=37), after data from a third clinical site was excluded due to a concentrated number of issues relating to patient selection.

- Consumer Launch

- For the year ended December 31, 2016, the Company recorded approximately \$1.0 million in total revenues for its consumer product, HOTSHOT, and approximately \$299,000 for the fourth quarter of 2016. Launched in June 2016, HOTSHOT is a new 1.7 fluid ounce sports shot that is scientifically proven to prevent and treat muscle cramps by stopping them where they start: at the nerve.
- In February 2017, Tim Reed, the reigning IRONMAN 70.3® champion, became an official brand ambassador for HOTSHOT. Reed started racing with HOTSHOT a year ago and, in 2016, had the most successful year of his career with wins at the IRONMAN 70.3 Asia Pacific Championship, IRONMAN® Australia and the IRONMAN 70.3 World Championship.
- In December 2016, James Develin, a fullback who played on the 2015 and 2017 championship professional football team and a Brown University graduate, became an official brand ambassador for HOTSHOT. Develin was first introduced to HOTSHOT through his team nutritionist and became an avid user after trying it following several long practices.
- In August 2016, four HOTSHOT brand ambassadors - marathoners Shalane Flanagan and Amy Cragg, and steeplechasers Evan Jager and Colleen Quigley - competed at the Rio Olympics. Evan Jager captured the silver medal in his event.
- HOTSHOT became available on Amazon.com in October 2016.

- Expanded Board of Directors and Scientific Advisory Board

- In August 2016, W. Larry Kenney, Ph.D., Professor of Physiology and Kinesiology at Penn State University, joined the Company's Scientific Advisory Board. As the Marie Underhill Noll Chair in Human Performance and Professor of Physiology and Kinesiology at Penn State University, Dr. Kenney is focused on research involving human physiological responses and adaptations to exercise and extreme environments. Dr. Kenney served as President of the American College of Sports Medicine from 2003-2004. He serves on the American Council of Exercise Scientific Advisory Panel, Nike's Science Advisory Board, and chaired the Gatorade® Sports Science Institute for several years.
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- In March 2016, Michelle Stacy, former President of Keurig Inc., joined the Board of Directors of Flex Pharma. As the former president of Keurig, Inc. and former vice president and general manager with Gillette/P&G, Ms. Stacy brings a wealth of experience leading consumer businesses and building global brands. During her five-year tenure at Keurig Inc., a division of Keurig Green Mountain, the company's revenue grew from \$493 million in FY2008 to \$4.3 billion in FY2013.

Fourth Quarter & Full Year 2016 Financial Results

- **Cash Position:** As of December 31, 2016, Flex Pharma had cash, cash equivalents and marketable securities of \$61.1 million. During the three months ended December 31, 2016, cash, cash equivalents and marketable securities decreased by \$6.3 million. For the year ended December 31, 2016, cash, cash equivalents and marketable securities decreased \$32.6 million.
 - **Total Revenue:** Total revenue for the three months ended December 31, 2016, was approximately \$299,000, including approximately \$291,000 of net product revenue and approximately \$8,000 of other revenue. Total revenue for the year ended December 31, 2016 was approximately \$1.0 million, including approximately \$990,000 of net product revenue and approximately \$21,000 of other revenue.
 - **Cost of Product Revenue:** Cost of product revenue for the three months ended December 31, 2016 was approximately \$134,000. Cost of product for the twelve months ended December 31, 2016 was approximately \$663,000 and included inventory write offs of approximately \$282,000.
 - **R&D Expense:** Research and development expense for the three months ended December 31, 2016 was \$4.2 million and \$20.4 million for the year ended December 31, 2016. Research and development expense for these time periods primarily included costs associated with the Company's clinical studies of FLX-787, IND-supporting activities, personnel costs (including salaries and stock-based compensation costs), and external consultant costs.
 - **SG&A Expense:** Selling, general and administrative expense for the three months ended December 31, 2016 was \$3.9 million and \$19.9 million for year ended December 31, 2016. Selling, general and administrative expense for these periods primarily included personnel costs
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(including salaries and stock-based compensation costs), sales, marketing and fulfillment costs related to launching the Company's consumer brand and HOTSHOT, legal costs, and external consultant costs.

- **Net Loss and Cash Flow:** Net loss for the three months ended December 31, 2016 was (\$7.9) million, or (\$0.48) per share and included \$1.2 million of stock compensation expense. For the year ended December 31, 2016, net loss was (\$39.5) million, or (\$2.43) per share and included \$6.6 million of stock-based compensation expense. As of December 31, 2016, Flex Pharma had 16,773,798 shares of common stock outstanding. The net loss for the fourth quarter of 2016, as well as for the year ended December 31, 2016, was primarily driven by the Company's operating expenses related to its research and development efforts, costs associated with the development and launch of the Company's consumer brand and 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 through early 2019.

Upcoming Events and Presentations

- Annual ROTH Conference, March 13-15, 2017 in Laguna Niguel, CA
- Oppenheimer Healthcare Conference, March 21-22, 2017 in New York, NY
- Jefferies Healthcare Conference, June 6-9, 2017 in New York, NY
- JMP Securities Life Sciences Conference, June 20-21, 2017 in New York, NY

Conference Call and Webcast

The company will host a conference call and webcast today at 8:30 a.m. ET to provide an update on the company and discuss full year 2016 financial results. To access the conference call, please dial (855) 780-7202 (U.S. and Canada) or (631) 485-4874 (International) five minutes prior to the start time. A live webcast may be accessed in the Investors section of the company's website at www.flex-pharma.com. Please log on to the Flex Pharma website approximately 15 minutes prior

to the scheduled webcast to ensure adequate time for any software downloads that may be required. A replay of the webcast will be available on Flex Pharma's website for three months.

About Flex Pharma

Flex Pharma, Inc. is a biotechnology company that is developing innovative and proprietary treatments for cramps and spasms associated with the severe neurological diseases of ALS, MS and peripheral neuropathies such as Charcot-Marie-Tooth (CMT). Flex Pharma was founded by National Academy of Science members Rod MacKinnon, M.D. (2003 Nobel Laureate), and Bruce Bean, Ph.D., recognized leaders in the fields of ion channels and neurobiology, along with Chair and CEO Christoph Westphal, M.D., Ph.D.

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 studies, our expectations regarding the availability of our capital resources, and our commercialization plans for our consumer product. 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; 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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SVP, Investor Relations & Corporate Communications

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- Financial Tables to Follow -

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

	<u>December 31, 2016</u>	<u>December 31, 2015</u>
Assets		
Cash and cash equivalents	\$ 22,416	\$ 66,687
Marketable securities	38,659	26,965
Accounts receivable	12	—
Inventory	454	—
Prepaid expenses and other current assets	926	909
Property and equipment, net	556	382
Other assets	192	127
Total assets	<u>\$ 63,215</u>	<u>\$ 95,070</u>
Liabilities and stockholders' equity		
Accounts payable and accrued expenses	\$ 3,780	\$ 2,823
Deferred revenue	88	—
Other liabilities	30	55
Stockholders' equity	<u>59,317</u>	<u>92,192</u>
Total liabilities and stockholders' equity	<u>\$ 63,215</u>	<u>\$ 95,070</u>

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

	Three Months Ended December 31, 2016	Three Months Ended December 31, 2015	Twelve Months Ended December 31, 2016	Twelve Months Ended December 31, 2015
Net product revenue	\$ 291	\$ —	\$ 990	\$ —
Other revenue	8	—	21	—
Total revenue	<u>299</u>	<u>—</u>	<u>1,011</u>	<u>—</u>
Costs and expenses:				
Cost of product revenue	134	—	663	—
Research and development	4,231	3,309	20,378	12,749
Selling, general and administrative	3,918	4,621	19,856	16,464
Total costs and expenses	<u>8,283</u>	<u>7,930</u>	<u>40,897</u>	<u>29,213</u>
Loss from operations	(7,984)	(7,930)	(39,886)	(29,213)
Interest income, net	84	37	393	72
Net loss	<u>\$ (7,900)</u>	<u>\$ (7,893)</u>	<u>\$ (39,493)</u>	<u>\$ (29,141)</u>
Net loss per share-basic and diluted	<u>\$ (0.48)</u>	<u>\$ (0.51)</u>	<u>\$ (2.43)</u>	<u>\$ (2.08)</u>
Weighted-average number of common shares outstanding (1)	<u>16,620</u>	<u>15,552</u>	<u>16,234</u>	<u>14,033</u>

(1) As of December 31, 2016, the Company had issued approximately 5.4 million shares of restricted stock that are subject to vesting. Of these shares, approximately 4.2 million shares had vested at December 31, 2016 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 1.2 years.