Flex Pharma Reports Year End 2017 Financial Results

-- FLX-787 Exploratory MS Spasticity Results at the end of March --

-- FLX-787 Phase 2 ALS & CMT Clinical Studies Ongoing --

-- Cash to Mid 2019 --

Conference Call Scheduled Today at 9:00 a.m. ET

March 7, 2018

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 year ended December 31, 2017 and provided an update on its clinical development and corporate activities.

"Late last year we achieved an important milestone with the positive data set from a small ALS study which provides the first clinical evidence that FLX-787 is active in patients with underlying neurological disease," stated Bill McVicar, Ph.D., President and CEO of Flex Pharma. "The next 12 months will be transformational for Flex as we expect to report results from a number of larger clinical trials -- first an exploratory spasticity study in MS, followed by two Phase 2 studies in ALS and Charcot-Marie-Tooth patients, with our current cash position taking us to mid 2019."

Business Highlights

- Clinical Efforts
    - On November 28, 2017, the Company announced that it had completed enrollment in its Phase 2 exploratory spasticity study in MS patients in Australia. The randomized, placebo-controlled, blinded, cross-over study is designed to evaluate the safety and efficacy of FLX-787, the Company's single molecule, chemically synthesized, dual A1/V1 transient receptor potential (TRPA1/V1) ion channel activator, in patients who suffer from spasticity, cramps and spasms as a consequence of MS. The Company expects to report topline results from this study by the end of the first quarter of 2018.

    - On November 6, 2017, the Company 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. 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 the Numerical Rating Scale

(NRS). Strong and consistent trends were demonstrated on multiple other 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 October 2017, the Company initiated a Phase 2 randomized, controlled, double-blinded, parallel design trial in the United States in patients with Charcot-Marie-Tooth, referred to as the **C**O**M**MI**T** trial. The COMMIT trial will evaluate FLX-787 in CMT patients who suffer from painful, debilitating cramps. Patients will be evaluated for changes in cramp frequency as the primary endpoint, with a number of secondary endpoints. The Company expects to report topline data from this study in early 2019.

- In August 2017, the Company initiated a Phase 2 randomized, controlled, double-blinded, parallel design trial in the US in patients with motor neuron disease (MND), focused on ALS, referred to as the COM**M**E**ND** trial. The COMMEND trial will evaluate FLX-787 in MND patients who suffer from painful, debilitating cramps. The FDA has granted FLX-787 Fast Track designation for the treatment of severe muscle cramps associated with ALS. The Company expects to report topline results from this study by early 2019.

- In July 2017, the US 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 United States 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.

- In April 2017, the Company's investigational new drug (IND) application for FLX-787 for patients with ALS became effective allowing the Company to commence its U.S. Phase 2 COMMEND clinical trial of FLX-787 in ALS patients.

- Consumer

  - For the year ended December 31, 2017, the Company recorded approximately $1.3 million in total revenue for its consumer product, HOTSHOT®, and approximately $283,000 for the fourth quarter of 2017. Launched in June 2016, HOTSHOT is a 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.

- Year-over-year HOTSHOT unit volume growth for the fourth quarter of 2017 was 10%.

- HOTSHOT has the potential to expand its recovery claims to address muscle soreness and muscle pain based upon a recent In-Home study, conducted among 288 endurance and non-endurance athletes using HOTSHOT over a two-week period before or after a workout. The vast majority of endurance and non-endurance athletes surveyed reported that muscle soreness and muscle pain can be reduced effectively by using HOTSHOT.

- In January 2018, the Company announced that it engaged an investment bank to assist with the consideration of strategic alternatives for its consumer business segment.

- Leadership and Board of Directors

  - In October 2017, Roger Tung, Ph.D. was appointed to Flex Pharma's Board of Directors. Dr. Tung is the scientific co-founder of Concert Pharmaceuticals, where he serves as President and Chief Executive Officer. Prior to Concert, Dr. Tung was a founding scientist at Vertex, a pharmaceutical company. Dr. Tung has more than 30 years of experience in the global pharmaceutical and biotechnology industries.

  - In July 2017, the Flex Pharma Board of Directors appointed William (Bill) McVicar, Ph.D., as President and Chief Executive Officer of Flex Pharma. Dr. McVicar joined Flex Pharma in April 2017 as President of Research & Development. Dr. McVicar has a track record of clinical development and operational success with nearly 30 years of experience, most recently serving as Chief Scientific Officer at Inotek. Prior to Inotek, he served as Vice President of Development Operations at Sepracor, where 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.

Fourth Quarter & Full Year 2017 Financial Results

- **Cash Position:** As of December 31, 2017, Flex Pharma had cash, cash equivalents and marketable securities of $33.3 million. During the three months ended December 31, 2017, cash, cash equivalents and marketable securities decreased by $5.6 million. For the year ended December 31, 2017, cash, cash equivalents and marketable securities decreased $27.8 million.

- **Total Revenue:** Total revenue for the three months ended December 31, 2017, was approximately $283,000. Total revenue for the year ended December 31, 2017 was

approximately $1.3 million, including approximately $1.3 million of net product revenue and approximately $14,000 of other revenue.

- **Cost of Product Revenue:** Cost of product revenue for the three months ended December 31, 2017 was approximately $133,000 and included inventory write offs of approximately $8,000. Cost of product for the twelve months ended December 31, 2017 was approximately $507,000 and included inventory write offs of approximately $42,000.

- **R&D Expense:** Research and development expense for the three months ended December 31, 2017 was $4.3 million and $17.0 million for the year ended December 31, 2017. Research and development expense for these time periods 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 December 31, 2017 was $4.0 million and $18.5 million for year ended December 31, 2017. Selling, general and administrative expense for these periods 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 December 31, 2017 was ($8.0) million, or ($0.46) per share and included $1.0 million of stock compensation expense. For the year ended December 31, 2017, net loss was ($34.4) million, or ($1.99) per share and included $4.2 million of stock-based compensation expense. As of December 31, 2017, Flex Pharma had 17,797,178 shares of common stock outstanding. The net loss for the fourth quarter of 2017, as well as for the year ended December 31, 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 to mid 2019.

Upcoming Events and Presentations

- Annual ROTH Conference, March 12-14, 2018 in Laguna Niguel, CA

Conference Call and Webcast

The company will host a conference call and webcast today at 9:00 a.m. ET to provide an update on the company and discuss full year 2017 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 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. These 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; 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; 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; and the inherent uncertainties associated with intellectual property. Other factors that may cause actual results to differ from those expressed or implied in the forward-looking statements in this press release are discussed in our filings with the U.S. Securities and Exchange Commission (SEC), including the "Risk Factors" contained therein. 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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- Financial Tables to Follow -

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

	December 31, 2017	December 31, 2016
Assets:		
Cash and cash equivalents	$ 19,186	$ 22,416
Marketable securities	14,130	38,659
Accounts receivable	10	12
Inventory	432	454
Prepaid expenses and other current assets	777	926
Property and equipment, net	331	556
Other assets	127	192
Total assets	$ 34,993	$ 63,215
Liabilities and stockholders' equity:		
Accounts payable and accrued expenses	$ 5,717	$ 3,780
Deferred revenue	72	88
Other liabilities	98	30
Stockholders’ equity	29,106	59,317
Total liabilities and stockholders’ equity	$ 34,993	$ 63,215

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

	Three Months Ended December 31, 2017	Three Months Ended December 31, 2016	Twelve Months Ended December 31, 2017	Twelve Months Ended December 31, 2016
Net product revenue	$ 283	$ 291	$ 1,261	$ 990
Other revenue	—	8	14	21
Total revenue	283	299	1,275	1,011
Costs and expenses:				
Cost of product revenue	133	134	507	663
Research and development	4,259	4,231	16,990	20,378
Selling, general and administrative	3,984	3,918	18,504	19,856
Total costs and expenses	8,376	8,283	36,001	40,897
Loss from operations	(8,093)	(7,984)	(34,726)	(39,886)
Interest income, net	64	84	292	393
Net loss	$ (8,029)	$ (7,900)	$ (34,434)	$ (39,493)
Net loss per share-basic and diluted	$ (0.46)	$ (0.48)	$ (1.99)	$ (2.43)
Weighted-average number of common shares outstanding (1)	17,643	16,620	17,261	16,234

(1) As of December 31, 2017, the Company had issued approximately 5.4 million shares of restricted stock that are subject to vesting. Of these shares, approximately 5.3 million shares had vested at December 31, 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 0.2 years.