



May 4, 2017

## Flexion Therapeutics Reports First Quarter 2017 Financial Results and Recent Business Highlights

- | Capital infusion of approximately \$201 million (gross proceeds) through recent offering of convertible senior notes expected to provide cash runway into 2019
- | New patents issued in U.S. further strengthen intellectual property (IP) estate for Zilretta™ (FX006), our lead product candidate
- | Clinical data on Zilretta presented at Osteoarthritis Research Society International (OARSI)
- | Yamo Deniz, M.D., named Chief Medical Officer
- | Conference call scheduled for today at 4:30 p.m. ET

BURLINGTON, Mass., May 04, 2017 (GLOBE NEWSWIRE) -- Flexion Therapeutics, Inc. (Nasdaq:FLXN) today reported financial results for the quarter ended March 31, 2017.

"The first few months of 2017 marked another period of impressive growth for Flexion," commented Michael Clayman, M.D., President and Chief Executive Officer. "We continued to attract top talent, made great progress building our commercial infrastructure, strengthened the IP estate for Zilretta and significantly advanced our launch plans. Furthermore, following our recent convertible debt offering, we believe we now have the capital to take us well into 2019, more than one year after the anticipated launch of Zilretta. We are excited about Flexion's future and the potential to make a meaningful difference for the millions of patients confronting OA."

### First Quarter Financial Results

The company reported a net loss of \$23.9 million for the first quarter of 2017, compared to a net loss of \$16.8 million for the same period of 2016.

Research and development costs were \$10.8 million in the first quarter in 2017, compared to \$12.0 million in the first quarter of 2016. General and administrative expenses increased to \$13.0 million in the first quarter of 2017, as compared to \$4.7 million for the same period in 2016, due primarily to costs associated with increased headcount and expenses related to the potential launch and commercialization of Zilretta (FX006), Flexion's lead investigational program for pain associated with osteoarthritis (OA) of the knee.

As of March 31, 2017, the company had approximately \$187.5 million in cash, cash equivalents, and marketable securities compared to \$210.3 million as of December 31, 2016.

### Recent News and Highlights:

- | Completed a convertible debt offering on May 2, 2017 providing a capital infusion of approximately \$201 million (gross proceeds) that is expected to extend the cash runway well into 2019.
- | Yamo Deniz, M.D., was named Chief Medical Officer. Neil Bodick, M.D., Ph.D., co-founder of Flexion, transitioned to Chief Scientific Officer and assumed responsibility for building Flexion's pipeline of new drug candidates and leading discovery research activities including the assessment of external opportunities and new applications for the company's proprietary formulation technologies.
- | The U.S. Patent and Trademark Office issued two new patents (U.S. Patent Numbers 9,555,048 and 9,555,047) covering Method of Use and Method of Manufacturing. The new patents further strengthen Zilretta's IP position which includes composition of matter, method of use and method of manufacturing patents providing protection into 2031.
- | Clinical data on Zilretta was presented at OARSI. In an analysis of pooled Phase 2/3 data, Zilretta demonstrated clinically meaningful pain relief and functional improvement in patients with OA of the knee. A separate Phase 2 study showed prolonged synovial localization and diminished systemic exposure of corticosteroid with Zilretta compared to traditional steroid injections.
- | Strong enrollment in the ongoing clinical trial to evaluate the safety of repeat administration of Zilretta in patients with OA of the knee. The trial is expected to be fully enrolled in the second half of 2017, and the readout is anticipated in 2018.
- | Recognized by the *Boston Business Journal* as one of the 2017 Best Places to Work.

## Conference Call

Flexion's management will host a conference call today at 4:30 p.m. ET. The dial-in number for the conference call is (855) 770-0022 for domestic participants and (908) 982-4677 for international participants, with Conference ID # 11984746. A live webcast of the conference call can also be accessed through the "[Investors](#)" tab on the Flexion Therapeutics website. A webcast replay will be available online after the call.

## About Osteoarthritis of the Knee

While OA is being diagnosed at increasingly younger ages, prevalence rises after age 45. In 2015, more than 14 million Americans were diagnosed with OA of the knee. OA represents an enormous burden on the U.S. healthcare system, affecting approximately 31 million individuals and accounting for more than \$185 billion in annual expenditures. About 13 percent of women and 10 percent of men aged 60 years and older have symptomatic OA of the knee, with rates likely to increase due to the aging of the population and the rate of obesity or overweight individuals in the general population.

Each year, more than five million OA patients in the United States receive either an immediate-release corticosteroid or hyaluronic acid intra-articular injection for knee pain.

## About Zilretta

Zilretta is being investigated as the first intra-articular, extended-release treatment for patients with OA related knee pain. Zilretta employs proprietary microsphere technology combining triamcinolone acetonide — a commonly administered, short-acting corticosteroid — with a poly lactic-co-glycolic acid (PLGA) matrix. To date, more than 800 patients have been treated with Zilretta in clinical trials.

## About Flexion Therapeutics

Flexion is a specialty pharmaceutical company focused on the development and commercialization of novel, local therapies for the treatment of patients with musculoskeletal conditions, beginning with OA. The company's lead product candidate, Zilretta, is being investigated for its potential to provide improved analgesia for the millions of U.S. patients who receive intra-articular injections for OA related knee pain annually.

## Forward-Looking Statements

Statements in this press release regarding matters that are not historical facts, including, but not limited to, statements relating to the future of Flexion; our ongoing development of Zilretta and the potential development of other product candidates; the expected timing of the clinical trial studying repeat administration of Zilretta; potential regulatory approval of Zilretta; our plans to commercialize Zilretta and its market potential; expected increases in the rate of individuals with OA of the knee; the potential therapeutic and other benefits of Zilretta and any other product candidates, and our expected cash runway, are forward-looking statements. 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, risks associated with the process of discovering, developing, manufacturing and obtaining regulatory approval for drugs that are safe and effective for use as human therapeutics; the fact that results of past clinical trials may not be predictive of subsequent trials; our reliance on third parties to manufacture and conduct clinical trials of Zilretta and our other product candidates, which could delay or limit their future development or regulatory approval; the fact that we may spend our available cash resources or require additional financing faster than we currently expect, whether due to pursuing additional business opportunities, unexpected expenditures or otherwise; our ability to meet anticipated clinical trial enrollment and completion dates; the risk that we may not be able to maintain and enforce our intellectual property, including intellectual property related to Zilretta; competition from alternative therapies; regulatory developments and safety issues, including difficulties or delays in obtaining regulatory approvals to market Zilretta; Zilretta may not receive regulatory approval or be successfully commercialized, including as a result of the FDA's or other regulatory authorities' decisions regarding labeling and other matters that could affect its availability or commercial potential; risks related to key employees, markets, economic conditions, health care reform, prices and reimbursement rates; and other risks and uncertainties described in our filings with the Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in our most recent Annual Report on Form 10-K and subsequent filings with the SEC. The forward-looking statements in this press release speak only as of the date of this press release, and we undertake no obligation to update or revise any of the statements. We caution investors not to place considerable reliance on the forward-looking statements contained in this press release.

**FLEXION THERAPEUTICS**  
**CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS**  
**(in thousands, except for per share information)**

**Three Months Ended**  
**March 31,**

**2017**

**2016**

Revenue	\$		-\$		-
Operating expenses:					
Research and development		10,756		11,981	
General and administrative		13,026		4,692	
Total expenses		<u>23,782</u>		<u>16,673</u>	
Loss from operations		(23,782)		(16,673)	
Interest income (expense), net		(75)		60	
Other income (expense)		(22)		(202)	
Loss from operations before income tax		<u>(23,879)</u>		<u>(16,815)</u>	
Net loss		<u>(23,879)</u>		<u>(16,815)</u>	
Basic and diluted net loss per share	\$	(0.75)	\$	(0.78)	
Basic and diluted weighted average number of common shares outstanding		<u>31,704</u>		<u>21,570</u>	

**FLEXION THERAPEUTICS  
SELECTED BALANCE SHEET DATA  
(in thousands)**

	<u>March 31, 2017</u>	<u>December 31, 2016</u>
Cash and cash equivalents	\$ 42,921	\$ 30,915
Marketable securities	144,624	179,413
Total current assets	190,124	209,393
Working capital	172,132	191,853
Total assets	204,293	226,262
Total notes payable	29,875	30,533
Total stockholders' equity (deficit)	166,099	187,032

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