March 9, 2017

Flexion Reports Year-End 2016 Financial Results

- *NDA for Zilretta™ (FX006) filed in December 2016 and accepted by FDA in February 2017*
- *PDUFA action date set for October 6, 2017*
- *Commercialization plans on target for potential Q4 launch of Zilretta*
- *Frederick Driscoll, Chief Financial Officer, to retire effective March 31, 2017*
- *Conference call scheduled for today at 4:30 p.m. ET*

BURLINGTON, Mass., March 09, 2017 (GLOBE NEWSWIRE) -- Flexion Therapeutics, Inc. (Nasdaq:FLXN) today reported financial results for the year-ended December 31, 2016 and provided an update on the Company's plans for a potential launch of Zilretta in Q4 2017. In February 2017, the Company announced that the U.S. Food and Drug Administration (FDA) accepted its New Drug Application (NDA) for Zilretta in osteoarthritis (OA) of the knee. Under the Prescription Drug User Fee Act (PDUFA), the agency has established a user fee goal date of October 6, 2017.

For 2016, the Company reported a net loss of $71.9 million as compared to a net loss of $46.3 million for 2015. Research and development expenses were $41.3 million and $32.7 million for the years ended December 31, 2016 and 2015, respectively. The increase in research and development expenses of $8.6 million in 2016, as compared to 2015 was primarily a result of increased costs related to the Company's clinical development program for Zilretta and expenses associated with the filing of an NDA for Zilretta in December 2016. General and administrative expenses were $28.5 million and $13.4 million for the years ended December 31, 2016 and 2015, respectively. The increase in general and administrative expenses of $15.1 million in 2016, as compared to 2015 was primarily due to the development of corporate and commercial infrastructure to support the potential launch of Zilretta.

As of December 31, 2016, the Company had $210.3 million in cash, cash equivalents and marketable securities compared to $118.6 million as of December 31, 2015.

"The previous 12 months marked a period of remarkable progress for Flexion Therapeutics," said Michael Clayman, M.D., President and Chief Executive Officer of Flexion. "We achieved many key milestones, most notably, the successful filing of the NDA for Zilretta. As a result, we have moved significantly closer to our goal of commercializing medicines that can potentially have a meaningful impact on patients, and we eagerly await the FDA's decision on Zilretta."

Additional Corporate Highlights from 2016 and Recent Months

- Presented Pivotal Phase 2b and Phase 3 trial result for Zilretta at Osteoarthritis Research Society International (OARSI) 2016 World Congress
- Reported data from a 33 patient Phase 2 study which assessed the effects of Zilretta on blood glucose levels in adults with OA of the knee who also have Type 2 diabetes
  - data showed that Zilretta was associated with a statistically significant and clinically relevant reduction in the rise of blood glucose compared to immediate-release triamcinolone acetonide (TA) injection over 72 hours post dosing
- Conducted two highly successful public offerings raising gross proceeds of approximately $147.9 million
- Initiated a clinical trial to investigate the safety of repeat administration of Zilretta
- Announced key commercial leadership appointments of John Magee, VP, Sales; Mark Fraga, VP, Marketing; and Dan Thornton, VP, Market Access, in preparation for potential launch of Zilretta
- Appointed Scott Kelley, M.D., as VP, Medical Affairs
- Added Mark Stejbach, Senior Vice President and Chief Commercial Officer at Alkermes plc, to the Board of Directors

Anticipated Events in 2017

- Potential approval of Zilretta NDA - PDUFA action date of October 6, 2017
- Potential launch of Zilretta
- Complete enrollment of Zilretta repeat administration clinical trial
- Ramp up of field sales force and other key positions, bringing anticipated head count to ~250 by Q4

- Opening of Flexion's Innovation Lab in Woburn, MA

Flexion also announced that Mr. Frederick Driscoll, Chief Financial Officer, intends to retire effective March 31, 2017, due to a personal family matter. To ensure a smooth transition, Mr. Driscoll will continue with the Company in an advisory capacity until his successor has been named.

Dr. Clayman added, "Working with Fred these past several years has been one of the real highlights of my professional career. Fred brought deep commitment, strategic insight and great goodwill to the CFO position and has helped us build strong relationships with investors and the banking community. His contributions to Flexion's success have been extraordinary. We wish him the very best in retirement and are pleased that he will be available to consult with us and assist in the identification of his successor."

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 # 77592180. 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, nearly 700 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 our other product candidates; our interpretation of the data and results from our Zilretta clinical trials, including our belief that we will not need to conduct any additional clinical trials prior to submitting an NDA, or receiving regulatory approval, for Zilretta; our plans for, and the expected timing of, our Zilretta NDA submission with the FDA; our plans to commercialize Zilretta and its market potential; the potential benefits of the FDA's Fast Track designation for Zilretta, including the potential for an expedited NDA review process; and the potential therapeutic and other benefits of Zilretta and our other product candidates, 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; our ability to meet anticipated clinical trial commencement, enrollment and completion dates and regulatory filing dates for Zilretta; the fact that we will require additional capital, including prior to commercializing Zilretta or any of our other product candidates, and may be unable to obtain such additional capital in sufficient amounts or on terms acceptable to us; the risk that we may not be able to maintain and enforce our intellectual property, including intellectual property related to Zilretta and our other product candidates; competition from alternative therapies; regulatory developments and safety issues, including difficulties or delays in obtaining regulatory approvals to market Zilretta or our other product candidates; the risk that the FDA and foreign regulatory authorities may not agree with our interpretation of the data from our clinical trials of Zilretta and may require us to conduct additional clinical trials prior to

filing applications for regulatory approval or granting regulatory approval; 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
CONSOLIDATED STATEMENT OF OPERATIONS
(in thousands, except for per share information)

	Year Ended December 31,	
	2016	**2015**
Revenue	$ -	$ -
Operating expenses:		
Research and development	41,314	32,691
General and administrative	28,466	13,372
Total expenses	69,780	46,063
Loss from operations	(69,780)	(46,063)
Interest income (expense), net	(226)	675
Other income (expense)	(1,887)	(927)
Loss from operations before income tax	(71,894)	(46,315)
Net loss	(71,894)	(46,315)
Basic and diluted net loss per share	$ (2.84)	$ (2.15)
Basic and diluted weighted average number of common shares outstanding	25,296	21,497

FLEXION THERAPEUTICS
SELECTED BALANCE SHEET DATA
(in thousands)

	December 31, 2016	December 31, 2015
Cash and cash equivalents	$ 30,915	$ 62,944
Marketable securities	179,413	55,660
Total current assets	209,394	112,103
Working capital	191,853	104,044
Total assets	226,262	127,139
Total notes payable	30,533	15,002
Total stockholders' equity (deficit)	187,032	103,986

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