March 10, 2016

Flexion Reports Year-End 2015 Financial Results

- *Pivotal registration trials completed in patients with osteoarthritis (OA) of the knee for Zilretta™, Flexion's lead drug candidate (also known as FX006)*
- *Zilretta received Fast-Track designation by U.S. Food & Drug Administration (FDA) in 2015; planned NDA submission on track for second half of 2016*
- *Conference call scheduled for today at 4:30 p.m. ET*

BURLINGTON, Mass., March 10, 2016 (GLOBE NEWSWIRE) -- Flexion Therapeutics, Inc. (Nasdaq:FLXN) today reported financial results for the year-ended December 31, 2015 and provided an update on the company's clinical development program for its lead drug candidate, Zilretta.

For 2015, the company reported a net loss of $46.3 million as compared to a net loss of $27.3 million for 2014. Research and development expenses were $32.7 million and $17.9 million for the years ended December 31, 2015 and 2014, respectively. The increase in research and development expenses of $14.8 million in 2015, as compared to 2014 was primarily a result of increased costs related to the company's clinical development program for Zilretta and expenses associated with headcount additions throughout 2015. General and administrative expenses were $13.4 million and $9.1 million for the years ended December 31, 2015 and 2014, respectively. The increase in general and administrative expenses of $4.3 million in 2015, as compared to 2014 was primarily due to an increase in stock compensation expense and other employee-related costs due to increased headcount.

Michael Clayman, M.D., President and Chief Executive Officer of Flexion, stated, "For Flexion Therapeutics, 2015 was a transformational year during which we made significant advancements across all mission critical functions with Zilretta. With the completion of our pivotal clinical trials with Zilretta, we are poised to achieve our goal of making this drug candidate available to the many millions of knee osteoarthritis (OA) patients who lack good pain relief options."

Dr. Clayman continued, "We view 2016 to be a game-changing year for the company with the expectation that we will file a New Drug Application (NDA) for Zilretta with the FDA in the second half of the year."

2015 and Recent Corporate Highlights

- Met primary endpoint in Phase 3 clinical trial with Zilretta, an investigational non-opioid/non-NSAID analgesic, demonstrating highly significant ($p<0.0001$), durable and clinically meaningful pain relief against placebo at week 12; also achieved statistical significance on WOMAC® A (pain), WOMAC B (stiffness) and WOMAC C (function) and the KOOS quality of life subscale through week 12 against both placebo and current standard of care (triamcinolone acetonide, or TCA)
- Received "Fast Track" designation from the FDA for Zilretta; drugs with the Fast Track designation may have an increased chance for priority review and the designation allows a company to submit completed sections of a related NDA on a rolling basis
- Completed and reported top-line results of a pivotal Phase 2b clinical trial, which showed that Zilretta demonstrated statistical significance to placebo in pain relief beginning at week 1, continuing to week 11 and also at week 13; the primary endpoint of this trial, superiority in pain relief at 12 weeks, did not reach statistical significance
- Entered into a $30-million syndicated senior secured-term loan facility in 2015, primarily to finance the expansion of manufacturing capacity
- Secured notice of allowance for the trademark Zilretta from the U.S. Patent and Trademark Office
- Published Phase 2b dose-ranging results for Zilretta in the *Journal of Bone and Joint Surgery*, demonstrating superior pain relief compared to the most commonly injected intra-articular corticosteroid (TCA) for knee OA
- Received a $2 million grant from the U.S. Department of Defense (DOD) for a Phase 2b clinical trial studying effects of Zilretta on OA of the knee in active duty military personnel and medically retired veterans
- Expanded supply capacity for manufacturing Zilretta by entering into an agreement with Patheon, a global provider of high-quality drug development and delivery solutions
- Added Scott Canute, former President of Global Manufacturing at Eli Lilly and Company and subsequently at Genzyme Corporation, to Flexion's Board of Directors

Anticipated Events in 2016

- Meet with the FDA to discuss the potential submission of an NDA for Zilretta in the second half of 2016
- Report clinical data from the ongoing pharmacokinetic clinical trial for Zilretta
- Initiate a double-blind, randomized, Phase 2 safety trial of Zilretta in patients with OA of the knee who also have type 2 (adult) diabetes
- Initiate a repeat-dose safety trial of Zilretta in patients with OA of the knee

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 # 53086231. 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 Zilretta

Zilretta is being investigated as the first IA sustained-release, non-opioid treatment for patients with moderate to severe OA pain. Zilretta employs proprietary microsphere technology combining TCA — a commonly administered, short-acting corticosteroid — with a polymer (PLGA) intended to provide persistent concentrations of drug locally to both amplify the magnitude and prolong the duration of pain relief.

To date, over 600 patients have been treated with Zilretta in clinical trials. No drug-related serious adverse events have been observed in these trials and adverse events have typically been localized, mild and comparable to those observed with immediate-release TCA and placebo. The data from these trials are consistent with Zilretta providing meaningful and durable pain relief.

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 analgesic therapy for the millions of U.S. patients who receive IA injections for knee OA annually. The company is also investigating another product candidate, FX007, a locally administered TrkA receptor antagonist for post-operative pain.

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,	
	2015	**2014**
Revenue	$ -	$ -
Operating expenses:		
Research and development	32,691	17,923
General and administrative	13,372	9,064
Total expenses	46,063	26,987
Loss from operations	(46,063)	(26,987)
Interest income (expense), net	675	77
Other income (expense)	(927)	(404)
Loss from operations before income tax	(46,315)	(27,314)
Net loss	(46,315)	(27,314)
Basic and diluted net loss per share	$ (2.15)	$ (1.97)
Basic and diluted weighted average number of common shares outstanding	21,497	13,894

FLEXION THERAPEUTICS
SELECTED BALANCE SHEET DATA
(in thousands)

	December 31,	December 31,
	2015	**2014**
Cash and cash equivalents	$ 62,944	$ 103,098
Marketable securities	55,660	48,527
Total current assets	112,103	152,110
Working capital	104,044	145,328
Total assets	127,139	153,348
Total notes payable	15,002	3,564
Total stockholders' equity (deficit)	103,986	144,942

Investor Contact
David Carey
Lazar Partners LTD
T: 212-867-1768
dcarey@lazarpartners.com

Media Contact
Mariann Caprino
TogoRun
T: 917.242.1087
M.Caprino@togorun.com

Corporate Contact
Fred Driscoll

Chief Financial Officer
Flexion Therapeutics, Inc.
T: 781-305-7763
fdriscoll@flexiontherapeutics.com