November 7, 2016

Flexion Therapeutics Reports Third Quarter 2016 Financial Results

Successfully completed the transfer of the Zilretta™ manufacturing technology to Patheon - on track for NDA submission in December

Met primary endpoint in clinical trial evaluating Zilretta in Type 2 diabetes patients with knee osteoarthritis

Conference call scheduled for today at 4:30 p.m. ET

BURLINGTON, Mass., Nov. 07, 2016 (GLOBE NEWSWIRE) -- Flexion Therapeutics, Inc. (Nasdaq:FLXN) today announced financial results for the third quarter ended September 30, 2016.

"Through recent executive hires and further expansion of our commercial and sales teams, we are laying the groundwork to realize our commercialization goals for our investigational therapy, Zilretta™ (also referred to as FX006), in 2017," said Michael Clayman, M.D., President and Chief Executive Officer of Flexion. "We are looking forward to the upcoming podium presentation of Phase 3 data evaluating Zilretta in patients with osteoarthritis of the knee at the American Association of Knee and Hip Surgeons (AAHKS) meeting on November 11th and remain on track to submit a new drug application (NDA) for Zilretta to the U.S. Food and Drug Administration in December."

Third-Quarter Financial Results

The company reported a net loss of $17.8 million for the third quarter of 2016, compared to a net loss of $11.1 million for the third quarter of 2015.

Research and development expenses increased to $9.0 million in the third quarter of 2016, compared to $7.8 million for the same period in 2015, due to an increase in personnel and other employee-related costs for additional headcount and stock based compensation.

General and administrative expenses increased to $8.4 million in the third quarter of 2016, as compared to $3.2 million for the same period in 2015, due primarily to additional costs associated with building a commercial infrastructure to effectively support the potential commercialization of Zilretta.

As of September 30, 2016, the company had $161.5 million in cash, cash equivalents, and marketable securities compared to $118.6 million as of December 31, 2015.

Third Quarter Highlights and Recent News:

- Met primary endpoint in clinical trial evaluating Zilretta in Type 2 diabetes patients with knee osteoarthritis; results demonstrated a markedly lower rise in blood glucose in patients receiving a Zilretta injection compared to patients receiving an immediate-release triamcinolone acetonide (TCA) injection; difference was statistically significant ($p<0.05$, 2-sided) and clinically relevant.
- Successfully completed the transfer of the Zilretta manufacturing technology to Patheon marking an important milestone that enables NDA submission in December.
- Hired several senior level executives in preparation of an anticipated Zilretta commercial launch in 2017, including:
  - Carolyn Beaty Scimemi, Esq. Chief Compliance Officer
  - Mark Fraga, Vice President, Marketing
  - John Magee, Vice President of Sales
  - Adam Muzikant, Ph.D., Vice President, Business Development
  - Dan Thornton, Vice President, Market Access

- Appointed Mark Stejbach to Flexion's Board of Directors. Mr. Stejbach is Senior Vice President and Chief Commercial Officer at Alkermes plc.

About Zilretta

Zilretta is being investigated as the first intra-articular extended-release, non-opioid treatment for patients with moderate to severe knee 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, more than 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. Zilretta is an investigational agent and, as such, has not been approved by the FDA or any other regulatory agencies.

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.

Conference Call

At 4:30 p.m. ET today, Flexion's management will host a conference call and webcast to review third quarter financial results and provide a general business update. 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# 4388754. The live webcast of the conference call can also be accessed through the "Investors" tab on the Flexion Therapeutics website at www.flexiontherapeutics.com. A webcast replay will be available online after the call.

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; our interpretation of the data and results from our Zilretta clinical trials; our plans for, and the expected timing of, our Zilretta NDA submission with the FDA; our plans to commercialize Zilretta, including the expected timing for commercial launch and Zilretta's market potential; and the potential therapeutic and other benefits of Zilretta, 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, which could delay or limit its 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 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; competition from alternative therapies; regulatory developments and safety issues, including difficulties or delays in obtaining regulatory approvals to market Zilretta; 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; 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 September 30,	
	2016	2015
Revenue	$ -	$ -
Operating expenses:		
Research and development	9,047	7,829
General and administrative	8,388	3,197
Total expenses	17,435	11,026
Loss from operations	(17,435)	(11,026)
Interest income (expense), net	(140)	72
Other income (expense)	(207)	(182)
Loss from operations before income tax	(17,782)	(11,136)
Net loss	(17,782)	(11,136)
Basic and diluted net loss per share	$ (0.65)	$ (0.52)
Basic and diluted weighted average number of common shares outstanding	27,524	21,507

FLEXION THERAPEUTICS
SELECTED BALANCE SHEET DATA
(in thousands)

	September 30, 2016	December 31, 2015
Cash and cash equivalents	$ 66,809	$ 62,944
Marketable securities	94,696	55,660
Total current assets	161,086	112,103
Working capital	148,699	104,044
Total assets	174,421	127,139
Total notes payable	30,298	15,002
Total stockholders' equity (deficit)	138,031	103,987

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