November 6, 2017

Flexion Therapeutics Reports Third-Quarter 2017 Financial Results and Recent Business Highlights

- *Zilretta™ (triamcinolone acetonide extended-release injectable suspension) received FDA approval for the management of osteoarthritis (OA) knee pain on October 6, 2017*
- *Product was made commercially available on October 23, 2017, with full launch planned for late November*
- *Recent equity offering generated gross proceeds of ~$140 million to support commercialization of Zilretta, pipeline development and ongoing company operations*
- *Clinical data presentations at 2017 American College of Rheumatology Annual Meeting affirm the effectiveness of Zilretta in delivering extended pain relief for OA of the knee*
- *Conference call scheduled for today at 4:30 p.m. ET*

BURLINGTON, Mass., Nov. 06, 2017 (GLOBE NEWSWIRE) -- Flexion Therapeutics, Inc. (Nasdaq:FLXN) today reported financial results and recent business highlights for the quarter ended September 30, 2017.

"In the past month alone, Flexion has achieved U.S. Food and Drug Administration (FDA) approval of Zilretta for the management of osteoarthritis (OA) knee pain; secured capital that we believe will be sufficient to bring us to profitability; hired our full field sales force; introduced product into our distribution channels and booked our first sales," said Michael Clayman, M.D., President and Chief Executive Officer. "While these accomplishments are extraordinary in their own right, they simply set the stage for us to execute a world-class launch of Zilretta. We are in a truly remarkable position for a company of our size. We have some of the best people in the industry, a comprehensive commercial strategy and the resources needed to deliver an important new medicine to millions of Americans who suffer from OA knee pain."

Third-Quarter Results & Recent Financial Highlights
The Company reported a net loss of $34.2 million for the third quarter of 2017, compared to a net loss of $17.8 million for the same period of 2016.

Research and development costs increased to $12.8 million in the third quarter of 2017, as compared to $9.0 million in the third quarter of 2016, due primarily to an increase of $1.9 million in personnel and other employee-related costs for additional headcount and stock compensation expense and an increase of $1.1 million in portfolio expansion costs. General and administrative expenses increased to $18.4 million in the third quarter of 2017, as compared to $8.4 million for the same period in 2016, due primarily to costs associated with increased headcount and expenses related to the launch and commercialization of Zilretta.

As of September 30, 2017, the Company had approximately $335.1 million in cash, cash equivalents and marketable securities compared with $210.3 million as of December 31, 2016.

On October 10, 2017, the Company announced its intention to offer 4,000,000 shares of stock to the public. Due to high demand, the offering was upsized to 4,800,000 shares, which was successfully completed on October 16, 2017. Additionally, Flexion granted the underwriters a 30-day option to purchase an additional 720,000 shares of common stock, which was exercised in full and closed on October 18, 2017. All of the shares were sold at a price to the public of $25.50 per share, resulting in total gross proceeds of $140.8 million.

Recent News and Business Highlights:

- On October 6, 2017, Flexion announced that the FDA approved Zilretta for the management of OA knee pain. The milestone marked the first product approval in the Company's 10-year history. Zilretta became commercially available on October 23, 2017, and the Company intends to commence the full commercial launch prior to Thanksgiving.

- Following approval, the Company converted contingent offers of employment to 103 sales representatives and has fully staffed its sales force. The Company expects to complete the training of the field force by mid-November.

- On September 7, 2017, Flexion presented data on Zilretta at PAINWeek 2017 that demonstrated a significant reduction in the use of rescue medications following treatment with Zilretta compared to placebo.

- Flexion delivered two clinical data presentations at the American College of Rheumatology Annual Meeting on November 3, 2017. A pooled analysis showed sustained clinical improvement in knee OA pain with Zilretta versus placebo, and the effect of Zilretta was generally enhanced more than two-fold in patients with baseline inflammation versus those without inflammation. In an expanded meta-analysis of two large Zilretta studies, analgesia appeared to be more effective through three months with Zilretta versus placebo.

- The compensation committee of Flexion's board of directors approved the grant of inducement stock options for an aggregate of 401,700 shares of common stock to 117 new employees, the vast majority of whom comprise the field sales force. Each stock option has an exercise price of $22.10 per share and vests over four years, with 25% of the shares vesting on the one-year anniversary of the applicable vesting commencement date and 1/48 of the shares vesting monthly thereafter, subject to the new employee's continued service relationship with the Company.

  Each grant is subject to the terms and conditions of the Company's 2013 Equity Incentive Plan and a stock option agreement. The options were granted as inducements material to the new employees entering into employment with the Company in accordance with NASDAQ Listing Rule 5635(c)(4).

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 # 7299359. A live webcast of the conference call can also be accessed through the "Investors" tab on the Flexion Therapeutics website, and a replay will be available online after the call.

Indication and Important Safety Information

Indication: ZILRETTA™ (triamcinolone acetonide extended-release injectable suspension) is indicated as an intra-articular injection for the management of osteoarthritis pain of the knee.

Limitation of Use: ZILRETTA is not intended for repeat administration.*

Contraindication: ZILRETTA is contraindicated in patients who are hypersensitive to triamcinolone acetonide, corticosteroids or any components of the product.

Warnings and Precautions

- **Intra-articular Use Only:** ZILRETTA has not been evaluated and should not be administered by epidural, intrathecal, intravenous, intraocular, intramuscular, intradermal or subcutaneous routes. Serious events have been reported with epidural and intrathecal administration of corticosteroids and none are approved for this use. ZILRETTA should not be considered safe for epidural or intrathecal administration.
- **Hypersensitivity Reactions:** Rare instances of anaphylaxis, including serious cases, have occurred in patients with hypersensitivity to corticosteroids.
- Joint Infection and Damage: A marked increase in pain accompanied by local swelling, restriction of joint motion, fever and malaise are suggestive of septic arthritis. Examine joint fluid to exclude a septic process. If diagnosis is confirmed, institute appropriate antimicrobial therapy. Avoid injecting corticosteroids into a previously infected or unstable joint. Intra-articular administration may result in damage to joint tissues.
- **Increased Risk of Infections:** Infection with any pathogen in any location of the body may be associated with corticosteroid use. Corticosteroids may increase the susceptibility to new infection and decrease resistance and the ability to localize infection.
- **Alterations in Endocrine Function:** Corticosteroids can produce reversible hypothalamic-pituitary-adrenal axis suppression, with potential for adrenal insufficiency after withdrawal of treatment, which may persist for months. In situations of stress during that period, institute corticosteroid replacement therapy.
- **Cardiovascular and Renal Effects:** Corticosteroids can cause blood pressure elevation, salt and water retention and increased potassium excretion. Monitor patients with congestive heart failure, hypertension and renal insufficiency for edema, weight gain and electrolyte imbalance. Dietary salt restriction and potassium supplementation may be needed.
- **Increased Intraocular Pressure:** Corticosteroid use may be associated with increased intraocular pressure. Monitor patients with elevated intraocular pressure for potential treatment adjustment.
- **Gastrointestinal Perforation:** Corticosteroid administration may increase risk of gastrointestinal perforation in patients with certain GI disorders and fresh intestinal anastomoses. Avoid corticosteroids in these patients.
- **Alterations in Bone Density:** Corticosteroids decrease bone formation and increase bone resorption. Special consideration should be given to patients with or at increased risk of osteoporosis prior to treatment.
- **Behavior and Mood Disturbances:** Corticosteroids may cause adverse psychiatric reactions. Prior to treatment,

special consideration should be given to patients with previous or current emotional instability or psychiatric illness. Advise patients to immediately report any behavior or mood disturbances.

Adverse Reactions: The most commonly reported adverse reactions (incidence ≥1%) in clinical studies included sinusitis, cough and contusions.

Please see the **full Prescribing Information** at www.ZILRETTAlabel.com.

***** The efficacy and safety of repeat administration of ZILRETTA have not been evaluated.

About ZILRETTA
ZILRETTA is the first and only FDA-approved extended-release intra-articular therapy for patients confronting osteoarthritis-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 provide extended pain relief over 12 weeks.

About Osteoarthritis (OA) of the Knee
OA, also known as degenerative joint disease, affects more than 30 million Americans and accounts for more than $185 billion in annual expenditures. In 2016, more than 15 million Americans were diagnosed with OA of the knee and the average age of physician-diagnosed knee OA has fallen by 16 years, from 72 in the 1990s to 56 in the 2010s. The prevalence of OA is expected to continue to increase as a result of aging, obesity and sports injuries. Each year, more than 15 million Americans are treated for OA-related knee pain, and approximately five million OA patients receive either an immediate-release corticosteroid or hyaluronic acid intra-articular injection to manage their knee pain.

About Flexion Therapeutics
Flexion Therapeutics (Nasdaq: FLXN) 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, a type of degenerative arthritis. The company's core values are focus, ingenuity, tenacity, transparency and fun. Flexion was named one of the *Boston Business Journal's* 2017 Best Places to Work.

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; timing for the expected full commercial launch of ZILRETTA; plans to commercialize ZILRETTA and its market potential; the sufficiency of our capital resources to achieve profitability; expected increases in the rate of individuals with OA of the knee; 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 launching a new pharmaceutical product in the United States; 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; the risk that we may not be able to successfully train and maintain an effective sales force to commercialize ZILRETTA; the risk that ZILRETTA may not be successfully commercialized, including as a result of limitations in ZILRETTA's label and package insert information; risks regarding our ability to obtain adequate reimbursement from payors for ZILRETTA; risks related to the manufacture and distribution of ZILRETTA, including our reliance on sole sources of supply and distribution; risks related to key employees, markets, economic conditions, health care reform, prices and reimbursement rates; the risk that we may use our capital resources in ways that we do not currently expect; the risk that we may not achieve profitability on the timeline we currently expect, or at all, 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,	
	2017	**2016**
Revenue	$ -	$ -

Operating expenses:		
Research and development	12,846	9,047
General and administrative	18,375	8,388
Total expenses	31,221	17,435
Loss from operations	(31,221)	(17,345)
Interest income (expense), net	(2,748)	(140)
Other income (expense)	(219)	(207)
Loss from operations before income tax	(34,188)	(17,782)
Net loss	(34,188)	(17,782)
Basic and diluted net loss per share	$ (1.07)	$ (0.65)
Basic and diluted weighted average number of common shares outstanding	31,931	27,524

FLEXION THERAPEUTICS SELECTED BALANCE SHEET DATA
(in thousands)

	September 30, 2017	December 31, 2016
Cash and cash equivalents	$ 159,179	$ 30,915
Marketable securities	175,921	179,413
Total current assets	338,709	209,393
Working capital	312,506	191,853
Total assets	350,790	226,262
Total notes payable	25,227	30,533
Total convertible notes	135,275	-
Total stockholders' equity (deficit)	173,653	187,032

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