May 8, 2018

Flexion Therapeutics Reports First-Quarter 2018 Financial Results and Recent Business Highlights

- *Company booked net ZILRETTA® sales of $2.2 million in Q1*
- *Positive developments in Medicare reimbursement with CMS issuing Q code for ZILRETTA (effective 7/1/18) and recommending dedicated J code (effective 1/1/19)*
- *Pivotal Phase 3 trial results published in the Journal of Bone and Joint Surgery*
- *Compelling data from repeat administration study of ZILRETTA presented at OARSI*
- *FX201 pre-IND meeting held with FDA; program on track for first-in-human trials in 2019*
- *Conference call scheduled for today at 4:30 p.m. ET*

BURLINGTON, Mass., May 08, 2018 (GLOBE NEWSWIRE) -- Flexion Therapeutics, Inc. (Nasdaq:FLXN) today reported financial results and recent business highlights for the quarter ended March 31, 2018.

"The first quarter of 2018 was marked by encouraging sales of ZILRETTA (triamcinolone acetonide extended-release injectable suspension), strong commercial execution, positive reimbursement developments and excellent progress advancing our clinical trials," said Michael Clayman, M.D., President and Chief Executive Officer. "With the first full quarter of sales behind us, our confidence in ZILRETTA's ability to make a meaningful difference for patients confronting osteoarthritis knee pain continues to grow."

First-Quarter Results & Financial Highlights

The Company reported a net loss of $41.6 million for the first quarter of 2018, compared to a net loss of $23.9 million for the same period of 2017. Net sales of ZILRETTA for the first quarter of 2018 totaled $2.2 million. During the three months ended March 31, 2018, the Company expensed $2.7 million of manufacturing costs to cost of sales.

Research and development expenses were $11.6 million and $10.8 million for the three months ended March 31, 2018 and 2017, respectively. The increase in research and development expenses of $0.8 million was primarily due to an increase of $1.0 million in personnel and other employee-related costs for additional headcount and stock compensation expense, as well as a $0.5 million increase in preclinical expenses related to our portfolio expansion and other program costs, offset by a $0.7 million decrease in development expenses for ZILRETTA.

Selling, general and administrative expenses were $26.9 million and $13.0 million for the three months ended March 31, 2018 and 2017, respectively. Selling expenses were $17.6 million and $5.2 million for the three months ended March 31, 2018 and 2017. The increase in selling expenses of $12.4 million was primarily due to salary and related costs associated with additional headcount and costs to establish commercial marketing and sales capabilities. General and administrative expenses increased by $1.5 million in the three months ended March 31, 2018 as compared to the same period in 2017 primarily due to salary and related costs associated with additional headcount and increased stock compensation expense.

Interest expense increased by $3.3 million in the three months ended March 31, 2018 as compared to the same period in 2017 primarily due to the May 2017 issuance of an aggregate of $201.3 million in 2024 Convertible Notes.

As of March 31, 2018, the Company had approximately $376.6 million in cash, cash equivalents and marketable securities compared with $423.9 million as of December 31, 2017.

Recent News and Business Highlights:

- In January, we fully enrolled our study to evaluate the pharmacokinetics of concurrent administration of ZILRETTA in bilateral knee osteoarthritis (OA). Topline results are anticipated by the end of the second quarter of 2018.

- In May, the Centers for Medicare and Medicaid Services (CMS) included ZILRETTA on its list of products recommended for a dedicated J code, effective January 1, 2019. Furthermore, in April, CMS issued a product-specific Q code for ZILRETTA (Q9993), which takes effect July 1, 2018. Q9993 will serve as a temporary universal

code covering Medicare claims for ZILRETTA in all settings until a dedicated J code is in place.

- Based on the results of preclinical studies, in March, we determined FX101 (fluticasone ER) would not meet our defined target product profile and announced our decision to discontinue the program.

- On April 18, the *Journal of Bone and Joint Surgery* published the full results from the pivotal Phase 3 trial which served as the basis of ZILRETTA's approval.

- We reported additional results from the ongoing Phase 3 repeat administration study at the Osteoarthritis Research Society International (OARSI) 2018 World Congress in April. These data showed:

  • the magnitude and duration of pain relief in a "real-world" patient group with OA of the knee are in line with the results seen in pivotal Phase 3 trial;

  • average time to second dose was more than 16 weeks; and

  • 74% (133/179) of subjects received a second administration of ZILRETTA between Weeks 16 and 24.

  The topline results from the Phase 3 repeat administration study are expected in the third quarter of 2018.

- We announced positive preclinical data supporting the FX201 program, which was presented in an oral session at OARSI. These data were shared with the FDA as part of a pre-Investigational New Drug (IND) meeting, and based on the discussion and subject to successful Good Laboratory Practice (GLP) toxicology studies, we anticipate filing an IND and initiating first-in-human clinical trials in 2019.

- Also in April, we presented positive results from a post-hoc analysis of patients with unilateral knee OA in a poster session at the Academy of Managed Care Pharmacy Annual Meeting.

- In May, we initiated an open-label study assessing the effect of a single administration of ZILRETTA on synovitis in patients with OA of the knee. Patients will undergo initial ultrasound examination and MRI with contrast of the index knee at baseline and then return to the clinic at Weeks 6 and 24 for MRI and other assessments. The study is expected to enroll over approximately six months and topline results are anticipated in 2019.

ZILRETTA Commercial Launch Metrics

Since launching ZILRETTA in November 2017, our Musculoskeletal Business Managers (MBMs) have called on approximately 8,500 out of the approximately 10,500 target prescribers who practice in approximately 3,700 target accounts. The number of target prescribers increased from 9,500 to 10,500 and the number of target accounts increased from 3,500 to 3,700 during the first quarter, as our MBMs identified additional prescribers and accounts in their territories.

Since launch, our MBMs and Field Access Managers have held in-depth discussions on reimbursement or conducted product preparation training at approximately 1,600 target accounts. Approximately 1,480 target accounts have gained experience with ZILRETTA through either purchases or product samples, and of the accounts that have purchased ZILRETTA, approximately 40% have placed a reorder.

With respect to commercial payers, we have engaged about 40 key commercial insurers that represent roughly 207 million covered lives and more than 95% of the benefits verifications processed through our FlexForward™ service have confirmed coverage of ZILRETTA.

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 # 2880817. 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 biopharmaceutical company focused on the development and commercialization of novel, local therapies for the treatment of patients with musculoskeletal conditions, beginning with osteoarthritis, a type of degenerative arthritis. The company's core values are focus, ingenuity, tenacity, transparency and fun. For the past two years, Flexion has been named one of the Best Places to Work by the Boston Business Journal, and Flexion was also recognized as a Top Place to Work in Massachusetts by The Boston Globe in 2017.

Forward-Looking Statements

This release contains forward-looking statements that are based on the current expectations and beliefs of Flexion. 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 plans to commercialize ZILRETTA and ZILRETTA's market potential; expected timing with respect to clinical trials and development milestones; expected increases in the rate of individuals with OA of the knee; the potential therapeutic and other benefits of ZILRETTA and FX201; opportunities to obtain regulatory approval for FX201 or further indications for ZILRETTA; and expectations regarding CMS codes, 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 designing and conducting clinical trials, including risks of delays or clinical holds; risks associated with developing and obtaining regulatory approval for product candidates; the fact that results of past clinical trials may not be predictive of subsequent trials; risks associated with commercializing new pharmaceutical products in the United States; the risk that we may not be able to successfully maintain an effective sales force to commercialize ZILRETTA; competition from alternative therapies; the risk that we may not be able to maintain and enforce our intellectual property, including intellectual property related to 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 payers 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; and other risks and uncertainties described in our filings with the Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2017 filed with the SEC on March 8, 2018 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,	
	2018	**2017**
Revenue	$ 2,194	$ -
Operating expenses:		
Cost of sales	2,698	-
Research and development	11,551	10,756
Selling, general and administrative	26,899	13,026
Total expenses	41,148	23,782
Loss from operations	(38,954)	(23,782)
Interest income (expense), net	(2,758)	(75)
Other income (expense)	143	(22)
Loss from operations before income tax	(41,569)	(23,879)
Net loss	(41,569)	(23,879)
Basic and diluted net loss per share	$ (1.10)	$ (0.75)
Basic and diluted weighted average number of common shares outstanding	37,620	31,704

FLEXION THERAPEUTICS SELECTED BALANCE SHEET DATA
(in thousands)

March 31, 2018	**December 31, 2017**

Cash and cash equivalents	$	147,304	$	127,789
Marketable securities and long-term investments		229,276		296,127
Total current assets		380,587		397,990
Working capital		356,140		367,418
Total assets		397,089		441,317
Total notes payable		20,579		22,903
Total convertible notes		138,983		137,107
Total stockholders' equity		222,607		260,274

Contact:

Scott Young
Vice President, Corporate Communications & Investor Relations
Flexion Therapeutics, Inc.
T: 781-305-7194
syoung@flexiontherapeutics.com