Flexion Therapeutics Inc
Form 8-K
April 04, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d)

of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): April 4, 2016

Flexion Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-36287**	**26-1388364**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

10 Mall Road, Suite 301

Burlington, Massachusetts **01803**
(Address of principal executive offices) **(Zip Code)**
Registrant s telephone number, including area code: (781) 305-7777

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations of the registrant under any of the following provisions:

¨ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

¨ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

¨ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

¨ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events.

On April 4, 2016, Flexion Therapeutics, Inc. (Flexion) reported additional results from Phase 2b and Phase 3 clinical trials for its lead drug candidate, Zilretta (also known as FX006).

The Phase 3 trial was a randomized, double-blind, placebo-controlled, active-comparator trial that enrolled 486 patients at approximately 40 centers worldwide. Patients were randomized to one of three treatment groups (1:1:1) and received either a single intra-articular injection of 40 mg of Zilretta, normal saline (placebo) or 40 mg of immediate-release triamcinolone acetonide (TCA). Each patient was evaluated for efficacy and safety during seven outpatient visits over 24 weeks after receiving an injection. The primary objective of the study was to assess the magnitude of pain relief of Zilretta at 12 weeks against placebo as measured by the weekly mean of the average daily pain (ADP) score. The secondary objectives of the study assessed the magnitude and duration of pain relief and effect of Zilretta against placebo and immediate-release TCA in additional pre-specified measures.

In the Phase 3 study, Zilretta (i) met its primary endpoint at week 12, demonstrating highly significant ($p<0.0001$, 2-sided) and clinically meaningful pain relief against placebo as measured by the weekly mean of the average daily pain (ADP) score; (ii) achieved statistically significant pain relief against placebo as measured by the weekly mean of the ADP score at weeks 1 through 16 and demonstrated, on average, an approximately 50 percent reduction in pain from baseline over weeks 1 through 12; (iii) achieved numerically superior pain relief against immediate-release TCA at weeks 2 through 12 as measured by the weekly mean of the ADP score, but did not achieve statistical significance in that measure during the course of the trial; (iv) achieved statistical significance against placebo and immediate-release TCA at each measured time point through 12 weeks on the Western Ontario and McMaster Universities Arthritis Index (WOMAC®) A (pain), WOMAC B (stiffness) and WOMAC C (function) and the Knee injury and Osteoarthritis Outcome Score (KOOS) quality of life subscale; (v) demonstrated in a pre-specified subset analysis of patients with unilateral knee pain (35 percent of subjects in the study), substantially magnified effects in the weekly mean of the ADP score, WOMAC A, B and C and KOOS quality of life and significantly enhanced separation from placebo and immediate-release TCA in all of these measures; and (vi) demonstrated reduced rescue medicine consumption compared with placebo and immediate-release TCA.

Flexion also evaluated the Phase 3 data for clinical relevance by applying established American Academy of Orthopedic Surgeons (AAOS) criteria. In its 2013 publication, Evidence-Based Guideline: Treatment of Osteoarthritis of the Knee, the AAOS reviewed available literature on existing treatments and determined a minimal relative improvement in WOMAC A, B and C measures that would be meaningful to patients. This is referred to as the Minimal Clinically Important Improvement (MCII). The Phase 3 data show that Zilretta exceeds the MCII in WOMAC A, B and C and thus demonstrates a clinically important effect, whereas immediate-release TCA in this study does not with respect to these measures.

The Phase 2b trial enrolled 310 participants in a multi-center, randomized, double-blind study, in which the participants received an injection of either 40 mg or 20 mg of FX006, or a placebo (saline). The 40 mg arm of Zilretta, compared to placebo, demonstrated statistical significance in average pain relief over weeks 1 through 12 ($p = 0.0012$; 2-sided) and over weeks 1 through 24 ($p = 0.0209$; 2-sided). At weekly time points, 40 mg of Zilretta also demonstrated superiority to placebo in pain relief beginning at week 1, continuing to week 11 and also at week 13 ($p < 0.05$ at each time point; 2-sided). The primary endpoint of the trial, superiority in pain relief at 12 weeks, did not reach statistical significance ($p = 0.0821$; 2-sided). A pre-specified, commonly applied sensitivity analysis (Baseline Observation Carried Forward/Last Observation Carried Forward (BOCF/LOCF)) that addresses patient dropouts, however, did demonstrate statistical significance for the primary endpoint at 12-weeks ($p = 0.042$).

Across both the Phase 2b and Phase 3 studies, there were no drug related serious adverse events for Zilretta and the frequency of treatment-related side effects was comparable across all study arms.

On April 4, 2016, Flexion issued a press release announcing additional results of the Phase 2b and Phase 3 trials. A copy of the press release is attached as Exhibit 99.1 hereto. Certain graphical representations of the Phase 2b and Phase 3 data are attached as Exhibit 99.2 hereto and incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.
(d) Exhibits.

Exhibit No.	Description
99.1	Press Release dated April 4, 2016.
99.2	Clinical Trial Graphical Representations

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Flexion Therapeutics, Inc.

Dated: April 4, 2016

By: /s/ Frederick W. Driscoll
Frederick W. Driscoll
Chief Financial Officer

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