Flexion Therapeutics Inc
Form 8-K
February 16, 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): February 16, 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 February 16, 2016, Flexion Therapeutics, Inc. (Flexion) reported that the Phase 3 clinical trial for its lead drug candidate, Zilretta (also known as FX006), met its primary endpoint at week 12, demonstrating highly statistically significant ($p<0.0001$), durable and clinically meaningful pain relief against placebo in patients with moderate to severe osteoarthritis (OA) knee pain. In addition, Zilretta achieved statistically significant analgesia against placebo at each of weeks 1 through 16 and patients treated with Zilretta experienced, on average, a 50 percent reduction in pain from baseline over weeks 1 through 12. In pre-specified analyses, Zilretta achieved statistical significance against placebo in validated OA and quality of life secondary measures at each measured time point through week 12.

In pre-specified secondary measures, compared to immediate-release triamcinolone acetonide (TCA), the most commonly injected intra-articular (IA) corticosteroid, Zilretta achieved statistical significance through 12 weeks on WOMAC® A (pain), WOMAC B (stiffness) and WOMAC C (function) and the validated Knee injury and Osteoarthritis Outcome Score (KOOS) quality of life subscale and was numerically superior at weeks 2 through 12 on the daily pain rating scale, although it did not achieve statistical significance in that measure.

The frequency of treatment-related side effects was comparable across all treatment arms in the trial. No drug-related serious adverse events were observed and no patients treated with Zilretta were discontinued from the study due to a treatment-related side effect.

The randomized, double-blind Phase 3 placebo-controlled, active-comparator trial 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 IA injection of 40 mg of Zilretta, normal saline (placebo) or 40 mg of immediate-release 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. The secondary objectives of the study were to assess the magnitude and duration of pain relief and effect of Zilretta against placebo and immediate-release TCA in a variety of additional pre-specified measures.

On February 16, 2016, Flexion issued a press release announcing the top-line results of the Phase 3 trial. A copy of the press release is attached as Exhibit 99.1 hereto.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	**Description**
99.1	Press Release dated February 16, 2016.

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: February 16, 2016

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

INDEX TO EXHIBITS

Exhibit No.	Description
99.1	Press Release dated February 16, 2016.