Flexion Therapeutics Inc
Form 8-K
September 09, 2015

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): September 8, 2015

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		**01803**

Burlington, Massachusetts
(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 September 8, 2015, Flexion Therapeutics, Inc. (Flexion) reported top-line results from the first of two pivotal clinical trials of its lead drug candidate FX006 in patients with moderate to severe osteoarthritis (OA) knee pain. In the trial, 40 mg of FX006, compared to placebo (saline), 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 FX006 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 ($p = 0.042$).

Overall, the 40 mg dose of FX006 performed better than the 20 mg FX006 dose. In particular, the 40 mg dose conferred more durable pain relief.

The frequency of treatment-related adverse events across the three groups (FX006 40 mg, FX006 20 mg and placebo) was comparable, and no drug-related serious adverse events were observed in the trial. Adverse events thought to be at least possibly related to study drug as assessed by the investigator were less frequent for FX006 than placebo.

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 primary outcome measure was the weekly mean of the average daily pain intensity scores, assessed using an 11-point numerical rating scale (NRS).

On September 8, 2015, Flexion issued a press release announcing the top-line results of the Phase 2b 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 September 8, 2015

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: September 8, 2015

By: */s/ Michael Clayman*
Michael Clayman
Chief Executive Officer

INDEX TO EXHIBITS

Exhibit No.	Description
99.1	Press Release dated September 8, 2015.