Flexion Therapeutics Inc
Form 8-K
September 07, 2017

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 7, 2017

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 obligation 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))
Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01 Other Events.

Flexion Therapeutics, Inc. announced that it will present results from an analysis that found patients treated in clinical trials of Zilretta (FX006), its lead candidate for the treatment of osteoarthritis (OA) knee pain, had a statistically significantly lower use of analgesic rescue medications following treatment compared to placebo. The data will be presented in a poster session at PAINWeek 2017.

A post hoc, pooled analysis of three Phase 2/3 double-blind, randomized, placebo-controlled clinical trials was conducted with 586 patients suffering from OA of the knee. Patients received a single, intra-articular (IA) injection of Zilretta (32 mgs) or saline-placebo, and average daily pain (ADP) intensity was assessed for a period of at least 12 weeks. Trial participants received a rescue medication (acetaminophen/paracetamol 500 mg tablets) at the beginning of the study. The patients consumption of the rescue medication was monitored through a daily diary reporting system, and pill counts were confirmed at the clinical sites.

Rescue medications are commonly provided to patients in clinical trials investigating analgesic therapies. Patients can use rescue medicines to manage pain on an as-needed basis during the trial, and their utilization can provide investigators with important information about the overall analgesic effect of the therapy being studied.

The analysis showed that the use of rescue medication was statistically significantly lower ($p<0.05$) with Zilretta compared to saline-placebo at each of Weeks 1 12. At Week 12, the mean number of daily rescue medication tablets taken was 0.86 for Zilretta compared with 1.23 for saline-placebo, resulting in a least-square-mean (LSM) difference of -0.37. These results support the analgesic efficacy of Zilretta through 12 weeks post-IA injection. The incidence of adverse and serious adverse events were similar across the Zilretta and saline-placebo groups (51.9% vs 49.2%, and 3.1% vs 1.1%, respectively). No drug-related serious adverse events were observed in these trials and adverse events have typically been localized, mild and comparable to those observed with saline-placebo.

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 7, 2017

By: /s/ Mark S. Levine
Mark S. Levine
General Counsel and Corporate Secretary