Flexion Therapeutics Inc
Form 8-K
October 06, 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): October 6, 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

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 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.

On October 6, 2017, we announced that the U.S. Food and Drug Administration approved Zilretta (triamcinolone acetonide extended-release injectable suspension), as the first and only extended-release, intra-articular injection for osteoarthritis knee pain. Zilretta employs proprietary microsphere technology combining triamcinolone acetonide a commonly administered, short-acting corticosteroid with a poly lactic-co-glycolic acid matrix to provide extended pain relief over 12 weeks. We plan to commence commercial sales of Zilretta in the United States in late October 2017 at a wholesale acquisition price of $570 per dose, with a full commercial launch expected in mid-November.

On October 6, 2017, we issued a press release announcing the approval of Zilretta, a copy of which is attached as Exhibit 99.1 to this Current Report.

Forward-Looking Statements

Statements in this Current Report that are not strictly historical in nature are forward-looking statements. These statements include, but are not limited to, statements related to timing for the expected commercial availability and full commercial launch of Zilretta, our plans to commercialize Zilretta in the United States, its market potential and the potential therapeutic and other benefits of Zilretta. These statements are only predictions based on current information and expectations and involve a number of risks and uncertainties. These risks and uncertainties include, without limitation, risks associated with the process of launching a new pharmaceutical product in the United States; the risk that we may not be able to maintain and enforce our intellectual property, including intellectual property related to Zilretta; competition from alternative therapies; the risk that we may not be able to successfully hire, train and maintain an effective sales force to commercialize 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 payors 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; and other risks and uncertainties described in our filings with the Securities and Exchange Commission, or SEC, including under the heading Risk Factors in our most recent Annual Report on Form 10-K and in our subsequent filings with the SEC. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. All forward-looking statements are qualified in their entirety by this cautionary statement, and we undertake no obligation to revise or update this Current Report to reflect events or circumstances after the date hereof, except as required by law.

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

Exhibit No.	**Description**
99.1	Press Release of Flexion Therapeutics, Inc., dated October 6, 2017.

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: October 6, 2017

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

INDEX TO EXHIBITS

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