Flexion Therapeutics Inc
Form 8-K
April 02, 2018
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 2, 2018

Flexion Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	001-36287	26-1388364
(State or other jurisdiction	(Commission	(IRS Employer
of incorporation)	File Number)	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))

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 April 2, 2018, the Centers for Medicare Services (CMS) issued a quarterly update to the Healthcare Common Procedure Coding System (HCPCS) that included a product-specific Q code for ZILRETTA® (Q9993), which CMS indicated will be effective July 1, 2018. CMS issues Q codes at their discretion when they identify a programmatic need to differentiate a single source drug from other products available in the marketplace.

Code Q9993 will cover all Medicare claims for ZILRETTA administered in a physician office setting, which we estimate to represent approximately half of the U.S. market for ZILRETTA. With a product-specific code, Medicare claims are generally adjudicated more expeditiously than under the manual review process required with a miscellaneous code.

In March, CMS also issued a product-specific C code for ZILRETTA (C9469) for Medicare claims in the hospital outpatient department, which became effective April 1, 2018.

Flexion filed for a dedicated J code for ZILRETTA in late 2017. Per the HCPCS review process, CMS is expected to publish the list of products under consideration for dedicated J codes by the end of April. CMS is scheduled to hold a public hearing in May, and the final list of J codes expected to take effect on January 1, 2019 is anticipated to be published in Q4 of 2018.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements that are based on the current expectations and beliefs of Flexion. Statements in this report regarding matters that are not historical facts, including, but not limited to, statements relating to the impact of the Q Code for ZILRETTA on the processing of Medicare claims, and the expected timing of future decisions regarding a dedicated J code for ZILRETTA, are forward-looking statements. These forward-looking statements are based on management's expectations and assumptions as of the date of this Current Report on Form 8-K and are subject to numerous risks and uncertainties which could cause actual results to differ materially from those expressed or implied by such statements. These risks and uncertainties include, without limitation, risks associated with commercializing new pharmaceutical products and other risks and uncertainties described in our filings with the Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2017 filed with the SEC on March 8, 2018 and subsequent filings with the SEC. The forward-looking statements in this Current Report on Form 8-K speak only as of April 2, 2018, and we undertake no obligation to update or revise any of the statements. We caution investors not to place considerable reliance on the forward-looking statements contained herein.

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 2, 2018   By: /s/ Mark S. Levine
                             Mark S. Levine

                             General Counsel and Corporate Secretary