

# FLEXION THERAPEUTICS INC

## **FORM 8-K** (Current report filing)

Filed 08/08/17 for the Period Ending 08/08/17

Address	10 MALL ROAD SUITE 301 BURLINGTON, MA 01803
Telephone	(781) 305-7777
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Symbol	FLXN
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

**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): August 8, 2017**

**Flexion Therapeutics, Inc.**  
(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-36287**  
(Commission  
File Number)

**26-1388364**  
(IRS Employer  
Identification No.)

**10 Mall Road, Suite 301**  
**Burlington, Massachusetts**  
(Address of principal executive offices)

**01803**  
(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 2.02 Results of Operations and Financial Condition.**

On August 8, 2017, Flexion Therapeutics, Inc. issued a press release announcing its financial results for the quarter ended June 30, 2017. A copy of the press release is attached hereto as Exhibit 99.1.

The information in this Item 2.02 and Exhibit 99.1 hereto is being furnished and shall not be deemed “ filed ” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference into any filing under the Exchange Act or the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Flexion Therapeutics, Inc. dated August 8, 2017.

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**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: August 8, 2017

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

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## EXHIBIT INDEX

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## Flexion Therapeutics Reports Second Quarter 2017 Financial Results and Recent Business Highlights

- *Commercial preparations for the potential launch of Zilretta™ (FX006) advancing rapidly*
- *Study evaluating the safety of repeat administration of Zilretta has been fully enrolled*
- *Management strengthened with recent appointments of Mark Levine, General Counsel and Corporate Secretary and Anna Diaz Triola, Vice President, Marketing*
- *Conference call scheduled for today at 4:30 p.m. ET*

**BURLINGTON, Mass., August 8, 2017** – Flexion Therapeutics, Inc. (Nasdaq:FLXN) today reported financial results for the quarter ended June 30, 2017. The company reported a net loss of \$28.9 million for the second quarter of 2017, compared to a net loss of \$14.2 million for the same period of 2016.

Research and development costs increased to \$11.8 million in the second quarter of 2017, as compared to \$8.9 million in the second quarter of 2016, due primarily to an increase of \$3.0 million in personnel and other employee-related costs for additional headcount and stock compensation expense. General and administrative expenses increased to \$15.1 million in the first quarter of 2017, as compared to \$5.2 million for the same period in 2016, due primarily to costs associated with increased headcount and expenses related to the potential launch and commercialization of Zilretta (FX006), Flexion's lead investigational program for pain associated with osteoarthritis (OA) of the knee.

As of June 30, 2017, the company had approximately \$359.9 million in cash, cash equivalents and marketable securities compared with \$210.3 million as of December 31, 2016.

### **Recent News and Highlights :**

- On May 2, 2017, Flexion completed an offering of convertible senior notes due in 2024, providing a capital infusion of approximately \$201 million (gross proceeds) and extending the company's cash runway well into 2019.
  - The company has fully staffed its sales leadership team and is actively recruiting approximately 100 field sales representatives who will be hired on a contingent basis conditional upon Zilretta's approval by the U.S. Food and Drug Administration (FDA). Pending regulatory approval, the company expects to launch Zilretta in the fourth quarter of 2017.
  - A Phase 3 clinical trial to evaluate the safety of repeat administration of Zilretta has been fully enrolled. Study participants will be followed for 52 weeks, and the final data readout is
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expected in the second half of 2018.

- The full data set from a Phase 2 clinical trial of Zilretta in patients with Type 2 diabetes and OA of the knee was presented at the American Diabetes Association's 77th Scientific Sessions. The data demonstrated that Zilretta was not associated with the significant rise in blood glucose seen with an immediate-release steroid in patients with Type 2 diabetes and OA of the knee.
- A health economics analysis of Zilretta was presented at the International Society for Pharmacoeconomics and Outcomes Research 22<sup>nd</sup> International Meeting. The study, which utilized established health economic metrics, demonstrated that Zilretta has the potential to be a cost-effective therapy in OA of the knee.
- Company executives provided updates on commercialization plans and two clinicians shared their medical perspectives on Zilretta during an Investor and Analyst Day held on July 10, 2017. Management announced plans to initiate clinical trials of Zilretta in OA of the hip and shoulder by year-end.
- During the Investor and Analyst Day presentation, the company unveiled a new pre-clinical pipeline candidate, FX101 (fluticasone extended-release), for the potential treatment of OA pain in large joints. The program is expected to follow the 505(b)(2) pathway. Based on robust pre-clinical pharmacokinetic data, the company believes FX101 has the potential to provide pain relief for up to six months.
- Flexion's executive team was strengthened by the recent appointment of Mark Levine as General Counsel and Corporate Secretary. Additionally, the company has named Anna Diaz Triola as Vice President, Marketing. Ms. Triola brings nearly 20 years of marketing experience in biotechnology companies and deep commercial expertise in new product launches, new product planning, and patient advocacy and engagement across a variety of disease areas.

"Flexion's strong momentum continued to build throughout the second quarter," said Michael Clayman, M.D., President and Chief Executive Officer. "Our commercial organization made impressive strides preparing for the potential launch of Zilretta, and we are eagerly anticipating our Prescription Drug User Fee Act (PDUFA) action date of October 6, 2017."

Dr. Clayman added, "The full enrollment of the repeat administration study of Zilretta represents a major milestone, and we look forward to our planned initiation of new clinical trials in OA of the hip and shoulder by year-end. We are also very pleased to introduce FX101, an important addition to our pipeline, which we believe has the potential to make a meaningful difference for patients confronting OA pain."

#### **Conference Call**

Flexion's management will host a conference call today at 4:30 p.m. ET. The dial-in number for the conference call is 855-770-0022 for domestic participants and 908-982-4677 for international participants, with Conference ID # 56227594. A live webcast of the conference call

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can also be accessed through the “ [Investors](#) ” tab on the Flexion Therapeutics website , and a replay will be available online after the call.

#### **About Osteoarthritis (OA) of the Knee**

OA is the most common joint disease, affecting more than 30 million Americans and accounting for more than \$185 billion in annual expenditures. In 2015, more than 14 million Americans were diagnosed with OA of the knee and the average age of physician-diagnosed knee OA has fallen by 16 years, from 72 in the 1990s to 56 in the 2010s. OA prevalence is expected to continue to increase as a result of aging, obesity and sports injuries. Each year, more than five million OA patients in the U.S. receive either an immediate-release corticosteroid or hyaluronic acid intra-articular injection for knee pain.

#### **About Zilretta**

Zilretta is being investigated as the first intra-articular, extended-release treatment for patients with OA related knee pain. Zilretta employs proprietary microsphere technology combining triamcinolone acetonide — a commonly administered, short-acting corticosteroid — with a poly lactic-co-glycolic acid matrix. In February 2017, the FDA accepted the company's New Drug Application for Zilretta in OA of the knee. Under the Prescription Drug User Fee Act, the agency has established a user fee goal date of October 6, 2017.

#### **About Flexion Therapeutics**

Flexion Therapeutics (Nasdaq:FLXN) is a specialty pharmaceutical company focused on the development and commercialization of novel, local therapies for the treatment of patients with musculoskeletal conditions, beginning with OA, a type of degenerative arthritis. The company's core values are focus, ingenuity, tenacity, transparency and fun. Flexion was named one of the *Boston Business Journal's* 2017 Best Places to Work.

#### **Forward-Looking Statements**

Statements in this press release regarding matters that are not historical facts, including, but not limited to, statements relating to the future of Flexion; our ongoing development of Zilretta and the planned development of FX101; the expected timing of the clinical trial studying repeat administration of Zilretta and planned clinical trials of Zilretta in hip and shoulder joints; potential regulatory approval of Zilretta; our plans to commercialize Zilretta and its market potential; expected increases in the rate of individuals with OA of the knee; the potential therapeutic and other benefits of Zilretta and any other product candidates; and our expected cash runway, are forward-looking statements. These forward-looking statements are based on management's expectations and assumptions as of the date of this press release 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 the process of discovering, developing, manufacturing and obtaining regulatory approval for drugs that are safe and effective for use as human therapeutics; the fact that results of past clinical trials may not be predictive of subsequent trials; our reliance on third parties to manufacture and conduct clinical trials of Zilretta and our other product candidates, which could delay or limit their future development or regulatory approval; the fact that we may spend our available cash resources or require additional financing faster

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than we currently expect, whether due to pursuing additional business opportunities, unexpected expenditures or otherwise; our ability to meet anticipated clinical trial enrollment and completion dates; 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; regulatory developments and safety issues, including difficulties or delays in obtaining regulatory approvals to market Zilretta; Zilretta may not be successfully commercialized, including as a result of the FDA's or other regulatory authorities' decisions regarding labeling and other matters that could affect its availability or commercial potential; 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 (SEC), including under the heading "Risk Factors" in our most recent Annual Report on Form 10-K and subsequent filings with the SEC. The forward-looking statements in this press release speak only as of the date of this press release, 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 in this press release.

**FLEXION THERAPEUTICS**  
**CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS**  
(in thousands, except for per share information)

	Three Months Ended June 30,	
	2017	2016
Revenue	\$ -	\$ -
Operating expenses:		
Research and development	11,769	8,905
General and administrative	15,133	5,215
Total expenses	26,902	14,120
Loss from operations	(26,902)	(14,120)
Interest income (expense), net	(2,090)	93
Other income (expense)	112	(158)
Loss from operations before income tax	(28,880)	(14,185)
Net loss	(28,880)	(14,185)
Basic and diluted net loss per share	\$ (0.91)	\$ (0.63)
Basic and diluted weighted average number of common shares outstanding	31,826	22,666



**FLEXION THERAPEUTICS SELECTED BALANCE SHEET DATA**  
(in thousands)

	<b>June 30, 2017</b>	<b>December 31, 2016</b>
Cash and cash equivalents	\$ 197,179	\$ 30,915
Marketable securities	162,680	179,413
Total current assets	362,193	209,393
Working capital	342,388	191,853
Total assets	374,656	226,262
Total notes payable	27,551	30,533
Total convertible notes	133,484	-
Total stockholders' equity (deficit)	203,379	187,032

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