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 7, 2018

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 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 7, 2018, Flexion Therapeutics, Inc. issued a press release announcing its financial results for the quarter ended June 30, 2018. 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

Exhibit No.	Description
99.1	Press Release of Flexion Therapeutics, Inc. dated August 7, 2018

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 7, 2018

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

EXHIBIT 99.1

Flexion Therapeutics Reports Second-Quarter 2018 Financial Results and Recent Business Highlights

- *Company reported net ZILRETTA® (triamcinolone acetonide extended-release injectable suspension) sales of $3.8 million in Q2 representing 73% growth over Q1*
- *Strong progress on the ZILRETTA commercial launch: 60% of target accounts have either purchased, or received samples of, ZILRETTA; more than 55% of ordering accounts have placed reorders since launch*
- *Product-specific reimbursement code for ZILRETTA (Q9993) became effective on July 1, 2018*
- *Topline results from the pharmacokinetic study to evaluate concurrent administration of ZILRETTA in patients with bilateral knee osteoarthritis demonstrated 10-fold lower triamcinolone acetonide peak plasma concentrations with ZILRETTA vs immediate-release steroid*
- *Conference call scheduled for today at 4:30 p.m. ET*

BURLINGTON, Mass., August 7, 2018 – Flexion Therapeutics, Inc. (Nasdaq:FLXN) today reported financial results and recent business highlights for the quarter ended June 30, 2018.

"We saw strong growth in demand for ZILRETTA in the second quarter, as evidenced by a 73% increase in sales over the first quarter, and we are very pleased that the launch is on track," said Michael Clayman, M.D., President and Chief Executive Officer. "Based on ZILRETTA's clinical performance, rapidly growing physician awareness, broad payer coverage, the recent introduction of a product-specific Q code and the anticipated J code in January of 2019, we remain highly encouraged about the long-term potential of this important product. Furthermore, we continue to advance our robust clinical development program with the aim of expanding the label for ZILRETTA and potentially providing a new treatment option for the hundreds of thousands of patients confronting painful osteoarthritis of the hip or shoulder."

Second-Quarter Results and Financial Highlights

The Company reported a net loss of $43.9 million for the second quarter of 2018, compared to a net loss of $28.9 million in the second quarter of 2017. Net sales of ZILRETTA for the second quarter of 2018 totaled $3.8 million. During the three months ended June 30, 2018, the cost of sales was $0.9 million.

Research and development expenses were $13.1 million for the second quarter of 2018 compared to $11.8 million for the same period in 2017. The increase in research and development expenses was primarily due to an increase of $0.8 million in salary and other employee-related costs associated with additional headcount and increased stock-based

compensation expense, as well as a $0.5 million increase in preclinical expenses related to portfolio expansion and other program costs.

Selling, general and administrative expenses were $31.0 million and $15.1 million for the second quarters of 2018 and 2017, respectively. Selling expenses were $22.7 million and $8.0 million for the three months ended June 30, 2018 and 2017. The year-over-year increase in selling expenses of $14.7 million was primarily due to salary and other employee-related costs associated with additional headcount and costs to establish commercial marketing and sales capabilities. General and administrative expenses increased by $1.2 million in the second quarter compared to the same period in 2017 primarily due to salary and other employee-related costs associated with additional headcount and increased stock-based compensation expense.

Interest expense was $3.9 million and $2.9 million for the second quarters of 2018 and 2017, respectively. The increase in interest expense was due to interest incurred on the 2024 Convertible Notes.

As of June 30, 2018, the Company had $340.4 million in cash, cash equivalents and marketable securities compared with $423.9 million as of December 31, 2017.

ZILRETTA Commercial Launch Metrics

Since launch, the Company's Musculoskeletal Business Managers (MBMs) have made calls on approximately 10,500 physician prescribers, representing virtually all initial targets. In addition, the MBMs and Field Access Managers have conducted in-depth discussions around reimbursement or product preparation training at approximately 2,600 of 3,700 target accounts, and roughly 2,240 target accounts have either purchased product or received samples of ZILRETTA. Of the accounts that have purchased ZILRETTA since launch, more than 55% have placed a reorder for additional product.

With respect to reimbursement, Flexion's Market Access team has engaged with 46 key commercial insurers that represent roughly 225 million covered lives. Commercial coverage for ZILRETTA remains strong with more than 95% of the benefits verifications processed through the FlexForward™ service indicating coverage of ZILRETTA.

Recent News and Business Highlights

- The Company completed the Phase 2 clinical trial evaluating the pharmacokinetics (PK) of concurrent administration of ZILRETTA in patients with bilateral knee osteoarthritis (OA) compared to immediate-release triamcinolone acetonide crystalline suspension (TAcs). Twenty-four patients were randomized and included in the safety and PK analyses.

  Topline results demonstrated that injection of ZILRETTA into both knees was generally safe and well tolerated, with similar adverse event profiles for both the ZILRETTA and TAcs groups. Furthermore, peak plasma concentrations of triamcinolone acetonide were approximately 10-fold lower in the patients treated with ZILRETTA, indicating reduced systemic exposure as compared to TAcs. The results have been submitted for presentation at a major medical conference in the fourth quarter of 2018.
- On July 1, 2018, the product-specific Q code for ZILRETTA took effect. Q9993 will serve as a temporary universal reimbursement code covering Medicare claims for ZILRETTA in all

settings until a product-specific J code is in place. The Centers for Medicare and Medicaid Services (CMS) is expected to publish the final list of product-specific J codes in the fourth quarter of 2018, which will be effective January 1, 2019. Approximately 50% of the market for ZILRETTA is covered by Medicare, and the vast majority of commercial payers are expected to utilize the Q code until a product-specific J code is established.

- At the Osteoarthritis Research Society International World Congress in April, the Company presented interim results from the Phase 3b, open-label study evaluating the overall safety and general tolerability of repeat administration of ZILRETTA in patients with OA of the knee. The results showed that the average time to second dose was more than 16 weeks after initial injection and that 74% (133/179) of patients received their second dose between Weeks 16 and 24. The study recently closed, and following analysis of the full data set, the results are anticipated in the fourth quarter of 2018.
- The Phase 2, open-label study evaluating the safety and PK of ZILRETTA in patients with OA of the shoulder or hip (known as the SHIP study) completed enrollment in July, and topline results are anticipated in the fourth quarter of 2018.
- The Phase 3b, open-label study assessing the effect of the administration of a single IA injection of ZILRETTA on synovitis in patients with OA of the knee is currently enrolling patients, and topline results are anticipated in late 2019.
- Preclinical studies are ongoing for FX201, an intra-articular gene therapy product candidate which is designed to induce the production of human interleukin-1 receptor antagonist (IL-1Ra), whenever inflammation is present within the joint. Pending successful results from planned Good Laboratory Practice (GLP) toxicology studies, the Company anticipates filing an Investigational New Drug (IND) application and initiating first-in-human clinical trials in 2019.

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 #1668119. A live webcast of the conference call can also be accessed through the "Investors" tab on the Flexion Therapeutics website, and a replay will be available online after the call.

ZILRETTA Indication and Important Safety Information

Indication: ZILRETTA (triamcinolone acetonide extended-release injectable suspension) is indicated as an intra-articular injection for the management of osteoarthritis pain of the knee. It is not intended for repeat administration.

Contraindication: ZILRETTA is contraindicated in patients who are hypersensitive to triamcinolone acetonide, corticosteroids or any components of the product.

Warnings and Precautions:

- **Intra-articular Use Only:** ZILRETTA has not been evaluated and should not be administered by epidural, intrathecal, intravenous, intraocular, intramuscular, intradermal, or subcutaneous routes. ZILRETTA should not be considered safe for epidural or intrathecal administration.
- **Serious Neurologic Adverse Reactions with Epidural and Intrathecal Administration:** Serious neurologic events have been reported following epidural or intrathecal corticosteroid administration. Corticosteroids are not approved for this use.
- **Hypersensitivity reactions:** Serious reactions have been reported with triamcinolone acetonide injection. Institute appropriate care if an anaphylactic reaction occurs.
- **Joint infection and damage:** A marked increase in joint pain, joint swelling, restricted motion, fever and malaise may suggest septic arthritis. If this occurs, conduct appropriate evaluation and if confirmed, institute appropriate antimicrobial treatment.

Adverse Reactions: The most commonly reported adverse reactions (incidence ≥1%) in clinical studies included sinusitis, cough, and contusions.

Please see ZilrettaLabel.com for full Prescribing Information.

About ZILRETTA
On October 6, 2017, ZILRETTA was approved by the U.S. FDA as the first and only extended-release intra-articular therapy for patients confronting osteoarthritis-related knee pain. ZILRETTA employs proprietary microsphere technology combining triamcinolone acetonide — a commonly administered, short-acting corticosteroid — with a poly lactic-co-glycolic acid (PLGA) matrix to provide extended pain relief over 12 weeks.

About Osteoarthritis (OA) of the Knee
OA, also known as degenerative joint disease, affects more than 30 million Americans and accounts for more than $185 billion in annual expenditures. In 2016, more than 15 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. The prevalence of OA is expected to continue to increase as a result of aging, obesity and sports injuries. Each year, more than 15 million Americans are treated for OA-related knee pain, and approximately five million OA patients receive either an immediate-release corticosteroid or hyaluronic acid intra-articular injection to manage their knee pain.

About Flexion Therapeutics
Flexion Therapeutics (Nasdaq:FLXN) is a biopharmaceutical company focused on the development and commercialization of novel, local therapies for the treatment of patients with musculoskeletal conditions, beginning with osteoarthritis, a type of degenerative arthritis. The Company's core values are focus, ingenuity, tenacity, transparency and fun. For the past two years, Flexion has been named one of the Best Places to Work by the Boston Business Journal, and Flexion was also recognized as a Top Place to Work in Massachusetts by The Boston Globe in 2017.

Forward-Looking Statements
This release contains forward-looking statements that are based on the current expectations and beliefs of Flexion. 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 plans to

commercialize ZILRETTA and ZILRETTA's market potential; expected timing with respect to clinical trials and development milestones; expected increases in the rate of individuals with OA of the knee; the potential therapeutic and other benefits of ZILRETTA and FX201; opportunities to obtain regulatory approval for FX201 or further indications for ZILRETTA; and expectations regarding CMS codes, 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 designing and conducting clinical trials, including risks of delays or clinical holds; risks associated with developing and obtaining regulatory approval for product candidates; the fact that results of past clinical trials may not be predictive of subsequent trials; risks associated with commercializing new pharmaceutical products in the United States; the risk that we may not be able to successfully maintain an effective sales force to commercialize ZILRETTA; competition from alternative therapies; the risk that we may not be able to maintain and enforce our intellectual property, including intellectual property related to 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 payers 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; the risk that we may use our capital resources in ways that we do not currently expect; and other risks and uncertainties described in our filings with the Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2018 filed with the SEC on May 8, 2018 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,	
	2018	**2017**
Revenue	$ 3,797	$ -
Operating expenses:		
Cost of sales	946	-
Research and development	13,094	11,769
Selling, general and administrative	31,036	15,133
Total operating expenses	45,076	26,902
Loss from operations	(41,279)	(26,902)
Interest income (expense), net	(2,672)	(2,090)
Other income	76	112
Loss from operations before income tax	(43,875)	(28,880)
Net loss	(43,875)	(28,880)
Basic and diluted net loss per share	$ (1.16)	$ (0.91)
Basic and diluted weighted average number of common shares outstanding	37,697	31,826

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

	Six Months Ended June 30,	
	2018	**2017**
Revenue	$ 5,991	$ -
Operating expenses:		
Cost of sales	3,644	-
Research and development	24,645	22,524
Selling, general and administrative	57,935	28,158
Total operating expenses	86,224	50,682
Loss from operations	(80,233)	(50,682)
Interest income (expense), net	(5,430)	(2,165)
Other income	219	83
Loss from operations before income tax	(85,444)	(52,764)
Net loss	(85,444)	(52,764)
Basic and diluted net loss per share	$ (2.27)	$ (1.66)
Basic and diluted weighted average number of common shares outstanding	37,659	31,765

FLEXION THERAPEUTICS SELECTED BALANCE SHEET DATA
(in thousands)

	June 30, 2018	December 31, 2017
Cash and cash equivalents	$ 174,565	$ 127,789
Marketable securities (current and non-current)	165,832	296,127
Total current assets	351,838	397,990
Working capital	324,559	367,418
Total assets	362,528	441,317
Total notes payable	18,255	22,903
Total convertible notes	140,902	137,107
Total stockholders' equity	185,507	260,274

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