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): March 10, 2021

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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	**FLXN**	**The Nasdaq Global Market**

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 March 10, 2021, Flexion Therapeutics, Inc. ("Flexion") issued a press release announcing its financial results for the fourth quarter and year ended December 31, 2020. 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.

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

(c) On March 10, 2021, Flexion announced that it had initiated a search for a new Chief Medical Officer and that Dr. Scott Kelley will continue to serve as Chief Medical Officer of Flexion until a successor has been appointed. At that point, Dr. Kelley will transition to a new role at Flexion leveraging his extensive knowledge, clinical experience, and business acumen.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release of Flexion Therapeutics, Inc. dated March 10, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 thereunto duly authorized.

Flexion Therapeutics, Inc.

Date: March 10, 2021

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

Exhibit 99.1

Flexion Therapeutics Reports Fourth-Quarter and Full-Year 2020 Financial Results

- *Company reported ZILRETTA® (triamcinolone acetonide extended-release injectable suspension) net sales of $85.6 million for full-year 2020 representing 17% growth over 2019*
- *First patient treated in high dose cohort of Phase 1 clinical trial evaluating the safety and tolerability of FX201 in patients with osteoarthritis of the knee*
- *Phase 1b trial of FX301 in post-operative pain expected to start in H1 2021*
- *Conference call scheduled for today at 4:30 p.m. ET*

BURLINGTON, Mass., March 10, 2021 – Flexion Therapeutics, Inc. (Nasdaq:FLXN) today reported financial results and recent business highlights for the quarter and the full year ended December 31, 2020.

“Despite the unprecedented challenges presented by the global pandemic, 2020 was marked by solid commercial performance and important progress across all areas of the business,” said Michael Clayman, M.D., President and Chief Executive Officer of Flexion Therapeutics. “While the impacts of COVID-19 continue to be felt across the nation, we believe 2021 promises to be an important and exciting year for ZILRETTA and our pipeline of potentially transformative product candidates. Our development programs for FX201, an investigational gene therapy candidate for osteoarthritis, and FX301, a locally administered NaV1.7 inhibitor for post-operative pain, are both expected to hit key milestones this year, and we look forward to sharing clinical data before year end.”

2020 Financial Highlights

The company reported a net loss of $113.7 million for full-year 2020 as compared to a net loss of $149.8 million for full-year 2019. Net sales of ZILRETTA were $26.3 million for fourth-quarter 2020 and totaled $85.6 million for full-year 2020, an increase of 17% compared to full-year 2019. The cost of sales for full-year 2020 was $19.2 million.

Research and development expenses were $54.3 million and $69.6 million for the years ended December 31, 2020 and 2019, respectively. The decrease in research and development expenses of $15.2 million was primarily due to expense reduction measures taken in response to COVID-19; in particular, a decrease of $13.2 million in development expenses for ZILRETTA due to a reduction in ZILRETTA life cycle management activities, a decrease of $1.5 million related to our portfolio expansion (including FX301) and other programs costs, and a decrease of $2.0 million in salary and other employee-related costs related to lower headcount. Those decreases were partially offset by an increase of $1.5 million in expenses related to FX201 clinical trial and related manufacturing activities.

Selling, general and administrative expenses were $105.0 million and $129.7 million for the years ended December 31, 2020 and 2019, respectively. Selling expenses were $72.3 million and $96.3 million for the years ended December 31, 2020 and 2019, respectively. The year-over-year decrease in selling expenses of $24.0 million was primarily due to expense reduction

measures taken in response to COVID-19; in particular, the elimination of live presence at industry conferences, reduction in in-person physician speaker programs, and reductions in select marketing programs and materials, as well as a reduction in travel expenses due to physician office limitations and travel guidelines and restrictions at the state and local level. General and administrative expenses were $32.7 million and $33.4 million for the years ended December 31, 2020 and 2019, respectively, which represents a decrease of $0.7 million year-over-year.

Interest expense was $20.0 million and $17.1 million for the years ended December 31, 2020 and 2019, respectively.

As of December 31, 2020, the company had approximately $175.3 million in cash, cash equivalents, and marketable securities compared with $136.7 million as of December 31, 2019. Based on the current operating plan, Flexion believes its current cash balance is sufficient to fund operations into at least mid-2022.

ZILRETTA Commercial Metrics

Since the launch of ZILRETTA in November 2017 through December 31, 2020:

- 4,248 accounts had purchased ZILRETTA, reflecting growth of 176 new purchasing accounts vs September 30, 2020, when 4,072 accounts had purchased product.
- 78% of purchasing accounts (3,321) placed at least one reorder, up from 3,153 accounts that had reordered ZILRETTA as of September 30, 2020.
- 1,242 accounts had made ZILRETTA purchases of more than 50 units; 1,170 accounts had purchased 11 to 50 units; and 1,836 accounts had purchased between 1 and 10 units.
- Accounts that had purchased more than 50 ZILRETTA units accounted for 307,988 of the total 345,697 ZILRETTA units purchased.

Recent News and 2020 Business Highlights

- In March 2021, the first patient was treated in the high dose cohort of the Phase 1 clinical trial evaluating the safety and tolerability of FX201 in patients with osteoarthritis (OA) of the knee. Clinical data from the first two cohorts indicate that FX201 appears to be generally safe and well-tolerated at the low and mid doses.

  The company previously announced the expansion of the trial to include up to 20 additional patients in both the low and mid dose treatment groups. Data through Week 52 for patients treated in the initial low and mid dose cohorts of the single ascending dose phase are expected by the end of 2021. In addition, preliminary data from the high dose cohort and expanded treatment groups are also anticipated before year-end.

- Also in March 2021, the company announced that the U.S. Food and Drug Administration (FDA) cleared the Investigational New Drug (IND) application for FX301, enabling the initiation of first-in-human trials. The company plans to initiate a Phase 1b proof of concept clinical trial of FX301 administered as a popliteal fossa block (a commonly used nerve block in foot and ankle-related surgeries) in patients undergoing bunionectomy and expects to treat the first patient in the first half of 2021. Initial data from the trial are anticipated by year-end.

- In February 2021, Flexion announced a partnership with the National Basketball Retired Players Association (NBRPA) and Sheryl Swoopes, WNBA Hall of Famer, to raise awareness of ZILRETTA as an effective treatment option for OA knee pain. This partnership complements the company's existing collaboration with NFL Hall of Famer Rod Woodson and 1980 USA Olympic Hockey Gold Medalist Mike Eurzione.

- In May 2020, the company completed an underwritten public offering of 10,615,385 shares of its common stock, including the exercise in full of the underwriters' option to purchase additional shares, raising total net proceeds of $97.3 million.

- On April 1, 2020, Flexion announced an exclusive license agreement with Hong Kong Tainuo Pharma Ltd. (HK Tainuo) and Jiangsu Tainuo Pharmaceutical Co. Ltd. (a subsidiary of China Shijiazhuang Pharmaceutical Co, Ltd.) for the development and commercialization of ZILRETTA in Greater China (consisting of mainland China, Hong Kong, Macau, and Taiwan). Under the terms of the agreement, Flexion received an upfront payment of $10 million and is eligible to receive up to $32.5 million in aggregate development, regulatory, and commercial sales milestone payments. HK Tainuo will be responsible for the clinical development, product registration, and commercialization of ZILRETTA.

Conference Call
Flexion's management will host a conference call today at 4:30 p.m. ET. A live webcast of the conference call can be accessed through the "Investors" tab on the Flexion Therapeutics website, and a replay will be available online after the call. For those planning to ask a question, 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 #7657415. Please dial in at least 15 minutes in advance to ensure a timely connection to the call.

Indication and Select Important Safety Information for ZILRETTA (triamcinolone acetonide extended-release injectable suspension)

Indication: ZILRETTA is indicated as an intra-articular injection for the management of osteoarthritis pain of the knee.

Limitation of Use: The efficacy and safety of repeat administration of ZILRETTA have not been demonstrated.

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. The pivotal Phase 3 trial on which the approval of ZILRETTA was based showed that ZILRETTA significantly reduced OA knee pain for 12 weeks, with some people experiencing pain relief through Week 16. Learn more at www.zilretta.com.

About Osteoarthritis (OA) of the Knee
OA, also known as degenerative joint disease, is the most common form of arthritis affecting more than 32.5 million adults living in the United States. In 2017, approximately 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, approximately five million OA patients receive either a corticosteroid (immediate-release or extended-release) or hyaluronic acid intra-articular injection to manage their knee pain.

About FX201
FX201 is an investigational gene therapy which utilizes a helper-dependent adenovirus (HDAd) vector devoid of all viral genes that carries a coding sequence for an anti-inflammatory protein called interleukin-1 receptor antagonist (IL-1Ra) under the control of an inflammation-responsive promoter. FX201 is injected directly into the joint space (also termed the intra-articular space)

and is intended to deliver as-needed anti-inflammatory activity to joint tissues over the long term, with the goal to improve outcomes for OA patients.

About FX301
FX301 is an investigational locally administered NaV1.7 inhibitor known as funapide, formulated for extended release in a thermosensitive hydrogel. The initial development of FX301 is intended to support administration as a peripheral analgesic nerve block for control of post-operative pain. Flexion believes FX301 has the potential to provide effective pain relief for at least three to five days while preserving motor function.

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, the most common form of arthritis. The company's core values are focus, ingenuity, tenacity, transparency and fun. Please visit flexiontherapeutics.com.

Forward-Looking Statements
This press 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; potential sales growth of ZILRETTA; expected clinical developments and clinical trial timelines; expected increases in the rate of individuals with OA of the knee; and the potential therapeutic and other benefits of ZILRETTA and Flexion's product candidates, 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, risk that we may not achieve anticipated growth or advancements in our development programs; 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 or adopted; 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 clinical trials, including potential delays, safety issues, or negative results; 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, filed with the SEC on November 4, 2020, 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.

Exhibit 99.1

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

	Year Ended December 31,	
	2020	**2019**
Revenue	$ 85,552	$ 72,957
Operating expenses:		
Cost of sales	19,249	9,960
Research and development	54,326	69,559
Selling, general and administrative	104,996	129,709
Total operating expenses	178,571	209,228
Loss from operations	(93,019)	(136,271)
Interest income (expense), net	(19,151)	(13,854)
Other (expense) income	(1,041)	352
Loss from operations before income tax	(113,211)	(149,773)
Income tax expense	495	—
Net loss	(113,706)	(149,773)
Basic and diluted net loss per share	$ (2.53)	$ (3.93)
Basic and diluted weighted average number of common shares outstanding	45,013	38,086

Exhibit 99.1

FLEXION THERAPEUTICS SELECTED BALANCE SHEET DATA
(in thousands)

	December 31, 2020	December 31, 2019
Cash and cash equivalents	$ 107,704	$ 82,253
Marketable securities	67,576	54,407
Total current assets	225,811	195,675
Working capital	170,543	159,456
Total assets	251,926	217,560
Total notes payable	60,920	40,176
Total convertible notes	162,786	153,413
Total stockholders' deficit	(16,660)	(20,108)

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