UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

FOR THE QUARTERLY PERIOD ENDED March 31, 2021

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

FOR THE TRANSITION PERIOD FROM _____ TO _____

Commission file number: 001-36287

Flexion Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**26-1388364**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
10 Mall Road, Suite 301 **Burlington, Massachusetts**	**01803**
(Address of Principal Executive Offices)	**(Zip Code)**

(781) 305-7777
(Registrant's Telephone Number, Including Area Code)

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, $0.001 par value per share	FLXN	Nasdaq Global Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
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 ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). ☐ Yes ☒ No

As of May 1, 2021, the registrant had 49,942,069 shares of Common Stock ($0.001 par value) outstanding.

FLEXION THERAPEUTICS, INC.
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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

Flexion Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(Unaudited in thousands, except share and per share amounts)

	March 31, 2021	December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	$ 98,707	$ 107,704
Marketable securities	55,573	67,576
Accounts receivable, net	30,365	30,025
Inventories	12,676	15,394
Prepaid expenses and other current assets	7,301	5,112
Total current assets	204,622	225,811
Property and equipment, net	19,610	19,538
Right-of-use assets	6,147	6,577
Total assets	$ 230,379	$ 251,926
Liabilities and Stockholders' Deficit		
Current liabilities		
Accounts payable	$ 6,650	$ 6,928
Accrued expenses and other current liabilities	21,453	20,008
Deferred revenue	10,000	10,000
Operating lease liabilities	1,546	1,526
Current portion of long-term debt	18,333	16,806
Total current liabilities	57,982	55,268
Long-term operating lease liability, net	5,746	6,123
Long-term debt, net	39,758	44,114
2024 convertible notes, net	165,271	162,786
Other long-term liabilities	489	295
Total liabilities	269,246	268,586
Commitments and contingencies		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at March 31, 2021 and December 31, 2020 and 0 shares issued and outstanding at March 31, 2021 and December 31, 2020	—	—
Stockholders' deficit		
Common stock, $0.001 par value; 100,000,000 shares authorized; 49,941,553 and 49,403,034 shares issued and outstanding, at March 31, 2021 and December 31, 2020, respectively	50	49
Additional paid-in capital	771,954	765,607
Accumulated other comprehensive loss	(10)	(11)
Accumulated deficit	(810,861)	(782,305)
Total stockholders' deficit	(38,867)	(16,660)
Total liabilities and stockholders' deficit	$ 230,379	$ 251,926

The accompanying notes are an integral part of these condensed consolidated financial statements.

Flexion Therapeutics, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited in thousands, except per share amounts)

	Three Months Ended March 31,	
	2021	**2020**
Revenues		
Product revenue, net	$ 24,589	$ 20,127
Operating expenses		
Cost of sales	6,085	2,276
Research and development	14,047	21,134
Selling, general and administrative	27,598	29,299
Total operating expenses	47,730	52,709
Loss from operations	(23,141)	(32,582)
Other (expense) income		
Interest income	300	427
Interest expense	(5,189)	(4,721)
Other (expense) income	(526)	74
Total other (expense) income	(5,415)	(4,220)
Net loss	$ (28,556)	$ (36,802)
Net loss per common share, basic and diluted	$ (0.57)	$ (0.95)
Weighted average common shares outstanding, basic and diluted	49,841	38,553
Other comprehensive income (loss):		
Unrealized gains (losses) from available-for-sale securities, net of tax of $0	1	(56)
Total other comprehensive income (loss)	1	(56)
Comprehensive loss	$ (28,555)	$ (36,858)

The accompanying notes are an integral part of these condensed consolidated financial statements.

Flexion Therapeutics, Inc.
Condensed Consolidated Statements of Changes in Stockholders' Deficit
(Unaudited in thousands)

	Common Stock		Additional Paid-in-Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Par Value				
Balance at December 31, 2020	49,403	$ 49	$ 765,607	$ (11)	$ (782,305)	$ (16,660)
Issuance of common stock, net of issuance costs	134		1,700			1,700
Issuance of common stock for equity awards, net of shares withheld for taxes	405	1	7			8
Stock-based compensation expense			4,640			4,640
Net loss					(28,556)	(28,556)
Other comprehensive income				1		1
Balance at March 31, 2021	49,942	$ 50	$ 771,954	$ (10)	$ (810,861)	$ (38,867)

	Common Stock		Additional Paid-in-Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Par Value				
Balance at December 31, 2019	38,361	$ 38	$ 648,391	$ 62	$ (668,599)	$ (20,108)
Issuance of common stock for equity awards, net of shares withheld for taxes	201	1	8			9
Stock-based compensation expense			4,651			4,651
Net loss					(36,802)	(36,802)
Other comprehensive loss				(56)		(56)
Balance at March 31, 2020	38,562	$ 39	$ 653,050	$ 6	$ (705,401)	$ (52,306)

The accompanying notes are an integral part of these condensed consolidated financial statements.

Flexion Therapeutics, Inc.
Condensed Consolidated Statements of Cash Flows
(Unaudited in thousands)

	Three Months Ended March 31,	
	2021	2020
Cash flows from operating activities		
Net loss	$ (28,556)	$ (36,802)
Adjustments to reconcile net loss to cash used in operating activities		
Depreciation	521	198
Amortization of right-of-use assets	430	401
Stock-based compensation expense	4,640	4,651
Provision for inventory	540	—
Non cash interest expense	226	106
Amortization (accretion) of premium (discount) on marketable securities	251	(59)
Loss on disposal of fixed assets	—	262
Amortization of debt discount and debt issuance costs	2,485	2,262
Premium paid on securities purchased	3	—
Changes in operating assets and liabilities:		
Accounts receivable	(340)	6,753
Inventory	2,178	(3,101)
Prepaid expenses and other current assets	(2,189)	(441)
Accounts payable	124	(3,035)
Accrued expenses and other current liabilities	1,570	1,025
Lease liabilities	(357)	(417)
Net cash used in operating activities	(18,474)	(28,197)
Cash flows from investing activities		
Purchases of property and equipment	(801)	(3,244)
Purchases of marketable securities	(2,000)	—
Sale and redemption of marketable securities	13,750	41,198
Net cash provided by investing activities	10,949	37,954
Cash flows from financing activities		
Proceeds from revolving line of credit	—	20,000
Proceeds from issuance of common stock (net of issuance costs)	1,700	—
Payments of public offering costs	(125)	—
Payments on notes payable	(3,055)	—
Proceeds from the exercise of stock options	8	9
Net cash (used in) provided by financing activities	(1,472)	20,009
Net (decrease) increase in cash and cash equivalents	(8,997)	29,766
Cash and cash equivalents at beginning of period	107,704	82,253
Cash and cash equivalents at end of period	$ 98,707	$ 112,019
Non-cash investing and financing activities		
Purchases of property and equipment in accounts payable and accrued expenses	30	1,436
Supplemental disclosures of cash flow information		
Cash paid for interest	955	703

The accompanying notes are an integral part of these condensed consolidated financial statements.

1. Overview and Nature of the Business

Flexion Therapeutics, Inc. ("Flexion" or the "Company") was incorporated under the laws of the state of Delaware on November 5, 2007. Flexion is a biopharmaceutical company focused on the discovery, development and commercialization of novel, local therapies for the treatment of patients with musculoskeletal conditions, beginning with osteoarthritis, or OA, the most common form of arthritis. The Company has an approved product, ZILRETTA®, which it markets in the United States. ZILRETTA is the first and only extended-release, intra-articular, or IA (meaning in the joint), injection indicated for the management of OA knee pain. ZILRETTA is a non-opioid therapy that employs Flexion's proprietary microsphere technology to provide pain relief. The pivotal Phase 3 trial, on which the approval of ZILRETTA was based, showed that ZILRETTA met the primary endpoint of pain reduction at Week 12, with statistically significant pain relief extending through Week 16. The Company also has two pipeline programs focused on the local treatment of musculoskeletal conditions: FX201, an investigational IA gene therapy product candidate in clinical development for the treatment of OA, and FX301, a product candidate in clinical development which is being investigated as a locally administered peripheral nerve block for control of post-operative pain.

The Company is subject to risks and uncertainties common to companies in the biopharmaceutical industry, including, but not limited to, new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, and the ability to secure additional capital to fund operations. Successfully commercializing ZILRETTA requires significant sales and marketing efforts and the Company's pipeline programs will require significant additional research and development efforts, including extensive preclinical and clinical testing. These activities will in turn require significant amounts of capital, qualified personnel and adequate infrastructure. There can be no assurance as to when, if ever, the Company will generate sales of ZILRETTA that are significant enough to achieve profitability or if the development efforts supporting the Company's pipeline, including future clinical trials, will be successful.

The accompanying condensed consolidated financial statements have been prepared on a basis which assumes that the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business. The Company has incurred recurring losses and negative cash flows from operations. As of March 31, 2021, the Company had cash, cash equivalents, and marketable securities of approximately $154.3 million.

Management believes that current cash, cash equivalents, and marketable securities on hand at March 31, 2021, will be sufficient to fund operations and debt obligations for at least the next 12 months from the issuance date of these financial statements. The Company currently expects to be able to maintain the liquidity threshold in the amended and restated credit agreement described in Note 9 for at least 12 months following the issuance of these financial statements. As a result, the revenue covenant under the amended and restated credit and security agreement is not expected to be applicable through 12 months from the issuance of the financial statements. As of March 31, 2021, the Company was in compliance with all covenants under the amended and restated credit and security agreement.

The Company's operations have been and continue to be affected by the ongoing global pandemic of a novel strain of coronavirus ("COVID-19") and the resulting volatility and uncertainty it has caused. In March 2020, the World Health Organization declared COVID-19 a pandemic and recommended containment and mitigation measures worldwide. The COVID-19 pandemic has caused significant volatility and uncertainty, which could result in a prolonged economic downturn that has disrupted and is expected to continue to disrupt the Company's business. While there have been no material asset impairments recorded to date, any prolonged material future disruptions to the work of the Company's employees, suppliers, contract manufacturers, or vendors, or to the operations of physicians that administer ZILRETTA could negatively impact the Company's operations, availability of supplies, carrying value of assets, operating results or cash flows.

The future viability of the Company is dependent on its ability to fund its operations through sales of ZILRETTA, and/or raising additional capital, such as through debt or equity offerings, as needed. If the Company is unable to grow sales of ZILRETTA in future periods, it is possible that the Company may not maintain compliance with the revenue covenant, in the event it applies, in future periods. As a result, the Company could be required to repay its outstanding borrowings under the term loan and revolving credit facility and would seek additional financing. The Company may not be able to obtain financing on acceptable terms, or at all. In particular, as a result of the COVID-19 pandemic and actions taken to slow its spread, the global credit and financial markets have experienced extreme volatility and disruptions, including declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. If the equity and credit markets deteriorate, it may make any additional debt or equity financing more difficult, more costly and more dilutive. If the Company is unable to obtain funding on a timely basis, the Company may need to curtail its operations, including the commercialization of ZILRETTA, and/or reduce the scope of, or delay certain research and development activities including the FX201 or FX301 programs, which could adversely affect its prospects.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying condensed consolidated financial statements as of March 31, 2021, and for the three months ended March 31, 2021, and 2020, have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission (the "SEC") and Generally Accepted Accounting Principles ("GAAP") for consolidated financial information including the accounts of the Company and its wholly owned subsidiary after elimination of all significant intercompany accounts and transactions. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, these condensed consolidated financial statements reflect all adjustments which are necessary for a fair statement of the Company's financial position and results of its operations, as of and for the periods presented. These condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto contained in the Company's Annual Report on Form 10-K filed with the SEC on March 10, 2021.

The information presented in the condensed consolidated financial statements and related notes as of March 31, 2021, and December 31, 2020, and for the three months ended March 31, 2021 and 2020, is unaudited. The December 31, 2020, condensed consolidated balance sheet included herein was derived from the audited financial statements as of that date, but does not include all disclosures, including notes, required by GAAP for complete financial statements.

Interim results for the three months ended March 31, 2021, are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2021, or any future period.

Recent Accounting Pronouncements

Accounting Standards Recently Issued

In August 2020, the FASB issued ASU No. 2020-06, ("ASU 2020-06"). The new standard simplifies the accounting for certain financial instruments with characteristics of liabilities and equity. The new guidance reduced the number of accounting models for convertible debt and convertible preferred stock instruments and made certain disclosure amendments intended to improve the information provided to users. The guidance also amended the derivative guidance for the "own stock" scope exception, which exempts qualifying instruments from being accounted for as derivatives if certain criteria are met. Finally, the standard changed the way certain convertible instruments are treated when calculating earnings per share. The standard is effective for the Company for fiscal years, and the interim periods within those years, beginning after December 15, 2021, and early adoption is permitted. The Company is currently evaluating the impact of ASU 2020-06 on the Company's condensed consolidated financial statements.

Consolidation

The accompanying condensed consolidated financial statements include the Company and its wholly owned subsidiary, Flexion Therapeutics Securities Corporation. The Company has eliminated all intercompany transactions for the three months ended March 31, 2021, and the year ended December 31, 2020.

Revenue Recognition

On October 6, 2017, the U.S. Food and Drug Administration ("FDA") approved ZILRETTA. The Company entered into a limited number of arrangements with specialty distributors and a specialty pharmacy in the U.S. to distribute ZILRETTA. The Company recognizes revenue in accordance with Accounting Standards Codification ("ASC") Topic 606 - Revenue from Contracts with Customers ("Topic 606"). Under Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to be entitled to in exchange for those goods or services.

To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the entity performs the following five steps: (i) identify the contract(s) with a customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations in the contract, and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to arrangements that meet the definition of a contract with a customer under Topic 606, including when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within each contract, determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Product Revenue, Net

The Company primarily sells ZILRETTA to specialty distributors and a specialty pharmacy, who then subsequently resell ZILRETTA to physicians, clinics and certain medical centers or hospitals. The Company also contracts directly with healthcare providers and intermediaries such as Group Purchasing Organizations ("GPOs"). In addition, the Company enters into arrangements with government payers that provide for government mandated rebates and chargebacks with respect to the purchase of ZILRETTA.

The Company recognizes revenue on product sales when the customer obtains control of the Company's product, which occurs at a point in time (upon delivery to the customer). The Company has determined that the delivery of ZILRETTA to its customers constitutes a single performance obligation. There are no other promises to deliver goods or services beyond what is specified in each accepted customer order. The Company has assessed the existence of a significant financing component in the agreements with its customers. The trade payment terms with customers do not exceed one year and therefore the Company has elected to apply the practical expedient and no amount of consideration has been allocated as a financing component. Product revenues are recorded net of applicable reserves for variable consideration, including discounts and allowances.

Transaction Price, including Variable Consideration

Revenues from product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established. Components of variable consideration include trade discounts and allowances, product returns, government chargebacks, discounts and rebates, and other incentives, such as voluntary patient assistance, and other fee for service amounts that are detailed within contracts between the Company and its customers relating to the Company's sale of its products. These reserves, as detailed below, are based on the amounts earned, or to be claimed on the related sales, and are classified as reductions of accounts receivable (if the amount is payable to the customer) or a current liability (if the amount is payable to a party other than a customer). These estimates take into consideration a range of possible outcomes which are probability-weighted in accordance with the expected value method in Topic 606 for relevant factors such as current contractual and statutory requirements, specific known market events and trends, industry data, and forecasted customer buying and payment patterns. Overall, these reserves reflect the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the respective underlying contracts.

The amount of variable consideration which is included in the transaction price may be constrained and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized under the contract will not occur in a future period. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from the Company's original estimates, the Company will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

Service Fees and Allowances

The Company compensates its customers and GPOs for sales order management, data, and distribution services. However, the Company has determined such services received to date are not distinct from the Company's sale of products to the customer and, therefore, these payments have been recorded as a reduction of revenue within the statement of operations and comprehensive loss through March 31, 2021, as well as a reduction to trade receivables, net on the condensed consolidated balance sheets.

Product Returns

Consistent with industry practice, the Company generally offers customers a limited right of return for product that has been purchased from the Company based on the product's expiration date. The Company estimates the amount of its product sales that may be returned by its customers and records this estimate as a reduction of revenue in the period the related product revenue is recognized, as well as within accrued expenses and other current liabilities, net, on the condensed consolidated balance sheets. The Company currently estimates product return liabilities using available industry data and its own sales information, including its visibility into the inventory remaining in the distribution channel. The Company has received an immaterial amount of returns to date and believes that future returns of ZILRETTA will be minimal.

Chargebacks

Chargebacks for fees and discounts to qualified government healthcare providers represent the estimated obligations resulting from contractual commitments to sell products to qualified VA hospitals and 340b entities at prices lower than the list prices charged to customers who directly purchase the product from the Company. The 340b Drug Discount Program is a U.S. federal government program created in 1992 that requires drug manufacturers to provide outpatient drugs to eligible health care organizations and covered entities at significantly reduced prices. Customers charge the Company for the difference between what they pay for the product and the statutory selling price to the qualified government entity. These reserves are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and trade receivables, net. Chargeback amounts are generally determined at the time of resale to the qualified government healthcare provider by customers, and the Company generally issues credits for such amounts within a few weeks of the customer's notification to the Company of the resale. Reserves for chargebacks consist of credits that the Company expects to issue for units that remain in the distribution channel inventories at each reporting period-end that the Company expects will be sold to qualified healthcare providers, and chargebacks that customers have claimed, but for which the Company has not yet issued a credit.

Government Rebates

The Company is subject to discount obligations under state Medicaid programs and Medicare. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses and other current liabilities on the condensed consolidated balance sheets. For Medicare, the Company also estimates the number of patients in the prescription drug coverage gap for whom the Company will owe an additional liability

under the Medicare Part D program. The Company estimates its exposure to utilization from the Medicare Part D coverage gap discount program to be immaterial. For Medicaid programs, the Company estimates the portion of sales attributed to Medicaid patients and records a liability for the rebates to be paid to the respective state Medicaid programs. The Company's liability for these rebates consists of invoices received for claims from prior quarters that have not been paid or for which an invoice has not yet been received, estimates of claims for the current quarter, and estimated future claims that will be made for product that has been recognized as revenue, but which remains in the distribution channel inventories at the end of each reporting period.

Purchaser/Provider Discounts and Rebates

The Company offers rebates to eligible purchasers and healthcare providers that are variable based on volume of product purchased. Rebates are based on actual purchase levels during the rebate purchase period. The Company estimates these rebates and records such estimates in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses and other current liabilities on the condensed consolidated balance sheets.

Other Incentives

Other incentives which the Company offers include voluntary patient assistance programs, such as the co-pay assistance program, which are intended to provide financial assistance to qualified commercially insured patients with prescription drug co-payments required by payers. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that the Company expects to receive associated with product that has been recognized as revenue, but remains in the distribution channel inventories at the end of each reporting period. The adjustments are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included as a component of accrued expenses and other current liabilities on the condensed consolidated balance sheets.

To date, the Company's only source of product revenue has been from the U.S. sales of ZILRETTA, which it began shipping to customers in October 2017.

The following table summarizes activity in each of the product revenue allowance and reserve categories for the three months ended March 31, 2021 and 2020:

(In thousands)	Service Fees, Allowances and Chargebacks	Government Rebates and Other Incentives	Product Returns	Purchaser/Provider Discounts and Rebates	Total
Balance as of December 31, 2020	$ 1,733	$ 530	$ 628	$ 1,832	$ 4,723
Provision related to sales in the current quarter	2,188	383	151	2,703	5,425
Credits and payments made	(1,969)	(266)	(9)	(1,832)	(4,076)
Adjustments related to prior period sales	—	—	(111)	—	(111)
Balance as of March 31, 2021	1,952	647	659	2,703	5,961
Balance as of December 31, 2019	$ 1,847	$ 248	$ 402	$ 1,656	$ 4,153
Provision related to sales in the current quarter	1,590	254	114	526	2,484
Credits and payments made	(1,852)	(199)	(10)	(1,656)	(3,717)
Adjustments related to prior period sales	—	95	—	—	95
Balance as of March 31, 2020	1,585	398	506	526	3,015

License Agreement – On March 30, 2020, the Company entered into an exclusive license agreement with Hong Kong Tainuo Pharma Ltd. ("HK Tainuo") and Jiangsu Tainuo Pharmaceutical Co. Ltd. ("Jiangsu Tainuo"), a subsidiary of China Shijiazhuang Pharmaceutical Co, Ltd. for the development and commercialization (other than manufacturing) of ZILRETTA in Greater China (consisting of mainland China, Hong Kong and Macau, and Taiwan). Under the terms of the agreement, HK Tainuo paid the Company an upfront payment of $10.0 million, of which $5.0 million was received as of June 30, 2020, and the remaining $5.0 million was received as of September 30, 2020. The Company is also eligible to receive up to $32.5 million in aggregate development, regulatory and commercial sales milestone payments. All payments received from HK Tainuo are subject to the applicable Hong Kong withholding taxes. HK Tainuo is responsible for the clinical development, product registration and commercialization of ZILRETTA in Greater China and Jiangsu Tainuo serves as the guarantor of HK Tainuo's obligations and responsibilities under the agreement. The Company is solely responsible for the manufacture and supply of ZILRETTA to HK Tainuo for all clinical and commercial activities. The terms related to product manufacturing and supply, including pricing and minimum purchase requirements agreed to in the license agreement, will be covered by a separate supply agreement, which has not yet been finalized. All amounts owed to the Company are nonrefundable and non-creditable once paid. Unless terminated earlier in accordance with its terms, the license agreement continues in effect in perpetuity or as long as HK Tainuo or Jiangsu Tainuo continue to sell ZILRETTA in Greater China. Either party may terminate the agreement prior to expiration in the event of a material breach if not cured within 60 days from the date of notice of such breach (30 days in the case of payment obligations), or either party files for bankruptcy. The Company also has the right to terminate the agreement if HK Tainuo, Jiangsu Tainuo or any affiliate of each commences any action or proceeding that challenges the validity, enforceability or scope of any Company patent in Greater China. Upon any such termination, the license granted to HK Tainuo will

terminate and all know-how and patents will revert back to the Company. The Company concluded that the license and supply obligations were not distinct performance obligations, and therefore the transaction price will be recognized as revenue as the Company's supply obligation is fulfilled over the term of the supply agreement, which has not yet commenced. No revenue was recognized associated with this contract as of March 31, 2021. The proceeds associated with the upfront payment have been recorded in short-term deferred revenue on the Company's condensed consolidated balance sheet as of March 31, 2021, as there is uncertainty around the timing of when the revenue will be recognized. The Company will re-evaluate the classification of deferred revenue when the supply agreement is finalized.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and judgments that may affect the reported amounts of assets and liabilities, revenue and expenses and related disclosures. The Company bases estimates and judgments on historical experience and on various other factors that it believes to be reasonable under the circumstances. The most significant estimates in these condensed consolidated financial statements include estimates related to revenue recognition and accrued expenses related to preclinical and clinical development costs. The Company's actual results may differ from these estimates under different assumptions or conditions. The Company evaluates its estimates on an ongoing basis. Changes in estimates are reflected in reported results in the period in which they become known by the Company's management.

The full extent to which the COVID-19 pandemic will directly or indirectly impact the Company's business, results of operations and financial condition, including sales, expenses, reserves and allowances, clinical trials, research and development expenses and employee-related amounts, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain or treat it, as well as the economic impact on local, regional, national and international customers and markets. The Company has made estimates of the impact of COVID-19 within its financial statements and there may be changes to those estimates in future periods.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation and amortization expense is recognized using the straight-line method over the following estimated useful lives:

	Estimated Useful Life (Years)
Computers, office equipment, and minor computer software	3
Computer software	7
Manufacturing equipment	7-10
Furniture and fixtures	5

Leasehold improvements are amortized over the shorter of the lease term or the estimated useful life of the related asset. Costs of major additions and improvements are capitalized and depreciated on a straight-line basis over their useful lives. Repairs and maintenance costs are expensed as incurred. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is credited or charged to income. Property and equipment includes construction-in-progress that is not yet in service.

Foreign Currencies

The Company maintains a bank account denominated in British Pounds. All foreign currency payables and cash balances are measured at the applicable exchange rate at the end of the reporting period. All associated gains and losses from foreign currency transactions are reflected in the consolidated statements of operations.

Leases

The Company determines if an arrangement is a lease at contract inception. Operating lease assets represent a right to use an underlying asset for the lease term and operating lease liabilities represent an obligation to make lease payments arising from the lease. Operating lease liabilities with a term greater than one year and their corresponding right-of-use assets are recognized on the balance sheet at the commencement date of the lease based on the present value of lease payments over the expected lease term. Certain adjustments to the right-of-use asset may be required for items such as initial direct costs paid or incentives received. The Company made an accounting policy election to expense leases with a term of one year or less on a straight-line basis over the lease term. To date, the Company has not identified any material short-term leases, either individually or in the aggregate.

As the Company's leases do not provide an implicit rate, the Company utilized the appropriate incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment. The Company estimated the incremental borrowing rate based on a yield curve analysis of companies with a similar credit rating to its own, which was calculated using a number of financial ratios and qualitative considerations of the Company's business. The yields on the Company's currently outstanding debt (the convertible senior notes and term loan described below) were

also used as inputs to the analysis to calculate a spread, adjusted for factors that reflect the profile of secured borrowing over the expected term of the lease.

The components of a lease should be split into three categories: lease components (*e.g.*, land, building, etc.), non-lease components (*e.g.*, common area maintenance, utilities, performance of manufacturing services, purchase of inventory, etc.), and non-components (*e.g.*, property taxes, insurance, etc.). Then the fixed contract consideration (including any related to non-components) must be allocated based on fair values to the lease components and non-lease components. Although separation of lease and non-lease components is required, certain practical expedients are available to entities. Entities electing the practical expedient would not separate lease and non-lease components. Rather, they would account for each lease component and the related non-lease component together as a single component. The Company has elected to use this practical expedient for its real estate leases and account for each lease component and related non-lease component as one single component. In contrast, the Company has elected not to apply the practical expedient for its lease of manufacturing space at Patheon and has instead allocated consideration between the lease and non-lease components of the contract. The Company calculated the fair value of the lease component using publicly available information to identify comparable rentals in the same geographic area. The remainder of the consideration was allocated to the non-lease components.

3. Fair Value of Financial Assets and Liabilities

The following tables present information about the Company's assets that are measured at fair value on a recurring basis as of March 31, 2021, and December 31, 2020, and indicate the level of the fair value hierarchy utilized to determine such fair value:

	Fair Value Measurements as of March 31, 2021 Using:			
(In thousands)	**Level 1**	**Level 2**	**Level 3**	**Total**
Assets:				
Cash equivalents	$ 78,021	$ —	$ —	$ 78,021
Marketable securities	—	55,573	—	55,573
	$ 78,021	$ 55,573	$ —	$ 133,594

	Fair Value Measurements as of December 31, 2020 Using:			
(In thousands)	**Level 1**	**Level 2**	**Level 3**	**Total**
Assets:				
Cash equivalents	$ 79,148	$ 6,832	$ —	$ 85,980
Marketable securities	—	67,576	—	67,576
	$ 79,148	$ 74,408	$ —	$ 153,556

As of March 31, 2021, and December 31, 2020, the Company's cash equivalents that are invested in money market funds are valued using Level 1 inputs based on quoted prices for identical securities in active markets. The Company's marketable securities are valued using Level 2 inputs and primarily rely on quoted prices in active markets for similar marketable securities. Amortization and accretion of discounts and premiums are recorded in other income.

The Company has a term loan outstanding under its 2019 credit facility with Silicon Valley Bank as agent, MidCap Financial Trust, and Flexpoint MCLS Holdings, LLC (the "2019 term loan"), as well as a revolving credit facility. The amount outstanding on the 2019 term loan is reported at its carrying value in the accompanying balance sheet as of March 31, 2021. The Company determined the fair value of the 2019 term loan using an income approach that utilizes a discounted cash flow analysis based on current market interest rates for debt issuances with similar remaining years to maturity, adjusted for credit risk. The 2019 term loan was valued using Level 2 inputs as of March 31, 2021. The result of the calculation yielded a fair value that approximates its carrying value. The Company also concluded that the carrying value of the revolving credit facility approximates fair value because of the short-term maturity of this debt instrument.

On May 2, 2017, the Company issued 3.375% convertible senior notes due 2024 (the "2024 Convertible Notes") with embedded conversion features. The Company estimated the fair value of the 2024 Convertible Notes using a discounted cash flow approach to derive the value of a debt instrument using the expected cash flows and the estimated yield related to the convertible notes. The significant assumptions used in estimating the expected cash flows were: the estimated market yield based on an implied yield and credit quality analysis of a term loan with similar attributes, and the average implied volatility of the Company's traded and quoted options available as of May 2, 2017. The Company recorded approximately $136.7 million as the fair value of the liability on May 2, 2017, with a corresponding amount recorded as a discount on the initial issuance of the 2024 Convertible Notes of approximately $64.5 million. The debt discount was recorded to equity and is being amortized to the debt liability over the life of the 2024 Convertible Notes using the effective interest method.

The fair value of the 2024 Convertible Notes, which differs from their carrying value, is influenced by interest rates, stock price and stock price volatility and is determined by prices for the 2024 Convertible Notes observed in market trading. The market for trading of the 2024 Convertible Notes is not considered to be an active market and therefore the estimate of fair value is based on Level 2 inputs. The estimated fair value of the 2024 Convertible Notes, face value of $201.3 million, was $181.5 million at March 31, 2021.

4. Marketable Securities

As of March 31, 2021, and December 31, 2020, the fair value of available-for-sale marketable securities by type of security was as follows:

	March 31, 2021			
(In thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Commercial paper	$ 8,893	$ —	$ —	$ 8,893
Corporate bonds	46,690	1	(11)	$ 46,680
	$ 55,583	$ 1	$ (11)	$ 55,573

	December 31, 2020			
(In thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Commercial paper	$ 6,890	$ —	$ —	$ 6,890
U.S. government obligations	9,997	1	—	9,998
Corporate bonds	50,700	2	(14)	50,688
	$ 67,587	$ 3	$ (14)	$ 67,576

As of March 31, 2021, and December 31, 2020, marketable securities consisted of $55.6 million and $67.6 million, respectively, of investments that mature within 12 months. There were no investments with maturities greater than 12 months as of March 31, 2021, and December 31, 2020. The Company assesses its available-for-sale marketable securities for impairment on a quarterly basis in accordance with ASU No. 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. There were no material impairments of the Company's available-for-sale marketable securities measured and carried at fair value during the three months ended March 31, 2021.

5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following as of March 31, 2021, and December 31, 2020:

(In thousands)	March 31, 2021	December 31, 2020
Prepaid expenses	$ 6,440	$ 4,346
Deposits	113	112
Interest receivable on marketable securities	304	246
Other	444	408
Total prepaid expenses and other current assets	$ 7,301	$ 5,112

6. Inventory

Inventory consisted of the following as of March 31, 2021, and December 31, 2020:

(In thousands)	March 31, 2021	December 31, 2020
Raw materials	$ 4,390	$ 4,287
Work in process	3,138	4,666
Finished goods	5,148	6,441
Total inventories	$ 12,676	$ 15,394

Finished goods manufactured by the Company have a shelf life of approximately 24 months from the date of manufacture.

The Company reduces its inventory to net realizable value for potentially excess, dated or obsolete inventory based on an analysis of forecasted demand compared to quantities on hand and any firm purchase orders, as well as product shelf life. During the three months ended March 31, 2021, the Company expensed $3.1 million to cost of sales for unabsorbed manufacturing and overhead costs related to the operation of the United Kingdom facility at Patheon UK Limited. In addition, cost of sales for the three months ended March 31, 2021, included a charge of $0.5 million resulting from the write-down of short-dated ZILRETTA inventory that is not expected to be sold prior to expiry.

7. Property and Equipment, Net

Property and equipment, net, as of March 31, 2021, and December 31, 2020, consisted of the following:

(In thousands)	March 31, 2021	December 31, 2020
Computer and office equipment	$ 1,203	$ 1,203
Manufacturing equipment	12,512	12,297
Furniture and fixtures	609	609
Software	495	495
Leasehold improvements	1,157	1,157
Construction in progress	14,302	13,924
	30,278	29,685
Less: Accumulated depreciation	(10,668)	(10,147)
Total property and equipment, net	$ 19,610	$ 19,538

Depreciation for the three months ended March 31, 2021 and 2020, was approximately $0.5 million and $0.2 million, respectively. No property and equipment was disposed of during the three months ended March 31, 2021. The company disposed of one piece of equipment during the three months ended March 31, 2020, and recorded a loss on the disposal of $0.3 million. As of March 31, 2021, construction in progress consisted primarily of equipment purchases related to the expansion of the Company's manufacturing capabilities at its contract manufacturer, Patheon U.K. Limited.

8. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following as of March 31, 2021, and December 31, 2020:

(In thousands)	March 31, 2021	December 31, 2020
Research and development	$ 3,565	$ 1,856
Payroll and other employee-related expenses	6,301	10,674
Professional services fees	2,688	2,094
Accrued interest	3,145	1,464
Product revenue reserves	4,010	2,990
Accrual for employee stock purchase plan	733	235
Foreign withholding taxes payable	495	495
Other	516	200
Total accrued expenses and other current liabilities	$ 21,453	$ 20,008

9. Debt

Amended and Restated Credit and Security Agreement

Term Loan

On August 4, 2015, the Company entered into a credit and security agreement with MidCap Financial Trust, as agent, and MidCap Financial Funding XIII Trust and Silicon Valley Bank, as lenders, to borrow up to $30.0 million in term loans (the "2015 term loan"). On August 2, 2019, the Company terminated the credit and security agreement and concurrently entered into an amended and restated credit and security agreement (the "amended and restated credit and security agreement") with Silicon Valley Bank as agent, MidCap Financial Trust, Flexpoint MCLS Holdings, LLC, and the other lenders from time to time party thereto (collectively, the "Lenders"), providing for a term loan of $40.0 million and a revolving credit facility of up to $20.0 million, both of which mature on January 1, 2024 (the "Maturity Date"). The Company concurrently borrowed the $40.0 million term loan and used $7.7 million of the proceeds to repay the remaining amount owed on the 2015 term loan.

The Company granted the Lenders a security interest in substantially all of its personal property, rights and assets, other than intellectual property, to secure the payment of all amounts owed under the amended and restated credit and security agreement. The Company agreed not to encumber any of its intellectual property without the Lenders' prior written consent.

The amended and restated credit and security agreement contains certain representations, warranties, and covenants of the Company, including a minimum revenue covenant that will be in effect at any time the Company's liquidity (defined as cash, cash equivalents and marketable securities held with Silicon Valley Bank and certain accounts receivable as deemed eligible under the amended and restated credit and security agreement) is below $80.0 million. Additionally, if the Company's liquidity is below $80.0 million, all amounts received from customer collections will be applied immediately to reduce the revolving credit facility. As filed in the Form 8-K issued by the Company on May 18, 2020, prior to May 2021, the minimum revenue covenant, if it applies in the future, is set annually and is based on the greater of (i) a conservative percentage of the year's approved forecast and (ii) modest growth over the

trailing twelve months of actual revenues. Beginning in May 2021, the minimum revenue covenant, if it applies, will be the greatest of (i) a conservative percentage of the year's approved forecast, (ii) modest growth over the trailing twelve months of actual revenues and (iii) 100% of the minimum revenue covenant amount for the preceding month.

On May 18, 2020, the Company borrowed $15.0 million under a new term loan advance and immediately used the proceeds to repay an equal amount under the revolving credit facility, and the maximum principal amount of the revolving credit facility was reduced from $20.0 million to $5.0 million. The new term loan is subject to substantially the same terms, including interest rate, amortization and maturity date, as the existing term loan under the credit facility.

The amended and restated credit and security agreement also has a material adverse event clause. If the minimum revenue covenant becomes applicable and the Company fails to comply with it, or a material adverse change as defined in the agreement occurs, the amounts due under the amended and restated credit and security agreement could be declared immediately due and payable. As of March 31, 2021, the Company was compliant with all covenants.

Term loan borrowings under the credit facility accrue interest monthly at a floating interest rate equal to the greater of the prime rate plus 1.5% or 6.5% per annum. Following an interest-only period of 18 months, principal is due in 36 equal monthly installments commencing February 1, 2021, and ending on the Maturity Date. Upon the Maturity Date, the Company will be obligated to pay a final payment equal to 6.75% of the total principal amounts borrowed under the facility. The final payment amount is being accreted to the carrying value of the debt using the straight-line method, which approximates the effective interest method. As of March 31, 2021, the carrying value of the term loan was approximately $53.1 million, of which $18.3 million is due within 12 months and $34.8 million is due in greater than 12 months.

The Company may prepay the term loan at any time by paying the outstanding principal balance, a final payment equal to 6.75% of the term loan amount, all accrued interest and a prepayment fee of 3% of the outstanding term loan amount if repaid in the first year, 2% of the outstanding term loan amount if repaid in the second year, and 1% of the outstanding term loan amount if repaid in the third year of the loan; no prepayment fee is required thereafter.

As of March 31, 2021, annual principal and interest payments due under the term loan were as follows:

Year	Aggregate Minimum Payments *(in thousands)*
2021	16,026
2022	20,296
2023	19,088
2024	5,249
Thereafter	—
Total	$ 60,659
Less interest	(5,002)
Less unamortized portion of final payment	(2,566)
Total	$ 53,091

Revolving Credit Facility

Borrowings under the revolving credit facility accrue interest monthly at a floating interest rate equal to the greater of the prime rate or 5.50% per annum. In addition to paying interest on any amounts borrowed under the revolving credit facility, the Company owes an unused revolving line facility fee equal to 0.25% per annum of the average unused portion of the revolving line, multiplied by the difference between the total amount available to be borrowed (the "Revolving Commitment Amount") and the greater of the average outstanding revolver balance and 25% of the Revolving Commitment Amount. The revolving credit facility and any related fees or interest payments became available to the Company beginning January 1, 2020, and in February 2020, the Company drew down the $20.0 million available. On May 18, 2020, the Company repaid $15.0 million of the outstanding principal balance, and the maximum principal amount of the revolving credit facility was reduced from $20.0 million to $5.0 million.

Beginning on January 1, 2020, if the interest payment on the revolving credit facility is less than the amount of interest that would have been payable had the Company borrowed 25% of the Revolving Commitment Amount, then the Company will be required to pay the difference.

The Company may retire the revolving credit facility early, at any time, by paying the outstanding principal balance, all accrued interest and a termination fee equal to 2% of the Revolving Commitment Amount if repaid in the first year, and 1% of the Revolving Commitment Amount if repaid in the second year; with no termination fee thereafter.

2024 Convertible Notes

On May 2, 2017, the Company issued an aggregate of $201.3 million principal amount of the 2024 Convertible Notes. The 2024 Convertible Notes have a maturity date of May 1, 2024, are unsecured and accrue interest at a rate of 3.375% per annum, payable

semi-annually on May 1 and November 1 of each year, beginning November 1, 2017. The Company received $194.8 million for the sale of the 2024 Convertible Notes, after deducting fees and expenses of $6.5 million.

Upon conversion of the 2024 Convertible Notes, at the election of each holder of a 2024 Convertible Note (the Holder), the note will be convertible into cash, shares of the Company's common stock, or a combination thereof, at the Company's election (subject to certain limitations in the 2015 term loan), at a conversion rate of approximately 37.3413 shares of common stock per $1,000 principal amount of the 2024 Convertible Notes, which corresponds to an initial conversion price of approximately $26.78 per share of the Company's common stock.

The conversion rate is subject to adjustment from time to time upon the occurrence of certain events, including, but not limited to, fundamental change events and certain corporate events that occur prior to the maturity date of the notes. In addition, if the Company delivers a notice of redemption, the Company will increase, in certain circumstances, the conversion rate for a Holder who elects to convert its notes in connection with such a corporate event or notice of redemption, as the case may be. At any time prior to the close of business on the business day immediately preceding February 1, 2024, Holders may convert all, or any portion, of the 2024 Convertible Notes at their option only under the following circumstances:

(1) during any calendar quarter commencing after the calendar quarter ending on June 30, 2017 (and only during such calendar quarter), if the last reported sale price of the common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day;

(2) during the five business day period after any ten consecutive trading day period (the "measurement period") in which the trading price per $1,000 principal amount of notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of the Company's common stock and the conversion rate on each such trading day;

(3) if the Company calls any or all of the notes for redemption, at any time prior to the close of business on the business day immediately preceding the redemption date; and

(4) upon the occurrence of specified corporate events.

On or after February 1, 2024, until the close of business on the business day immediately preceding the maturity date, Holders may convert their notes at any time, regardless of the foregoing circumstances. The Company may redeem, for cash, all or any portion of the 2024 Convertible Notes, at its option, on or after May 6, 2020, if the last reported sale price of the Company's common stock has been at least 130% of the conversion price for at least 20 trading days during any 30 consecutive day trading period, at a redemption price equal to 100% of the principal amount of the 2024 Convertible Notes to be redeemed, plus accrued and unpaid interest, subject to the Holders' right to convert as described above.

The 2024 Convertible Notes are considered convertible debt with a cash conversion feature. Per ASC 470-20, Debt with Conversion and Other Options, the Company has separated the convertible debt into liability and equity components based on the fair value of a similar debt instrument excluding the embedded conversion option. The carrying amount of the liability component was calculated by measuring the fair value of a similar liability that does not have an associated convertible feature. The allocation was performed in a manner that reflected our non-convertible debt borrowing rate for similar debt. The equity component of the 2024 Convertible Notes was recognized as a debt discount and represents the difference between the proceeds from the issuance of the 2024 Convertible Notes and the fair value of the liability of the 2024 Convertible Notes on their respective dates of issuance. The excess of the principal amount of the liability component over its carrying amount ("debt discount") is amortized to interest expense using the effective interest method over seven years. The equity component is not re-measured as long as it continues to meet the conditions for equity classification. The liability component of $136.7 million was recorded as long-term debt at May 2, 2017, with the remaining equity component of $64.5 million recorded as additional paid-in capital.

In connection with the issuance of the 2024 Convertible Notes, the Company incurred approximately $6.5 million of debt issuance costs, which primarily consisted of underwriting, legal and other professional fees, and allocated these costs to the liability and equity components based on the allocation of the proceeds. Of the total debt issuance costs, $4.4 million was allocated to the liability component and are recorded as a reduction of the 2024 Convertible Notes in our consolidated balance sheets. The remaining $2.1 million was allocated to the equity component and is recorded as a reduction to additional paid-in capital.

Debt discount and issuance costs of $68.9 million are being amortized to interest expense over the life of the 2024 Convertible Notes using the effective interest rate method. As of March 31, 2021, the stated interest rate was 3.375%, and the effective interest rate was 9.71%. Interest expense related to the 2024 Convertible Notes for the three months ended March 31, 2021, was $4.0 million, including $2.3 million, related to amortization of the debt discount.

The table below summarizes the carrying value of the 2024 Convertible Notes as of March 31, 2021:

	(in thousands)
Gross proceeds	$ 201,250
Portion of proceeds allocated to equity component (additional paid-in capital)	(64,541)
Debt issuance costs	(6,470)
Portion of issuance costs allocated to equity component (additional paid-in capital)	2,075
Amortization of debt discount and debt issuance costs	32,957
Carrying value 2024 Convertible Notes	$ 165,271

10. Stock-Based Compensation

Stock Option Valuation

The fair value of each of the Company's stock option grants is estimated on the date of grant using the Black-Scholes option-pricing model. Expected volatility is based on historical volatility of the Company's common stock. The expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain vanilla" options. The expected term of stock options granted to non-employees is equal to the contractual term of the option award. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future. The relevant data used to determine the value of the stock option grants for the three months ended March 31, 2021 and 2020, were as follows:

	Three months ended March 31,	
	2021	2020
Risk-free interest rates	1.12%	1.01% - 1.79%
Expected dividend yield	0.00%	0.00%
Expected term (in years)	6.0	6.0
Expected volatility	72.4%	65.4% - 66.3%

The following table summarizes stock option activity for the three months ended March 31, 2021:

(In thousands, except per share amounts)	Shares Issuable Under Options	Weighted Average Exercise Price Per Share
Outstanding as of December 31, 2020	4,592	$ 17.77
Granted	120	11.41
Exercised	(43)	3.40
Cancelled	(56)	19.81
Outstanding as of March 31, 2021	4,613	$ 17.71
Options vested and expected to vest at March 31, 2021	4,613	$ 17.71
Options exercisable at March 31, 2021	3,661	$ 18.23

The aggregate intrinsic value of options is calculated as the difference between the exercise price of the options and the fair value of the Company's common stock for those options that had exercise prices lower than the fair value of the Company's common stock. Options to purchase a total of 42,682 shares of the Company's common stock, with an aggregate intrinsic value of approximately $386,138, were exercised during the three months ended March 31, 2021.

At March 31, 2021 and 2020, there were options for the purchase of 4,613,050 and 4,934,879 shares of the Company's common stock outstanding, respectively, with a weighted average remaining contractual term of 5.9 years and 6.9 years, respectively, and with a weighted average exercise price of $17.71 and $17.92 per share, respectively.

The weighted average grant date fair value of options granted during the three months ended March 31, 2021 and 2020, was $7.27 and $9.63 per share, respectively.

Restricted Stock Units

During the three months ended March 31, 2021, the Company awarded 944,715 restricted stock units ("RSUs") to employees at a weighted average grant date fair value of $9.89 per share. The majority of the RSUs vest in four substantially equal installments on each of the first four anniversaries of the vesting commencement date, subject to the employee's continued employment with, or services to, the Company on each vesting date. Compensation expense is recognized on a straight-line basis.

Included in the 2021 RSU awards was a grant of 106,100 RSUs to the Company's chief executive officer. These RSUs have two performance conditions relating to achieving a certain revenue threshold for the year ending December 31, 2021, as well as progressing at least one of the Company's current pipeline assets. The number of shares ultimately eligible for vesting under the RSU award will depend upon the degree to which the performance conditions are achieved. The maximum number of shares that are eligible for vesting under the award is 159,150, which would be earned based on 150% achievement of the performance conditions. The portion of the RSUs eligible for vesting will vest in four substantially equal installments starting in 2022 upon confirmation of such performance metrics being achieved and thereafter on January 1 of the subsequent three years so that all of such shares will have vested on January 1, 2025, subject to the employee's continued employment with, or services to, the Company on each vesting date. As of March 31, 2021, the Company concluded that it was not probable that either performance condition would be met. Therefore, no expense has been recognized on these awards during the three months ended March 31, 2021.

The following table summarizes the RSU activity for the three months ended March 31, 2021:

(In thousands, except per share amounts)	Number of Shares	Weighted Average Grant Date Fair Value Per Share
Nonvested balance as of December 31, 2020	2,193	$ 14.15
Granted	945	9.89
Vested/Released	(373)	15.33
Cancelled	(79)	13.51
Nonvested Balance as of March 31, 2021	2,686	$ 12.51

Stock-based Compensation

The Company recorded stock-based compensation expense related to stock options and RSUs and shares purchased under the Employee Stock Purchase Plan for the three months ended March 31, 2021 and 2020, as follows:

	For the three months ended March 31,	
(In thousands)	2021	2020
Research and development	$ 1,279	$ 2,202
Selling, general and administrative	3,361	2,449
Total	$ 4,640	$ 4,651

As of March 31, 2021, unrecognized stock-based compensation expense for stock options outstanding was approximately $9.0 million which is expected to be recognized over a weighted average period of 2.1 years. As of March 31, 2021, unrecognized stock-based compensation expense for RSUs outstanding was $29.0 million which is expected to be recognized over a weighted average period of 2.6 years.

11. Net Loss per Share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows for the three months ended March 31, 2021 and 2020:

	For the three months ended March 31,	
(In thousands, except per share amounts)	2021	2020
Numerator:		
Net loss	$ (28,556)	$ (36,802)
Net loss:	$ (28,556)	$ (36,802)
Denominator:		
Weighted average common shares outstanding, basic and diluted	49,841	38,553
Net loss per share, basic and diluted	$ (0.57)	$ (0.95)

The following common stock equivalents were excluded from the calculation of diluted net loss per share for the periods indicated as including them would have an anti-dilutive effect:

	For the three months ended March 31,	
(In thousands)	**2021**	**2020**
Shares issuable upon conversion of the 2024 Convertible Notes	7,515	7,515
Stock options	4,660	4,864
Restricted stock units	2,153	912
Total	14,328	13,291

12. Commitments and Contingencies

Operating Leases

Burlington Lease

In May 2013, the Company entered into a lease for office space in Burlington, Massachusetts (the "Lease") for an initial term of 42 months. In June 2019, the Company amended the Lease to add additional square feet of office space and extend the term of the Lease through April 30, 2025 (the "Amended Lease"). As a result of the Amended Lease, the total rentable floor area is 41,873 square feet. Starting in August 2019, the Company's minimum monthly lease payment is approximately $108,000, which increases over the term of the Amended Lease. In addition to the base rent for the office space, the Company is responsible for its share of operating expenses and real estate taxes.

The straight-line lease cost for the Amended Lease (including the expense relating to the original Lease) amounted to $0.5 million for the three months ended March 31, 2021 and 2020, and was included in operating expenses. As of March 31, 2021, the remaining lease term on the Amended Lease was 4.1 years, which includes the 18-month extension resulting from the amendment signed in June 2019.

Woburn Lease

In February 2017, the Company entered into a five-year lease for laboratory space located in Woburn, Massachusetts with a monthly lease payment of approximately $15,000, which increases over the term of the lease, plus a share of operating expenses. The straight-line lease cost for the Woburn lease amounted to $46,000 for the three months ended March 31, 2021 and 2020, and was included in operating expenses. As of March 31, 2021, the remaining lease term on the Woburn lease was 11 months.

Manufacturing and Supply Agreement with Patheon UK Limited

In July 2015, the Company and Patheon UK Limited ("Patheon") entered into a Manufacturing and Supply Agreement (the "Manufacturing Agreement") and Technical Transfer and Service Agreement (the "Technical Transfer Agreement") for the manufacture of ZILRETTA.

Patheon agreed in the Technical Transfer Agreement to undertake certain transfer activities and construction services needed to prepare Patheon's United Kingdom facility for the commercial manufacture of ZILRETTA in dedicated manufacturing suites. The Company provided Patheon with certain equipment and materials necessary to manufacture ZILRETTA and pays Patheon a monthly fee for such activities and reimburses Patheon for certain material, equipment and miscellaneous expenses and additional services.

The initial term of the Manufacturing Agreement is 10 years from approval by the FDA of the Patheon manufacturing suites for ZILRETTA, or until October 6, 2027. The Company pays a monthly base fee to Patheon for the operation of the manufacturing suites and a per product fee for each vial based upon a forecast of commercial demand. The Company also reimburses Patheon for purchases of materials and equipment made on its behalf, certain nominal expenses and additional services. The Manufacturing Agreement will remain in full effect unless and until it expires or is terminated. Upon termination of the Manufacturing Agreement (other than termination by Flexion in the event that Patheon does not meet the construction and manufacturing milestones or for a breach by Patheon), Flexion will be obligated to pay for the costs incurred by Patheon associated with the removal of Flexion's manufacturing equipment and for Patheon's termination costs up to a capped amount.

The Manufacturing Agreement with Patheon contains an operating lease for the use of dedicated manufacturing suites. With the adoption of ASU 2016-02, the Company recorded a right-of-use asset and corresponding lease liability for the operating lease.

In June 2019, the Company and Patheon amended the Manufacturing Agreement and the Technical Transfer Agreement. The amendment primarily modifies the compensation structure, which is comprised of base fees and per product fees the Company pays to Patheon and does not result in any additional rights of use. The Company accounted for the amendment as a lease modification that is not a separate contract from the original lease. As part of the modification, the Company reassessed whether the contract is or contains a lease and determined that there is an operating lease component for the use of dedicated manufacturing suites. The remainder of the consideration is allocated to the service component. The Company also reassessed the lease liability by calculating the present value of

the remaining lease payments as of the modification date, discounted at 6.1%. The modification resulted in an increase to each of the lease liability and right of use asset of $0.5 million.

In April 2020, the Company entered into a side letter amending the Manufacturing Agreement with Patheon pursuant to which the parties agreed that the Company would continue to pay the monthly base fee for maintaining the manufacturing suites, but minimum purchase obligations would be cancelled for 2020 as the Company temporarily suspended manufacturing activities for ZILRETTA. The amendment did not change the amount of fixed consideration owed to Patheon over the life of the contract, nor did it grant the Company any additional rights of use. As such, there was no change in the accounting for the embedded lease as a result of this amendment. The Company restarted manufacturing at Patheon in the fourth quarter of 2020.

As of March 31, 2021, the remaining lease term on the Patheon lease was 6.6 years. The straight-line lease cost amounted to $62,000, respectively for the three months ended March 31, 2021, respectively, and is included in inventory as part of manufacturing overhead.

The components of lease expense and related cash flows were as follows:

(In thousands)	For the three months ended March 31,	
Operating lease cost	**2021**	**2020**
Operating lease cost included in operating expenses	$ 513	$ 513
Operating lease cost included in inventory	62	57
Total operating lease cost	575	570
Operating cash flows from operating leases	786	818

Maturities of lease liability due under these lease agreements as of March 31, 2021, were as follows:

Year	Operating Lease Obligations (in thousands)
2021	1,536
2022	1,888
2023	1,896
2024	1,938
2025	815
Thereafter	432
Present value of imputed interest	(2,257)
Total	$ 6,248

Other Commitments and Contingencies

Evonik Supply Agreement

In November 2016, the Company entered into a Supply Agreement with Evonik Corporation (“Evonik”) for the purchase of PLGA which is used in the manufacturing of clinical and commercial supply of ZILRETTA. Pursuant to the Supply Agreement, Flexion is obligated to submit rolling monthly forecasts to Evonik for PLGA supply, a portion of which will constitute binding orders. In addition, Flexion agreed to certain minimum purchase requirements, which do not apply (i) during periods in which Evonik is in material breach of the Supply Agreement or is unable to perform its obligations due to a force majeure event, (ii) with respect to orders that Evonik is unable to supply in excess of binding orders, (iii) for orders Evonik is unable to timely deliver or does not deliver conforming product and provides a credit for such order, or (iv) during an uncured material quality failure by Evonik. Flexion agreed to purchase PLGA batches at a specified price per gram in U.S. dollars, subject to adjustment from time to time, including due to changes in price indices and in the event the initial term of the Supply Agreement was extended. The initial term of the agreement was five years, commencing in July 2016. In May 2021, the Company entered into an amendment to the Supply Agreement that will be effective on June 30, 2021. The total term of the Supply Agreement, as amended, is eight years. Upon termination of the Supply Agreement (other than termination due to the bankruptcy of either Evonik or Flexion), Flexion is obligated to pay the costs associated with the binding supply forecast provided to Evonik.

FX201-Related Agreements

In December 2017, the Company entered into a definitive agreement with GeneQuine Biotherapeutics GmbH ("GeneQuine") to acquire the global rights to FX201. As part of the asset purchase transaction with GeneQuine, the Company made an upfront payment to GeneQuine of $2.0 million. The upfront fee was attributed to the intellectual property acquired and recognized as research and development expense in December 2017 as the FX201 rights had not been commercially approved and had no alternative future use. In 2018, the Company paid GeneQuine $750,000 for initiating a GLP toxicology study of FX201. In addition, the Company paid GeneQuine $750,000 in November 2019 following the FDA acceptance of the IND application for FX201. The next milestone of $2.5 million was achieved in March 2020 when the first patient was treated in the Phase 1 clinical trial. The Company may also be required to make additional milestone payments during the development of FX201, including up to $4.5 million for the initiation of a Phase 2 proof of concept (PoC), clinical trial and, following successful PoC, up to an additional $51.5 million in development and global regulatory approval milestone payments. The transaction was accounted for as an asset acquisition, as it did not qualify as a business combination. Milestone payments earned prior to regulatory approval of FX201 are recognized as research and development expense in the period when the milestone events become probable of being achieved. Future milestones earned upon regulatory approval would be recognized as an intangible asset and amortized to expense over its estimated life. As of March 31, 2021, no other milestones under the arrangement were probable of being achieved. As part of the transaction, the Company became the direct licensee of certain underlying Baylor College of Medicine (Baylor) patents and other proprietary rights related to FX201 for human applications. The Baylor license agreement grants the Company an exclusive, royalty-bearing, world-wide right and license (with a right to sublicense) for human applications under its patent and other proprietary rights directly related to FX201, with a similar non-exclusive license to certain Baylor intellectual property rights that are not specific to FX201. The license agreement with Baylor includes a low single-digit royalty on net sales of FX201 and requires the Company to use reasonable efforts to develop FX201 according to timelines set out in the license agreement. In December 2017, the Company also entered into a Master Production Services Agreement with SAFC Carlsbad, Inc., a part of MilliporeSigma, for the manufacturing of preclinical and initial clinical supplies of FX201. In addition, in February 2020 the Company entered into a manufacturing agreement with another vendor for clinical trial supply of FX201 through Phase 3 clinical trials.

FX301-Related Agreements

In September 2019, the Company entered into a definitive agreement with Xenon Pharmaceuticals, Inc. ("Xenon") that provides the Company with the global rights to develop and commercialize XEN402, Xenon's NaV1.7 inhibitor known as funapide, formulated for extended release with a novel, Flexion proprietary thermosensitive hydrogel under the Company's preclinical program known as FX301. The transaction was accounted for as an asset acquisition, as it did not qualify as a business combination. As part of the asset purchase transaction with Xenon, the Company made an upfront payment to Xenon of $3.0 million. The upfront fee was attributed to the intellectual property acquired and was recognized as research and development expense in September 2019 as the FX301 product candidate had not been commercially approved and had no alternative future use. The next milestone of $0.5 million was achieved following the commencement of the GLP toxicology study. This milestone was recognized as research and development expense in the first quarter of 2020. Two milestones were achieved in the first quarter of 2021, including $1.0 million earned upon the clearing of the IND by FDA in February 2021 and $2.0 million earned upon the initiation of the Phase 1b clinical trial. These milestones were recognized as research and development expenses in the first quarter of 2021. The Company may also be required to make additional milestone payments during the development of FX301, including up to $5.0 million through initiation of a Phase 2 PoC clinical trial and, following successful PoC, up to $40.8 million in development and global regulatory approval milestone payments and up to an additional $75.0 million in sales-related milestone payments. Future milestone payments earned prior to regulatory approval of FX301 would be recognized as research and development expense in the period when the milestone events become probable of being achieved. Future milestones earned subsequent to regulatory approval would be recognized as an intangible asset and amortized to expense over the estimated life of FX301. As of March 31, 2021, no other milestones under the arrangement were probable of being achieved. As part of the transaction, the Company became the direct licensee of certain underlying Xenon patents and other proprietary rights related to XEN402 for human applications. The Xenon agreement grants the Company an exclusive, royalty-bearing, world-wide right and license (with a right to sublicense) for human applications under its patents directly related to XEN402, with a similar royalty-free license to other Xenon proprietary rights directly related to XEN402. The agreement with Xenon includes a tiered royalty ranging from mid-single digits to low double digits that is based on aggregate annual net sales of FX301 and requires the Company to use reasonable efforts to develop FX301 according to timelines set out in the agreement.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read in conjunction with our financial statements and accompanying notes included in this Quarterly Report on Form 10-Q and the financial statements and accompanying notes thereto for the fiscal year ended December 31, 2020, and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K filed by us with the Securities and Exchange Commission, or SEC, on March 10, 2021.

Forward-Looking Statements

This discussion and analysis contains "forward-looking statements" that is statements related to future, not past, events – as defined in Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act that reflect our current expectations regarding future development activities, results of operations, financial condition, cash flow, performance and business prospects, and opportunities, as well as assumptions made by and information currently available to our management. Forward-looking statements, include any statement that does not directly relate to a current historical fact. We have tried to identify forward-looking statements by using words such as "may," "will," "expect," "anticipate," "estimate," "intend," "plan," "predict," "potential," "believe," "should" and similar expressions. Although we believe the expectations reflected in these forward-looking statements are reasonable,

we cannot guarantee future results, events, levels of activity, performance or achievement. We undertake no obligation to update these forward-looking statements to reflect events or circumstances after the date of this report or to reflect actual outcomes.

Overview

We are a biopharmaceutical company focused on the discovery, development and commercialization of novel, local therapies for the treatment of patients with musculoskeletal conditions, beginning with osteoarthritis, the most common form of arthritis, referred to as OA.

On October 6, 2017, the U.S. Food and Drug Administration (FDA), approved our product, ZILRETTA, for marketing in the United States. ZILRETTA is the first and only extended-release, intra-articular, or IA (meaning in the joint), injection indicated for the management of OA related knee pain. ZILRETTA is a non-opioid therapy that employs our proprietary microsphere technology to provide pain relief. The pivotal Phase 3 trial, on which the approval of ZILRETTA was based, showed that ZILRETTA met the primary endpoint of pain reduction at Week 12, with statistically significant pain relief extending through Week 16.

We also have two pipeline programs focused on the local treatment of musculoskeletal conditions: FX201, which is an investigational IA gene therapy product candidate in clinical development for the treatment of OA, and FX301, an investigational NaV1.7 inhibitor product candidate in clinical development as a locally administered peripheral analgesic nerve block for control of post-operative pain.

We were incorporated in Delaware in November 2007, and to date, we have devoted substantially all of our resources to developing our product candidates, including conducting clinical trials with our product candidates, preparing for and undertaking the commercialization of ZILRETTA, providing general and administrative support for these operations and protecting our intellectual property. From our inception through March 31, 2021, we have funded our operations primarily through the sale of our common stock, convertible preferred stock, and convertible debt, as well as debt financing. Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, government or third-party funding, and licensing or collaboration arrangements.

Financing Transaction

On November 4, 2020, we entered into an Equity Distribution Agreement (the “Distribution Agreement”) with Goldman Sachs & Co. LLC and Credit Suisse Securities (USA) LLC (collectively, the “Managers”) relating to the issuance and sale from time to time of up to $100,000,000 of shares of our common stock. Under the terms of the Distribution Agreement, we will pay the Managers a commission of up to 3% of the gross sales price of any shares sold. As of March 31, 2021, 134,048 shares have been sold under the Distribution Agreement, for total net proceeds of $1.7 million.

Impact of the Coronavirus Global Pandemic (“COVID-19”)

In December 2019, a novel strain of coronavirus, which causes the COVID-19 disease, was first reported in Wuhan, China and has since become a global pandemic (“COVID-19”). COVID-19 has presented a substantial public health and economic challenge around the world and has affected our employees, patients, communities and business operations, as well as the U.S. economy and financial markets. COVID-19 continues to affect patient flows to healthcare providers, and we expect visits to orthopedic practices will remain at approximately 80% of their pre-COVID levels through at least the middle of this year.

With respect to the rollout of the COVID-19 vaccines, despite the absence of guidance from the Centers for Disease Control and Prevention (CDC), out of an abundance of caution, some physicians opted to defer IA steroid injections for a period of two weeks prior to COVID-19 vaccination through two weeks post completion of the vaccination regimen. ZILRETTA's market largely consists of Medicare age patients and seniors who were prioritized for COVID vaccinations throughout the first quarter of 2021. At the end of February, we conducted a spot survey of 30 physicians and orthopedic practices and approximately 30% of respondents indicated their steroid administrations were between 20% and 50% lower than they were prior to the availability of the COVID-19 vaccines. As of April 5, the CDC reported that nearly 60% of all people aged 65 and older had been fully vaccinated, and we believe that the impacts from COVID-19 vaccinations on steroid injections will become less meaningful in the second quarter.

In spite of these challenges, in the first quarter of 2021 we saw ZILRETTA units purchased by health care providers grow by 6% over the fourth quarter of 2020. We believe that as more clinicians and patients gain more experience with ZILRETTA, it can become a leading treatment option for patients with OA knee pain. While we are encouraged by the growth of ZILRETTA purchases by healthcare providers we saw in the first quarter of 2021, the future impact of COVID-19 on our business remains uncertain and unpredictable.

Q1 2021 Commercial Metrics

In May 2021, we introduced updated commercial metrics to provide increased visibility and insights into the commercial performance of ZILRETTA. In the first quarter of 2021:

- 2,044 accounts purchased ZILRETTA
- 90% of accounts that purchased ZILRETTA had purchased ZILRETTA in a prior quarter
- Total account purchases grew by 6% over the fourth quarter of 2020

- Approximately 38% of ZILRETTA purchases came from accounts purchasing more than 100 units

Pipeline Updates

ZILRETTA/FX006 (triamcinolone acetonide extended-release injectable suspension) - IA treatment for OA

ZILRETTA is the first and only extended-release IA therapy for patients confronting OA-related knee pain, and we believe ZILRETTA's extended-release profile may also provide effective treatment for OA pain in other large joints, including the shoulder. We intend to initiate a registration trial investigating ZILRETTA in shoulder OA in 2021.

FX201 (humantakinogene hadenovec) – Locally Administered Gene Therapy for the Treatment of OA

FX201 is our novel, clinical stage, investigational IA gene therapy product candidate which is designed to induce the production of interleukin-1 receptor antagonist (IL-1Ra), an anti-inflammatory protein. Preclinical data suggest that following injection of FX201, its genetic material is incorporated into local cells, and IL-1Ra is expressed in response to inflammation in the joint tissues. Inflammation is a known cause of pain, and chronic inflammation is thought to play a major role in the progression of OA. By persistently suppressing inflammation, we believe FX201 has the potential to both reduce pain and possibly modify disease progression. We acquired the rights to FX201 via a definitive agreement with GeneQuine Biotherapeutics GmbH, or GeneQuine, and have an exclusive license to the underlying intellectual property rights for human use of FX201 from Baylor College of Medicine in Houston, Texas. In June, the U.S. Patent and Trademark Office (USPTO) issued patent number 10,301,647, which covers the composition of matter and method of use of FX201 in the treatment of OA with a term through January 2033.

In March 2020, we initiated a Phase 1 single ascending dose study to evaluate the safety and tolerability of FX201 in patients with painful OA of the knee. The multicenter, open-label study is expected to evaluate three doses (low, mid and high dose) of FX201 in cohorts of five to eight patients. The initial trial is expected to enroll approximately 15 to 24 patients with symptomatic knee OA who will be followed for 104 weeks. Clinical data from the first two cohorts indicate that FX201 appears to be generally safe and well-tolerated at the low and mid doses. There were no serious adverse events and there was no evidence of systemic biodistribution in plasma or shedding in urine observed in any patient. In February 2021, following an independent Data Monitoring Committee (DMC) review of the mid dose safety data, we announced the expansion of the trial to include up to 20 additional patients in each of the low and mid dose treatment groups. In March 2021, the first patient was treated in the high dose cohort.

On May 11, we presented preliminary FX201 data at the 2021 American Society of Gene & Cell Therapy (ASGCT) annual meeting. Key findings from the Phase 1 dose-escalation study evaluating the safety and tolerability of FX201 in patients with knee OA include:

- FX201 was generally well-tolerated in the initial low-dose cohort (1.4E10 genome copies of FX201), and all five patients remain in the study at 38 to 56 weeks post-treatment.
    - Two patients had self-limited Grade 2 index-knee adverse events (pain, swelling, effusion) possibly related to treatment these were managed conservatively.
- No evidence of systemic biodistribution of FX201 in plasma or shedding in urine or swab samples from the injection site observed in any patient.
- Improvement in WOMAC-A (pain) from baseline was observed in four of the five patients at Week 12 and 24, and in two of the three patients with Week 52 data.
- In a responder analysis based on IMMPACT criteria, two out of the five patients demonstrated substantial improvement in knee OA pain at Weeks 8, 12 and 24 following treatment with FX201.
    - One of the three patients with data available at Week 52 continued to demonstrate substantial improvement in pain.
- Functional improvement from baseline assessed by the KOOS questionnaire was observed in four of the five patients at Week 24, and all three patients with Week 52 data reported an improved KOOS score compared to baseline at Week 52.

In May 2021, one participant in the high-dose cohort experienced gastrointestinal bleeding and atrial fibrillation, which required hospitalization. An adverse event resulting in hospitalization is deemed serious; however, the investigator determined it to be unrelated to the study drug. As dictated by the protocol, any serious adverse event (SAE), regardless of relatedness, requires a pause in study enrollment, followed by a review of the event by the independent Data Monitoring Committee (DMC) for the study and FDA. Both the DMC and FDA agreed with the investigator's assessment and endorsed the re-initiation of the trial, and enrollment has resumed.

Additional data readouts are expected by the end of 2021, including the interrogation of synovial fluid from patients to assess biological activity of FX201 locally in the joint and potential correlation with clinical endpoints over time.

FX301 (funapide in a proprietary thermosensitive hydrogel) – Locally Administered NaV1.7 Inhibitor for the Treatment of Post-Operative Pain

In September 2019, we entered into a definitive agreement with Xenon Pharmaceuticals that provides us with the global rights to develop and commercialize XEN402, a NaV1.7 inhibitor, for control of post-operative pain. Our investigational product candidate, known as FX301, consists of funapide formulated for extended release from a Flexion proprietary thermosensitive hydrogel for administration as a peripheral nerve block for control of post-operative pain. Within minutes following injection, the thermosensitive formulation has been shown to transition from a liquid to a gel, an effect that we believe can provide local delivery of funapide near target nerves for up to a week. Unlike typical local anesthetics, the selective pharmacology of funapide has the potential to provide effective pain relief while preserving motor function. As such, we believe FX301 could enable ambulation, rapid discharge, and early rehabilitation following musculoskeletal surgery.

In a validated post-operative pain model in pigs, a single injection of FX301 provided both greater analgesic effect from 12 through 72 hours and a longer duration of effect through 72 hours compared to liposomal bupivacaine or placebo. In addition, treatment with FX301 did not significantly affect total walking distance in animals at 2 and 24 hours post-injection whereas animals treated with liposomal bupivacaine experienced a significant reduction in total walking distance compared with baseline at 2 and 24 hours post-injection.

These data formed the basis of our Investigational New Drug (IND) application for FX301, which the FDA cleared in February 2021. In March 2021, we announced the treatment of the first patient in a Phase 1b proof-of-concept trial evaluating the safety and tolerability of FX301 administered as a single-dose, popliteal fossa block (a commonly used nerve block in foot and ankle-related surgeries) in patients undergoing bunionectomy. The Phase 1b randomized, double-blind, placebo-controlled study will be conducted in two parts beginning with a single ascending dose portion which will investigate FX301 at low and high doses of funapide administered at two volumes in four cohorts of patients undergoing bunionectomy. A total of 48 patients (12 patients per cohort), will be randomized to receive either FX301 or placebo. A Safety Monitoring Committee will review data from each dose cohort before the study escalates into higher doses. The data from the single ascending dose portion of the trial will be reviewed and a decision made regarding expanding a selected dose and volume cohort by another 36 patients. This would support broader understanding of the safety and efficacy in that cohort. Results from this trial could potentially be available in late 2021.

Financial Overview

Revenue

Product Revenue

Net product sales consist of sales of ZILRETTA, which was approved by the FDA on October 6, 2017, and launched in the United States in October 2017. We had not generated any revenue prior to the launch of ZILRETTA.

License Revenue

On March 30, 2020, we entered into an exclusive license agreement with HK Tainuo and Jiangsu Tainuo, a subsidiary of China Shijiazhuang Pharmaceutical Co, Ltd. for the development and commercialization of ZILRETTA in Greater China (consisting of mainland China, Hong Kong and Macau, and Taiwan). Under the terms of the agreement, HK Tainuo paid us an upfront payment of $10.0 million, of which $5.0 million was received as of June 30, 2020, and the remaining $5.0 million was received as of September 30, 2020. We are also eligible to receive up to $32.5 million in aggregate development, regulatory and commercial sales milestone payments. All payments received from HK Tainuo are subject to the applicable Hong Kong withholding taxes. HK Tainuo is responsible for the clinical development, product registration and commercialization of ZILRETTA in Greater China and Jiangsu Tainuo serves as the guarantor of HK Tainuo's obligations and responsibilities under the agreement. We are solely responsible for the manufacture and supply of ZILRETTA to HK Tainuo for all clinical and commercial activities. The terms related to product manufacturing and supply, including pricing and minimum purchase requirements agreed to in the license agreement, will be covered by a separate supply agreement. All amounts owed to us are nonrefundable and non-creditable once paid. We concluded that the license and supply obligations were not distinct performance obligations, and therefore the transaction price will be recognized as revenue as our supply obligation is fulfilled over the term of the supply agreement, which has not yet commenced. No revenue was recognized associated with this contract as of March 31, 2021.

Cost of Sales

Cost of sales consists of third-party manufacturing costs, freight and indirect overhead costs associated with sales of ZILRETTA. Cost of sales also includes period costs related to certain inventory manufacturing services, inventory adjustment charges, and unabsorbed manufacturing and overhead costs, as well as any write-offs of inventory that fails to meet specifications or is otherwise no longer suitable for commercial manufacture.

Research and Development Expenses

Our research and development activities include: preclinical studies, clinical trials, and chemistry, manufacturing, and controls, or CMC, activities. Our research and development expenses consist primarily of:

- expenses incurred under agreements with consultants, contract research organizations, or CROs, and investigative sites that conduct our preclinical studies and clinical trials;
- costs of acquiring, developing and manufacturing clinical trial materials;
- personnel costs, including salaries, benefits, stock-based compensation and travel expenses for employees engaged in scientific research and development functions;
- costs related to compliance with certain regulatory requirements;
- expenses related to the in-license of certain technologies; and
- allocated expenses for rent and maintenance of facilities, insurance and other general overhead.

We expense research and development expenses as incurred. Our direct research and development expenses consist primarily of external-based costs, such as fees paid to investigators, consultants, investigative sites, CROs and companies that manufacture our clinical trial materials and potential future commercial supplies and are tracked on a program-by-program basis. We do not allocate personnel costs, facilities or other indirect expenses to specific research and development programs. These indirect expenses are included within the amounts designated as “Personnel and other costs” in the Results of Operations section below. Inventory acquired prior to receipt of the marketing approval of a product candidate is recorded as research and development expense as incurred.

Our research and development expenses are expected to increase relative to the prior year and for the foreseeable future. Due to the expense reduction measures taken in 2020 in response to the COVID-19 pandemic, in particular a deferral of spending related to clinical trials, research and development expenses were lower than pre-pandemic levels. While the duration of COVID-19 and its impact on our ability to conduct clinical development are highly uncertain, we expect that a return to normal operations will likely result in an increase in future research and development expenses. Specifically, our costs will increase as we conduct additional clinical trials for ZILRETTA, including our planned registration trial in shoulder OA, and conduct further development activities for our pipeline programs, including our on-going clinical trials of FX2021 and FX301.

We cannot determine with certainty the duration of and completion costs associated with ongoing and future clinical trials or the associated regulatory approval process, post-marketing development of ZILRETTA or development of any product candidates in our pipeline. The duration, costs and timing associated with the further development of ZILRETTA or the development of other product candidates will depend on a variety of factors, including uncertainties associated with the results of our clinical trials. As a result of these uncertainties, we are currently unable to estimate with any precision our future research and development expenses for expanded indications for ZILRETTA or the product candidates in our pipeline.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of personnel costs, including salaries, related benefits, travel expenses and stock-based compensation of our executive, finance, business development, commercial, information technology, legal and human resources functions. Other selling, general and administrative expenses include an allocation of facility-related costs, patent filing expenses, and professional fees for legal, consulting, auditing and tax services.

We anticipate that our selling, general and administrative expenses will increase in the foreseeable future as we continue to build our corporate and commercial infrastructure to support the continued development and commercialization of ZILRETTA and other product candidates. In 2020, as a result of the adverse effect of COVID-19 on our revenues, we took steps to reduce our sales and marketing expenses through the elimination of live presence at medical and industry conferences, reductions in in-person physician speaker programs and reductions in select marketing programs and materials. While certain selling and marketing activities have resumed, travel is still restricted in many areas and all conferences and speaker programs remain virtual, resulting in operating expenses for the first quarter of 2021 that were lower than pre-pandemic levels. We cannot determine with certainty the duration and timing of COVID-19, but we expect that a return to normal operations will likely result in an increase in future selling, general, and administrative expenses, including external marketing expenses and the operation of our field sales force.

Other Income (Expense)

Interest income

Interest income consists of interest earned on our cash and cash equivalents balances and our marketable securities. The primary objective of our investment policy is capital preservation.

Interest expense

Interest expense consists of contractual interest on our 2024 Convertible Notes, which accrue interest at a rate of 3.375% per annum, payable semi-annually, our term loan facility, which accrues interest at a floating interest rate equal to the greater of the Prime Rate (as reported in the Wall Street Journal) plus 1.50% or 6.50% per annum, and our revolving credit facility, which accrues interest at a

floating interest rate equal to the greater of the Prime Rate (as reported in the Wall Street Journal) or 5.50% per annum. Also included in interest expense is the amortization of the final payment on the term loan and the debt discount related to the convertible notes, which is being amortized to interest expense using the effective interest method over the expected life of the debt.

Foreign currency gain (loss)

We maintain a bank account denominated in British Pounds. All foreign currency payables and cash balances are measured at the applicable exchange rate at the end of the reporting period. All associated gains and losses from foreign currency transactions are reflected in the consolidated statements of operations, within other income and expense.

Other income (expense)

Other income (expense) consists of the amortization of premiums or accretion of discounts related to our marketable securities and our realized gains (losses) on redemptions of our marketable securities. We will continue to record either income or expense related to accretion of discounts or amortization of premiums on marketable securities for as long as we hold these investments. Also included in other income (expense) is the amortization of debt issuance costs on our term loan facility and the 2024 Convertible Notes, which are being amortized over the respective terms of the loans.

Provision for income taxes

The provision for income taxes consists of foreign withholding taxes related to our license agreement with HK Tainuo.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of our financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of our financial statements, and the reported revenue and expenses during the reported periods. We evaluate these estimates and judgments, including those described below, on an ongoing basis. We base our estimates on historical experience, known trends and events, contractual milestones and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe that the estimates, assumptions and judgments involved in the accounting policies described in Management's Discussion and Analysis of Financial Condition and Results of Operations in Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2020, have the greatest potential impact on our financial statements, so we consider them to be our critical accounting policies and estimates. There were no material changes to our critical accounting policies and estimates during the three months ended March 31, 2021.

RESULTS OF OPERATIONS

Comparison of the Three Months Ended March 31, 2021 and 2020

The following tables summarize our results of operations for the three months ended March 31, 2021:

	Three Months Ended March 31,			
(In thousands)	**2021**	**2020**	**Change**	**% Increase/ (Decrease)**
Revenues:				
Product revenue, net	$ 24,589	$ 20,127	$ 4,462	22.2%
Operating expenses:				
Cost of sales	6,085	2,276	3,809	167.4%
Research and development	14,047	21,134	(7,087)	(33.5)%
Selling, general and administrative	27,598	29,299	(1,701)	(5.8)%
Total operating expenses	47,730	52,709	(4,979)	(9.4)%
Loss from operations	(23,141)	(32,582)	9,441	(29.0)%
Other (expense) income:				
Interest income	300	427	(127)	(29.7)%
Interest expense	(5,189)	(4,721)	(468)	9.9%
Other expense (income)	(526)	74	(600)	NM
Total other (expense) income	(5,415)	(4,220)	(1,195)	28.3%
Net loss	$ (28,556)	$ (36,802)	8,246	(22.4)%

Product Revenue

The following table presents the adjustments deducted from gross product revenue to arrive at net product revenue for sales of ZILRETTA during the three months ended March 31, 2021 and 2020:

	Three Months Ended March 31,			
(In thousands, except for % of sales)	2021	% of Sales	2020	% of Sales
Product revenue, gross	$ 29,906	100.0%	$ 22,715	100.0%
Adjustments to product revenue, gross				
Provider discounts and rebates	(2,703)	(9.0)%	(526)	(2.3)%
All other	(2,614)	(8.7)%	(2,062)	(9.1)%
Product revenue, net	$ 24,589	82.2%	$ 20,127	88.6%

Net product revenue for the three months ended March 31, 2021 and 2020, was $24.6 million and $20.1 million, respectively. The period-over-period increase was due to an increase in the number of ZILRETTA units sold, which resulted in an increase in net revenue of $5.9 million, offset by a decrease of $1.4 million which was attributable to a decrease in the net price per unit primarily due to provider rebate offerings and other discounts. We are unable to predict the long-term impact of COVID-19 and the pace of recovery and how this may impact purchases of ZILRETTA by healthcare providers, as individual providers and their patients have had different responses to the pandemic. For further discussion regarding our revenue recognition policy, see Note 2, “Summary of Significant Accounting Policies,” in the Notes to Condensed Consolidated Financial Statements included in Part I, Item I of this Quarterly Report on Form 10-Q.

Cost of Sales

Cost of sales was $6.1 million and $2.3 million for the three months ended March 31, 2021 and 2020, respectively. For the three months ended March 31, 2021, cost of sales was comprised of $2.5 million related to the actual cost of units sold, $3.1 million of unabsorbed manufacturing and overhead costs related to the operation of the facility at Patheon, and a charge resulting from the write-down of short-dated inventory that is not expected to be sold prior to expiry of $0.5 million. For the three months ended March 31, 2020, cost of sales was $2.3 million which was comprised of $2.0 million related to the actual cost of units sold and $0.3 million of period costs and other adjustments.

Research and Development Expenses

	Three Months Ended March 31,			
(In thousands)	2021	2020	Change	% Increase/ (Decrease)
Direct research and development expenses by program:				
ZILRETTA	$ 1,185	$ 4,826	$ (3,641)	(75.4)%
FX201	1,468	3,716	(2,248)	(60.5)%
FX301	4,143	1,722	2,421	140.6%
Portfolio expansion	176	176	—	—
Other	459	640	(181)	(28.3)%
Total direct research and development expenses	7,431	11,080	(3,649)	(32.9)%
Personnel and other costs	6,616	10,054	(3,438)	(34.2)%
Total research and development expenses	$ 14,047	$ 21,134	$ (7,087)	(33.5)%

Research and development expenses were $14.0 million and $21.1 million for the three months ended March 31, 2021 and 2020, respectively. The decrease in research and development expenses of $7.1 million was primarily due to a decrease of $3.6 million in development expenses for ZILRETTA due to a reduction in ZILRETTA life cycle management activities, a decrease of $2.2 million related to FX201 program costs, which is largely due to the $2.5 million milestone payment related to dosing the first human patient in the Phase 1 clinical trial which occurred in the first quarter of 2020, as well as a decrease of $3.4 million in salary and other employee-related costs and stock-based compensation expense related to lower headcount. Decreases were partially offset by an increase of $2.4 million in expenses related to FX301, which is attributed to the achievement of certain development milestones, including the clearing of the IND by FDA and the initiation of the Phase 1b clinical trial, both of which occurred in the first quarter of 2021.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $27.6 million and $29.3 million for the three months ended March 31, 2021 and 2020, respectively. Selling expenses were $19.1 million and $20.5 million for the three months ended March 31, 2021 and 2020, respectively. The year over year decrease in selling expenses of $1.4 million was primarily due to the fact that the majority of industry conferences and physician speaker programs remained virtual due to COVID-19, and although more physician offices are opening,

business travel remains low compared to pre-pandemic levels. General and administrative expenses were $8.5 million and $8.8 million for the three months ended March 31, 2021 and 2020, respectively, which represents a decrease of $0.3 million.

Other Income (Expense)

Interest income was $0.3 million and $0.4 million for the three months ended March 31, 2021 and 2020, respectively. The decrease in interest income was primarily due to a decrease in the average investment balance as well as a decrease in interest rates over the period.

Interest expense was $5.2 million and $4.7 million for the three months ended March 31, 2021 and 2020, respectively. The increase in interest expense can be attributed to the restructuring of our 2019 term loan in May 2020, which resulted in interest being paid on a higher principal amount.

We recorded other expense of $0.5 million for the three months ended March 31, 2021, compared to other income of $0.1 million for the three months ended March 31, 2020. The increase in other expense was primarily due to changes in the price of debt securities resulting in amortization of premiums rather than accretion of discounts, as well as an increase in losses on foreign currency transactions due to an increase in exchange rates.

Liquidity and Capital Resources

For the three months ended March 31, 2021, we generated $24.6 million in net product revenue. We have incurred significant net losses in each year since our inception, including net losses of $113.7 million, $149.8 million, and $169.7 million, for fiscal years 2020, 2019, and 2018, respectively, and $28.6 million for the three months ended March 31, 2021. As of March 31, 2021, we had an accumulated deficit of $810.9 million. We anticipate that we will continue to incur losses over the next few years.

Since our inception through March 31, 2021, we have funded our operations primarily through the sale of our common stock and convertible preferred stock and convertible debt, and through venture debt financing, including amounts from our initial and follow-on public offerings during 2014, 2016, 2017, and most recently in May 2020, as well as our term loan facility entered into in 2015 and 2019 and our 2024 Convertible Notes issuance in 2017. This funding is necessary to support the commercialization of ZILRETTA and to perform the research and development activities required to develop our other product candidates in order to generate future revenue streams. We may not be able to obtain financing on acceptable terms, or at all. In particular, as a result of the COVID-19 pandemic and actions taken to slow its spread, the global credit and financial markets have experienced extreme volatility and disruptions, including diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. If the equity and credit markets deteriorate, it may make any additional debt or equity financing more difficult, more costly and more dilutive.

We expect that our research and development and selling, general and administrative expenses will increase in 2021 and beyond and, as a result, we may need additional capital to fund our operations, which we may seek to obtain through one or more equity offerings, debt and convertible debt financings, government or other third-party funding, and licensing or collaboration arrangements.

As of March 31, 2021, we had cash, cash equivalents, and marketable securities of $154.3 million. Based on our current operating plan we anticipate that our existing cash, cash equivalents, and marketable securities will fund our operations for at least the next 12 months from the issuance date of the financial statements included in this report. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with an objective of capital preservation.

On August 2, 2019, we entered into the Amended and Restated Credit and Security Agreement with Silicon Valley Bank, MidCap Financial Trust, Flexpoint MCLS Holdings, LLC, and the other Lenders, providing for a term loan of $40.0 million and a revolving credit facility of up to $20.0 million, both of which mature on January 1, 2024. We concurrently borrowed the $40.0 million term loan and used $7.7 million of the proceeds to repay the remaining amount owed on our existing term loan with Silicon Valley Bank and MidCap Funding XIII Trust. The revolving credit facility became available to us beginning January 1, 2020, and in February 2020, we borrowed the full $20.0 million available under the revolver.

On May 18, 2020, we entered into an amendment to the amended and restated credit and security agreement (the “amendment”). Pursuant to the amendment, we borrowed $15.0 million under a new term loan advance and immediately used the proceeds to repay an equal amount under the revolving credit facility, and the maximum principal amount of the revolving credit facility was reduced from $20.0 million to $5.0 million. The new term loan is subject to substantially the same terms, including interest rate, amortization and maturity date, as the existing term loan under the credit facility. Additionally, if our liquidity (as defined in Note 9 to our unaudited consolidated financial statements included elsewhere in this report) should decrease below $80.0 million, under the terms of the amended and restated credit and security agreement, we would become subject to a minimum revenue covenant. If we become subject to the minimum revenue covenant and fail to comply with it, the lenders could elect to declare all amounts outstanding to be immediately due and payable. Additionally, if our liquidity is below $80.0 million, all amounts received from customer collections will be applied immediately to reduce the revolving credit facility.

Term loan borrowings under the credit facility accrue interest monthly at a floating interest rate equal to the greater of the Prime Rate (as reported in the Wall Street Journal) plus 1.50% or 6.50% per annum. Under the term loan credit facility, following an 18-month interest-only period, principal is due in 36 equal monthly installments commencing February 1, 2021, and ending on the Maturity

Date. We may prepay the term loan at any time by paying the outstanding principal balance, a final payment equal to 6.75% of the term loan amount, all accrued interest and a prepayment fee of 3% of the outstanding term loan amount if repaid in the first year, 2% of the outstanding term loan amount if repaid in the second year, and 1% of the outstanding term loan amount if repaid in the third year of the loan; no prepayment fee is required thereafter.

Borrowings under the revolving credit facility accrue interest monthly at a floating interest rate equal to the greater of the Prime Rate (as reported in the Wall Street Journal) or 5.50% per annum. The revolving credit facility is co-terminus with the term loan. If the interest payment on the revolving credit facility is less than the amount of interest that would have been payable had we borrowed 25% of the total commitment under the revolving credit facility, or the Revolving Commitment Amount, then we will be required to pay the difference. We are also required to pay a facility fee in respect of the revolving credit facility equal to 1% of the Revolving Commitment Amount. We may retire the revolving credit facility early, at any time, by paying the outstanding principal balance, all accrued interest and a termination fee equal to 2% of the Revolving Commitment Amount if repaid in the first year, and 1% of the Revolving Commitment Amount if repaid in the second year; with no termination fee thereafter. To the extent any portion of the Revolving Commitment Amount is undrawn, we will be required to pay an "unused line fee" equal to 0.25% per annum of the average unused portion of the Revolving Commitment Amount, calculated on a calendar year basis as an amount equal to the difference between (i) the Revolving Commitment Amount and (ii) the greater of (A) 25.0% of the Revolving Commitment Amount, and (B) the average for the period of the daily closing balance of the Revolving Commitment Amount outstanding.

On November 4, 2020, we entered into the Distribution Agreement with Goldman Sachs & Co. LLC and Credit Suisse Securities (USA) LLC (collectively, the "Managers") relating to the issuance and sale from time to time of up to $100,000,000 of shares of our common stock. Under the terms of the Distribution Agreement, we will pay the Managers a commission of up to 3% of the gross sales price of any shares sold. As of March 31, 2021, 134,048 shares had been sold under the Distribution Agreement, for total net proceeds of $1.7 million.

The following table shows a summary of our cash flows for each of the three months ended March 31, 2021 and 2020:

	Three Months Ended March 31,	
(In thousands)	**2021**	**2020**
Cash flows used in operating activities	$ (18,474)	$ (28,197)
Cash flows provided by investing activities	10,949	37,954
Cash flows (used in) provided by financing activities	(1,472)	20,009
Net (decrease) increase in cash and cash equivalents	$ (8,997)	$ 29,766

Net Cash Used in Operating Activities

Operating activities used $18.5 million of cash in the three months ended March 31, 2021. Cash used in operating activities resulted primarily from our net loss for the period of $28.6 million, partially offset by changes in our operating assets and liabilities of $1.0 million and non-cash charges of $9.1 million. Changes in our operating assets and liabilities consisted primarily of a $2.2 million decrease in inventory and an increase of $1.7 million in accounts payable and accrued expenses, partially offset by a $0.3 million increase in accounts receivable, a $2.2 million increase in prepaid expenses and other current assets, and a $0.4 million decrease in lease liabilities primarily due to principal lease payments. Our non-cash charges consisted primarily of $4.6 million of stock-based compensation expense, $2.5 million related to the amortization of the debt discount and debt issuance costs related to the 2024 Convertible Notes, $0.4 million related to the amortization of right-of-use assets, $0.5 million of depreciation, $0.2 million of non-cash interest expense related to amortization of the final payment due on the 2019 term loan, and $0.2 million of amortization of premiums paid for the purchase of marketable securities.

Operating activities used $28.2 million of cash in the three months ended March 31, 2020. Cash used in operating activities resulted primarily from our net loss for the period of $36.8 million and changes in our operating assets and liabilities of $0.8 million, offset by non-cash charges of $7.8 million. Changes in our operating assets and liabilities consisted primarily of a $6.8 million increase in accounts receivable, a $3.1 million increase in inventory, a $0.4 million increase in prepaid expenses and other current assets, a decrease of $2.0 million in accounts payable and accrued expenses and a $0.4 million decrease in lease liabilities and other long-term liabilities primarily due to principal lease payments. Our non-cash charges consisted primarily of $4.7 million of stock-based compensation expense, $2.3 million related to the amortization of the debt discount and debt issuance costs related to the 2024 Convertible Notes, $0.4 million related to the amortization of right-of-use assets, $0.2 million of depreciation, $0.1 million of non-cash interest expense related to amortization of the final payment due on the 2019 term loan and $0.3 million related to the loss on disposal of fixed assets, partially offset by $0.1 million of net accretion of discounts related to our investments.

Net Cash Provided by Investing Activities

Net cash provided by investing activities was $10.9 million in the three months ended March 31, 2021. Net cash provided by investing activities consisted primarily of cash received for the redemption and sale of marketable securities of $13.8 million, partially offset by cash used to purchase marketable securities of $2.0 million and capital expenditures of $0.8 million, primarily relating to the purchase of equipment associated with the expansion of our manufacturing facilities at Patheon.

Net cash provided by investing activities was $38.0 million in the three months ended March 31, 2020. Net cash provided by investing activities consisted primarily of cash received for the redemption and sale of marketable securities of $41.2 million, partially offset by $3.2 million of cash used for capital expenditures, primarily relating to the purchase of equipment associated with the expansion of our manufacturing facilities at Patheon.

Net Cash (Used in) Provided by Financing Activities

Net cash used in financing activities was $1.5 million for the three months ended March 31, 2021, which consisted of $3.1 million related the payment of principal on our 2019 term loan and public offering costs paid during the period of $0.1 million, partially offset by $1.7 million related to the net proceeds received from the sale of common stock under our Distribution Agreement.

Net cash provided by financing activities was $20.0 million for the three months ended March 31, 2020, which related to the total amount borrowed under the revolving credit facility associated with our 2019 term loan.

Contractual Obligations

For a discussion of our contractual obligations, see “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our 2020 Annual Report on Form 10-K. There have not been any material changes to such contractual obligations or potential milestone payments since December 31, 2020, other than as described in Notes 9, 12 and 13 to our unaudited consolidated financial statements included elsewhere in this report.

Off-Balance Sheet Arrangements

During the periods presented, we did not have, nor do we currently have, any off-balance sheet arrangements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our primary exposures to market risk are interest income sensitivity and equity price risk. Interest income is affected by changes in the general level of U.S. interest rates. Due to the short-term duration of a majority of our investment portfolio and the low risk profile of our investments, an immediate 10.0% change in interest rates would not have a material effect on the fair market value of our portfolio. Accordingly, we would not expect our operating results or cash flows to be affected to any significant degree by a sudden change in market interest rates on our investment portfolio.

Investments

We do not believe that our cash, cash equivalents, and marketable securities have significant risk of default or illiquidity. While our cash and investments are invested with the goal of capital preservation, we cannot provide absolute assurance that in the future our investments will not be subject to adverse changes in market value. In addition, we maintain significant amounts of cash and cash equivalents at one or more financial institutions that are in excess of federally insured limits.

Term Loans

We have borrowed $55.0 million in term loans under our credit facility. Term loan borrowings under the credit facility accrue interest monthly at a floating interest rate equal to the greater of the prime rate plus 1.5% or 6.5% per annum.

Revolving Credit Facility

We have borrowed $5.0 million under the revolving credit facility. Borrowings under the revolving credit facility accrue interest monthly at a floating interest rate equal to the greater of the prime rate or 5.50% per annum. In addition to paying interest on any amounts borrowed under the revolving credit facility, we may in the future owe an unused revolving line facility fee equal to 0.25% per annum of the average unused portion of the revolving line, multiplied by the difference between the total amount available to be borrowed (the “Revolving Commitment Amount”) and the greater of the average outstanding revolver balance and 25% of the Revolving Commitment Amount.

Convertible Notes

On May 2, 2017, we issued $201.3 million aggregate principal amount of 2024 Convertible Notes. The 2024 Convertible Notes are senior unsecured obligations and bear interest at a rate of 3.375% per year, payable semi-annually in arrears on May and November 1st of each year. The 2024 Convertible Notes will mature on May 1, 2024, unless repurchased or converted earlier. The 2024 Convertible Notes will be convertible into cash, shares of our common stock, or a combination thereof, at our election (subject to certain limitations in the 2015 term loan), at a conversion rate of approximately 37.3413 shares of common stock per $1,000 principal amount of the 2024 Convertible Notes, which corresponds to a conversion price of approximately $26.78 per share of our common stock and represents a conversion premium of approximately 35% based on the last reported sale price of our common stock of $19.72 on May 2, 2017, the date the 2024 Convertible Notes offering was priced. As of May 2, 2017, the fair value of the 2024 Convertible Notes was $136.7 million. Our 2024 Convertible Notes include conversion and settlement provisions that are based on the price of our common stock at conversion or at maturity of the 2024 Convertible Notes. The amount of cash we may be required to pay is

determined by the price of our common stock. The fair value of our 2024 Convertible Notes are dependent on the price and volatility of our common stock and will generally increase or decrease as the market price of our common stock changes. The estimated fair value of the 2024 Convertible Notes, face value of $201.3 million, was $181.5 million at March 31, 2021.

Foreign Currency Exchange

Most of our transactions are conducted in the U.S. dollar. We do have certain agreements with vendors located outside the United States, which have transactions conducted primarily in British Pounds and Euros. As of March 31, 2021, we had $1.2 million in liabilities denominated in British Pounds. A hypothetical 10% change in foreign exchange rates would result in a $0.1 million change in the value of our liabilities. No other payables to vendors were denominated in currencies other than in U.S. dollars. As of March 31, 2021, we had $3.0 million of cash denominated in British Pounds. A hypothetical 10% change in foreign exchange rates would result in a $0.3 million change in the amount of cash denominated in British Pounds.

ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

We are responsible for maintaining disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Disclosure controls and procedures are controls and other procedures designed to ensure that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

In designing and evaluating our disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Based on our management's evaluation (with the participation of our principal executive officer and principal financial officer) of our disclosure controls and procedures as required by Rule 13a-15 under the Exchange Act, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures were effective to achieve their stated purpose as of March 31, 2021, the end of the period covered by this report.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended March 31, 2021, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are not currently a party to any material legal proceedings.

ITEM 1A. RISK FACTORS

As disclosed in "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2020, which was filed on March 10, 2021, there are a number of risks and uncertainties that may have a material effect on our business, financial condition, results of operations, and future growth prospects. There are also additional risks and uncertainties that we are unaware of that may become important factors that affect us. The following risk factors are either new or have changed materially from those set forth in our Annual Report on Form 10-K for the year ended December 31, 2020. You should carefully review the risks described below and in our Annual Report on Form 10-K and in other reports we file with the Securities and Exchange Commission in evaluating our business.

COVID-19 will likely continue to have an adverse impact on our clinical trials and further development of our pipeline.

COVID-19's impact on the healthcare industry is significant and has impacted our on-going clinical trials and may disrupt further development of our pipeline. For example, in April 2020, we temporarily suspended the active Phase 1 clinical trial evaluating the safety and tolerability of FX201. The decision was made in consideration of guidance from the FDA to ensure the safety of trial participants and minimize risk to trial integrity from disruptions caused by COVID-19. In addition, we decided to terminate the Phase 2 trial evaluating the efficacy of ZILRETTA in patients with shoulder OA and adhesive capsulitis, given the small number of patients enrolled in the trial, the uncertainty as to when we would be able to restart the study, and the costs required to maintain it in an inactive status. While we subsequently restarted our Phase 1 clinical trial of FX201 in late May 2020, and we intend to initiate a trial investigating ZILRETTA in patients with shoulder OA in 2021 and have started clinical development of FX301, we cannot guarantee that COVID-19's impact or restrictions implemented by government agencies or healthcare facilities in response to COVID-19 will not force us to delay, suspend, or terminate these trials, and we cannot predict how access to, utilization of, and efficacy of COVID-19 vaccines may influence such impacts and restrictions. These impacts of COVID-19 will increase the costs of completing clinical development and delay our ability to obtain marketing approval for our pipeline product candidates and ZILRETTA for additional indications.

The market price of our common stock may be highly volatile, you may not be able to resell your shares at a desired market price, and you could lose all or part of your investment.

The trading price of our common stock is likely to be volatile due to a variety of factors, including the following:

- success or perceived success of the commercialization of ZILRETTA;
- the impact and duration of COVID-19 and actions taken to mitigate its spread;
- inability to obtain approval for additional indications for ZILRETTA;
- failure to successfully develop and commercialize additional product candidates;
- changes in the structure of healthcare payment systems;
- adverse results or delays in clinical trials;
- inability to obtain additional funding;
- changes in laws or regulations applicable to our products or product candidates;
- inability to obtain adequate supply for our products or product candidates, or the inability to do so at acceptable prices;
- adverse regulatory decisions;
- introduction of new products or technologies by our competitors;
- failure to meet or exceed product development or financial projections we provide to the public;
- failure to meet or exceed the estimates and projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators, and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures, or capital commitments by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- significant lawsuits, including patent, product liability, or stockholder litigation;

- changes in the market valuations of similar companies;
- sales of our common stock by us or our stockholders in the future; and
- trading volume of our common stock.

The trading price of our common stock may also be dependent upon the valuations and recommendations of the analysts who cover our company. If our results do not meet these analysts' forecasts, the expectations of our investors, or any financial guidance or expectations we provide to investors, the market price of our common stock could decline. Our ability to meet analysts' forecasts (including revenue and profitability), investors' expectations, and our own guidance or financial expectations is substantially dependent on our ability to increase sales of ZILRETTA and to successfully commercialize ZILRETTA in the United States. Because we have not yet fully commercialized ZILRETTA, we and the analysts who cover our company have limited ability to accurately predict future sales results, and actual results may differ materially from expectations.

In addition, the stock market in general, and the Nasdaq Global Market in particular, has experienced extreme price and volume fluctuations, and we have in the past experienced volatility that we believe has been unrelated or disproportionate to our operating performance. For example, during the first quarter of 2020, the closing price of our common stock ranged from $5.53 to $21.13 per share. Broad market and industry factors may continue to negatively affect the market price of our common stock, regardless of our operating performance. For example, there have been instances of groups of investors buying shares of a company's stock in order to drive up its market price, thereby causing traders who have bet that the stock price would fall and contracted to sell shares of that stock with a plan to buy those shares after the share price has fallen (*i.e.*, those who have "shorted" the stock) to buy in as well to forestall even greater losses; this is known as a "short squeeze." These short squeezes have caused extreme volatility in both the stock prices of the companies involved and in the market and have led to the shares of those companies trading at a significantly inflated price per share that is disconnected from the underlying value of the company. Many investors who have purchased shares in those companies at an inflated share price face the risk of losing a significant portion of their original investment, as in many cases the price per share has declined steadily as interest in those stocks has abated. While we do not believe that our common stock has been the target of a short squeeze, there can be no assurance that our common stock will not be impacted by unusual trading activity in the future or that the price of our common stock will not become significantly disconnected from our underlying value.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Recent sales of Unregistered Securities

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit number	Description of document
3.1	Amended and Restated Certificate of Incorporation of Flexion (Exhibit 3.1, Current Report on Form 8-K, filed with the SEC on February 19, 2014).
3.2	Amended and Restated Bylaws of Flexion (Exhibit 3.2, Current Report on Form 8-K, filed with the SEC on February 19, 2014).
4.1	Form of Common Stock Certificate of Flexion (Exhibit 4.1, Registration Statement on Form S-1 (File No. 333-193233), as amended, filed with the SEC on January 29, 2014).
4.2	Indenture, dated May 2, 2017, by and between Flexion and Wells Fargo Bank, National Association, as trustee (Exhibit 4.1, Current Report on Form 8-K, filed with the SEC on May 2, 2017).
4.3	Form of Note representing Flexion's 3.375% Convertible Senior Notes due 2024 (included as Exhibit A to the Indenture filed as Exhibit 4.1, Current Report on Form 8-K, filed with the SEC on May 2, 2017).
31.1	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
31.2	Certification of the Principal Accounting and Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
32.1	Certification of the Principal Executive Officer and Principal Accounting and Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline eXtensible Business Reporting Language (XBRL) Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

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: May 12, 2021

By: /s/ Michael D. Clayman
Michael D. Clayman
Chief Executive Officer
(Principal Executive Officer)

Date: May 12, 2021

By: /s/ David Arkowitz
David Arkowitz
Chief Financial Officer
(Principal Accounting and Financial Officer)

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael D. Clayman, M.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Flexion Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 12, 2021

/s/ Michael D. Clayman, M.D.
Michael D. Clayman, M.D.
President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL AND ACCOUNTING OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, David A. Arkowitz., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Flexion Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 12, 2021

/s/ David A. Arkowitz
David A. Arkowitz
Principal Financial and Accounting Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Each of Michael D. Clayman, M.D., President and Chief Executive Officer of Flexion Therapeutics, Inc. (the "Registrant"), and David A. Arkowitz, Chief Financial Officer of the Registrant, do hereby certify in accordance with 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, based upon our knowledge:

(1) this Quarterly Report on Form 10-Q of the Registrant, to which this certification is attached as an exhibit (the "Report"), fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m); and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Date: May 12, 2021

/s/ Michael D. Clayman, M.D.
Michael D. Clayman, M.D.
President and Chief Executive Officer

Date: May 12, 2021

/s/ David A. Arkowitz
David A. Arkowitz
Principal Financial and Accounting Officer

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350 and is not being filed as part of the Report or as a separate disclosure document.